

**ENVIRONMENT DIRECTORATE
CHEMICALS COMMITTEE**

Working Party on Manufactured Nanomaterials

**LIGHT ANALYSIS OF RESPONSES TO THE SURVEY TO COMPILE AVAILABLE INFORMATION
AND DATA USED FOR ASSESSING CONSUMER AND ENVIRONMENTAL EXPOSURES TO
MANUFACTURED NANOMATERIALS**

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As agreed at WPMN-13, Steering Group 8 (SG8) of the WPMN (*Exposure Measurement and Exposure Mitigation*) has conducted a survey to identify available information and data on consumer and environmental exposure assessment and mitigation measures with the aim to prioritize future work and research needs within SG8.

This report is a light analysis of the data collected via the survey which included information on the importance and availability of information and data related to six categories: 1) Material Characterization; 2) Production, Use, and Market; 3) Releases to the Environment (Direct, Indirect, and via Consumer Use); 4) Environmental Fate and Transport; 5) Exposure Assessment (Direct and Indirect); and 6) Exposure Control.

In addition, the analysis involves the identification of data gaps, priorities, and volunteers to lead or contribute to OECD projects which would be used in identifying high interest/priority topics for future work by SG8.

The survey responses were received from three delegations: Japan, United States, and Italy. Each delegation completed one survey, except the United States completed two.

Further work on this project is underway within SG8 to analyse additional responses from other delegations and a final draft report will be considered at WPMN-16.

ACTION REQUIRED: The WPMN is invited to take note of this report and discuss the next steps.

Light Analysis of Responses to the Survey to Compile Available Information and Data Used for Assessing Consumer and Environmental Exposures to Manufactured Nanomaterials

August 2015

1. The Organization for Economic Cooperation and Development (OECD) created Steering Group 8 (SG8) within the Working Party on Manufactured Nanomaterials (WPMN) to focus on exposure measurement and mitigation. In 2015, SG8 was tasked with developing a survey to compile available information and data from participants on consumer and environmental assessment of manufactured nanomaterials. Surveys were completed by the United States Environmental Protection Agency (U.S. EPA), the United States National Institute of Standards and Technology (U.S. NIST), the Italian Istituto Superiore di Sanita (ISS), and the Japanese Ministry of the Environment. The survey aimed to collect information and data used to evaluate and mitigate consumer and environmental exposure to manufactured nanomaterials, and mitigation and suggestions for further steps to be taken by the SG8 in this field. The completed surveys from each organization were evaluated and a summary of the responses with a light analysis was prepared and submitted to the SG8 members for review and comment.

BACKGROUND

2. Previous SG8 activities have focused on occupational exposure, and there is an ongoing need for guidance on exposure measurements and mitigation for consumer and environmental exposures. In addition to workers, members of the general public, consumers, and aquatic, avian, and terrestrial organisms may come into contact with nanomaterials through a wide range of applications during various stages of the life cycle of nanomaterials and products containing nanomaterials. This survey provides an opportunity to build on experience with occupational exposures and to initiate SG8 projects that would contribute to the characterization of both consumer and environmental exposures to manufactured nanomaterials in the context of human and ecological risk assessments. New projects in this area could also utilize recent developments in other organizations such as an ILSI-administered international project “NanoRelease Consumer Products” (<http://www.ilsi.org/ResearchFoundation/RSIA/Pages/NanoRelease1.aspx>).

GOAL

3. The goal of this project is to identify available information and data on consumer and environmental exposure assessment and mitigation measures, including specific consumer products, nanomaterials and exposure situations with the aim to prioritize future work and research needs.

SCOPE

4. This project involved a survey to collect information used to characterize consumer and environmental exposures for human and ecological risk assessment. The data collected via the survey included information on the importance and availability of information and data related to six categories: 1) Material Characterization; 2) Production, Use, and Market; 3) Releases to the Environment (Direct, Indirect, and via Consumer Use); 4) Environmental Fate and Transport; 5) Exposure Assessment (Direct and Indirect); and 6) Exposure Control. In addition, the survey asked for the identification of data gaps, priorities, and volunteers to lead or contribute to OECD projects which would be used in identifying high interest/priority topics for future work by SG8. SG8 participants were able to provide more than one response per delegation (e.g., research agencies and regulatory authorities were able to provide separate responses per delegation).

SUMMARY & ANALYSIS OF SURVEY RESPONSES

5. Responses were received from three OECD member countries: Japan, United States, and Italy. Each delegation completed one survey, except the United States completed two. The survey consisted of three sections, with each section asking for information and data relating to 33 issues that were divided into the six categories identified above. Section 1 required the country to indicate the importance and availability of the data or information, as well as the framework for generation of issues, the linkages with other issues, and the potential for contribution to SG8 projects. Each issue had the option to be considered to relate predominantly to consumer exposure assessment, environmental exposure assessment, or both. (NOTE: Japan only included responses for environmental exposure assessment and did not include responses for consumer exposure assessment).

6. Section 2 allowed countries to identify the type of available information, including any data development, research, case studies, methods, databases, tools, or models for the previously indicated consumer and/or environmental exposure assessment from Section 1. The section also identified the status of the information or data as completed, ongoing, or planned. Section 3 allowed countries to provide additional descriptive information related to Sections 1 and 2.

