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CONSUMER AND ENVIRONMENTAL EXPOSURE TO MANUFACTURED NANOMATERIALS
Information used to characterize exposures: Analysis of a Survey

Series on the Safety of Manufactured Nanomaterials
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Information used to characterize exposures: Analysis of a Survey

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
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No.67, *Developments in delegations on the safety of manufactured nanomaterials - tour de table (2016)*

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No.69, *Fullerenes (C60): summary of the dossier (2016)*

No.70, *Single walled carbon nanotubes (SWCNTs): summary of the dossier (2016)*

No.71, *Silicon dioxide: summary of the dossier (2016)*

No.72, *Toxicokinetics of manufactured nanomaterials: report from the OECD expert meeting (2016)*

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The Environment, Health and Safety Division publishes free-of-charge documents in 11 different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides; Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and Safety of Manufactured Nanomaterials**. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organisations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

The OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting) held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety (June 2005). This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety related aspects of manufactured nanomaterials. The scope of this session was intended to address the chemicals sector.

As a follow-up, the Joint Meeting decided to hold a Workshop on the Safety of Manufactured Nanomaterials in December 2005, in Washington, D.C. The main objective was to determine the "state of the art" for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee in September 2006. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. It promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document was led by Canada and the United States as part of the work on Exposure Measurement and Exposure Mitigation undertaken by the OECD Working Party on Manufactured Nanomaterials.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, pesticides and Biotechnology of the OECD.

TABLE OF CONTENTS

Tables

Figures

EXECUTIVE SUMMARY

1. The purpose of this report is to provide a light analysis of results of the survey, *Consumer and Environmental Exposures to Manufactured Nanomaterials*, which was done by the Working Party on Manufactured Nanomaterials (hereafter WPMN) within the Organization for Economic Cooperation and Development (OECD). Initiated in 2015, the survey was designed to collect **information used to characterize consumer and environmental exposures for human and ecological risk assessment**. The survey was intended to be used as a tool to inform potential avenues for future research and collaboration in the area of exposure assessment as it relates to manufactured nanomaterials. The information presented in this document is not intended to imply scientific and/or policy endorsement of any specific exposure assessment methods or models.

2. The survey collected data on the importance and availability of information and data in six broad 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 and Mitigation.

3. It also requested information on perceived data gaps and priorities, and solicited volunteers to lead or contribute to OECD projects which may arise from the information obtained from the survey.

4. This report presents an analysis of the survey data by broad category (listed above), and highlights the importance of multiple types of information, ranging from material characterization to environmental release and exposure analysis. The report also contains a more detailed analysis of the issues in each of the six broad categories (Table 1), with respect to perceived importance, data availability and framework.

5. Based on the analysis presented herein, this report also recommends potential avenues for future work by the OECD; these are grouped into the following three themes, based on linkages identified by the survey:

- Theme 1 includes projects related to the development and use of exposure models for manufactured nanomaterials. This includes information on production/import quantities, exposure pathways, and exposure measurement in the environment, for consumers and of emissions from consumer articles and products.

- Theme 2 includes projects on issues related to environmental behaviour and transformation, and includes information on nanomaterials released from the use of articles and products to the environment.

- Theme 3 includes projects related to the material characterization of manufactured nanomaterials and includes data on the physical form of nanomaterials in products.

6. Future OECD activities could include a more in-depth study of those issues (Table 1), which emerged as priorities, or potential harmonization within OECD member countries, within the context of consumer and environmental exposure assessment.

7. Overall, this survey has demonstrated that there are many opportunities for collecting additional information to be shared among OECD member countries, perhaps through a more in-depth survey of priority issues, or potential harmonization among OECD member countries.

8. Recommended next steps include obtaining feedback on the direction proposed for future OECD projects and identifying specific projects that can be undertaken by the WPMN. Follow up on selected survey responses is also recommended in order to determine the feasibility and applicability of data for future activities.

INTRODUCTION

Purpose

9. In 2015, the OECD's Steering Group on Exposure Measurement and Mitigation within the Working Party on Manufactured Nanomaterials (WPMN) was tasked with identifying available information and data on consumer and environmental exposure assessment and mitigation measures, including specific consumer products, nanomaterials and exposure situations with the aim of prioritizing future work and research needs. To this end, the OECD oversaw a survey on ***Consumer and Environmental Exposures to Manufactured Nanomaterials*** (Appendix A). The following report summarizes the responses received from the survey and identifies potential avenues for future research and collaboration, based on the survey results.

10. Previous OECD's 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 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".

Scope

11. The survey, *Consumer and Environmental Exposures to Manufactured Nanomaterials,* collected information used to characterize consumer and environmental exposures for human and ecological risk assessment. The data collected included information on importance (very high, high or low), data availability (available/planned or not available) and the framework under which the data or information is being developed or used (research, regulatory or other). For importance, respondents were asked to limit their responses of high or very high to a maximum of 12 and 6 issues, respectively. The survey spanned the following six broad 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)
6. Exposure Control and Mitigation

12. In addition, the survey requested information on perceived data gaps and priorities, and solicited volunteers to lead or contribute to OECD projects which may be used in identifying high interest/priority topics for future work by the WPMN. WPMN delegations were able to provide more

than one response per country (e.g., research agencies and regulatory authorities we able to provide separate responses within a single country).

13. The survey was divided into three overall sections, which requested information and data relating to 33 issues encompassing the six broad categories listed above (Table 1).

Table 1. List of issues considered under each category

# ISSUES	SUBJECT
Category 1 - Material Characterization	
1.	Name of the nanomaterial which accurately reflects the substance and impurities
2.	Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, surface area, density, dustiness, etc.)
3.	Concentrations of nanomaterials (bound or unbound) in the products/formulations
4.	Physical form of nanomaterials (bound and unbound) in products and articles
Category 2 - Production, Use, and Market	
5.	Information on manufacturing and processing into product or article
6.	Information on current and anticipated production/import quantities
7.	Information on current and potential uses, including consumer goods
8.	Market share information for uses, including consumer goods
9.	Information on use of nanomaterials in products used by children
Category 3 - Releases to the Environment (Direct, Indirect, and via Consumer Use)	
10.	Information on sources of nanomaterials released from manufacture and processing
11.	Information on frequency, duration, and magnitude of release from manufacture and processing
12.	Information of nanomaterials released from the use of articles and products into the environment
13.	Information on frequency, duration, and magnitude of release from use of the nanomaterial itself into the environment
14.	Applicability of OECD emission scenarios (ESDs) for nanomaterials
15.	OECD emission scenarios (ESDs) under development for nanomaterials
Category 4 - Environmental Fate and Transport	
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).
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.
18.	Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate.
19.	Test data to determine whether releases of nanomaterials escape the POTWs or sorb to sludge.
20.	Test data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs.
Category 5 - Exposure Assessment (Direct and Indirect)	
21.	Information on the number of consumers potentially exposed to nanomaterials during use of an article or product
22.	Information on the number of children potentially exposed to nanomaterials during use of an article or product
23.	Information on exposure pathways for nanomaterials which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking

	water, other)
24.	Information on the routes of exposure (inhalation, ingestion, dermal) to nanomaterials with which to assess consumer and environmental exposure
25.	Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials
26.	Accurate exposure measurements of nanomaterials in various environmental media
27.	Accurate exposure measurements for consumers exposed to nanomaterials
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)
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)
Category 6 - Exposure Control and Mitigation	
30.	Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)
31.	Information on controls for mitigating environmental exposure to nanomaterials (if available, please describe)
32.	Information on controls for mitigating consumer exposure to nanomaterials (if available, please describe)
33.	Information on effectiveness of controls for mitigating consumer exposure to nanomaterials (if available, please describe)

14. Appendix A shows the survey form as it was provided.

15. Section 1 required respondents to indicate the level of importance, availability of data or information, and the framework for generation or use of the data for each of the 33 issues (i.e., research or regulatory), and to identify linkages with other issues, and the potential for contribution to OECD projects. In addition, respondents were asked to denote each issue response as pertaining to consumer exposure assessment, environmental exposure assessment, or both.

16. Section 2 required respondents to identify the type of available information for each issue, including any data development, research, case studies, methods, databases, tools, or models which pertain to consumer and/or environmental exposure assessment. Respondents also denoted the status of the information or data as completed, ongoing, or planned.

