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REPORT ON THE IMPLEMENTATION OF THE OECD RECOMMENDATION ON THE SAFETY TESTING AND ASSESSMENT OF MANUFACTURED NANOMATERIALS

(Note by the Secretary-General)

JT03569822

This document, as well as any data and 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.

1. This document presents, in its Annex, a Report by the Chemicals and Biotechnology Committee (hereafter the "CBC" or the "Committee") on the implementation of the OECD Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials [OECD/LEGAL/0400] (hereafter, the "Recommendation"), including on the implementation of its substantive provisions, its dissemination and its continued relevance. The Report also includes conclusions on whether the Recommendation requires revision or whether further actions to support its dissemination and implementation are necessary.

2. The CBC approved, at its meeting on 10-12 June 2025, the Report set out in the Annex and its transmission to Council to be noted and declassified [ENV/CBC(2025)7]. Once declassified, the Report will be published on the online Compendium of OECD legal instruments.

Background

Origin and scope of the Recommendation

3. The Recommendation was adopted by the Council on 19 September 2013 [C(2013)107 and C/M(2013)16, Item 163] and was last amended on 30 October 2023 [ENV/CBC/WRPR(2023)74]. It aims to align the safety testing and assessment of nanomaterials with the measures used for chemicals, as outlined in existing OECD legal instruments[1].

4. The Recommendation recognises that existing regulatory systems can be adapted to cover nanomaterials, including the provisions and instruments associated with them for safety testing and assessment. Therefore, it calls on Adherents [2] to apply existing international and national chemical regulatory frameworks and use the tools listed in the Annex for testing and assessment, alongside the OECD Guidelines for the Testing of Chemicals (hereafter the "OECD Test Guidelines") adapted to consider the specific properties of manufactured nanomaterials. This ensures that the tests used to address the safety of nanomaterials are consistent and defensible.

5. Additionally, the Working Party on Manufactured Nanomaterials (WPMN) and the Working Party of National Coordinators of the Test Guidelines Programme (WNT) of the CBC have been working to align the safety testing and assessment of nanomaterials with the methodologies used for traditional chemicals, as described in existing OECD legal instruments.

6. The Recommendation contains five substantive provisions:

- First, it recognises that existing national and international regulatory frameworks for traditional chemicals are valid for nanomaterials, and it recommends that Adherents apply such regulatory frameworks to manage the risks of manufactured nanomaterials, while acknowledging that these may need to be adapted to consider the specific properties of nanomaterials.

[1] Including the Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals ("MAD Decision") [OECD/LEGAL/0194] and the Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [OECD/LEGAL/0252] ("OECD GLP Principles").

[2] To date, in addition to the 38 OECD Members, Argentina, Brazil and Bulgaria have adhered to the Recommendation.

- Second, it recommends that Adherents use the OECD Test Guidelines – an integral part of the MAD Decision that is regularly updated – when assessing the potential effects of nanomaterials on human health and the environment.
- Third, it recommends that Adherents update, in line with OECD rules and procedures, the OECD Test Guidelines in the light of experience with manufactured nanomaterials.
- Fourth, the Recommendation, in its Annex, includes tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials. The Annex was drafted with the intention that it would be updated by the addition of new or updated tools as scientific knowledge developed. Adherents are recommended to apprise the CBC on a regular basis of any technical issues related to the safety testing and assessment of nanomaterials that need to be addressed.
- Fifth, it recommends that Adherents make safety data related to nanomaterials available to the public.

Developments in the field since the adoption of the Recommendation

7. Since the adoption of the Recommendation, the evolving dynamics of nanotechnologies, industries, and regulatory regimes have introduced new challenges and opportunities for its implementation. In response, the WPMN has continuously adapted its structure to reflect the programme's shifting needs and priorities, adjusting to changes in the external environment and emerging trends.

8. One key development is the advancement of nanotechnologies, which has led to the creation of newer and more complex materials, referred to as advanced materials[3]. In 2018, the CBC agreed that the WPMN was best placed to consider advanced materials [ENV/JM/M(2018)2].[4]

9. The rapid development of new advanced materials led the WPMN to identify new strategies to boost innovation while enhancing prevention and safety from the earliest stages of the design phase. The WPMN therefore developed the Safer and Sustainable Innovation Approach (SSIA), which includes functionality and emphasises the shift from remediation to prevention of risks.

10. In parallel, the WPMN developed the Early Awareness and Action System for Advanced Materials (Early4AdMa), an anticipatory risk governance tool to strengthen timely decision-making.[5]

[3] OECD (2023), *Advanced Materials: Working Description*, OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, https://doi.org/10.1787/4b5ba38d-en.

[44] Consequently, the WPMN revised its mandate to include "other advanced materials," providing the necessary flexibility to address emerging materials.

[5] Early4AdMa identifies potential safety, sustainability, and regulatory issues for advanced materials at an early stage. This includes the applicability of test methods, the suitability of sample preparation, and identifying potential follow-up actions.

Methodology and Process

11. In order to collect information on the implementation, dissemination and continued relevance of the Recommendation, a survey questionnaire was developed by the Secretariat and circulated to the Adherents to the Recommendation as well as the European Union (EU) considering that the management framework for chemicals is coordinated and enacted at European Union level [ENV/CBC(2024)14]. Responses were collected between May and September 2024. Fourteen Adherents and the EU[6] (hereafter "Respondents") provided responses to the questionnaire[7].

12. For several substantive provisions, additional sources of information were used to complement results from the questionnaire. This includes OECD activities led by the WPMN which supports the implementation of the Recommendation. The OECD activities on information exchange, outreach and capacity-building are supporting the dissemination as well as implementation of the Recommendation. This information is provided in Section 4 of the Report.

13. After the survey questionnaire was circulated to the CBC, the Secretariat presented the process for developing the Report at the WPMN meeting on 26 June 2024 [ENV/CBC/NANO/A(2024)1]. A first draft Report was circulated for written feedback by the WPMN and WNT by 26 February 2025 [ENV/CBC/NANO(2025)1].

14. The second draft Report took account of the feedback received and was approved, as well as its transmission to Council to be noted and declassified, by the CBC at its meeting on 10-12 June 2025 [ENV/CBC(2025)7]. This second draft was also shared with the WPMN and WNT for their information.

Summary of results and conclusions

Implementation

15. The information gathered by the Secretariat, and the collected survey responses suggest that Adherents, domestically and in the context of collaborative work at the OECD, have made significant and continued efforts to implement the Recommendation over the past five years.

16. The main conclusions on implementation of the Recommendation in this Report can be summarised as follows. The provision of the Recommendation on:

- The application of existing regulatory frameworks has been implemented to a high level across Respondents. The majority of Respondents have adapted their chemical regulatory frameworks accordingly.
- The application of the OECD Test Guidelines and OECD GLP Principles has also been implemented well among Respondents. Most Respondents have applied or encouraged the use of OECD Test Guidelines adapted for nanomaterials. All Respondents have applied the OECD GLP Principles, often embedding them into

[6] For the purpose of the Report, the responses provided by the EU describe the collective activities at the EU level related to implementation and are therefore reflective of activities of Adherents that are EU Member States. Several EU Member States also provided individual responses (Austria, Denmark, Germany, Spain, Sweden, Italy, and the Netherlands).

[7] Austria, Australia, Canada, Denmark, Germany, Italy, Japan, Korea, the Netherlands, Spain, Sweden, Switzerland, the United Kingdom, and the United States, as well as the EU (whose activities represent those of 23 Adherents).

national legislation or regulations. This underscores a strong global commitment to ensuring high-quality, reliable data in chemical safety assessments.

- The updating of the OECD Test Guidelines has been implemented through collective efforts. Significant progress has been made with various projects completed or underway to develop or update the OECD Test Guidelines and Guidance Documents. However, most Respondents believe that current Test Guidelines and Guidance Documents do not cover all relevant areas necessary for full implementation. Key areas identified for further development include environmental fate and behaviour, human health effects, exposure assessment, New Approach Methodologies (NAMs), and advanced materials. Prioritisation efforts for future work are underway both within and outside the OECD.
- The use and update of the Annex to the Recommendation has been implemented by most Respondents and through collective actions. Most Respondents have used these tools, though their use varies depending on their regulatory needs. Respondents agree on the need to regularly update the Annex to make it more effective by including the latest documents and removing obsolete references. Suggestions include updating outdated documents, adding new Test Guidelines and Guidance Documents, and incorporating topics like Safe(r) and Sustainable by Design and the work on Advanced Materials.
- Public availability of safety data has been widely implemented by Respondents. The majority have done so through various platforms and databases, demonstrating a commitment to transparency and public health. Diverse approaches are taken to balance public access with the protection of confidential business information, including anonymisation of data and legal provisions for confidentiality.

17. While the Recommendation is generally well-implemented by Adherents and through collective actions, there are some challenges, mainly due to the evolving nature of the field. As scientific knowledge advances, testing methodologies and nanotechnologies continue to evolve. As a result, regularly updating the Test Guidelines, 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.

Dissemination

18. Adherents have actively disseminated the Recommendation at various levels of government. Some Respondents have shared the Recommendation within their relevant governments and public institutions, typically through communications and briefings. Additional methods used include establishing inter-agency working groups, managing dedicated web links, and conducting training courses to raise awareness.

19. Regarding external dissemination to non-governmental actors and non-Adherents, some Adherents have shared the Recommendation through communications, briefings, and web links. However, it appears that there is still a lack of widespread external communication of the Recommendation to non-governmental entities.

20. Since some elements of the Recommendation are implemented through collaborative activities at the OECD, these implementation activities are also reflected in the context of ‘dissemination’ in the Report. The Secretariat has presented elements of the work implemented under the Recommendation on a regular basis at external events (i.e. workshops, webinars, accession). The annual publication of the “Tour de Table on Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced

Materials" [8] provides an opportunity of information sharing on comprehensive implementing activities of Adherents and stakeholders. It is also a tool for anticipating new trends and priorities Adherents, which has allowed to better anticipate and respond to their needs in this rapidly evolving field.

21. The OECD co-operates closely with other international organisations, especially through the Inter-organization Programme for the Sound Management of Chemicals (IOMC)[9] to strengthen international co-operation in the field of chemicals. The OECD also collaborates with the International Organization for Standardization (ISO) and specifically its Technical Committee on Nanotechnologies (ISO/TC 229); and other international initiatives/ research programmes to keep abreast of the latest developments.