7. The summary & analysis of survey responses is organized into the following sections: “Importance”, “Data Availability”, and “Framework”. Each section identifies the categories that observed notable trends among each of the organizations, as well as which issues had universally similar results for their importance, the type/availability of data, and any regulatory/research framework for each of the countries. These issues are then used to suggest future activities for SG8 on this topic. Appendix 1 provides a comprehensive listing of survey results from each organization.

Importance

8. The survey asked respondents to indicate whether they consider the issue to be “very high”, “high”, or “less” important. Respondents were limited to scoring issues as “very high” and “high” for a maximum of 6 and 12 issues, respectively.

9. “Material Characterization” (Category 1) was generally of higher importance to the two U.S. organizations than Japan and Italy for both consumer and environmental exposure. The reason for this difference was not clearly articulated. However, of the four issues in “Material Characterization”, the one that was universally reported to be most important to all four organizations was *material characterization* (e.g. *purity, particle size, shape, aggregation/agglomeration potential, surface area, density, dustiness, etc.*).

10. Figure 1 presents the responses for each organization on the importance of “Material Characterization” issues, with the two U.S. organizations categorizing the issues as generally more important.

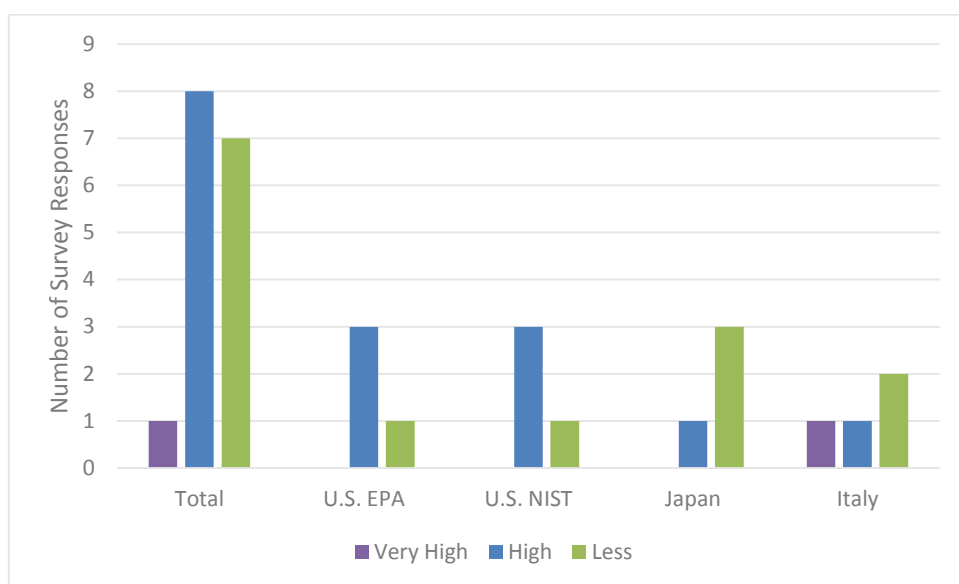


Figure 1. Survey Responses for “Material Characterization” Importance

11. “Production, Use, and Market” (Category 2) was also of more concern to the two U.S. organizations for both consumer and environmental exposure, but the U.S. NIST identified some of these important issues as pertaining more to consumer exposure over environmental. The differences within and between member countries was not clearly articulated. The issue that was universally important to all countries was *information on current and anticipated production/import quantities*.

12. Japan identified all of the issues in “Releases to the Environment” (Category 3) as either very high or high importance for environmental exposure, and there was no single issue that was universally important to all countries in this category. Figure 2 presents the responses for each organization on the importance of “Releases to the Environment” issues, with Japan visibly identifying higher importance than other delegations.

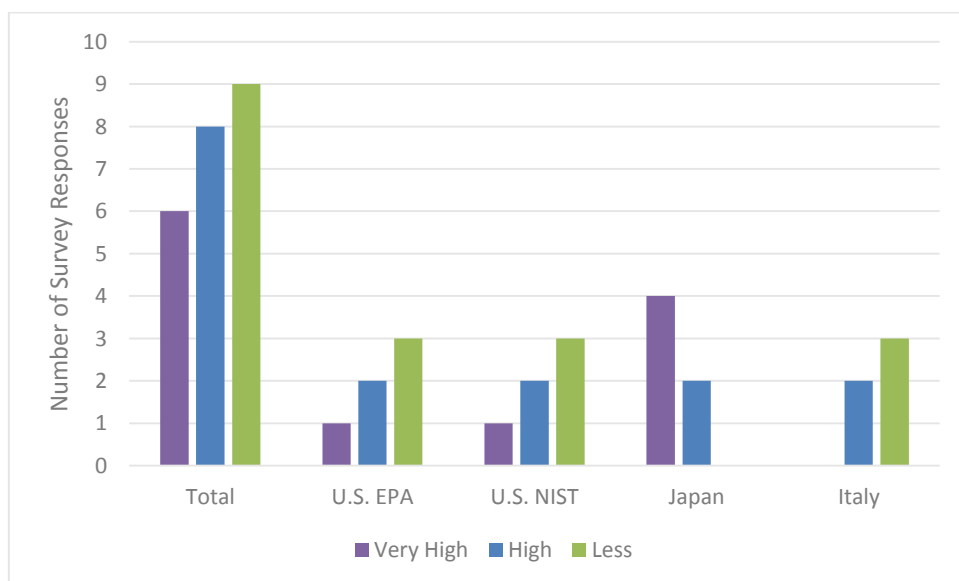


Figure 2. Survey Responses for “Releases to the Environment” Importance

13. The information provided via the survey for “Environmental Fate and Transport” (Category 4) applied predominantly to environmental exposure assessment for all three delegations. Figure 3 presents the responses of each organization for which “Environmental Fate and Transport” issues applied predominantly to consumer exposure assessment, environmental exposure assessment, or both.