17. Section 3 allowed countries to provide additional descriptive information related to Sections 1 and 2.

Survey Respondents

18. Fifteen completed surveys were received from ten OECD member countries as well as the European Commission (six countries and the European Commission completed one survey each, while four countries completed two):

- **Canada**
  - Environment Canada/Health Canada (EC/HC)
- **European Commission** (REACH)

- **Germany**
  - German Federal Institute for Risk Assessment (BfR)
  - German Federal Environmental Agency (UBA)
- **Italy**
  - Istituto Superiore di Sanita (ISS) (i.e., National Institute of Health)
- **Japan**
  - Ministry of the Environment (MoE)
  - National Institute of Health Sciences (NIHS)
- **Korea**
  - Korean Agency for Technology and Standards (KATS)
  - Hoseo University (HU)
- **Netherlands**
  - National Institute for Public Health and the Environment (RIVM)
- **South Africa**
- **Spain**
  - LEITAT Technological Center (LEITAT)
- **United Kingdom**
  - NERC Centre for Ecology and Hydrology (NanoFASE project)
- **United States**
  - Environmental Protection Agency (US EPA)
  - National Institute of Standards and Technology (NIST)

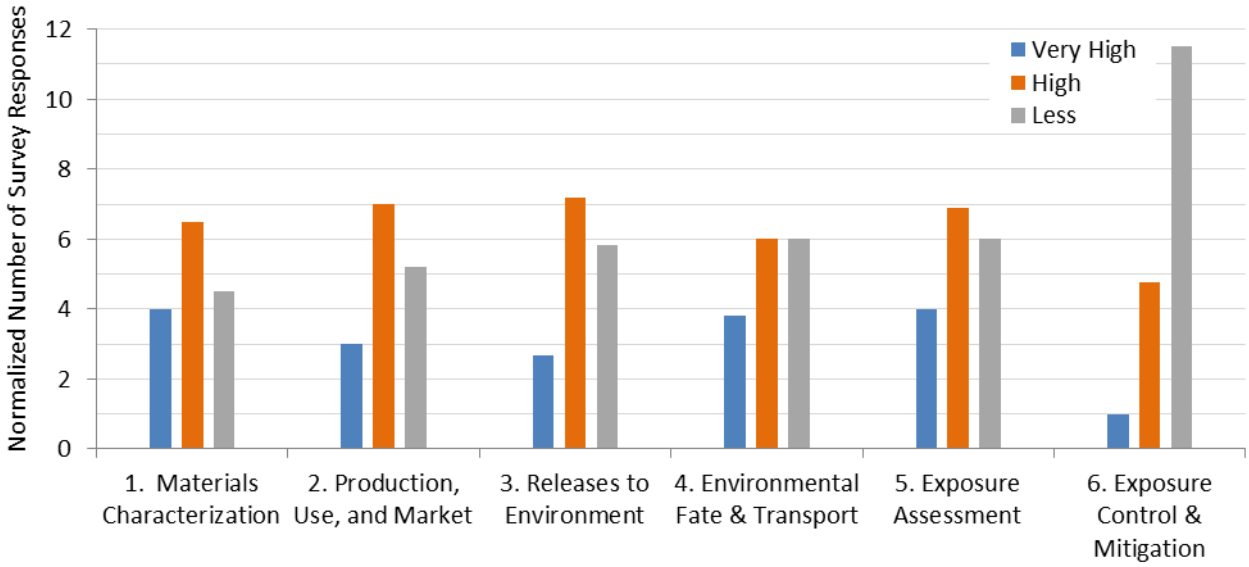
SURVEY OBSERVATIONS

19. Overall, the survey results indicate the importance of multiple types of information for environmental and consumer exposure assessment of manufactured nanomaterials. The survey also highlights serious data gaps in all categories. An overall comparison of importance, data availability, and framework for the development or use of data/ information is shown in Figures 1, 2 and 3, respectively.

Importance

20. All of the categories were determined to be of similar relative importance, with the exception of Category 6 (Exposure Control and Mitigation) which was consistently denoted as being of lower importance relative to other categories (Figure 1). Issues in Categories 1 through 5 were denoted as being of high or very high importance approximately twice as often as they were denoted as being of low importance. The opposite was true for Category 6, where survey respondents indicated that these issues were of lesser importance twice as often as they were indicated as being of very high or high importance.

Figure 1. Importance of survey issues, organized by category



21. When the importance of all survey issues are compared against each other, some issues emerge as being perceived as being of higher relative importance. The following issues were ranked as being the most important by survey respondents:

- Material characterization (***Issue 2***)
- Current and anticipated production/import quantities (***Issue 6***)
- Information on current and potential uses, including consumer goods (***Issue 7***)
- Test data to determine how nanomaterials behave in the environment (***Issue 16***)
- Test data to determine how nanomaterials are transformed in the environment (***Issue 17***)
- Exposure models (***Issue 25***)
- Accurate exposure measurement in various environmental media (***Issue 26***)
- Concentration of nanomaterials in products/formulations (***Issue 3***)

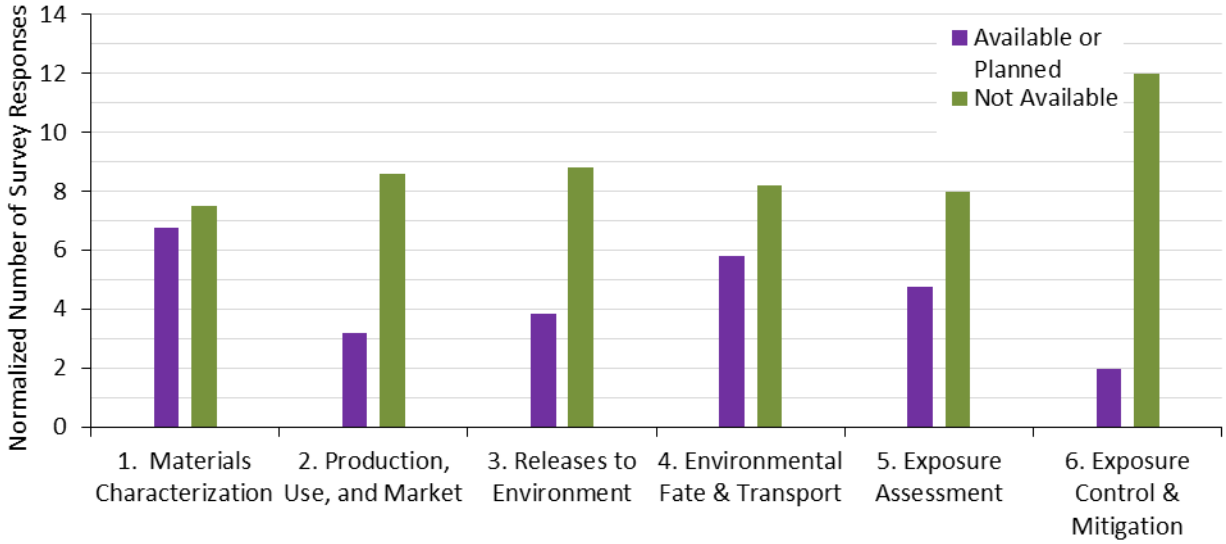
- Information on frequency, duration, and magnitude of release from manufacture and processing (***Issue 11***)
- Accurate exposure measurement for consumers exposed to nanomaterials (***Issue 27***)
- Measured data on leaching of nanomaterials from consumer articles and products (***Issue 28***)
- Measured emissions of nanomaterials from consumer products (***Issue 29***)

22. The above issues can largely be considered as common priorities by the WPMN, and might be considered as topics for future projects to be taken on by OECD.

Data availability

23. Survey results on data availability demonstrate an overarching lack of data and information across categories (Figure 2). Data gaps pertaining to exposure control and mitigation issues (Category 6) appear to be especially significant; however, this category was also perceived as being generally less important by responding organizations.

Figure 2. Overall Framework of survey issues, organized by category



24. When responses for data availability of all survey issues are compared against each other, the following issues emerge as having the most data available or planned:

- Name of the nanomaterial accurately reflecting the substance and impurities (***Issue 1***)
- Material characterization (***Issue 2***)
- Information on exposure pathways (***Issue 23***)
- Information on route of exposure (***Issue 24***)
- Exposure models (***Issue 25***)

25. Interestingly, two of these same issues also emerge as the most important (e.g., material characterization, exposure models; see above), and may therefore prove to be useful starting points for information sharing and collaboration, as future work is planned.

26. Conversely, many issues emerged as highly important, but have less available or planned data. These issues present potential data gaps, and may also benefit from future OECD work. These include:

- Current and anticipated production/import quantities (***Issue 6***)
- Information on current and potential uses, including consumer goods (***Issue 7***)
- Test data to determine how nanomaterials behave in the environment (***Issue 16***)
- Test data to determine how nanomaterials are transformed in the environment (***Issue 17***)
- Accurate exposure measurement in various environmental media (***Issue 26***)
- Concentration of nanomaterials in products/formulations (***Issue 3***)
- Information on frequency, duration, and magnitude of release from manufacture and processing (***Issue 11***)
- Accurate exposure measurement for consumers exposed to nanomaterials (***Issue 27***)
- Measured data on leaching of nanomaterials from consumer articles and products (***Issue 28***)
- Measured emissions of nanomaterials from consumer products (***Issue 29***)

27. A compilation of available data cited by survey participants can be found in Appendix C.

Linkage Analysis

28. Section 2 of the survey asked countries to identify linkages between important issues that could be addressed in the same project; this information was requested with the aim of reducing the overall number of projects and pooling resources between countries. Seven of fifteen countries responded to this part of the survey. Appendix B provides a graphical representation of the linkages that were identified.

29. Issues relating to Materials Characterization (Category 1) were the most linked to other issues overall, demonstrating the broad applicability and importance of material characterization data. This relationship was particularly strong for issues relating to Releases to the Environment (Category 3), Environmental Fate & Transport (Category 4), and Exposure Assessment (Category 5). Other strongly interrelated categories include those on Production Use and Market (Category 2), which was strongly related to categories of Releases to the Environment (Category 3) and Exposure assessment (Category 5). Issues relating to Environmental Fate and Transport (Category 4) were also strongly related to data on Releases to the Environment (Category 3). Data on issues relating to Exposure Control and Mitigation were least often identified as being linked to issues in other categories. This is consistent with the relative low importance given to issues in this category (see above).