22. Some non-Adherents have been active participants in the activities of the WPMN and have aligned their domestic activities with the provisions of the Recommendation. Their contributions include sharing domestic information, actively participating in OECD projects or in the drafting of documents, and providing technical inputs, which enrich the discussions related to the implementation of the Recommendation.

23. While these actions have already contributed to the wide dissemination of the Recommendation to both Adherents and non-Adherents, additional efforts could be made to further disseminate the Recommendation to non-Adherents.

Continued relevance

24. Views on the need to revise the Recommendation at this stage vary among Respondents. While many Respondents acknowledge the importance of exploring new areas, there is divergence in how these should be reflected in the Recommendation. Based on the aggregated responses, the Report finds that the Annex should be regularly updated to reflect state-of-the-art developments in the field, rather than underscoring a need to revise the provisions of the Recommendation in the short term. However, the need to revise the provisions of the Recommendation could be reconsidered in the medium term to ensure its continued relevance.

25. Accordingly, the CBC will continue to support Adherents in implementing the Recommendation and it is proposed to report back to the Council on the implementation, dissemination and continued relevance of the Recommendation in 10 years. The rationale for a longer reporting period is that this will enable to accommodate emerging needs of Adherents in implementing the Recommendation prior to a third report on its implementation being presented to the Council. An earlier report would be prepared if changes in the area would warrant it.

Proposed action

26. In light of the above, the Secretary General invites the Council to adopt the following draft conclusions:

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[8] The Tour de Table compiles information provided by delegations on their current developments and activities related to manufactured nanomaterials, as well as other activities on nanotechnologies at the international level.

[9] https://partnership.who.int/iomc

a) noted document C(2025)72, in particular the Report set out in its Annex, and agreed to its declassification;

b) encouraged Adherents to continue disseminating and implementing the Recommendation, and in particular address the challenges identified in the "Summary and conclusions" section of the Report;

c) invited the Chemicals and Biotechnological Committee (CBC), through the Working Party on Manufactured Nanomaterials (WPMN) and Working Party of National Coordinators to the Test Guidelines Programme (WNT) to:

   i. continue supporting the implementation of the Recommendation, notably by:

      1. ensuring collaborative work towards implementation of the provisions of the Recommendation in the relevant subsidiary bodies of the CBC;

      2. strengthening its efforts to ensure co-operation with other international organisations, in particular with the other Participating Organisations of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC);

   ii. continue promoting international awareness and dissemination of the Recommendation, with a view to encouraging non-Adherents to request adherence to it and participate in the OECD's work in the field of safety testing of manufactured nanomaterials and advanced materials;

   iii. report back to Council on the implementation, dissemination and continued relevance of the Recommendation in 10 years or earlier, if developments in the field warrant it.

Annex. Report on the implementation of the OECD Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials

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Background

Origin and scope of the Recommendation

1. The Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials (the "Recommendation") was adopted by the OECD Council on 19 September 2013 ([C(2013)107] and [C/M(2013)16], Item 163), following a proposal from the Chemicals Committee (now under the responsibility of the Chemicals and Biotechnology Committee, hereafter the CBC).

2. The Recommendation aims to align the safety testing and assessment of nanomaterials with the measures used for chemicals, as outlined in existing OECD legal instruments. Notably, these include the Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals (MAD Decision) [OECD/LEGAL/0194] and the Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [OECD/LEGAL/0252] ("OECD GLP Principles").

3. The Recommendation was developed in response to uncertainties about how nanomaterials should be regulated, particularly regarding their safety for human health and the environment. It was anticipated that nanomaterials would be increasingly used in various applications, such as paints, food, clothing, cosmetics, medical products, buildings, and batteries. Due to their unique physical-chemical properties, nanomaterials may require additional testing beyond the standard suite used for other chemicals.

4. The Recommendation recognises that existing regulatory systems can be adapted to cover nanomaterials, including the provisions and instruments associated with them for safety testing and assessment. Therefore, it calls on Members and non-Members having adhered to it (the "Adherents") [10] to apply existing international and national chemical regulatory frameworks and use the tools listed in the Annex for testing and assessment, alongside the OECD Guidelines for the Testing of Chemicals (hereafter the "OECD Test Guidelines") adapted to consider the specific properties of manufactured nanomaterials. This ensures that the tests used to address the safety of nanomaterials are consistent and defensible.

5. Additionally, the Working Party on Manufactured Nanomaterials (WPMN) and the Working Party of National Coordinators of the Test Guidelines Programme (WNT) of the Chemicals and Biotechnology Committee have been working to align the safety testing and assessment of nanomaterials with the methodologies used for traditional chemicals, as described in existing OECD legal instruments.

6. The Recommendation contains 5 substantive provisions.

a) First, it recognises that existing national and international regulatory frameworks for traditional chemicals are valid for nanomaterials, and it recommends that Adherents apply such regulatory frameworks to manage the risks of manufactured nanomaterials, while acknowledging that these may need to be adapted to consider the specific properties of nanomaterials.

b) Second, it recommends that Adherents use the OECD Test Guidelines – an integral part of the MAD Decision that is regularly updated – when assessing the potential effects of nanomaterials on human health and the environment.

[10] To date, in addition to the 38 OECD Members, Argentina, Brazil and Bulgaria have adhered to the Recommendation.

c) Third, it recommends that Adherents update, in line with OECD rules and procedures, the OECD Test Guidelines in the light of experience with manufactured nanomaterials

d) Fourth, the Recommendation, in its Annex, includes tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials. The Annex was drafted with the intention that it would be updated by the addition of new or updated tools as scientific knowledge developed. Adherents are recommended to apprise the CBC on a regular basis of any technical issues related to the safety testing and assessment of nanomaterials that need to be addressed.

e) Fifth, it recommends that Adherents make safety data related to nanomaterials available to the public.

Developments in the field since the adoption of the Recommendation

7. Since the adoption of the Recommendation in 2013, the evolving dynamics of nanotechnologies, industries, and regulatory regimes have introduced new challenges and opportunities for its implementation. In response, the WPMN has continuously adapted its structure to reflect the programme's shifting needs and priorities, adjusting to changes in the external environment and emerging trends.

8. One key development is the advancement of nanotechnologies, which has led to the creation of newer and more complex materials, referred to as advanced materials[11]. This trend raised the question for the OECD about whether these advanced materials could also be addressed within the context of the Recommendation. In 2018, the CBC agreed that the WPMN was best placed to consider advanced materials [ENV/JM/M(2018)2]. Consequently, the WPMN revised its mandate to include "other advanced materials," providing the necessary flexibility to address emerging materials. In 2020, the CBC included the issue of advanced materials in the Environment, Health and Safety Programme for 2021-2023, and this has been a growing area of interest since then.

9. The development of innovative new safety tools for chemicals, including the development of New Approach Methodologies (NAMs) in the field of chemical safety testing is an important trend for future chemical risk assessment, including its application to nanomaterials. For this reason, an important task of the WPMN has been to complement the work of other Working Parties under the CBC on issues specific to nanomaterials and advanced materials, which ensures an aligned approach to chemical safety. For example, the WPMN has supported the development of Test Guidelines, Guidance Documents, scoping reviews and study reports in cooperation with WNT. The WPMN also led the drafting of a specific chapter of the OECD Guidance Document on Grouping of Chemicals[12] , which was developed under the responsibility of the OECD's Working Party on Hazard Assessment (WPHA).

10. The rapid development of new advanced materials led the WPMN to identify new strategies to boost innovation while enhancing prevention and safety from the earliest stages of the design phase. As such, the WPMN developed the Safer and Sustainable

[11] OECD (2023), *Advanced Materials: Working Description*, OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, https://doi.org/10.1787/4b5ba38d-en

[12] OECD (2017), Guidance on Grouping of Chemicals, Second Edition, OECD Series on Testing and Assessment, No. 194, OECD Publishing, Paris, https://doi.org/10.1787/9789264274679-en.

Innovation Approach (SSIA), which includes functionality and emphasises the shift from remediation to prevention of risks. It recognizes that early safety and sustainability assessments can prevent long-term negative impacts of innovations. SSIA is committed to prioritising safety and sustainability, ensuring that materials, products, processes, and technologies do not pose risks to people or the environment, nor burden the planet. Accordingly, SSIA aims to: (i) enhance the ability of all stakeholders to assess the safety and sustainability of innovations in a robust yet agile manner; and (ii) reduce the time gap between the emergence of technological innovations and the development of suitable risk assessment tools and frameworks.

11. In parallel, the WPMN developed the Early Awareness and Action System for Advanced Materials (Early4AdMa), an anticipatory risk governance tool to strengthen timely decision-making. Early4AdMa identifies potential safety, sustainability, and regulatory issues for advanced materials at an early stage. This includes the applicability of test methods, the suitability of sample preparation, and identifying potential follow-up actions. These actions may involve developing guidance, addressing research needs, steering towards Safe and Sustainable by Design (SSbD), and streamlining the identification of priority areas to ensure the safety of nanomaterials and advanced materials.

Purpose and methodology

Purpose

12. In the Recommendation, the Council instructs the CBC "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".

13. In line with this instruction, the first implementation Report [C(2019)55/REV1] was noted and declassified by the OECD Council and published in 2019 (hereinafter, the "2019 Report"). The 2019 Report acknowledged that, although significant progress has been made in implementing the Recommendation, its provisions remain highly relevant, and much work still needs to be done. This is particularly true regarding the development and updating of Test Guidelines and the tools listed in the Annex to the Recommendation, which require continuous implementation. According to the 2019 Report, to ensure the relevance of the Recommendation and its applicability to more advanced forms of nanomaterials, the Council invited the Chemicals Committee (now Chemicals and Biotechnology Committee) to continue disseminating and monitoring the implementation of the Recommendation, and to report to the Council in five years.

14. The purpose of this Report is to focus on the latest reporting cycle of 2019-2024 and set out the findings of the assessment of:

a) the implementation and dissemination of the Recommendation, and

b) the continued relevance of the Recommendation, including whether developments in the field warrant any revisions or updates to the Recommendation.

Methodology

15. In order to collect information on the implementation, dissemination and continued relevance of the Recommendation, a survey questionnaire was developed by the Secretariat and circulated to the Adherents to the Recommendation as well as the European Union (EU) considering that the management framework for chemicals is coordinated and enacted at European Union level [ENV/CBC(2024)14].