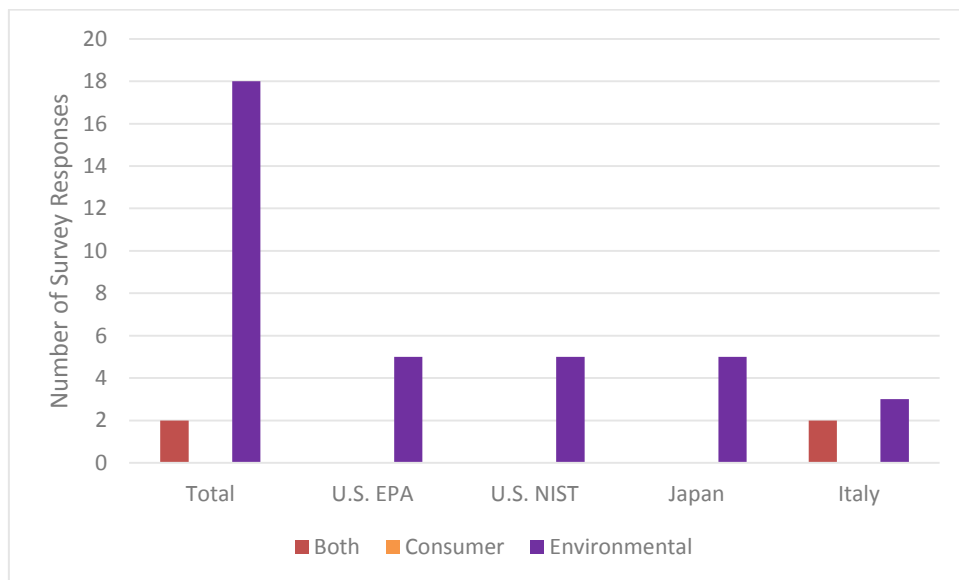


Figure 3. Survey Responses for “Environmental Fate and Transport” Consumer vs. Environmental Exposure

14. In addition, Japan declared all five issues in this category as “high” importance, and the U.S. EPA, U.S. NIST, and Italy each declared three out of five as either “high” or “very high” importance (Figure 4). There is potential for future projects relating to environmental exposure assessment in this category with collaboration among each of the delegations. The two universally important issues were:

- (1) *Test data to evaluate how the nanomaterials behave in the environment (i.e. migration to ground water, surface water, migration through and sorption to soil, air, sediment, including sorption to sediment, sludge/biosolids, landfill and land application), and*
- (2) *Test data to determine how the nanomaterials are transformed in the environment (i.e. aerobic and anaerobic biodegradation, bioavailability, bioaccumulation, hydrolysis, atmospheric oxidation, other abiotic degradation, and incineration).*

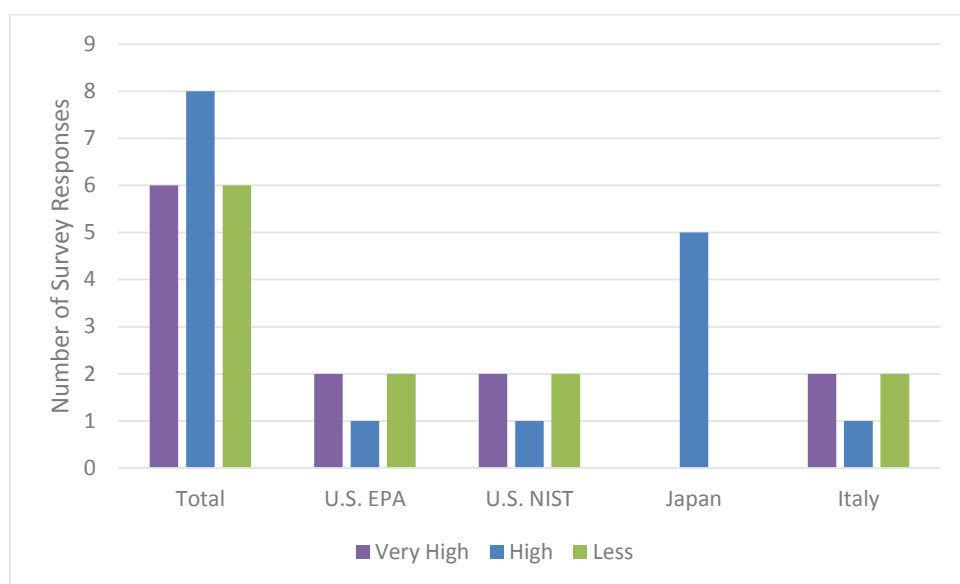


Figure 4. Survey Responses for “Environmental Fate and Transport” Importance

15. “Exposure Assessment” (Category 5) contained nine different issues, including information on the number of consumers potentially exposed, exposure pathways, exposure models, etc. Each of the countries gave varied results for the importance of the issues in this category. For example, each organization declared roughly half of the nine issues as important and half as less important. However, the two universally important issues among each of the delegations were:

- (1) *Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials, and*
- (2) *Accurate exposure measurements of nanomaterials in various environmental media.*

16. In total, the U.S. and Japan declared roughly the same amount of issues as “very high” importance, “high” importance, and “less” importance, respectively. Italy, however, declared slightly less issues as “very high” importance and slightly more issues as “less” importance, as shown in figure 5.

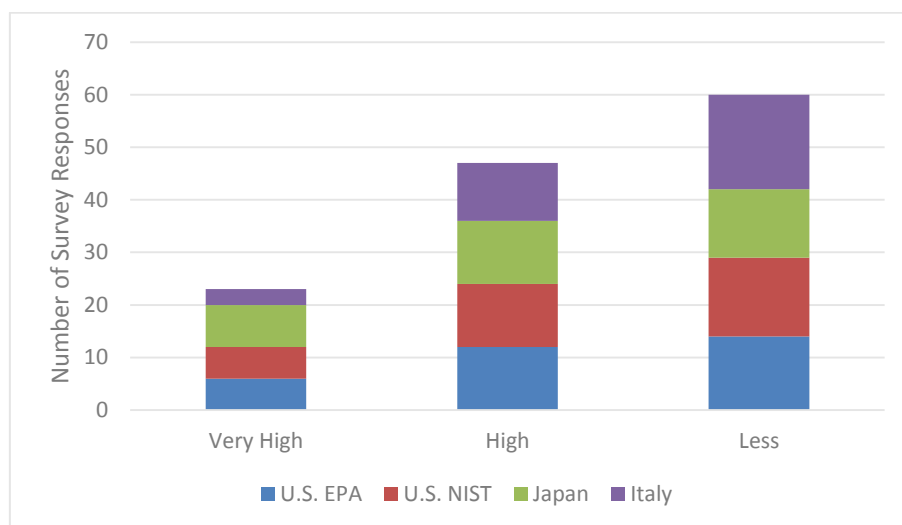


Figure 5. Survey Responses of Importance for All 33 Issues

17. In almost all categories, there were one or more issues that were valued highly among all four organizations, meaning that there is potential for collaboration on future projects to be taken on by SG8 to evaluate this. These issues include:

- “Material Characterization” (Category 1): *material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, surface area, density, dustiness, etc.).*
- “Production, Use, and Market” (Category 2): *information on current and anticipated production/import quantities.*
- “Environmental Fate and Transport” (Category 4): *test data to evaluate how the nanomaterials behave in the environment (i.e. migration to ground water, surface water, migration through and sorption to soil, air, sediment, including sorption to sediment, sludge/biosolids, landfill and land application), and test data to determine how the nanomaterials are transformed in the environment (i.e. aerobic and anaerobic biodegradation, bioavailability, bioaccumulation, hydrolysis, atmospheric oxidation, other abiotic degradation, and incineration).*
- “Exposure Assessment” (Category 5): *exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials, and accurate exposure measurements of nanomaterials in various environmental media.*

Data Availability

18. The amount and type of data available varied greatly among all four organizations. Japan stated that data was not available for all issues in all categories. All organizations (except for Japan) stated that data was available or planned for the *name of the nanomaterial which accurately reflects the substance and impurities* in “Material Characterization” (Category 1).

19. For “Exposure Assessment” (Category 5), Italy stated that half of the issues had data available or planned, and the U.S. EPA and U.S. NIST declared availability for slightly more than half (Figure 6). Additionally, the U.S. EPA, U.S. NIST, and Italy all stated that the following issues in “Exposure Assessment” had data available or planned:

- (1) *Information on exposure pathways for nanomaterials which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other);*
- (2) *Information on the routes of exposure (inhalation, ingestion, dermal) to nanomaterials with which to assess consumer and environmental exposure;*
- (3) *Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials; and*
- (4) *Accurate exposure measurements of nanomaterials in various environmental media.*