30. An analysis of the linkages between individual survey issues is limited to those issues which were identified as the most important by survey respondents. Table 2 lists the most prominent linkages identified by the survey. The themes that emerge through this analysis are suggested as starting points for identifying themes for future OECD projects.

31. In some instances, data-rich issues appear to be linked to issues with identified data gaps. For example, materials characterization (***Issue 2***), an issue with high data availability was strongly linked to five issues with identified data gaps (Table 2). In cases such as these, combining issues into common projects could maximize resources and provide a good starting point for those issues for which less data is available. Of course, prior to initiating any new project, a suitability check is recommended in order to evaluate the usefulness of the available data from one issue for filling a data gap of another.

32. In other instances, data-poor issues cluster together. This is the case for most linkages identified by the survey, and reflects the overarching lack of data for both consumer and environmental exposure to manufactured nanomaterials. For example, data on the environmental behaviour of nanomaterials in the environment (***Issue 16***) clusters together with three other data-poor issues (Table 2). Combining future OECD projects such that they include linked issues with identified data needs may also be beneficial.

Table 2. Main linkages for issues identified as most important by OECD member countries

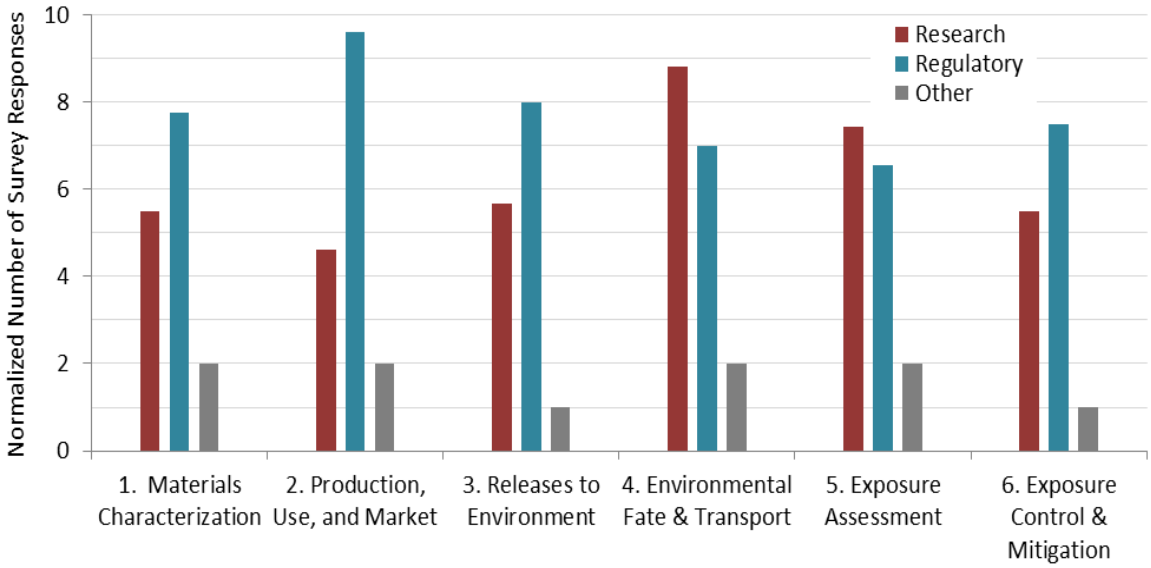
Issue	Most prominent linkages
2. Material characterization	**4.** Physical form of nanomaterial in products 26. Accurate exposure measurement nanomaterials in environmental media **27.** Exposure measurements for consumers exposed to nanomaterials **28.** Data on leaching of nanomaterials from consumer articles and products **29.** Measured emissions of nanomaterials from consumer products
6. Production/import quantities	**25.** Exposure models
7. Current and potential uses, including consumer goods	**9.** Use of nanomaterials in products used by children
16. Environmental behaviour	**12.** Information on nanomaterials released from the use of articles and products into the environment **17.** Environmental transformation data **20.** Data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs
17. Environmental transformation	**16.** Environmental behaviour
25. Exposure models	**23**. Exposure pathways **26.** Accurate exposure measurement nanomaterials in environmental media **27.** Exposure measurements for consumers exposed to nanomaterials **29.** Measured emissions of nanomaterials from consumer articles and products
26. Exposure measurement in environmental media	**2**. Material characterization **25**. Exposure models
3. Concentration in product/formulation	**12.** Nanomaterials released from the use of articles and products into the environment **13.** Frequency, duration, and magnitude of release from use of the nanomaterial into the environment **28**. Data on leaching of nanomaterials from consumer articles and products **29.** Measured emissions of nanomaterials from consumer articles and products
11. Frequency, duration, and magnitude of release from manufacture and processing	**10.** Sources of nanomaterials released from manufacture and processing
27. Exposure measurements for consumers exposed to nanomaterials	**2.** Material characterization **25.** Exposure Models
28. Data on leaching of nanomaterials from consumer articles and products	**2.** Material characterization **3.** Concentration in product/formulation **4.** Physical form of nanomaterial in products
29. Measured emissions of nanomaterials from consumer articles and products	**2.** Material characterization **3.** Concentration in product/formulation **4.** Physical form of nanomaterial in products **25.** Exposure Models

Note: Issues in bold are considered data-rich (i.e., have available or planned data by at least nine OECD countries).

Framework

33. There were differing responses regarding the framework relevant for the development or use of data for nanomaterial environmental and consumer exposure assessment. Both the regulatory and research frameworks are being used to develop and use data on nanomaterial exposure; however, differences are observed between categories. The regulatory framework was most often cited for Categories 1, 2, 3 and 6, while a research framework was most often cited for Categories 4 and 5 (Figure 3). It should be noted, however, that differences in the responses obtained for this section of the survey may be due to inherent differences between the responsibilities of the responders. For example, it is anticipated that those responders which are government organizations (e.g., HC/EC Canada, US EPA, UBA Germany, etc.) will, by the nature of their work, generate and use exposure data differently, than would scientific research institutions (e.g., NERC U.K., LEITAT Spain, ISS Italy, etc.).

Figure 3. Overall Framework of survey issues, organized by category



RECOMMENDATIONS

34. Based on the survey analysis presented in this report, three major themes emerge as possible avenues for future work by OECD.

35. Theme 1 encompasses projects related to the development and use of exposure models for manufactured nanomaterials. This includes information on production/import quantities, exposure pathways, and exposure measurement in the environment, for consumers and of emissions from consumer articles and products.

36. Theme 2 encompasses projects on issues related to environmental behaviour and transformation, and includes information on nanomaterials released from the use of articles and products to the environment.

37. Theme 3 encompasses projects related to the material characterization of manufactured nanomaterials and includes data on the physical form of nanomaterials in products. Material characterization of nanomaterials is integral to many exposure issues and is expected to be critical for any future projects undertaken by OECD.

38. Recommended next steps include:

- Obtain feedback from OECD members on the direction proposed for future projects
- Identify specific projects that can be undertaken by OECD
- Follow-up on selected survey responses to determine the feasibility and applicability of data for future activities.

ANALYSIS OF SURVEY RESPONSES, BY CATEGORY

Category 1: Material Characterization

39. Issues related to material characterization were addressed with questions 1 through 4 of the survey (Appendix A). Overall, these issues were mostly deemed to be of high importance by survey respondents (Figure 4.a), with Korea (KATS and HU), South Africa, and Spain indicating these issues as more highly important than other countries. Moreover, most countries indicated issues in this category as being important for both consumer and environmental exposure assessment (data not shown). The issue of material characterization (***Issue 2***) was overwhelmingly denoted as being the most important issue in this category (Figure 4.b), with every respondent listing it as being of either very high or high importance. The next most important issue was that relating to the concentration in the product/formulation (***Issue 3***), followed by that relating to the name accurately reflecting the substance (***Issue 1***).

40. The availability of data on issues related to material characterization was almost evenly split between 'available or planned' and 'not available', with the European Commission, Korea (KATS and HU), Spain, the U.K., and the U.S.A. (NIST) most often denoting data in this category as available or planned (Figure 5a). Furthermore, Spain and the U.K. indicated that the issue related to materials characterization (***Issue 2***) was available or planned for environmental exposure, but not available for consumer exposure. Data on issues related to the name accurately reflecting the substance and material characterization (***Issue 2***) were most often denoted as available or planned (Figure 5b). Overall, the results suggests that data for the nanomaterials themselves (e.g., name and physical/chemical characterization data) are available more so than data on nanomaterials in products (e.g., concentration and physical form in products).

41. Material characterization issues were most often denoted by survey respondents as being developed and/or used in a regulatory context (Figure 6a); however, differences exist between organizations. For example, Korea (KATS and HU), Spain, the U.K. and the U.S.A. (NIST) predominantly indicated the relevance of research for developing or using this type of data, while Canada, the European Commission, Germany (BfR and UBA), Italy, Japan (NIHS), South Africa, and the U.S.A (EPA) predominantly indicated a regulatory context for these purposes. South Africa indicated material characterization data as being developed and used by industry, and Japan (MoE) indicated that this information was being gathered via a ministry's study. While each of the four issues in this category was most often denoted as being developed or used within a regulatory framework (Figure 6b), research was also considered highly important for developing or using material characterization data itself (***Issue 2***).