16. The survey questionnaire consisted of two main parts, a Part I consisting of questions related to the implementation of the Recommendation and a Part II focussing on dissemination and continued relevance of the Recommendation. The survey included multiple questions about Adherents' application of international and national chemical regulatory frameworks, specific tools, the OECD Test Guidelines, public safety data, and dissemination of the provisions of the Recommendation at various levels. The questions for implementation were not subjective, requiring a 'yes' or 'no' response, followed by additional prompts that allowed Adherents to provide further information.

17. Responses were collected between May and September 2024. Fourteen Adherents and the EU (hereafter "Respondents") provided responses to the questionnaire: Austria, Australia, Canada, Denmark, Germany, Italy, Japan, Korea, the Netherlands, Spain, Sweden, Switzerland, the United Kingdom, and the United States, as well as the EU (whose activities represent those of 23 Adherents). For the purpose of this Report, the responses provided by the EU describe the collective activities at the EU level related to implementation and are therefore reflective of activities of Adherents that are EU Member States. Several EU Member States also provided individual responses (Austria, Denmark, Germany, Spain, Sweden, Italy, and the Netherlands).

18. For several substantive provisions, additional sources of information were used to complement results from the questionnaire. This includes OECD activities led by the WPMN which supports the implementation of the Recommendation, specifically on information exchange, outreach and capacity-building. This information is provided in Section 4 of this Report.

19. At each WPMN meeting, delegations (Adherents and non-Adherents including Business at OECD and international organisations) provided written statements of current nanosafety-related activities in their country or regions. Some of these statements explicitly address the implementation of the Recommendation and/or technical needs associated with its implementation, such as work on the testing and assessment of nanomaterials. They are published every year as *Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced Materials – Tour de Table* and serve as an ongoing review of the Recommendation. This Report builds on responses to the questionnaire, and it is complemented with those written reports.

Implementation by Adherents (domestic and regional activities) and through collective action

Application of Adapted Chemical Regulatory Frameworks for Manufactured Nanomaterials

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.

20. This provision of the Recommendation recognises that existing national and international regulatory frameworks for traditional chemicals are, in general, applicable to nanomaterials and recommends that Adherents apply these frameworks to manage the risks associated with manufactured nanomaterials. The Recommendation acknowledges that these frameworks may need to be adapted to account for the specific properties of nanomaterials.

21. When asked whether they have applied existing international and national chemical regulatory frameworks or other management systems adapted to take into account the specific properties of manufactured nanomaterials, all Respondents indicate that they have adapted their chemical regulatory frameworks or management systems to take into account the specific properties of manufactured nanomaterials.

22. The EU has taken a proactive role in adapting regulations and providing guidance on nanomaterials, influencing neighbouring countries. EU Member States that are among the Respondents (Austria, Germany[13], Italy, Netherlands, Spain, Sweden) show strong alignment with EU regulations, such as the Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH[14](Regulation (EC)1907/2006)), Classification, labelling and packaging of chemicals (CLP)[15], and sector-specific regulations. Switzerland, while not an EU Member State, has harmonised some of its regulations with the EU (e.g., on biocides), including mutual recognition agreements on authorisations. The UK incorporates a version of the definition of a nanomaterial recommended by the European Commission. Furthermore, several EU Member States have set further nanomaterial registries at national level. At EU level, the European Observatory for Nanomaterials (EUON) has been set up to compile and support dissemination of already existing information on nanomaterials, also in view of support to their responsible management.

23. Australia, Canada, Switzerland, the UK, the US, Japan and Korea have reported introducing their national regulatory schemes, initiatives and action plans. The UK and Korea have set up their own regulatory framework of registration and assessment (see UK

[13] Germany indicated that for other substance-related EU regulations, nanospecific adaptations of the regulation (e.g. plant protection products, human pharmaceutical products) or regulatory guidance (e.g. biocidal products, environmental risk assessment of human pharmaceutical products) are still pending.

[14] The EU REACH Regulation (Regulation (EC)1907/2006) has been adapted in 2018 by the inclusion of a set of specific information requirements for nanoforms of a substance. Based on this, registrants are obligated to provide specific information on nanoforms separate to the required information for the bulk substance. The OECD principle of Mutual Acceptance of Data (MAD) is applied to the European Test Methods Regulation (Regulation (EC) No 440/2008), which sets test methods under the REACH Regulation.

[15] https://environment.ec.europa.eu/topics/chemicals/classification-labelling-and-packaging-chemicals_en

registration, evaluation, authorisation and restriction of chemicals -UK REACH[16]; and The Act on the Registration and Evaluation of Chemicals (known as Korea REACH[17]), including specific requirements for nanomaterials. Switzerland has implemented a comprehensive Action Plan for Synthetic Nanomaterials, developing guidelines and adapting regulations across multiple sectors. In Australia, assessments of manufactured nanomaterials follow the framework for conventional chemicals using internationally harmonized risk assessment paradigms under the Australian Industrial Chemicals Introduction Scheme (AICIS)[18]. Under the Canadian Environmental Protection Act Registry (CEPA)[19], Canada applies existing principles developed for chemical risk assessment with specific adaptations to address the specificities of manufactured nanomaterials. Canada will publish an updated Framework for the Risk Assessment of Manufactured Nanomaterials in 2025.

24. Under the Chemical Substances Control Law (CSCL), Japan regulates chemicals on a substance-by-substance basis, regardless of their particle size. In addition, the Japanese government asks companies to voluntarily submit annual reports on their management activities related to manufactured nanomaterials including details on their safe handling. This information is then made publicly available.

25. All Respondents have applied the existing legal frameworks to the management of manufactured nanomaterials. Furthermore, the analysis of responses highlights a concerted effort among many Respondents to adapt their chemical regulatory frameworks to account for the specific properties of manufactured nanomaterials. Continued collaboration, information exchange, and efforts for harmonisation will support effective regulation and facilitate innovation in the field of nanotechnology.

Apply the OECD Test Guidelines and the OECD Principles of Good Laboratory Practice when assessing the potential effects of nanomaterials on human health and the environment

> 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].

Apply the OECD Test Guidelines

26. The Recommendation recommends that Adherents use the OECD Test Guidelines (TGs)– an integral part of the Mutual Acceptance of Data (MAD) Decision that is regularly updated - when assessing the potential effects of nanomaterials on human health and the environment.

27. In the responses to the question of whether they apply the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured

[16] https://www.hse.gov.uk/reach/

[17] Law (in English): Act, Enforcemnet Decree of the Act, Portal system (in Korean): https://kreach.me.go.kr/repwrt/index.do

[18] https://www.industrialchemicals.gov.au/

[19] https://laws-lois.justice.gc.ca/eng/acts/c-15.31/index.html#wb-cont

nanomaterials, in the testing of manufactured nanomaterials, most Respondents (14 out of 15) reported having applied or encouraged the use of OECD Test Guidelines.

28. EU Member States (Austria, Denmark, Germany, Italy, Spain, and Sweden) state that they follow EU regulations such as the REACH[20] and the Test Method Regulation[21], which are continuously updated with all the relevant OECD Test Guidelines on nanomaterials as they become available. In EU's regulatory framework, the OECD Test Guidelines and supporting OECD Guidance Documents are then referenced in the guidance supporting implementation of individual pieces of legislation. Switzerland also aligns with EU regulations despite not being an EU Member State.

29. The UK encourages the use of OECD Test Guidelines adapted for nanomaterials in hazard assessment. Australia indicates that the Australian Industrial Chemicals Introduction Scheme (AICIS) recommends using specific OECD Test Guidelines for nanomaterials. Canada notes that the Draft risk assessment framework under the Canadian Environmental Protection Act (CEPA) includes guidance for OECD Test Guidelines for nanomaterials. Korea notes that the OECD Test Guidelines and OECD Guidance Documents are used as references when deciding on national test methods under the K-REACH.

30. The EU and Germany noted that it is the responsibility of the applicants or registrants to apply the information requirements set out in the regulation, use the relevant guidance, generate data applying the appropriate Test Guidelines, include the data in their dossiers and demonstrate the safe management of nanomaterial. In this regard, they highlight that while regulatory bodies provide guidelines and encourage the use of adapted Test Guidelines, it is ultimately up to industry to apply these in meeting regulatory requirements.

31. In conclusion, the application of OECD Test Guidelines for nanomaterials is widely accepted by Respondents. However, there are requests for further guidance and adaptations to better address specific properties of nanomaterials. These needs are being assessed within the Working Party on Manufactured Nanomaterials and specific Guidance Documents and Test Guidelines are under preparation by the Working Party of the National Coordinators of the Test Guidelines Programme (WNT) with the support of joint WPMN/WNT Expert Groups under the WNT. Furthermore, there is an emphasis on the industry's responsibility to apply these guidelines to meet regulatory requirements, with support and encouragement from governmental bodies.

Apply the OECD Principles of Good Laboratory Practice

32. The Recommendation also recommends that Adherents, in the testing of manufactured nanomaterials, use the OECD Principles of Good Laboratory Practice[22] (GLP) set forth respectively in Annexes I and II to the Decision concerning the Mutual Acceptance of Data (MAD). The GLP Principles are a managerial quality control system covering the organisational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived). The GLP Principles are followed by test facilities carrying out studies to be

[20] Regulation EC 1907/2006

[21] Regulation EC 440/2008

[22] https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/good-laboratory-practice-and-compliance-monitoring.html

submitted to receiving authorities for the purposes of assessing the safety of chemicals and chemical products.

33. The MAD system[23] is a multilateral agreement allowing the results of a variety of non-clinical safety test done on chemicals and chemical products, to be shared across OECD Members and non-Members that adhere to the system. The GLP Principles supports the MAD system by ensuring data quality, reducing duplication of efforts and facilitating international data sharing.

34. In the response to the question of whether they have applied the OECD GLP Principles, all Respondents confirmed that they have applied the OECD GLP Principles in their chemical assessment processes. Many Respondents (Canada, Italy, Japan, Korea, UK, Switzerland, and EU) note that they have embedded GLP into national legislation, regulation, or guidance documents.

35. Germany further emphasises that, while the country itself does not apply the GLP Principles, it requires GLP compliance for submitted data, highlighting the distinction between the role of regulatory bodies and the responsibilities of industry.