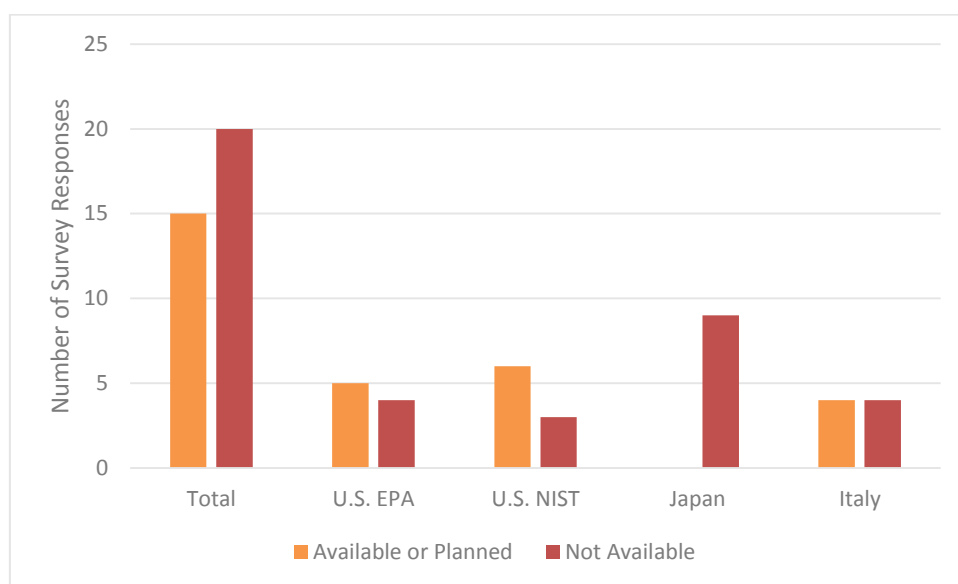


Figure 6. Survey Responses for “Exposure Assessment” Data Availability

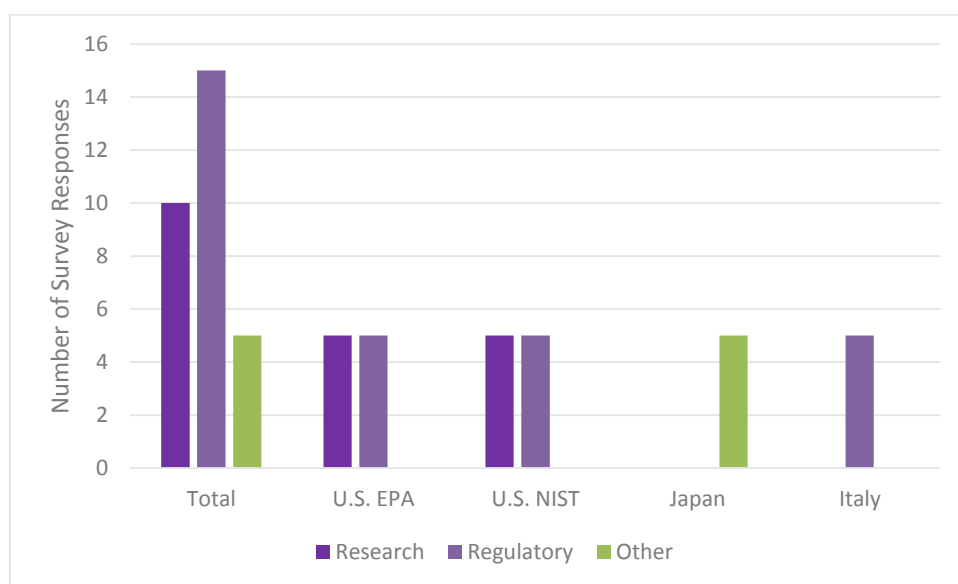
20. All organizations, particularly the U.S. NIST, stated that several issues had ongoing or completed methods, models, databases, or tools for the available information and data (except for Japan). The U.S. NIST stated this for 11 issues of the total 33. Appendix 2 includes a listing of citations/references provided by the organizations for the type of available information and data.

21. For *Information of nanomaterials released from the use of articles and products into the environment* in “Releases to the Environment” (Category 3), all organizations responded to the type of available information and data, with the U.S. EPA stating that some case studies were completed, and the U.S. NIST and Italy identifying some ongoing methods, models, databases, and tools.

Framework

22. The survey asked respondents to indicate the type of program (i.e., research, regulatory, or other) under which the data or information is being developed or used. For all issues in all six categories, Japan stated that information is being gathered via the ministry’s study. Additionally, Italy responded that they have regulatory framework for all of the issues.

23. For the two U.S. organizations, the framework was predominantly regulatory for all six categories. However, the U.S. NIST and U.S. EPA identified many of the issues as undergoing research in addition to a regulatory framework. For “Environmental Fate and Transport” (Category 4), both organizations stated that each issue had both research and regulatory framework, as shown in figure 7.



**Figure 7. Survey Responses for “Environmental Fate and Transport” Framework
Additional Descriptions**

24. The U.S. EPA provided additional descriptions for two issues. For *information on current and potential uses, including consumer goods* in “Production, Use, and Market” (Category 2), the U.S. EPA identified three sources of information:

- The Wilson Center Project on Emerging Nanotechnologies (PEN) Inventory of Nanomaterials in Consumer Products (<http://www.nanotechproject.org/cpi/>)
- The U.S. EPA Nanomaterials Stewardship Program Interim Report
- The NLM Household Products Database (<http://hpd.nlm.nih.gov/cgi-bin/household/list?tbl=TblBrands&alpha=A>)

25. For *test data to evaluate how these materials behave in the environment* in “Environmental Fate and Transport” (Category 4), the U.S. EPA stated that a number of research grants are ongoing which address transformation behavior of nanomaterials in the environment, including during waste water treatment.

(http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/research.display/rpt/abs/rfa_list/534,516,461,462,431,398,389,352,309,225)

26. Italy provided a number of citations for ongoing data development, or other projects related to materials characterization, exposure assessment, and exposure control and mitigation. These references and information provided by the other respondents has been included in Appendix 2 – Listing of Citations and References by Issue.