42. The type of available information/data on material characterization issues was reported by nine of fifteen survey respondents. Data development on the name of the nanomaterial (***Issue 1***) is ongoing in Germany (UBA) and Korea (HU and KATS). All nine respondents indicated that data was completed, ongoing, or planned for material characterization itself (***Issue 2***). For example, case studies have been completed by Canada, methods/models/databases/tools completed by the U.S.A. (NIST) for material characterization, and data development is ongoing in this area in Germany and Korea. Five countries specified the type of nanomaterial concentration data available (***Issue 3***). For example, Korea (KATS and HU) indicated ongoing data development, and Spain indicated ongoing research and case studies in this area. Case studies and research on the physical form of nanomaterials in products in articles (***Issue 4***) are ongoing in Spain. The U.K. and the U.S.A. (NIST)

also have planned and ongoing methods/models/databases/tools for this issue. Citations and further information provided by countries on available or planned data are available in Appendix C.

43. Overall, compared to other categories in the survey, material characterization issues were more often rated as being of very high importance, highlighting the importance of these issues for many OECD participants. Nevertheless, the survey data highlight existing data gaps in this area, particularly for nanomaterials in products. It is recommended that OECD countries interested in material characterization data, such as Germany, Korea and Spain, consider opportunities for collecting and sharing information with those that currently have this type of data available, or planned, such as Korea (KATS and HU), Spain, the U.K., the U.S.A. (NIST) and the European Commission.

Figure 4. Overall Framework of survey issues, organized by category

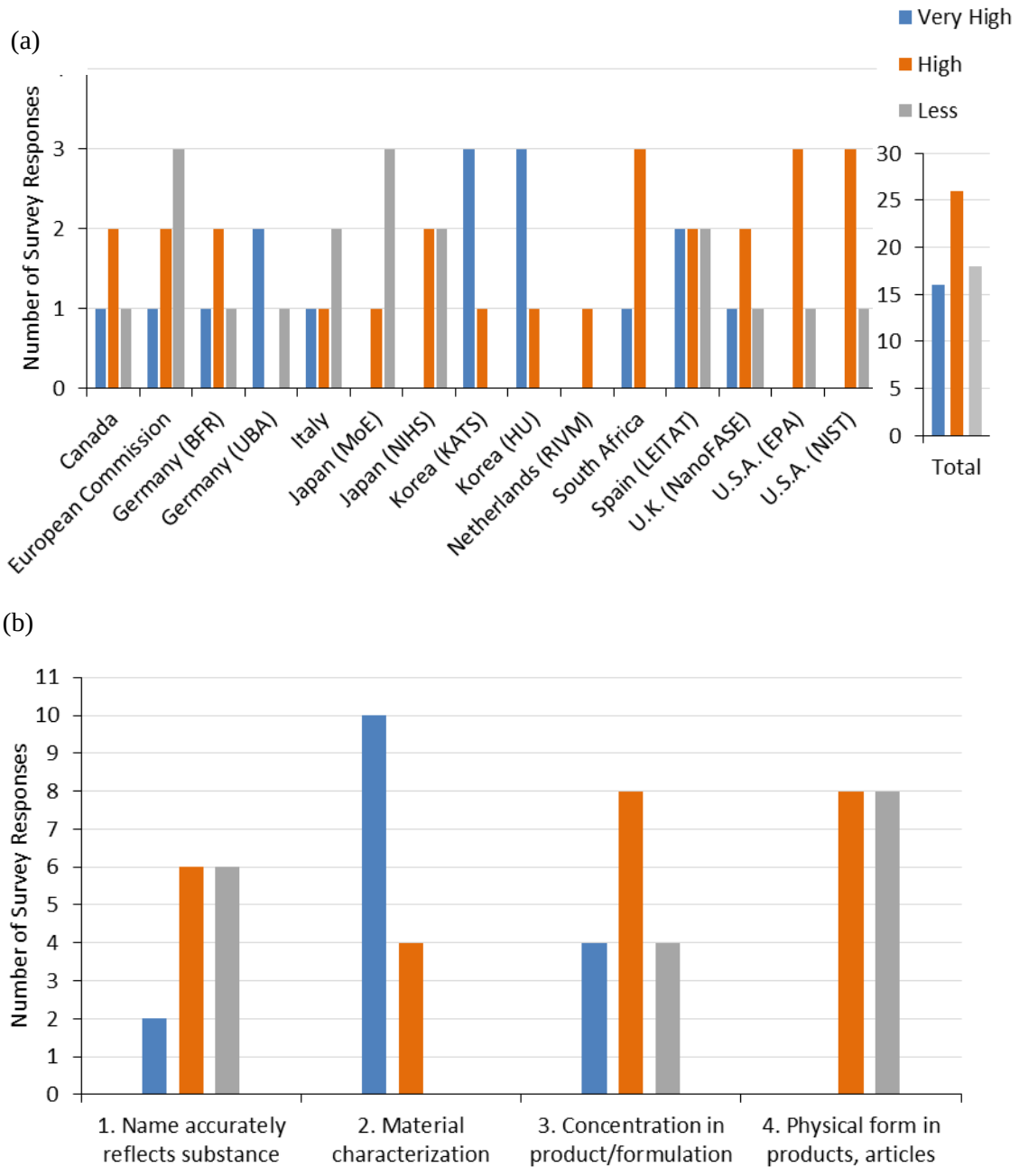
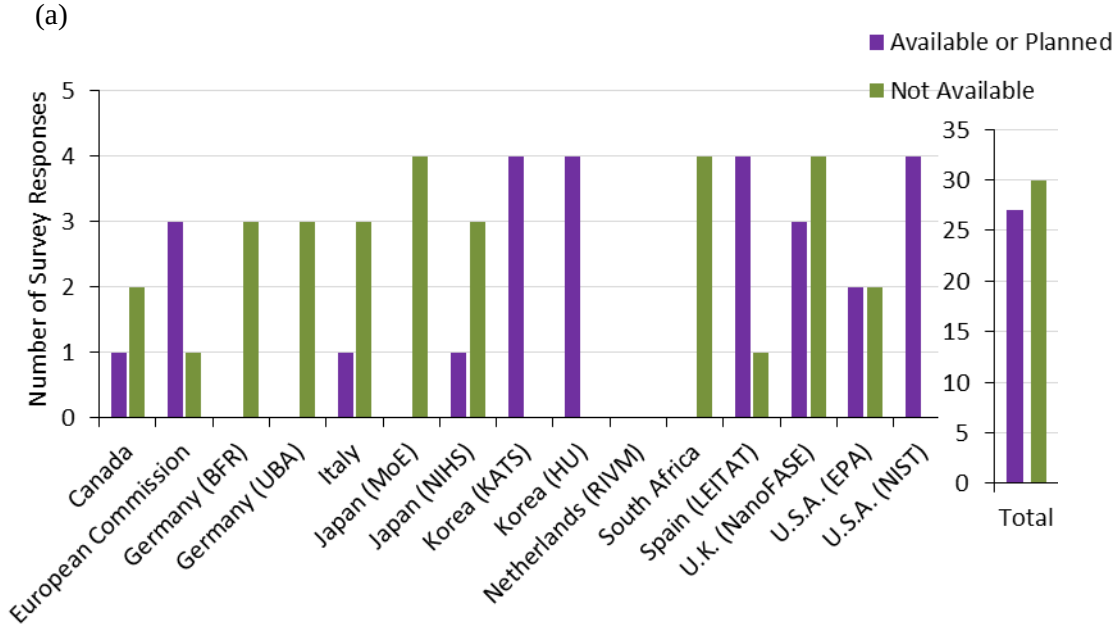


Figure 5. Data availability of material characterization issues, depicted by (a) country responses and (b) issue.