36. The analysis reveals a strong commitment among Respondents to apply the OECD GLP Principles in the assessment of chemicals to nanomaterials. This widespread adoption emphasises the global recognition of the GLP Principles as a cornerstone for ensuring high-quality and reliable data in chemical safety assessments, as well as their applicability to nanomaterials.

Box 1 Adherent case on applying the OECD Principles of Good Laboratory Practice - Canada

For new substance risk assessments (including nanomaterials that are new to the Canadian market) the New Substances Notification Regulations (Chemicals and Polymers) (NSNR (C&P)) under CEPA apply. These Regulations prescribe technical information which must be addressed by submitting test data or waiver requests. Canada may accept the use of appropriate alternative approaches (also known as New Approach Methods (NAM)) to meet these technical information requirements. The development of certain test data must comply with the practices set out in the Principles of Good Laboratory Practice that are current at the time the test data are developed, this includes data for manufactured nanomaterials.

Additionally, Canada screens and validates studies that are used in the assessment of nanoforms of existing substances on the Domestic Substances List (DSL) (i.e., currently in commerce in Canada) by applying greater weight to studies that were performed under GLP.

[23] Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals [OECD/LEGAL/0194]; Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [OECD/LEGAL/0252].

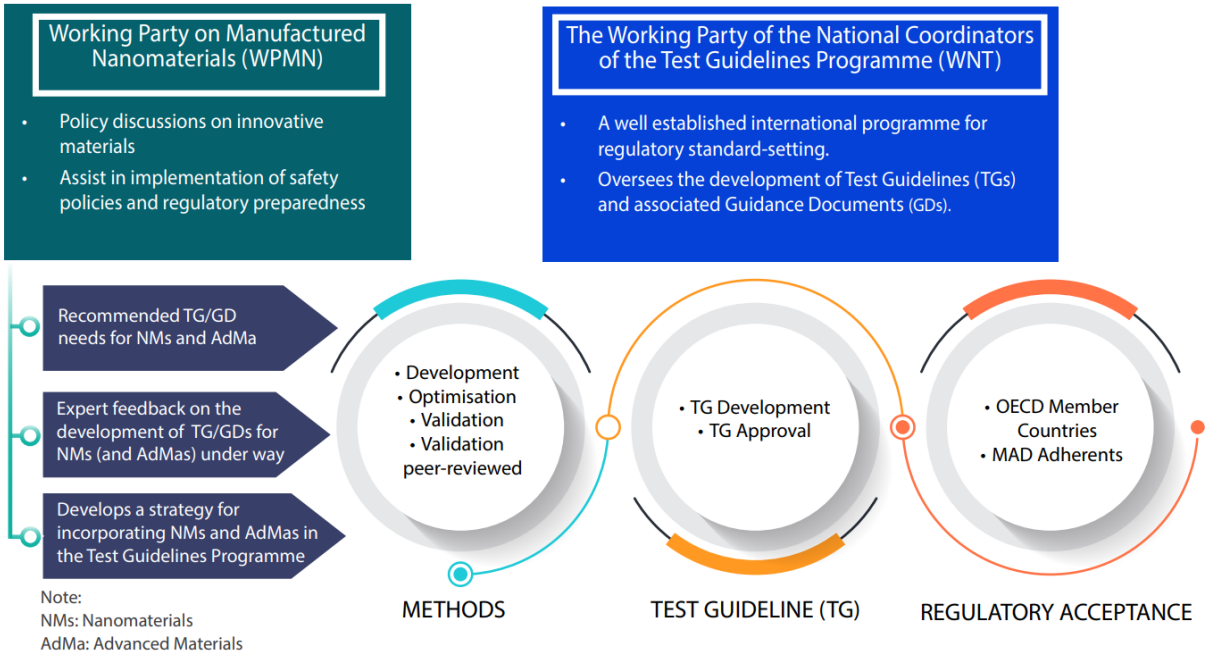
Update the OECD Test Guidelines(TGs) – Develop new TGs, update existing TGs

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.

37. The Recommendation recommends that Adherents update, in line with OECD rules and procedures, the OECD Test Guidelines in the light of experience with manufactured nanomaterials. The CBC is responsible for the Recommendation, and Test Guidelines and Guidance Documents have been developed in its subsidiary bodies notably, the WPMN and the WNT.

38. Work is underway in the WPMN, in cooperation with the WNT, to identify needs and then update or develop the OECD Test Guidelines or Guidance Documents. The initial technical work to assess the need for a Test Guideline or Guidance Document to address specific properties of nanomaterials is undertaken by the WPMN. If a need exists, a proposal (a standard project submission form – SPSF) is developed by Member countries and submitted to the WNT. Both the WPMN and WNT are supported by expert groups gathering expertise on the topic addressed (e.g., physico-chemical properties, ecotoxicology, human health effects of nanomaterials). Figure 1 explains the relationship between the two bodies in supporting the development of standardise methods for nanomaterials and advanced materials.

Figure 1 Developing standardised methods to generate trusted safety data for nanomaterials (and advanced materials)[24]



[24] Towards tailored safety testing methods for nanomaterials, May 2020 -Sept 2023, OECD (2023), page 10

39. Since the establishment of the Nanosafety Programme, a central area of work has been to assess whether existing methods and guidance used for testing and assessing "traditional" chemicals are suitable for nanomaterials. The initial efforts led to focus on filling the essential data gaps for the development of harmonised instruments for generating data and assessing manufactured nanomaterials. In 2007, the WPMN identified three key areas related to the testing and assessment of manufactured nanomaterials. First, the Safety Testing of a Representative Set of Manufactured Nanomaterial (also known as the Sponsorship Programme, completed in 2013), provided valuable insights into the specific characteristics of MNs. The other two areas are: a) Manufactured Nanomaterials and Test Guidelines; and b) The Role of Alternative Methods in Nanotoxicology. Both of these areas focused on the development of Test Guidelines and their accompanying Guidance Documents[25].

40. Since then, the Nanosafety Programme has adapted its work programme to account for scientific progress and available expertise and has supported the WNT in addressing the physical-chemical properties, environmental fate and behaviour, and health effects of nanomaterials through updated Test Guidelines and Guidance Documents. Between 2017 and 2024, the WNT and WPMN completed 15 projects, including OECD Test Guidelines, Guidance Documents and study reports. Additionally, there are currently 15 draft Test Guidelines or related Guidance Documents under development. A full list of completed and ongoing projects can be found in Table 1.

Table 1 List of OECD Test Guidelines/Guidance Documents and study documents for safety testing of nanomaterials by WPMN and WNT (2017-2024)

Project Title	TG/GD No. or Project ID	progress
Section 1: Physical Chemical Properties		
Test Guideline on Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials	TG 124[26]	Completed (2022)
Test Guideline on Particle Size and Size Distribution of Manufactured Nanomaterials	TG 125[27]	Completed (2022)
Test Guideline on Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement	TG 126[28]	Completed (2023)
Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biologically mediums	TGP Project 1.5	In progress

[25] Evolution of the Nanosafety Programme [ENV/CBC/NANO(2023)8]

[26] OECD (2022), Test No. 124: Determination of the Volume Specific Surface Area of Manufactured Nanomaterials, OECD Guidelines for the Testing of Chemicals, Section 1, OECD Publishing, Paris, https://doi.org/10.1787/abb72f8f-en

[27] OECD (2023), Test No. 125: Nanomaterial Particle Size and Size Distribution of Nanomaterials, OECD Guidelines for the Testing of Chemicals, Section 1, OECD Publishing, Paris, https://doi.org/10.1787/af5f9bda-en

[28] OECD (2023), Test No. 126: Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement, OECD Guidelines for the Testing of Chemicals, Section 1, OECD Publishing, Paris, https://doi.org/10.1787/ae9c0fd1-en

Project Title	TG/GD No. or Project ID	progress
Identification and quantification of the surface chemistry and coatings on nano- and microscale materials	TGP Project 1.6	In progress
Test Guideline on Determination of the Dustiness of Manufactured Nanomaterials	TGP Project 1.8a	Expected 2026
Guidance Document on Determination of the Dustiness of Manufactured Nanomaterials	TGP Project 1.8b	Expected 2026
Guidance Document on the determination of concentrations of nano-particles in biological samples for (eco)toxicity studies	TGP Project 1.10	In progress
Section 2: Effects on Biotic Systems		
Updating Guidance Document Technical recommendations for conducting assays with ENMs according to OECD Test Guidelines 201, 202 and 203	TGP Project 2.71	Expected publication in June 2025
Section 3: Environmental Fate and Behaviour		
Test Guideline on Dispersion stability in simulated environmental media	TG 318[29]	Completed (2017)
Guidance Document 317 on Aquatic and Sediment Toxicological Testing of Nanomaterials	ENV/JM/MONO(2020)8	Completed (2020) (update in 2025)
Guidance Document 318 for the testing of dissolution and dispersion stability of nanomaterials and the use of the data for further environmental testing and assessment strategies and an accompanying Excel Tool	ENV/JM/MONO(2020)9	Completed (2020)
Guidance Document 342 on Behaviour in Soils Using TG 312 for NMs	ENV/CBC/MONO(2021)17	Completed (2021)
Study Report on a Test for removal in Wastewater Plants of Gold Manufactured Nanomaterials: Activated Sludge Sorption Isotherm	ENV/CBC/MONO(2021)15	Completed (2021)
(Scoping review) A Tiered Approach for Reliable Bioaccumulation Assessment of Manufactured Nanomaterials in the Environment Whilst Minimising the Use of Vertebrate Testing	ENV/CBC/MONO(2024)2	Completed (2024)
Test Guideline on dissolution rate of nanomaterials in aquatic environment	TGP Project 3.10	In progress
Guidance Document on assessing the apparent accumulation potential for nanomaterials (TG 305)	TGP Project 3.12	Expected publication in June 2025
Guidance Document on environmental aquatic Transformation of Nanomaterials	TGP Project 3.16	Expected publication in 2027
Section 4: Health Effects		

[29] OECD (2017) Test No. 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media. Organisation for Economic Co-operation and Development (OECD), Paris, France, https://doi.org/10.1787/9789264284142-en. .