SUGGESTED FUTURE ACTIVITIES

27. The issues identified above where countries provided similar results for importance, data availability, and/or framework present an opportunity for collaboration on possible future projects relating to risk assessment of manufactured nanomaterials by SG8.

28. There were two issues in particular where each organization declared high importance and had data available or planned in “Exposure Assessment” (Category 5), which have the potential to be studied further. These include:

- (1) *Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials*
- (2) *Accurate exposure measurements of nanomaterials in various environmental media*

29. Additionally, for *accurate exposure measurements of nanomaterials in various environmental media*, the U.S. NIST also has ongoing methods, models, databases, and tools, and Japan has ongoing and planned research, methods, models, databases, and tools. Future activities could include a more in-depth study of these issues or potential harmonization within OECD member countries, within the context of consumer and environmental exposure assessment.

Appendix 1 – Listing of Survey Results from Each Organization

Issue	Importance				Data Availability				Framework			
	EPA	NIST	Japan	Italy	EPA	NIST	Japan	Italy	EPA	NIST	Japan	Italy
<i>Material Characterization Relevant to Consumer or Environmental Exposure:</i>												
1. Name of the nanomaterial which accurately reflects the substance and impurities	High (both)	High (both)	Less (E)	Less (both)	Available or planned (both)	Available or planned (both)	Not available (E)	Available or planned (both)	Regulatory	Research; Regulatory	Other (information gathering vis the ministry's	Regulatory
2. Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, surface area, density, dustiness, etc.)	High (both)	High (both)	High (E)	Very high (both)	Available or planned (both)	Available or planned (both)	Not available (E)	Not available (both)	n/a	Research; Regulatory	Other (information gathering vis the ministry's	Regulatory
3. Concentrations of nanomaterials (bound or unbound) in the products/formulations	High (both)	High (both)	Less (E)	High (both)	Not available (C)	Available or planned (both)	Not available (E)	Not available (both)	n/a	Research; Regulatory	Other (information gathering vis the ministry's	Regulatory
4. Physical form of nanomaterials (bound and unbound) in products and articles	Less (both)	Less (both)	Less (E)	Less (both)	Not available (both)	Not available (both)	Not available (E)	Not available (both)	n/a	Regulatory	Other (information gathering vis the ministry's	Regulatory
<i>Production, Use, and Market:</i>												
5. Information on manufacturing and processing into product or article	High (both)	High (both)	Less (E)	Less (both)	Available or planned (both)	Not available (both)	Not available (E)	Not available (both)	Regulatory	Regulatory	Other (information gathering vis the ministry's	Regulatory
6. Information on current and anticipated production/import quantities	High (both)	High (both)	High (E)	High (both)	Available or planned (both)	Not available (both)	Not available (E)	Not available (both)	Regulatory	Research; Regulatory	Other (information gathering vis the ministry's	Regulatory
7. Information on current and potential uses, including consumer goods	High (both)	High (both)	High (E)	Less (both)	Available or planned (both)	Not available (both)	Not available (E)	Available or planned (both)	Regulatory	Research; Regulatory	Other (information gathering vis the ministry's	Regulatory
8. Market share information for uses, including consumer goods	Less (both)	High (C)	Less (E)	Less (both)	n/a	Not available (C)	Not available (E)	Available or planned (both)	Regulatory	Regulatory	Other (information gathering vis the ministry's	Regulatory
9. Information on use of nanomaterials in n/a products used by children		Very high (C)	Less (E)	High (both)	Not available (both)	Not available (C)	Not available (E)	Not available (both)	Regulatory	Regulatory	Other (information gathering vis the ministry's	Regulatory

10. Information on sources of nanomaterials released from manufacture and processing	High (E)	High (E)	Very high (E)	Less (both)	Available or planned (E - some)	Available or planned (E)	Not available (E)	Not available (both)	Regulatory	Regulatory	Other (information gathering vis the ministry's)	Regulatory
11. Information on frequency, duration, and magnitude of release from manufacture and processing	Very high (both)	Very high (both)	Very high (E)	Less (both)	Available or planned (E - some)	Available or planned (C)	Not available (E)	Not available (both)	Regulatory	Research; Regulatory	Other (information gathering vis the ministry's)	Regulatory
12. Information of nanomaterials released from the use of articles and products into the environment	High (both)	High (E)	Very high (E)	n/a	Not available (both)	Available or planned (E)	Not available (E)	n/a	Research; Regulatory	Research; Regulatory	Other (information gathering vis the ministry's)	n/a
13. Information on frequency, duration, and magnitude of release from use of the nanomaterials itself into the environment	Less (E)	Less (E)	Very high (E)	Less (both)	Not available (both)	Available or planned (E)	Not available (E)	Not available (both)	Research; Regulatory	Research; Regulatory	Other (information gathering vis the ministry's)	Regulatory
14. Applicability of OECD emission scenarios (ESDs) for nanomaterials	Less (both)	Less (both)	High (E)	High (both)	Not available (E)	Not available (both)	Not available (E)	Not available (both)	n/a	Regulatory	Other (information gathering vis the ministry's)	Regulatory
15. OECD emission scenarios (ESDs) under development for nanomaterials	Less (E)	Less (both)	High (E)	High (both)	Available or planned (E - some)	Not available (both)	Not available (E)	Available or planned (E)	Regulatory	Regulatory	Other (information gathering vis the ministry's)	Regulatory
<i>Environmental Fate and Transport:</i>												
16. Test data to evaluate how the nanomaterials behave in the environment (water migration to ground water; surface water; migration through and sorption to soil; air; sediment; including sorption to sediment; sludge/biosolids; landfill and land application)	Very high (E)	Very high (E)	High (E)	Very high (E)	Not available (E)	Available or planned (E)	Not available (E)	Not available (E)	Research; Regulatory	Research; Regulatory	Other (information gathering vis the ministry's study)	Regulatory
17. Test data to determine how the nanomaterials are transformed in the environment, including biodegradation (aerobic and anaerobic), bioavailability, bioaccumulation, hydrolysis, atmospheric oxidation, other abiotic degradation, incineration	Very high (E)	Very high (E)	High (E)	Very high (E)	Not available (E)	Available or planned (E)	Not available (E)	Not available (E)	Research; Regulatory	Research; Regulatory	Other (information gathering vis the ministry's study)	Regulatory

18. Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate	High (E)	Less (E)	High (E)	High (E)	High (E)	Available or planned (both)	Available or planned (E)	Not available (E)	Not available (E)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory
19. Test data to determine whether releases of nanomaterials escape the POTW's or sort to sludge	Less (E)	High (E)	High (E)	Less (both)	Available or planned (both)	Available or planned (both)	Not available (E)	Not available (both)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory	
20. Test data to determine whether natural organic matter and sunlight lead to solution transformation products if nanomaterials escape the POTW's	Less (E)	Less (E)	High (E)	Less (both)	Available or planned (both)	Available or planned (E)	Not available (E)	Not available (both)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory	
<i>Exposure Assessment (Direct and Indirect) for Consumer and Environmental Exposure to Manufactured Nanomaterials:</i>													
21. Information on the number of consumers potentially exposed to nanomaterials during use of an article or product	Less (C)	Less (C)	Less (E)	Less (C)	Not available (C)	Not available (C)	Not available (E)	Not available (C)	Regulatory	Regulatory	Other (information gathering vis the ministry's	Regulatory	
22. Information on the number of children potentially exposed to nanomaterials during use of an article or product	High (C)	High (C)	Less (E)	Less (C)	Not available (C)	Not available (C)	Not available (E)	Not available (C)	Regulatory	Regulatory	Other (information gathering vis the ministry's	Research	
23. Information on exposure pathways for nanomaterials which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other)	Less (both)	Less (both)	Very high (E)	Less (both)	Available or planned (both)	Available or planned (both)	Not available (E)	Available or planned (both)	Regulatory	Regulatory	Other (information gathering vis the ministry's	Regulatory	
24. Information on the routes of exposure (inhalation, ingestion, dermal) to nanomaterials with which to assess consumer and environmental exposure	Less (both)	Less (both)	Less (E)	Less (both)	Available or planned (both)	Available or planned (both)	Not available (E)	Available or planned (both)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	n/a	
25. Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials	Very high (both)	High (both)	High (E)	High (both)	Available or planned (both)	Available or planned (both)	Not available (E)	Available or planned (both)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory	

26. Accurate exposure measurements of nanomaterials in various environmental media	Very high (both)	Very high (E)	Very high (E)	High (both)	Available or planned (both)	Available or planned (E)	Not available (E)	Available or planned (both)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	n/a
27. Accurate exposure measurements for consumers exposed to nanomaterials	Very high (C)	Very high (C)	Less (E)	High (C)	Not available (both)	Available or planned (C)	Not available (E)	Not available (C)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory
28. Measured data on leaching of nanomaterials from consumer articles and products (if available, please describe what was measured [e.g., particles, mass, surface area, size distribution])	High (C)	Less (both)	Less (E)	High (C)	Not available (both)	Available or planned (both)	Not available (E)	Not available (C)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory
29. Measured data on emissions of nanomaterials from consumer articles and products (if available, please describe what was measured [e.g., particles, mass, surface area, size distribution])	High (C)	Less (both)	Very high (E)	High (C)	Available or planned (C)	Not available (both)	Not available (E)	n/a	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	n/a
<i>Exposure Control and Mitigation, as it Pertains to Consumers and Environment:</i>												
30. Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)	Less (E)	Less (E)	Very high (E)	Less (both)	Not available (both)	Not available (E)	Not available (E)	Not available (both)	Research: Regulatory	Research	Other (information gathering vis the ministry's	Regulatory
31. Information on controls for mitigating environmental exposure to nanomaterials (if available, please describe)	Less (E)	Less (E)	High (E)	Less (both)	Not available (E)	Not available (E)	Not available (E)	Not available (both)	n/a	Research	Other (information gathering vis the ministry's	Regulatory
32. Information on controls for mitigating consumer exposure to nanomaterials (if available, please describe)	Less (C)	Less (C)	Less (E)	Less (both)	Not available (E)	Not available (C)	Not available (E)	Not available (both)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	Regulatory
33. Information on effectiveness of controls for mitigating consumer exposure to nanomaterials (if available, please describe)	Less (C)	Less (C)	Less (E)	Less (C)	Not available (C)	Not available (C)	Not available (E)	Not available (C)	Research: Regulatory	Research: Regulatory	Other (information gathering vis the ministry's	n/a