(a)



(b)

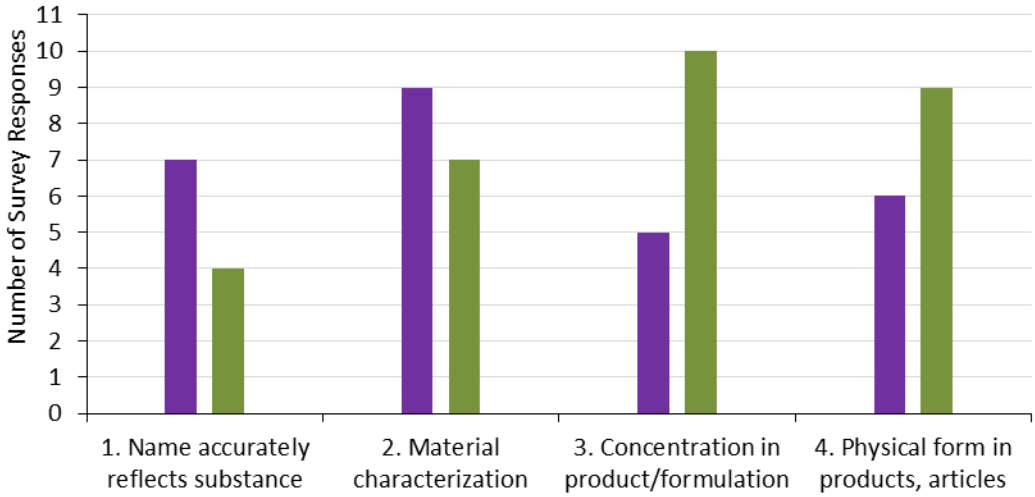
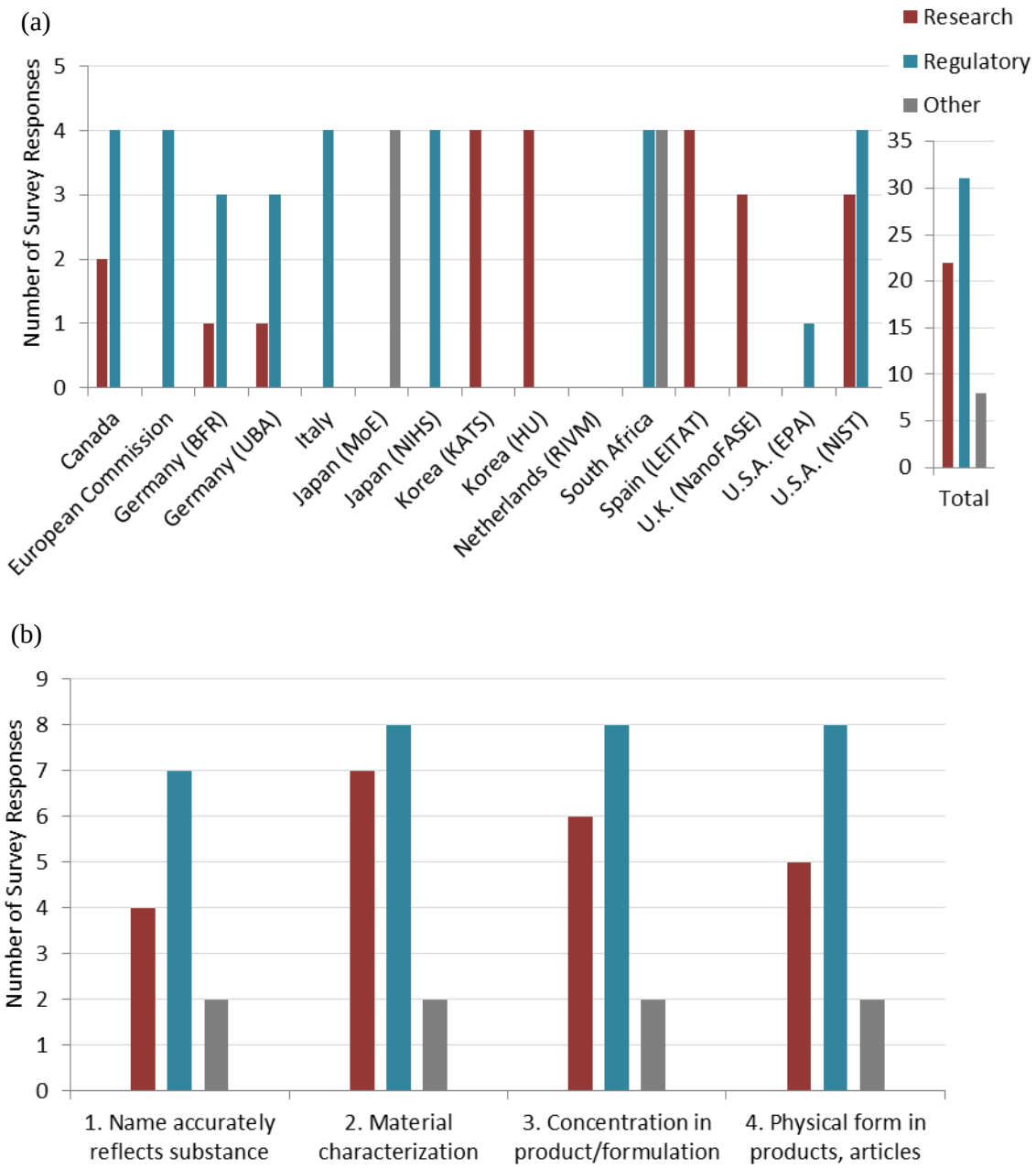


Figure 6. Framework for material characterization issues, depicted by (a) country responses and (b) issue.



Category 2: Production, Use, and Market

44. Issues related to production, use and market were addressed with questions 5 through 9 of the survey (Appendix A). Overall, these issues were indicated to be of high importance by survey respondents (Figure 7a). Countries which indicated issues in this category as being of higher relative importance include Canada, Germany (BfR), Korea (KATS and HU), and the U.S.A. (NIST). The most important issue in this category was that pertaining to information on current and anticipated production/import quantities (***Issue 6***), followed closely by the issue pertaining to information on current and potential uses (***Issue 7***) (Figure 7b). Respondents overwhelmingly indicated the importance of this type of data for either environmental and consumer exposure assessment (both) or only consumer exposure assessment, with very few respondents indicating the importance for only environmental exposure assessment (data not shown).

45. Survey responses indicated that there appears to be large data gaps for all four issues that relate to production, use and market (Figure 8a). Respondents that indicated data in this category was available or planned include Canada, the European Commission, South Africa, Spain, the U.K., and the U.S.A. (EPA), while others did not have data available in this category. Three organizations did not provide responses regarding data availability. Similar to issues related to material characterization (Category 1), both Spain and the U.K. indicated that data relevant to environmental exposure assessment on production, use and market was available or planned, but no such data was available or planned relating to consumer exposure assessment (data not shown). While data in this category is largely unavailable, issues related to manufacturing and processing, current and anticipated production/import and current and potential uses (***Issues 5***, ***6*** and ***7***, respectively) were available more often than other issues in this category (Figure 8b).

46. Most survey respondents indicated that data pertaining to production, use and market issues are being developed or used in a regulatory context (Figure 9a) In this category, the data was only being developed or used by research for Germany (BfR and UBA), Korea (KATS and HU), Spain, the U.K. and the U.S.A. (NIST). Of the countries who indicated relevance of another type of framework, Japan (MoE) indicated that the data was being obtained through an information gathering exercise via the ministry's study, and South Africa indicated a role for industry in this context, similar to issues related to material characterization (Category 1). The regulatory framework was denoted as most important source and use of all five issues in this category; however, the utility of research was also cited as an important source and use of data on current and potential uses (***Issue 7***) compared to other issues in this category (Figure 9b).

47. Seven countries reported the type of production use and market data available. Korea (KATS and HU) indicated ongoing data development, research, case studies and methods/models/databases/tools for each of the five issues in this category. The U.K. indicated that research was planned, which would generate data on production/import quantities (***Issue 6***) as well as current and potential uses, including consumer goods (***Issue 8***). Data development was also planned by Canada on many issues in this category. Spain and the U.K. indicated that case studies were ongoing, which would generate data on manufacturing and processing (***Issue 5***), while Italy is generating data on current and potential uses, and use of nanomaterials in products used by children via methods/models/databases/tools (***Issues 7*** and ***9***, respectively). Citations and further information provided by countries on available or planned data are available in Appendix C.

48. Overall, there appears to be considerable knowledge gaps relating to production, use and market information, with the exception of a few organizations including Canada, the European Commission, the U.K., and the U.S.A. (EPA). It is recommended that OECD countries interested in this information, such as the Korea, consider opportunities for collecting and sharing production, use and market information as it relates to both consumer and environmental exposure assessment. It is recognized, however, that due to the confidential nature of this type of information, this may not always be possible.

Figure 7. Importance of production, use and market issues, depicted by (a) country responses (b) issue.