Project Title	TG/GD No. or Project ID	progress
Test Guideline on Subacute Inhalation Toxicity: 28-Day Study	TG 412 (Updated) [30]	Completed (2018)
Test Guideline on Subchronic Inhalation Toxicity: 90-day Study	TG 413 (Updated) [31]	Completed (2018)
Guidance Document on Inhalation Toxicity Studies	ENV/JM/MONO(2009)28/REV1	Completed (2018)
Study Report and preliminary guidance on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity TGs for Testing of MNs	ENV/CBC/MONO(2022)15	Completed (2022)
Study Report on Applicability of the key event-based TG 442D for *in vitro* skin sensitisation testing of nanomaterials	ENV/CBC/MONO(2023)18	Completed (2024)
Guidance Document on toxicokinetics to accommodate testing of nanoparticles	TGP Project 4.146	Expected 2026
Guidance Document on IATA for intestinal fate of orally ingested nanomaterials	TGP Project 4.158	Expected 2026
Validation of the *In Vitro* Micronucleus assay for Engineered Nanomaterials	TGP Project 4.174	In progress
Others: Cross – cutting		
Assessment of the Biodurability of Nanomaterials and their surface ligands	ENV/JM/MONO(2018)11	Completed (2018)
(Update) Guidance Document on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (GSPD) (Annex to the Recommendation)	WPMN Project	Expected 2025
(Update) Section 6.9 of the OECD Guidance 194 on Grouping of Chemicals	WPHA/WPMN Project	Expected 2025
Guidance on Release Tests for Manufactured Nanomaterials	WPMN	Expected 2025

41. Furthermore, the EU has an ambitious and well-funded research community that has launched vast research projects aimed at contributing to the safety testing of manufactured nanomaterials. The projects made major strides in establishing the science necessary for the subsequent development of standards within the OECD. The collaboration with several EU projects has encouraged a wider network of experts to participate in the development of OECD Test Guidelines/ Guidance Documents, the organisation of workshops, and the development of training materials. By releasing the relevant materials to the public, it also helps other Adherents and non-Adherents in implementing the Recommendation. Some of the EU-led projects are listed below.

- NanoHarmony [32] (2020-2023) : supported the development of documents (TGs, GDs, technical recommendations and scoping reviews) towards 8 nano-specific

[30] OECD (2018) Test No. 412: Subacute Inhalation Toxicity: 28-Day Study. Organisation for Economic Co-operation and Development (OECD), Paris, France, https://doi.org/10.1787/9789264070783-en.
[31] OECD (2018) Test No. 413: Subchronic Inhalation Toxicity: 90-Day Study. Organisation for Economic Co-operation and Development (OECD), Paris, France, https://doi.org/10.1787/9789264070806-en

[32] OECD TG/GD Process Mentor: www.testguideline-development.org

endpoints, and developed an interactive webpage of OECD TG/GD Process Mentor.

- NANOMET [33] (2020-2023): supported the OECD's activities on developing standardized testing methods for nanomaterials.
- MACRAMÉ[34] (2023~): launched to widen the development of harmonised TGs and GDs (OECD) and standards (CEN, ISO) to market-relevant Advanced Materials

42. Malta Initiative[35] (2017~) is a voluntary network and encourage a multi stakeholder to contribute nano-specific OECD TG/GD development and update. The European Commission, European Member States[36], industry associations and NGOs are engaged in its activities.

Prioritising future work

43. In response to the question of whether they consider that the development of OECD Test Guidelines and Guidance Documents for manufactured nanomaterials covers all relevant areas to support the implementation of the Recommendation, 2/3 of Respondents (10 out of 15) believe that the current development of OECD Test Guidelines and Guidance Documents does not adequately cover all relevant areas needed to support the implementation of the Recommendation. In other words, while major progress has been recognised, further development of Test Guidelines and Guidance Documents in these areas is necessary to fully support the implementation of the Recommendation for manufactured nanomaterials.

44. The development or updating of Test Guidelines is highly technical in nature, and very resource intensive. The pace of progress largely depends on the resources available in different countries to lead these efforts, provide expert advice, and support the Secretariat in facilitating development. Therefore, a strategic approach to prioritise future work is necessary.

45. The detailed feedback from Switzerland, Spain, Germany, and Italy provides valuable direction for future development. Key areas identified for further development are listed in Table 2.

46. Several EU Member States (Austria, Sweden, Germany, Netherlands) reference the Malta Initiative's priority list[37], published in March 2024. The list prioritises actions to support the development and amendment of OECD Test Guidelines for nanomaterials and advanced materials, as listed in Table 2. The priority list is based on a survey conducted by the Malta Initiative, which included responses from 31 experts from 16 Adherents and non-

[33] https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/nanomet.html

[34] https://macrame-project.eu/

[35] malta-initiative.org – The Test Methods Initiative

[36] Germany, Austria, Denmark, Finland, France, Greece, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden and Switzerland

[37] https://malta-initiative.org/MaltaInitiative_UPLOADS/20240301_The_Malta_Initiative_Priority_List.pdf

Adherents[38] participated in the online survey. The topics are assessed in consideration of the required time and the relevance for the OECD Test Guidelines/endpoints, regulation, and industry.

47. In responding to the survey questionnaire, Germany and the Netherlands mentioned a recent research paper on the proposal for further action[39]. This paper identifies priority areas for developing testing methods to meet regulatory requirements of the EU. When it comes to the development or adaptation of OECD Test Guidelines and Guidance Documents for nanomaterials, this paper emphasises that priority should be given to activities that are in support of New Approach Methodologies.

Table 2. Future work items identified from the responses to the OECD survey questionnaire and Malta Initiative's priority list

Sections	OECD Questionnaire	Malta Initiative's priority list[40] (Score[41])
Physical Chemical Properties	-	• Preparation and measurement of stable dispersions in liquid test media (27) • Aerosol generation for toxicity testing for *in vivo* and *in vitro* (18) • Determination of concentration of carbon-based materials in biological media /tissues (16) • Determination of concentration of carbon-based materials in environmental test compartments (8) • Determination of critical fibre rigidity (5)
Effects on Biotic Systems	-	• Effects on terrestrial organisms (16)
Environmental Fate and Behaviour	• Validated analytical methods, adapt tests for soil and sediment	• Bioaccumulation potential (12) • Biotic degradation (8)
Health Effects	• Mutagenicity • Reproductive toxicity • Acute toxicity • Toxicokinetics • Endocrine disruption	• Testing nanomaterials in *in vitro* assays (24) • Acute toxicity inhalation (*in vivo*) (21) • Genotoxicity / mutagenicity (*in vitro*) (18) • Developmental neurotoxicity (*in vitro*) (16) • Acute toxicity inhalation / respiratory sensitisation (*in vitro*) (14)

[38] Participants were distributed over the different countries in and outside of Europe : Belgium, Sweden, France, Germany, Switzerland, Netherlands, Spain, Denmark, Italy, Norway, Japan, Canada, US, Algeria, Chile, Pakistan

[39] Bleeker et al. (2023), Towards Harmonisation of Testing of Nanomaterials for EU Regulatory Requirements on Chemical Safety – A Proposal for Further Actions, https://doi.org/10.1016/j.yrtph.2023.105360

[40] Actions that are currently ongoing in the OECD Test Guidelines Programme are not included in the Priority List; as its purpose is to highlight needs that are not already covered by an ongoing OECD project.

[41] Total score = (a+b+c)*d

a, b, c : Scoring for relevance - a) for TGs/endpoints, b)for regulation c)for industry : 1(low), 2(medium), 3(high)

d: Scoring for time needed for the development of Guidance Document or Test Guideline TGs or GDs: 3 (≤ 3 years); 2 (4 – 6 years); 1 (> 6 years)

		• Skin sensitisation (*in vitro*) (14) • Fibre toxicity (14) • Testing the reactivity of nanomaterials (12) • Reproductive toxicity (9) • Inflammation induction (*in vitro*) (8)
Other issues	• Exposure assessment: the reliance on modelled data for environmental exposure and the need for measured environmental data to adjust or validate models. • New Approach Methodologies (NAMs) • Advanced Materials	• Exposure assessment (21) • Predictivity and sensitivity of *in vitro* assays and other NAMs for nanomaterials (14)

48. In conclusion, the findings of this Report show that the OECD has made significant progress in developing Test Guidelines and Guidance Documents for the safety testing of nanomaterials, by collective efforts of Adherents through WPMN and WNT. Despite this progress, Respondents still indicate that more efforts are needed for developing Test Guidelines and Guidance Documents for the safety testing of nanomaterials. Prioritisation of future work in developing Test Guidelines and Guidance Documents have been undertaken both within and outside of the OECD to ensure effective implementation of the Recommendation.

Use and update the Annex to the Recommendation

Use the Annex in adaptation of chemical regulatory frameworks

> 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.

49. The Annex of the Recommendation references tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials. A list of documents is provided in the areas of testing, exposure assessment, and risk assessment.

50. In response to the subsequent question of whether they have used the tools listed in the Annex to the Recommendation, of which it forms an integral part, in adapting existing regulations to manufactured nanomaterials, most Respondents (13 out of 15) indicate that they have utilised the tools to adapt their regulatory frameworks.

51. The level of implementation varies according to Adherents and tools (See Table 3). The EU responded that the EU regulatory framework on chemicals relies on the application of OECD tools, including tools developed to support implementation of the Recommendation. Several EU Member States (Austria, Denmark, Italy, Netherlands, Spain, Sweden, and Germany to some extent) indicated that they align their practices with EU regulations, which incorporate these tools. Germany indicates partial use of the tools referenced in the Annex, incorporating them indirectly in its domestic framework. While not an EU Member State, Switzerland references EU REACH and CLP legislation, integrating OECD tools, into its national regulations. Canada and Australia emphasise their adoption of the OECD Test Guidelines for testing nanomaterials and the tools for implementing it.

52. The UK indicates that while OECD tools have useful content, they have not been specifically used to adapt their regulatory framework. Japan does not use the tools referenced in the Annex, as its regulatory framework does not differentiate nanomaterials from other chemicals.