Appendix 2 – Listing of Citations and References by Issue

"Material Characterization" (Category 1)		
Issue	Organization	Citations/References
<i>Name of the nanomaterial which accurately reflects the substance and impurities</i>	U.S. NIST	Numerous standards completed by ASTM E56 and ISO TC 229
<i>Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, etc.</i>	U.S. NIST	Numerous standards completed by ASTM E56 and ISO TC 229
	Italy	FP7-NanoReg
<i>Concentrations of nanomaterials in the products/formulations</i>	U.S. NIST	Ongoing work at NIST to develop protocols to make and quantify ENM concentrations in polymer nanocomposites and a thread with AgNPs
<i>Physical form of nanomaterials in products and articles</i>	U.S. NIST	Ongoing work at NIST to measure the form of CNTs in polymer composites
"Releases to the Environment" (Category 3)		
Issue	Organization	Citation
<i>Information on sources of nanomaterials released from manufacture and processing</i>	U.S. EPA	http://www.epa.gov/oppt/nano/nano-fact-sheet.html
<i>Information of nanomaterials released from the use of articles and products into the environment</i>	U.S. EPA	http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=241665 , http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=230972 , http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=244011
	U.S. NIST	Work is ongoing at NIST to develop protocols to characterize ENMs released from consumer products after aging (e.g., http://www.publish.csiro.au/paper/EN14072.htm)
<i>Information on frequency, duration, and magnitude of release from use into the environment</i>	U.S. EPA	http://www.epa.gov/oppt/exposure/pubs/cebnanodraft_05_12.pdf
	U.S. NIST	Work is ongoing at NIST to develop protocols release of ENMs from consumer products after aging (e.g., http://www.publish.csiro.au/paper/EN14072.htm)

"Environmental Fate and Transport" (Category 4)		
Issue	Organization	Citation
<i>Test data to evaluate how these materials behave in the environment (water (migration to ground water, surface water, migration through and sorption to soil, air, sediment, including sorption to sediment, sludge/biosolids, landfill and land application).</i>	U.S. NIST	Numerous studies have been conducted at NIST to develop methods to characterize the environmental fate of ENMs (e.g., http://pubs.acs.org/doi/abs/10.1021/es2017076)
	Italy	GUIDENANO-FP7 Project (Consorzio Venezia Ricerche); SUN –FP7 project (Università Ca' Foscari di Venezia, Veneto Nanotech, Colorobbia, MBN Nanomaterialia, Plastic Components and Modules automative)
<i>Test data to determine how the nanomaterials are transformed in the environment, including biodegradation (aerobic and anaerobic), bioavailability, bioaccumulation, hydrolysis, atmospheric oxidation, other abiotic degradation, incineration.</i>	U.S. NIST	Numerous studies have been conducted at NIST to develop methods to characterize the environmental transformations of ENMs (e.g., http://www.sciencedirect.com/science/article/pii/S0048969711002737)
<i>Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate.</i>	U.S. EPA	OECD Test Guidelines project “Development of a Draft Test Guideline for Nanomaterial Removal via Sorption During Wastewater Treatment”: http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=499980
	U.S. NIST	One study was conducted at NIST to assess CNT removal by coagulation (http://pubs.acs.org/doi/abs/10.1021/es902946j) while a review paper on CNTs covered all aspects of the environmental fate of CNTs including removal by waste water treatment plants (http://pubs.acs.org/doi/abs/10.1021/es201579y)
<i>Test data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs.</i>	U.S. NIST	Methods to assess interactions between natural organic matter and ENMs have been developed at NIST (e.g., http://pubs.acs.org/doi/abs/10.1021/es1026097)

"Exposure Assessment" (Category 5)		
Issue	Organization	Citation
<i>Information on exposure pathways which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other)</i>	U.S. EPA	http://www.epa.gov/oppt/exposure/pubs/nanomaterial.pdf
<i>Information on the routes of exposure (inhalation, ingestion, dermal) with which to assess consumer and environmental exposure</i>	U.S. EPA	http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=499980
<i>Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials</i>	Italy	SUN-EU FP7Project
<i>Accurate exposure measurements of nanomaterials in various environmental media</i>	U.S. NIST	Numerous studies have been conducted at NIST to accurately quantify and characterize ENMs in various environmentally relevant media (e.g., http://link.springer.com/article/10.1007%2Fs11051-011-0298-y)
	Italy	SUN-EU FP7Project
<i>Accurate exposure measurements for consumers exposed to nanomaterials</i>	Italy	SUN-EU FP7Project
<i>Measured data on leaching of nanomaterials from consumer articles and products (if available, please describe what was measured (e.g., particles, mass, surface area, size distribution))</i>	Italy	SUN-EU FP7Project
"Exposure Control and Mitigation" (Category 6)		
Issue	Organization	Citation
<i>Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)</i>	Italy	SUN-EU FP7 Project