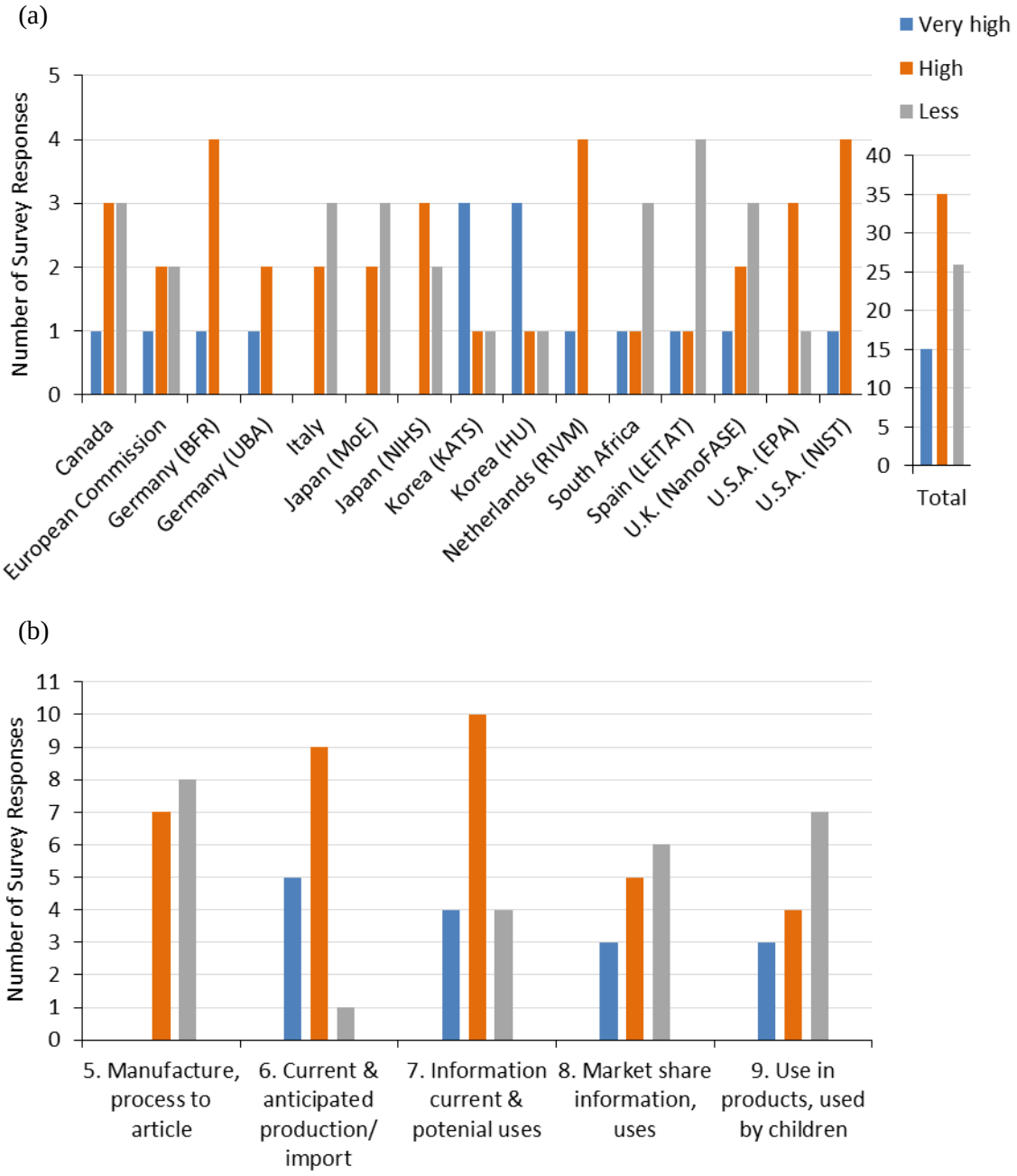


Figure 8. Data availability of production, use and market issues, depicted by (a) country responses and (b) issue.

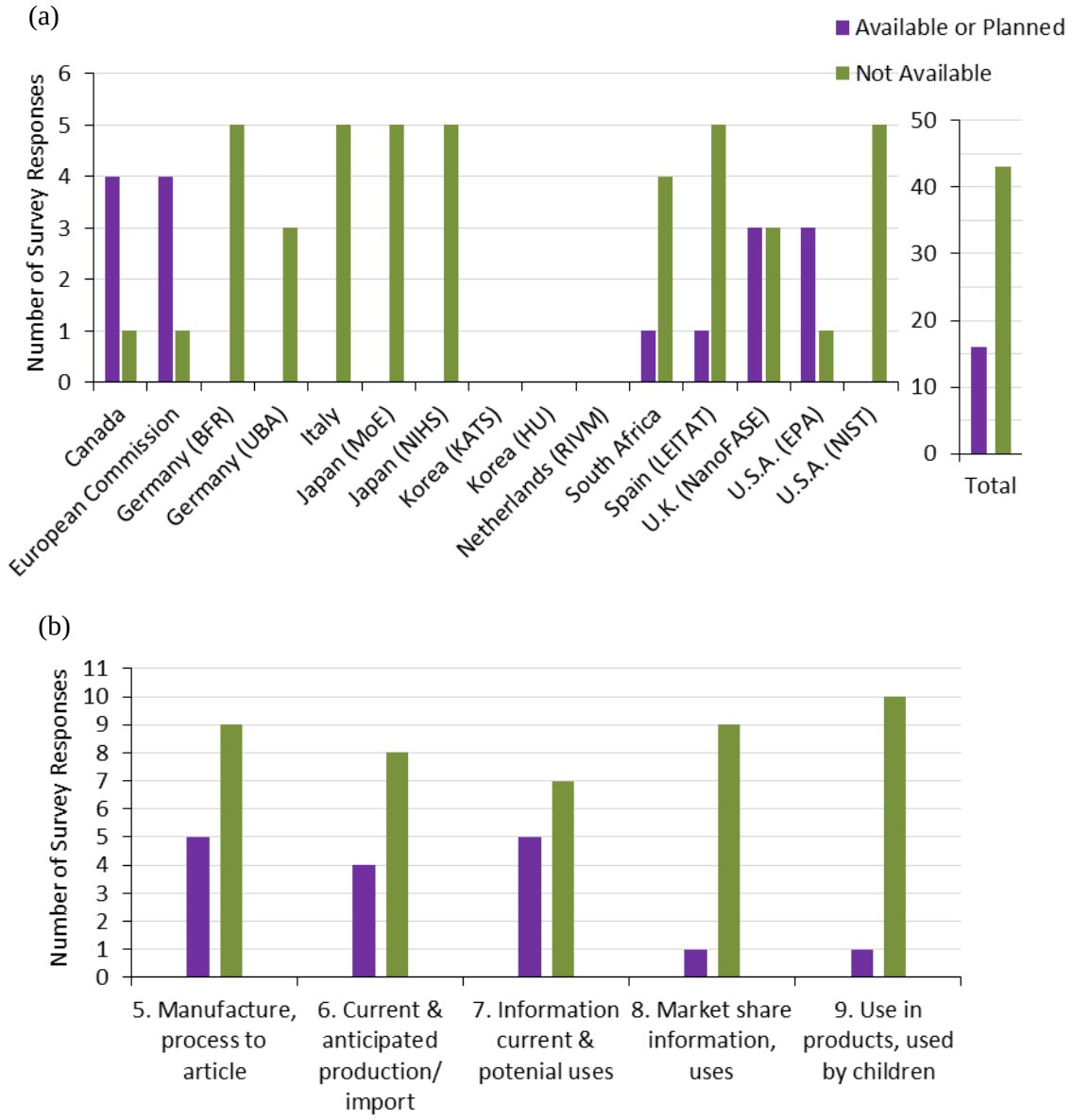
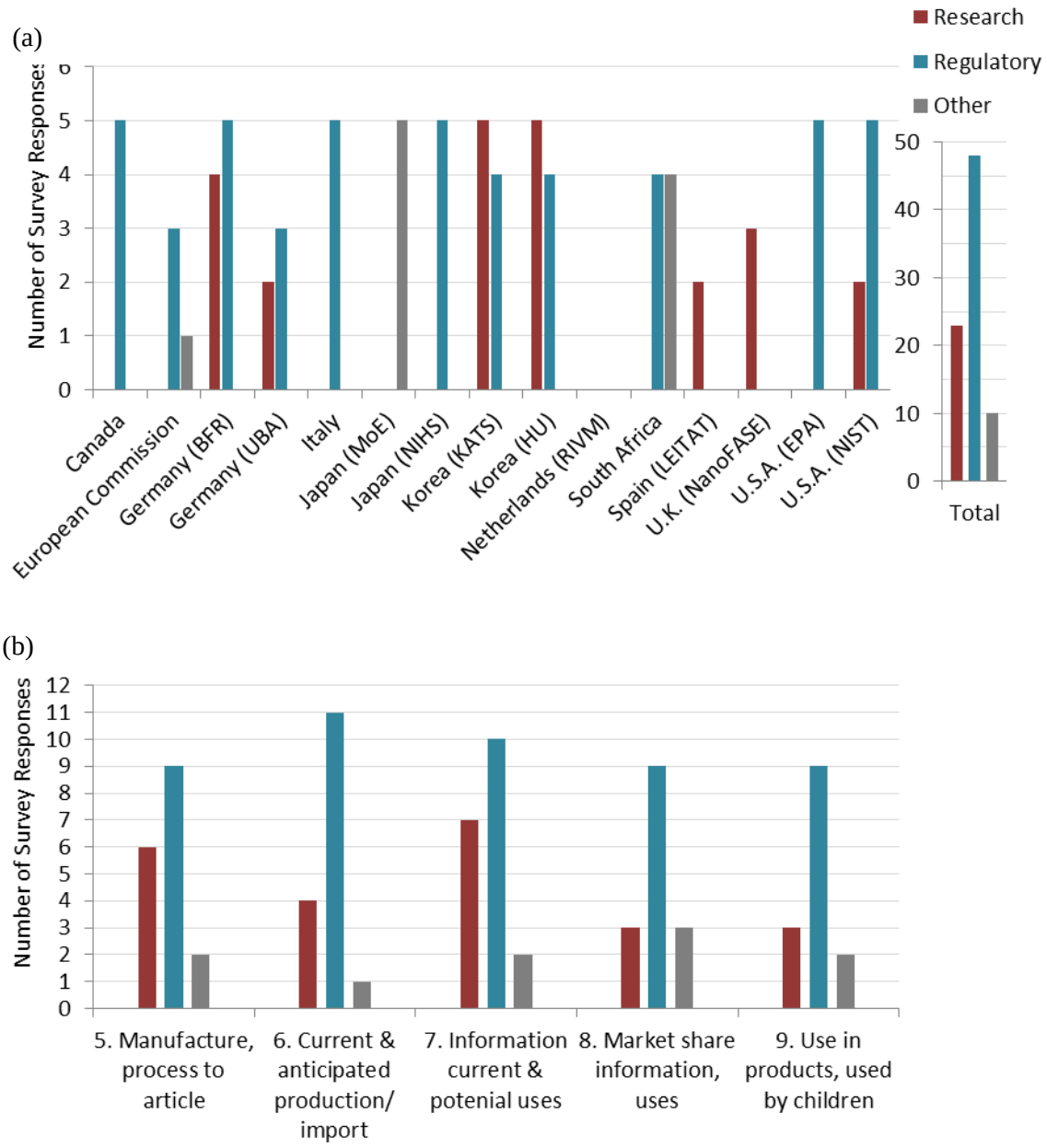


Figure 9. Framework of production, use and market issues, depicted by (a) country responses and (b) issue.