Table 3 Tools referenced in the Annex to the Recommendation and use by Adherents

Area	*Tools*	Level of Use by Adherents
I.Testing	*Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials* [ENV/JM/MONO(2009)21]	• It has been taken into account in its national action plan on manufactured nanomaterial. (Switzerland)
	Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials [ENV/JM/MONO(2012)40]	• Many Respondents cite this document as a crucial regulatory tool, especially for preparing and characterising nanomaterial samples. • It is necessary when studies on nanomaterials are required for submission under the New Substances Notification Regulations (Chemicals and Polymers) (NSNR (C&P)) (Canada) • It is cited in the OECD TGs and GDs
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]	• The document has been used within the framework of the German occupational and safety regulation and is partially part of the TRGS 527. (Germany) • The UK takes alternative approaches by following ISO standards instead of OECD guidelines. (UK)
III.Risk Assessment	*Important Issues in Risk Assessment of Manufactured Nanomaterials* [ENV/CBC/MONO(2022)3]	• This document is broadly recognised by many Respondents as valuable for regulatory purposes and guiding research priorities. • This has been a valuable tool in providing context in relevant implementation guidance and through its listing of research needs and supported preparation of EU research calls. (EU) • This helps the delegation to prioritise national and international research programs, and it can also support the process of evaluation of registration dossiers and provides an overview of available TGs and GDs for risk assessment of manufactured nanomaterials for regulatory purposes. (Switzerland)

53. In addition to the use of tools referenced in the Annex, Adherents have actively contributed to their refinement, ensuring they remain current and effective. The WPMN updated the Important Issues in Risk Assessment of Manufactured Nanomaterials document in 2022. Currently the Guidance on Sample Preparation and Dosimetry is under revision by the WPMN, with the help of an informal *ad-hoc* group of experts nominated by Adherents and co-led by the EU and Luxembourg. Germany has been a major player in developing/ reviewing test guidelines development, influencing the tools' evolution.

54. In conclusion, the analysis of responses highlights that there is widespread acceptance and use of the tools listed in the Annex among Adherents for adapting regulations related to nanomaterials. On the other hand, differences exist in how Adherents implement and encourage the use of specific tools. While many Adherents use these tools referenced in the Recommendation, some prefer alternative standards based on specific needs or contexts. To stay in line with scientific and technological developments, Adherents have actively contributed to the development and refinement of these OECD tools, ensuring they remain up to date and effective.

Amend the Annex

> I . (…) This Annex may be amended by the Chemicals Committee, in accordance with Section VII below.
>
> 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.
>
> 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.

55. The Recommendation, in its Annex, includes tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials. The Annex was drafted with the intention that it would be updated by the addition of new or updated tools as scientific knowledge developed.

56. Since nanotechnology 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.

57. 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 [C(2019)55/REV1], 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.

58. The need to update the Annex was discussed at the 22nd WPMN meeting in June 2022, 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 [ENV/CBC/WRPR(2023)74] aimed at replacing the document Important Issues on Risk Assessment of Manufactured Nanomaterials with a newer version[42]. During the revision process, it was noted that several documents currently in preparation will be relevant for inclusion in the Annex, indicating that additional updates to the Annex will be needed in the future[43].

59. Furthermore, in response to the question of whether Adherents consider any changes in the existing Annex of the Recommendation are necessary, most Respondents (12 out of 15) agree on the need to change the Annex. Respondents indicate that these changes aim to make the Annex a more effective tool by including the latest documents and removing obsolete references. Accordingly, some Respondents provided specific suggestions as shown in Table 4.

[42] Annex III. Risk Assessment: Important : the document of Issues in Risk Assessment of Manufactured Nanomaterials [ENV/JM/MONO(2012)8] was replaced with the 2022 version [ENV/CBC/MONO(2022)3]

[43] OECD Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials: Proposed Revision of the Annex [ENV/CBC/WRPR(2023)74]

60. Responses from Austria and Sweden suggested to add information on the most recent WPMN work on Safe(r) and Sustainable by Design, Safety and sustainability of advanced materials.

Table 4 Tools of Annex to the Recommendation and Adherent's suggested updates

Area	*Current Tools*	Needs for updating
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].	• *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials* is outdated and requires an update. Alternatively, the document needs to be deleted. (Australia, Germany and EU) • The adopted TGs and GDs, and ongoing WNT projects need to be added (Germany and Spain) • *The Guidance on Sample preparation and dosimetry for the Safety Testing of Manufactured Nanomaterials (GSPD),* which is currently under revision, should be updated (Canada, Germany, Italy, and EU) • OECD Documents developed for chemicals in general which include specific provisions on nanomaterials can be included: for example, - *Guidance on Grouping of Chemicals: Section 6.9,* which is currently under the revision (EU), - New Approach Methodologies (NAMs) for nanomaterials (Switzerland and EU)
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].	• The Annex is updated in 2017 [ENV/JM(2017)3], to reflect the current document [ENV/JM/MONO(2015)19].
III.Risk Assessment	*Important Issues in Risk Assessment of Manufactured Nanomaterials* [ENV/CBC/MONO(2022)3].	• The Annex is updated in 2023 [ENV/CBC/WRPR(2023)74], to reflect the latest document [ENV/CBC/MONO(2022)3]. • Continue updating the important issues document to maintain its relevance (Canada and EU)
Others	-	• Add Documents related to the issues of Safe(r) and Sustainable by Design, Safety and sustainability of advanced materials as they become available (Austria and Sweden)

61. The majority of Respondents agree that changes are necessary in the existing Annex of the Recommendation to reflect significant advancements in science, regulation, and testing methodologies of nanomaterials and the work on advanced materials. Key areas identified for updating include updating outdated documents, incorporating new Test Guidelines and Guidance Documents, and expanding the scope to include Safe(r) and Sustainable Innovative Approach and advanced materials. To keep pace with emerging developments, a regular review process under the WPMN may be needed for assessing the relevance of the Annex. By implementing these changes, the Annex can better serve the safety assessment of nanomaterials and advanced materials, strengthening the implementation of the Recommendation.

Public Availability of Safety Data: Make safety data related to nanomaterials available to the public

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

62. The Recommendation recommends that Adherents make safety data related to nanomaterials available to the public. Public access to safety data is considered important for informed decision-making and promoting safe use of nanomaterials.

63. The 2019 Report emphasised that all the data generated through the OECD nanosafety programme have been made available to the public, notably through a Testing Programme (Sponsorship Programme, completed in 2013). In this programme, 19 Adherents worked together to undertake the safety testing of 11 nanomaterials, and all the safety data generated have been made available to the public. However, the 2019 Report also expected that in the future, focus could be placed on the data that authorities receive from manufactures of nanomaterials complying with national/regional regulatory requirements. To this end, the survey includes a question about whether Adherents make safety data related to nanomaterials available to the public. In most cases, the data is collected from the private sector such as manufacturers and importers, so the question also addresses the Adherent's confidentiality policy.

64. In response to the question, most Respondents (14 out of 15) have made safety data related to nanomaterials available to the public. EU Member States such as Italy, Netherlands, Spain and Sweden align with EU regulations and use EU platforms for data dissemination. Some of the EU Member States have their own platform for information sharing. The United Kingdom noted that while some safety data is available on government websites, comprehensive nanomaterials data is not yet provided.

65. There are diverse approaches to data sharing (see Table 5). Many Respondents have established specific platforms or websites to disseminate nanomaterials safety data (e.g., Switzerland's InfoNano, EU's EUON, Australia's AICIS). Some Respondents provide nanomaterials safety data through existing chemical databases (e.g., ECHA Chem, OpenFoodTox, COSING). Germany and Italy disseminate information via research institutes and national health agencies.

66. Respondents also reported on their approaches regarding confidentiality and proprietary data protection. 8 Respondents indicated that they have implemented measures to protect confidential data and proprietary rights when disseminating safety information. Canada and Switzerland reference legal provisions or regulations that govern data confidentiality (e.g., Switzerland's Art. 73 of ChemO, Canada's CEPA section 313). Australia, Canada and US indicate that confidential or proprietary information is redacted or masked before public dissemination. In Japan, certain types of data are excluded from confidentiality, such as general safety summaries or non-identifying information.

67. The above cases of data dissemination imply a broad public engagement and accessibility. In many cases, platforms are designed to serve different stakeholders, including the general public, researchers, industry, and policymakers. Some platforms provide comprehensive information on nanomaterials, including risks, safe handling, and regulatory guidelines.

Table 5 Selected Cases for Data Dissemination of Respondents

	Transparency (Tools for information sharing)	Confidentiality

Austria	• www.nanoinformation.at • NanoTrust-Dossiers (oeaw.ac.at)	The data is anonymised.
Australia	All new industrial nanomaterial risk assessment statements are available on the Australian Industrial Chemicals Introduction Scheme (AICIS) website: Search assessments	Confidential data, including chemical identity and specific uses, are masked in published assessment statements.
Canada	Provides risk assessment summaries for new substance notifications under the Canadian Environmental Protection Act (CEPA): • Substances Search - Canada.ca • Nanomaterials - Canada.ca These websites provide information to the public on government activities related to the risk assessment of manufactured nanomaterials	In accordance with section 313 of CEPA, any person who provides information may request confidentiality. Confidential data and proprietary rights are removed or masked prior to public dissemination.
Germany	Provides links to several websites: • Federal Institute for Risk Assessment (BfR): https://www.bfr.bund.de/en/home.html • DaNa Project: https://nanopartikel.info/en/research/projects/dana-2-0/ • eNanoMapper: https://www.enanomapper.net/data • ECHA Registered Substances: https://chem.echa.europa.eu/ • Federal Environment Agency Publications: https://www.umweltbundesamt.de/en/publications • Federal Institute of Occupational Safety and Health (BAuA) publications: https://www.baua.de/EN/Service/Publications	Registrants may withhold data subject to business confidentiality. By default, safety data from publicly funded research must be accessible to the public.
Italy	Provides links to websites: • National Institute of Health (ISS): https://www.iss.it/ • Ministry of Health: https://www.salute.gov.it/portale/home.html • ECHA: https://chem.echa.europa.eu/	Established data protection rules to ensure the application of principles of confidential data protection and proprietary rights.
Japan	https://www.meti.go.jp/policy/chemical_management/other/nano.html (only in Japanese)	The information is provided and updated by the manufacturers and exclude confidential data from the publicised information.
Korea	The Chemical Substance Information Processing System is portal system of K-REACH regulation, including information sharing platform of chemicals and chemical products. • https://kreach.me.go.kr/repwrt/index.do (Korean) • https://kreach.me.go.kr/repwrt/mttr/en/mttrList.do (chemicals search engine available in English)	If a person who has submitted data in compliance with regulatory or risk assessment requirements requests confidentially, information concerning the chemical substance's components will be protected and kept confidential.
Switzerland	Established or co-financed four information platforms aimed at different stakeholders, including the general public: • InfoNano: Central information hub for nanotechnology providing information on opportunities, risks, and safe handling of nanomaterials. • contactpointnano.ch: Independent and national platform conveying scientific and regulatory	Art. 73 of the Chemical Ordinance specifies which data are confidential, including specifics for nanomaterials. Certain data are not deemed confidential, such as trade names, physico-chemical properties, summaries of test results, etc.

	knowledge on safe handling of synthetic nanomaterials to companies. • DaNa platform: Contains information on nanomaterials and nanosafety research (now called MANTRA focusing on Advanced Materials). Public version of the product register for chemicals: Allows searching for products on the market with relevant safety information.	
EU	Safety data related to nanomaterials is disseminated alongside information on chemicals through various platforms: • ECHA Chem**:** Dissemination portal of the European Chemicals Agency (ECHA). • OpenFoodTox**:** Chemicals hazards database by the European Food Safety Authority (EFSA). • CosIng**:** Database of cosmetic ingredients. • EUON (European Union Observatory for Nanomaterials)**:** Developed to compile and disseminate information on nanomaterials, including safety data, applicable regulations, uses, and activities.	Confidential data shared by manufacturers is not made publicly available. Proprietary rights are addressed through disclaimers and explicit consent forms. Regulatory decisions and opinions relating to the safety of nanomaterials are public and unrestricted.

68. Most Respondents have made safety data related to nanomaterials publicly available, demonstrating a commitment to transparency and public health. Furthermore, they balance the need for public access to safety data with the protection of confidential business information. As it is done for chemicals in general, Respondents have established mechanisms to protect confidential data and proprietary rights, ensuring that sensitive information is not disclosed while still providing essential safety data to the public. The responses also reveal that collaboration through international bodies like the EU facilitates broader access to safety data and harmonises dissemination processes.

Dissemination of the Recommendation

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.

(…)

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.

Dissemination By Adherents

69. Respondents indicated a broad dissemination of the Recommendation at government levels such as among the relevant ministries, levels of government and other relevant public institutions. Most Respondents (13 out of 15) indicate that they had disseminated the Recommendation at governmental level. Communications and briefings are a common method used by Australia, Denmark, Sweden, Netherlands, the US, and EU. Germany and Italy have established inter-agency or national working groups focused on nanomaterials and advanced materials, enhancing cross-governmental collaboration. Some Respondents noted other channels for dissemination, such as managing web-links, and specific awareness-raising efforts (e.g., training courses).

70. In response to the question of whether they disseminate the Recommendation externally, most Respondents (11 out of 15) indicated that they had circulated the Recommendation to non-governmental stakeholders (e.g., industry, academia, civil society). The EU noted that its dissemination efforts for the Recommendation extended to include non-Adherents. These efforts include communication and briefing, websites, specific awareness-raising efforts including training courses, and publications. Germany translated the Recommendation into German to enhance accessibility.

Dissemination through collaborative OECD action and by the OECD Secretariat

71. The OECD cooperates with relevant intergovernmental organisations under the umbrella of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC). The full membership of the IOMC includes FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, the World Bank, the Basel, Rotterdam and Stockholm Conventions and OECD. The IOMC is actively involved in the implementation of the Strategic Approach to International Chemicals Management (SAICM) and its successor, the Global Framework on Chemicals[44]. This has enhanced the dissemination of the Recommendation to all the UN Regions, as well as other intergovernmental organisations. Under SAICM, the resolutions

[44] On 30 September 2023, the Global Framework on Chemicals – for a Planet Free of Harm from Chemicals and Waste (GFC) was adopted, as a successor to SAICM. The Framework was launched on October 1 2024 (www.chemicalsframework.org).

II/4E and III/2E [45] were adopted by the International Conference on Chemicals Management (ICCM), recognising nanotechnology and nanomaterials as emerging policy issues.

72. Among others, the OECD and the United Nations Institute for Training and Research (UNITAR) have collaborated to implement, in particular, resolution III/2E, in "….enhancing stakeholder capacity for the sound management of nanotechnologies and manufactured nanomaterials". A series of workshops were organised in different UN regions to present the OECD Nanosafety Programme, and introduce the tools being developed. More recently, UNITAR invited the OECD Secretariat to present at their webinar on the sound management of waste containing nanomaterials. The OECD Secretariat participates on a regular basis in international conferences where it presents the OECD Nanosafety Programme. These events provide an opportunity for promoting the Recommendation and further promote the use of the tools and approaches outlined in the Recommendation beyond Adherents.

73. Since its inception, the WPMN established a collaboration mechanism with relevant organisations working on nanomaterials including the International Standard Organisation Technical Committee 229 "Nanotechnologies" (ISO TC 229). Over the years, the two organisations have built a common understanding of the areas that are relevant to one another and have complemented their respective work in developing standards for nanomaterials. This exchange has been particularly important in addressing the physico-chemical properties of nanomaterials and the development of Test Guidelines.

74. The OECD has a long-standing experience in collaborating with the Business and Industry Advisory Committee (BIAC) as well. The experts from BIAC have been active in WPMN discussions for developing the different nanosafety tools over the years. Updates of the work of the OECD are shared and discussed with business and industry members.

75. The annual OECD publications *Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced Materials – Tour de Table*[46] provides an opportunity to share valuable information among peers. This publication includes the activities of non-governmental organisations working on human health and the environment and/or animal welfare (e.g., The International Council on Animal Protection in OECD Programmes (ICAPO)), as well as both non-Adherents and Adherents. This fosters the dissemination of the Recommendation by offering wide range of up-to-date information and exemplary practices from peers.

76. The OECD activities on dissemination of the Recommendation, such as seminars and workshops, are summarised in Table 6 and Table 7.

45 https://www.saicm.org/Portals/12/Documents/saicmtexts/New%20SAICM%20Text%20with%20ICCM%20resolutions_E.pdf (the resolutions II/4E: p.123, the resolution III/2E: p. 156)

46 The most recent TdT is OECD (2024), Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced Materials between July 2023 and June 2024 – Tour de Table, OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, https://doi.org/10.1787/74413c15-en

Table 6 List of OECD Seminars (webinars) and Workshops (2019-2024)

Date	Type / Venue	Title
20 September 2023	Webinar	Determination of the Hydrophobicity Index of Nanomaterials Through an Affinity Measurement: OECD Test Guideline No. 126
7 February 2023	Webinar	Particle Size and Size Distribution of Nanomaterials: OECD Test Guideline 125
2 December 2021	Webinar	How to assess exposure to nanomaterials? The evaluation results of existing tools/models
25 February 2021	Webinar	Assessing the dispersion stability & dissolution rate of nanomaterials in the environment: Test Guideline No. 318 and its accompanying Guidance Document
26 January 2021	Webinar	Guidance document No. 317 on aquatic & sediment ecotoxicity testing of nanomaterials
1 September 2019	Workshop at OECD	Advancing Adverse Outcome Pathway (NanoAOP) Development for Nanomaterials Risk Assessment and Categorization (ENV/CHEM/NANO/A(2019)4)

77. NanoHarmony held multiple webinars and three international virtual workshops together with NANOMET to facilitate the needed exchange on TG development for nanomaterials[47]. These activities were continued in the MACRAMÉ project[48]. The three projects were funded by the EU to facilitate the development OECD Test Guidelines.

Table 7 NANOMET, NanoHarmony and MACRAMÉ events

Date	Type	Title
18-19 November 2024	Workshop	Harmonisation & Standardisation of Test Methods for Nanomaterials and Advanced Materials
22-23 November 2023	Workshop	Harmonisation of test methods for nano and advanced materials
31 January 2023	Conference	Future-proof Approaches for Risk Governance – Lessons Learned from Nanomaterials
29-30 November 2022	Workshop	Test Guideline development for Nanomaterials
29-30 June 2022	Conference	International NanoHarmony & NANOMET Workshop on nano-related OECD TG Development
4 May 2022	Webinar	Improving the OECD Test Guidelines Process' series dedicated to Phases 2 and 3 Technical development and commenting and approval
30 March 2022	Webinar	NanoHarmony Improving the OECD Test Guidelines Process: Project Proposals
1 March 2022	Webinar	NanoHarmony Improving the OECD Test Guidelines Process: Using TGs
17 March 2021	Webinar	Identification and solving barriers for translating science to regulation
3-5 November 2020	Workshop	Gap Analysis and Data Requirements to support TG and GD Development
16 December 2020	Webinar	Data requirements in Test Guideline and Guidance Document development
16 September 2020	Webinar	The pathway to Test Guidelines: from science to standards for nanomaterials

Adherence by non-Members and engagement with non-Adherents

78. To this date, Argentina, Brazil and Bulgaria have adhered to the Recommendation. Some non-Adherents, South Africa, Malaysia, Thailand and Croatia, have been very active in the activities of the WPMN (see also Box 2 and Box 3). They not only share their domestic information, but have also played an active role in leading or drafting documents and for providing technical inputs. Their participation has taken place in line with the

[47] The recordings can be accessed at https://www.testguideline-development.org/useful-resources#Workshops-webinars.

[48] The MACRAMÉ events can be accessed via https://macrame-project.eu/press-and-events/#MACRAME-Events.

Global Relations Strategy of the Chemicals and Biotechnology Committee[49] and as discussed by the WPMN.

Box 2 Case of non-Adherents aligning with the Recommendation : Malaysia

National Nanotechnology Policy and Strategy 2021-2030 (DSNN), launched on 15th November 2021, consists of four strategic thrusts which includes strengthening standards, safety, and regulation on nanotechnology. The Ministry of Science, Technology, and Innovation of Malaysia, through the National Nanotechnology Centre (NNC), oversees the planning and implementation of 32 initiatives under 15 strategies within this policy. The National Nano Product and Technology Roadmap 2021-2025 was launched on 13th April 2022 to support DSNN. The local nano ecosystem has been mapped towards these sectors: Energy; Environment; Food and Agriculture; Medical and Well-being; Healthcare; and Electronics and Devices.