Category 3: Releases to the Environment (Direct, Indirect, and Via Consumer Use)

49. The importance of knowledge on releases of nanomaterials to the environment was assessed via questions 10 through 15 of the survey (Appendix A). For the most part, the issues pertaining to releases to the environment were determined to be of high importance (Figure 10a). The responding countries that were especially interested in these issues include Japan (MoE), Germany (UBA) and the Netherlands. When survey responses were divided by question, the issue of information on frequency, duration, and magnitude of the release from manufacture and processing (***Issue 11***) emerges as the most important issue in this category, though the results indicated relatively similar importance across issues (Figure 10b). Not surprisingly, when responses were separated between

environmental or consumer relevance, most issues in this category were considered of high to very high importance for environmental exposure assessment (data not shown).

50. The survey responses indicated large data gaps for issues related to environmental releases of nanomaterials either directly, indirectly or via consumer uses. The European Commission, Germany (UBA), Italy, Korea (KATS and HU), Spain, the U.K. and the U.S.A (EPA and NIST) indicated available or planned data, whereas other respondents did not show any data availability (Figure 11a). Data in this category were largely unavailable across all issues though this was especially the case for applicability of OECD emission scenarios for nanomaterials (***Issue 14***), for which no data was available (Figure 11b). The European Commission indicated available or planned data pertaining to both environmental and consumer scenarios whereas Spain, the U.K. and the U.S.A. (EPA and NIST) indicated available or planned data relevant to environmental exposure assessment (data not shown).

51. Overall, data pertaining to releases to the environment was most often being developed or used by or for regulatory purposes rather than for research purposes although this varied significantly across organizations. Some of the countries indicated that the data was to be developed or used exclusively in a regulatory context (e.g., Canada, European Commission, Italy and Japan (NIHS)), whereas research was identified as the more relevant framework for Spain, Korea (KATS and HU) and the U.K. (Figure 12a). South Africa indicated releases to the environment data as being developed and used by industry, and Japan (MoE) indicated that this information was being gathered via the ministry's study. When the data were divided by issue, it was noted that data pertaining to OECD emissions scenario and scenarios under development (***issues 14*** and ***15***) in particular were more relevant to the regulatory framework than the other four issues (Figure 12b).

52. Survey results obtained regarding the type of data available indicate that Korea (KATS and HU) has ongoing research, data development, case studies, and methods/models/databases/tools for each issue in this category. The U.S.A (EPA) is the only survey respondent that has completed data in this category, with completed case studies on nanomaterials environmental release from articles and products (***Issue 12***). Spain and the U.K have numerous ongoing and planned case studies (respectively) that are expected to produce information on ***issues 10*** through ***13***. Moreover, Canada is involved in ongoing research that will generate data on environmental nanomaterial release from articles and products (***Issue 12***) as well as the magnitude, duration, and frequency of release due to usage of the nanomaterials themselves (***Issue 13***). Citations and further information provided by countries on available or planned data are available in Appendix C.

53. Overall, there appears to be significant knowledge gaps in the area of environmental releases of nanomaterials to the environment. Organizations that indicated available or planned data also noted missing data for both consumer and environmental exposure assessment, indicating the need for additional data across most countries. It is recommended that OECD countries interested in this information, such as Japan, Germany and the Netherlands, consider opportunities for collecting and sharing information on nanomaterial releases to the environment.

Figure 10. Importance of releases to the environment, depicted by (a) country responses (b) issue.

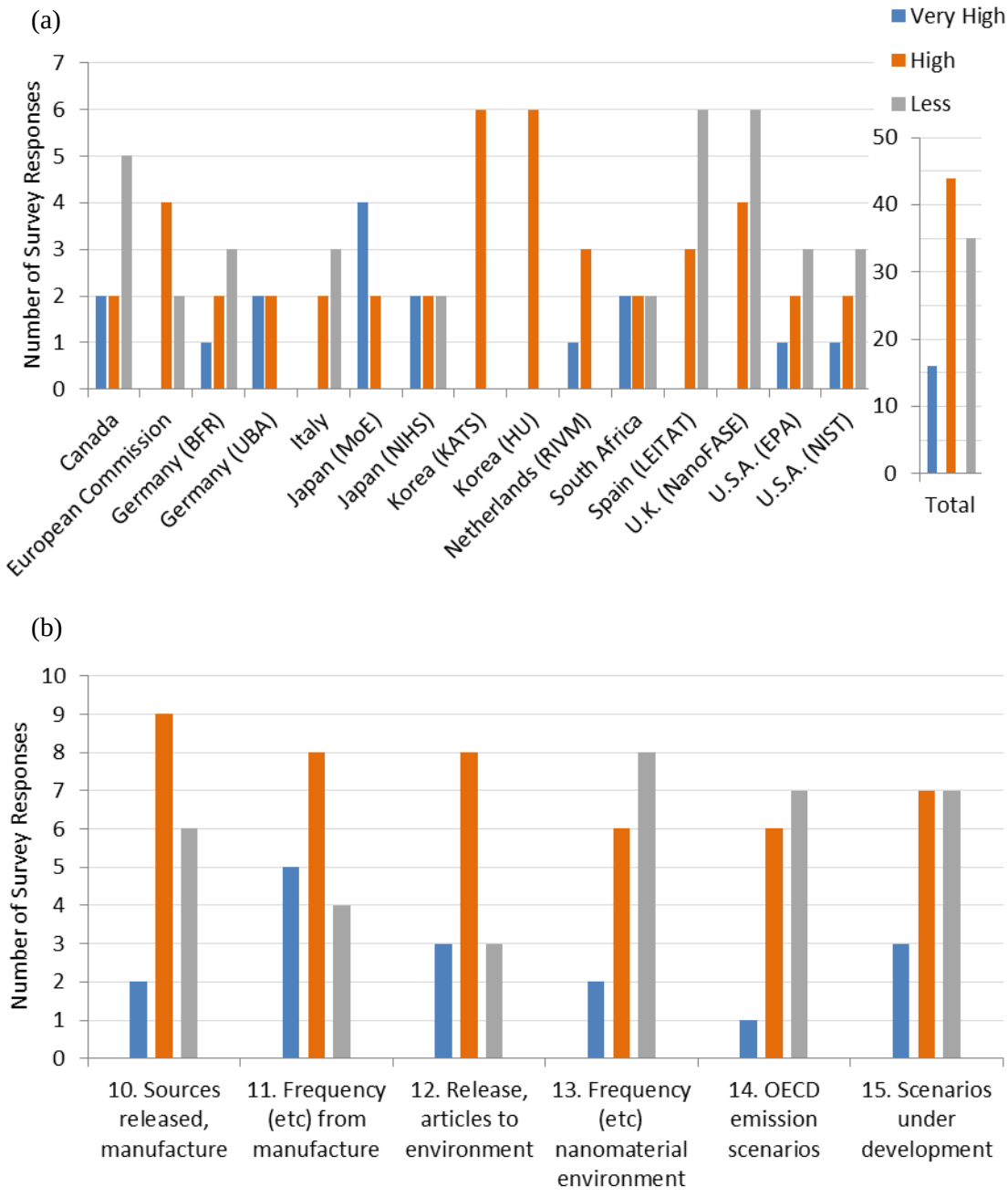


Figure 11. Data availability on releases to the environment issues, depicted by (a) country responses and (b) issue.