Malaysia's four-year nationwide project to benchmark risks of nano-based products ended in 2023. An inventory of locally available nano-based products has been established. Primary data on physical-chemical, toxicology, ecotoxicology, environmental effects and life cycle assessment (LCA) studies on selected products, based on specific criteria including product category, nanomaterial in use and exposure risk, have been established. These studies were conducted in accredited laboratories and GLP certified facilities according to OECD Test Guidelines and ISO standards. The safety data have been uploaded into an online Nanosafety Referral System (nrs.mosti.gov.my) as reference for regulators, industries, academicians, and the public. Based on available data from this study, NNC has established a Task Force on Standards, Regulatory and Safety of Nanotechnology comprising of local stakeholders to oversee the development of technical guidelines for verification of products with 'nano' claims.

NNC will seek collaborations with related national departments and agencies to expand NRS through the inclusion of nano-products within the ASEAN region. NNC jointly organised a Nanosafety Course with UNITAR in Putrajaya in 2018.

The NANOVerify Programme is fostering trust, facilitating trade, and driving nanotechnology growth in Malaysia and the ASEAN region. Through new schemes, strategic thrusts, collaborations, international accreditation, and setting a regional "Gold Standard", the programme is paving the way for a robust nanotechnology landscape.

Box 3 Case of non-Adherents aligning with the Recommendation : South Africa

South Africa has established the Health Safety and Environment (HSE) Platform in 2006 by then the Department of Science and Technology (DST) to conduct research on the safety of nanomaterials, develop infrastructure to assess safety, and build human capital capable of performing these safety assessments. Within the HSE Platform, the recommendations of the OECD TGs and GDs were implemented and also contributions were made towards the development of these documents. The safety of nanomaterials assessed have included metal- and oxide-based nanomaterials. In recent years, carbon-based nanomaterials including carbon nanotubes/fibres and graphene are included. Most importantly, exposure assessment in research and industrial setting is implemented and steps are taken for exposure mitigation. In addition, molecular modelling is developed to assist in the prediction of behaviour and effects of the synthesized nanomaterials.

[49] Draft revised Global Relations Strategy of the Chemicals and Biotechnology Committee [ENV/JM(2020)26]

Summary and conclusions

Implementation

79. The information gathered by the Secretariat, and the collected survey responses suggest that Adherents, domestically and in the context of collaborative work at the OECD, have made significant and continued efforts to implement the Recommendation over the past five years.

80. The main conclusions on implementation of the Recommendation in this Report can be summarised as follows, the provision of the Recommendation on:

- the application of existing regulatory frameworks has been implemented to a high level across Respondents. The majority of Respondents have adapted their chemical regulatory frameworks accordingly.
- the application of the OECD Test Guidelines and OECD GLP Principles has also been implemented well among Respondents. Most Respondents have applied or encouraged the use of OECD Test Guidelines adapted for nanomaterials. All Respondents have applied the OECD GLP Principles, often embedding them into national legislation or regulations. This underscores a strong global commitment to ensuring high-quality, reliable data in chemical safety assessments.
- the updating of the OECD Test Guidelines has been implemented through collective efforts. Significant progress has been made with various projects completed or underway to develop or update Test Guidelines and Guidance Documents. However, most Respondents believe that current OECD Test Guidelines and Guidance Documents do not cover all relevant areas necessary for full implementation. Key areas identified for further development include environmental fate and behaviour, human health effects, exposure assessment, New Approach Methodologies (NAMs), and advanced materials. Prioritisation efforts for future work are underway both within and outside the OECD.
- the use and update of the Annex to the Recommendation has been implemented by most Respondents and through collective actions. The majority of Respondents have used these tools, though their use will vary depending on their regulatory needs. In the Recommendation, the Council instructs the CBC to amend the documents listed in the Annex according to Section I of the Recommendation and to add new documents as appropriate in light of the information provided by Adherents. Accordingly, the Annex was last amended on 30 October 2023 [ENV/CBC/WRPR(2023)74]. Respondents agree on the need to regularly update the Annex to make it more effective by including the latest documents and removing obsolete references. Suggestions include updating outdated documents, adding new OECD Test Guidelines and Guidance Documents, and incorporating topics like Safe(r) and Sustainable by Design and the work on Advanced Materials.
- public availability of safety data has widely implemented by Respondents. The majority have done so through various platforms and databases, demonstrating a commitment to transparency and public health. Diverse approaches are taken to balance public access with the protection of confidential business information, including anonymisation of data and legal provisions for confidentiality.

81. While the Recommendation is generally well-implemented by Adherents and through collective actions, there are some challenges, mainly due to the evolving nature of the field. As scientific knowledge advance, testing methodologies and nanotechnologies continue to evolve. As a result, regularly updating the OECD Test Guidelines and Guidance

Documents, and tools in the Annex will remain ongoing goals 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 toward.

Dissemination

82. Adherents have actively disseminated the Recommendation at various levels of government. Some Respondents have shared the Recommendation within their relevant governments and public institutions, typically through communications and briefings. Additional methods used include establishing inter-agency working groups, managing dedicated web links, and conducting training courses to raise awareness. Regarding external dissemination to non-governmental actors and non-Adherents, some Respondents have shared the Recommendation through communications, briefings, and web links. However, it appears that there is still a lack of widespread external communication of the Recommendation to non-governmental entities.

83. Since some elements of the Recommendation are implemented through collaborative activities at the OECD, these implementation activities are also reflected in the context of 'dissemination' in this Report. The Secretariat has presented elements of the work implemented under the Recommendation on a regular basis at external events (i.e. workshops, webinars, accession). The annual publication of the Tour de Table provides an opportunity of information sharing on comprehensive implementing activities of Adherents and stakeholders. It is also a tool for anticipating new trends and priorities among participants to the WPMN, which has allowed them to better respond to and anticipate their needs in this rapidly evolving field.

84. The OECD co-operates closely with other international organisations, especially through the Inter-organization Programme for the Sound Management of Chemicals (IOMC) [50] to strengthen international co-operation in the field of chemicals as the Recommendation considers. The OECD also collaborate with ISO TC 229 and other international initiatives/ research programmes to keep abreast on the latest developments.

85. Some Non-Adherents have been active participants in the activities of the WPMN, as well as in aligning the Recommendation with their domestic scene. Their contributions include sharing domestic information, actively participating in OECD activities or drafting documents, and providing technical inputs, which enrich the discussions related to the Recommendation.

86. While these actions have already contributed to the wide dissemination of the Recommendation to both Adherents and non-Adherents, additional efforts could be made to further disseminate the Recommendation to non-Adherents.

Continued relevance

87. Views on the need to revise the Recommendation at this stage vary among Respondents. While many Respondents acknowledge the importance of exploring new areas, there is divergence in how these should be reflected in the Recommendation. Overall, the need to revise the Annex is much higher to include ongoing work of the WPMN, compared to the need to revise the main text of the Recommendation.

88. On the question of Respondent's view on the overall relevance of the Recommendation, most of the Respondents (14 out of 15) agree that the Recommendation is still relevant. Half of positive responses in relevance (7 out of 14) suggest that it may

[50] www.iomc.info

need updates to address emerging issues, including technological changes and gaps in existing test guidelines. There are also interests in expanding the guidelines to cover additional areas such as advanced materials and NAMs. A Respondent (EU) mentioned the needs of update for the Annex.

89. Recognising the accumulated knowledge, a respondent (Italy) emphasises the need for a more tailored approach to developing Test Guidelines specifically for manufactured nanomaterials, rather than adaptations of the existing chemical framework to address their specific properties.

90. On the question of whether any new issues related to the mandate of the WPMN have arisen that the OECD should subsequently work on, the majority of Respondents answered yes (11 out of 15). In more specified responses, NAMs (100%) was identified as the most important area to explore, followed by Safe(r) and Sustainable by Design (64%) and Safety and Sustainability of Advanced Materials (64%) (See Table 8).

Table 8 New issues identified that the OECD should work on

Respondent/ New issues	Safe(r) and Sustainable by Design	Safety and Sustainability of Advanced Materials	New Approach Methodologies (NAMs)
Austria	1	1	1
Australia	0	0	1
Canada	0	0	1
Germany	1	1	1
Italy	0	0	1
Netherlands	1	1	1
Switzerland	1	1	1
Spain	1	1	1
United States	0	0	1
Sweden	1	1	1
European Union	1	1	1
Total	7	7	11

91. Regarding whether these issues should be addressed within the framework of the Recommendation, and whether the Recommendation is broad enough to cover the issues identified above or would this require an update, there are divergent views on the need for revision.

92. Half of the Respondents (8 out of 14) believe that the issues should be addressed within the framework of the Recommendation. Among those who said yes, over half (5 out of 8, Austria, Italy, the Netherlands, Sweden, and Switzerland) advocate for updating the Recommendation to address identified issues. Italy highlights the importance of integrating New Approach Methodologies (NAMs) into risk assessment frameworks.

93. Some Respondents (Germany, Korea, Spain) are satisfied with the current Recommendation, indicating that it sufficiently covers the issues. Nevertheless, even among those who think an update is unnecessary, there is recognition of the importance of addressing new developments within the existing framework. Germany specifically mentions that any necessary adjustments can be made within the Annex, avoiding a full revision of the legal instrument.

94. Australia, the US and the EU do not see that the issues should be addressed within the framework of the Recommendation. The EU provides a detailed rationale for each

issue, emphasising the need for careful consideration before making any changes. For advanced materials, EU notes the need for considering the Recommendation explicitly covering specific kind of advanced materials in time, although the Recommendation's approach for manufactured nanomaterials could serve as a default for advanced materials, at least those identified to date. For Safe(r) and sustainable by design, the EU advocates for a generic approach that should apply across the entire chemical scope. While the EU believes that NAMs is likely well-integrated into existing references, it also acknowledges the need for supporting tools in the Annex.

95. Based on the aggregated responses, this report finds that the Annex should be regularly updated to reflect state-of-the-art developments in the field, rather than underscoring a need to revise the provisions of the Recommendation in the short term. However, the need to revise the provisions of the Recommendation could be reconsidered in the medium term to ensure its continued relevance.

96. Accordingly, the CBC will continue to support Adherents in implementing the Recommendation and it is proposed to report back to the Council on the implementation, dissemination and continued relevance of the Recommendation in 10 years. The rationale for a longer reporting period is that this will enable accommodate emerging needs of Adherents in implementing the Recommendation prior to a third report on its implementation being presented to the Council. An earlier report would be prepared if changes in the area would warrant it.