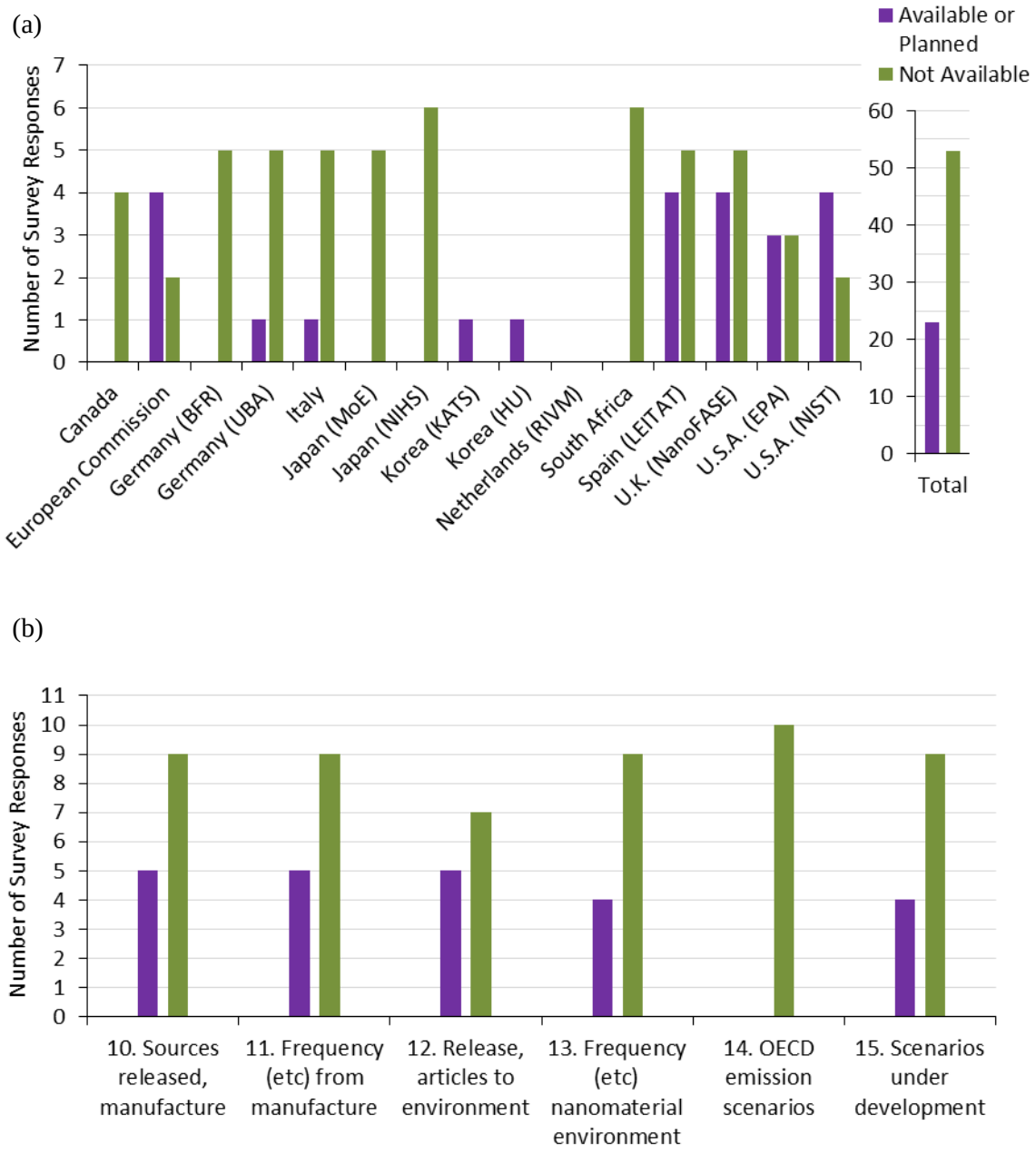
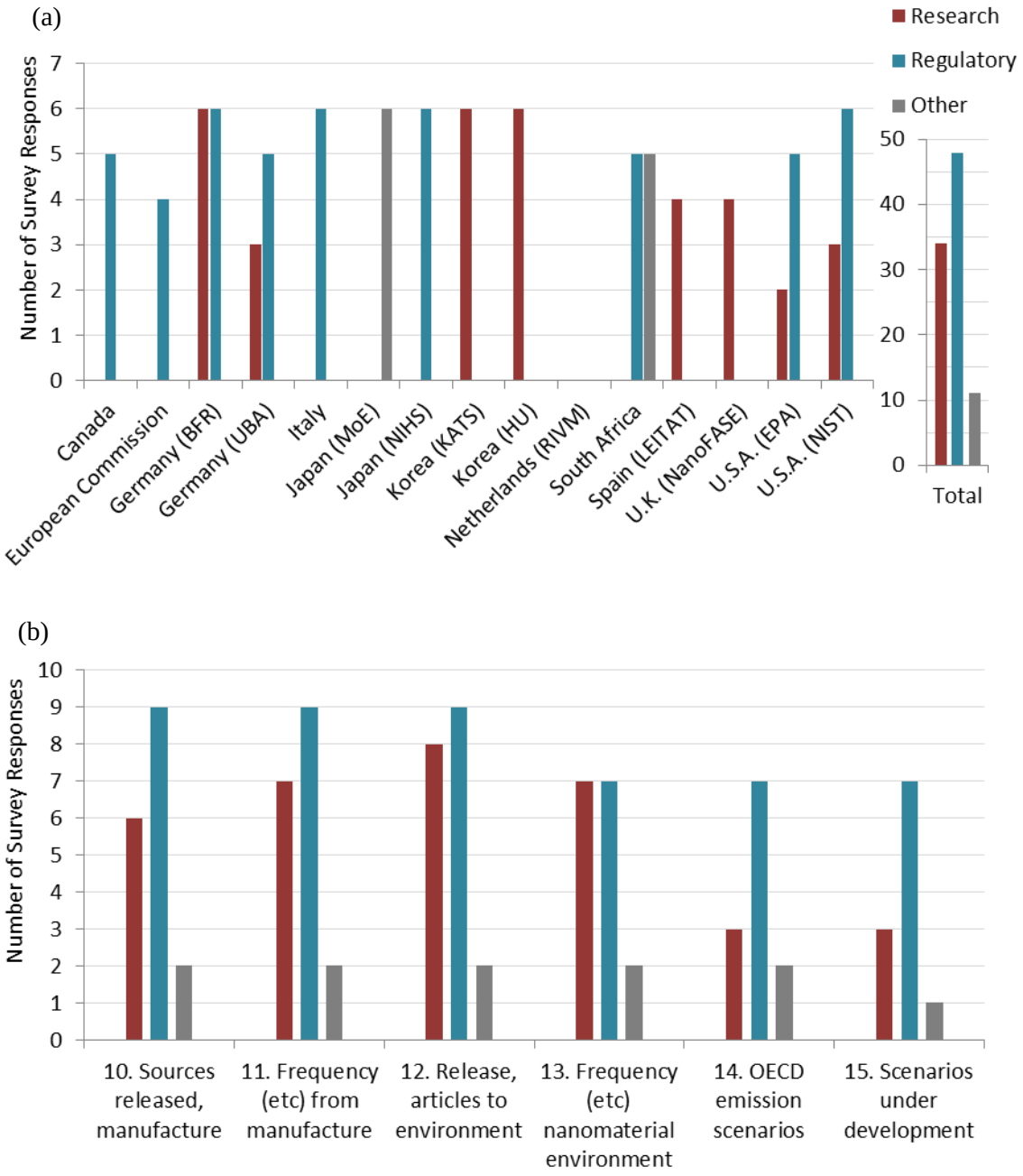


Figure 12. Framework of releases to the environment issues, depicted by (a) country responses and (b) issue.



Category 4: Environmental Fate & Transport

54. Issues related to environmental fate and transport were assessed with questions 16 through 20 of the survey (Appendix A). Issues in this category were most often rated as being of high importance or less important among survey respondents, with only 17 of 79 total responses in this category ranked as being of very high importance (Figure 13a). Countries which indicated issues in this category as being of very high importance most often include Canada, Netherlands, and U.K. The two issues identified most often as being of importance were those pertaining to test data to evaluate how nanomaterials behave and transform in the environment (***Issues 16, 17***) (Figure 13b). Not surprisingly, no survey respondents indicated relevance to consumer-only issues within this category;

respondents overwhelmingly indicated relevance to environmental exposures of issues in this category (data not shown).

55. With regards to data availability, 8 of 12 respondents indicated that they had available or planned data on environmental fate and transport, while 3 of 12 respondents did not have access to such data (Figure 14a). Three organizations did not provide responses regarding data availability. There was no one issue for which there appeared to be more data available or planned; however, data on the issue pertaining to soluble transformation products (***Issue 20***) was denoted as 'not available' more often than other issues in this category (Figure 14b), highlighting a potential knowledge gap.

56. Overall, environmental fate and transport issues were described as being developed or used within a research framework versus a regulatory framework more often; however, this varied significantly between survey respondents (Figure 15a). Italy was the only country that indicated only a regulatory framework for all issues in this category, while Japan (NIHS), Korea (KATS and HU), Spain and the U.K. indicated only a research framework for the same issues. When expressed by individual issue, the research framework always predominated over regulatory framework for each of the five issues in this category (Figure 15b).

57. Survey responses regarding the type of available data indicate that research was the type of information available for issues relating to environmental fate and transport, with 6 out of 8 survey respondents citing planned, ongoing, or completed work in this area. Korea (KATS and HU) indicated the ongoing development of case studies, research, data development, and methods/models/databases/tools for all issues in this category. Similarly, the U.K indicated planned data for each issue in this category. Germany (UBA) reported planned, ongoing, and completed research and case studies on test data for the determination of behaviour in waste water (Issue 18), while the U.S.A. (EPA and NIST) reported ongoing and completed methods/ models/databases/tools in this area (respectively). Canada has currently ongoing research to produce test data on the environmental behaviour of nanomaterials (***Issue 16***) and test data to determine how nanomaterials are transformed in the environment (***Issue 17***). Citations and further information provided by countries on available or planned data are available in Appendix C.

58. Countries which denoted at least two issues in this category as being of very high importance include Canada, Italy, Japan, Netherlands, U.K. and U.S.A. It is suggested that these countries consider potential opportunities to collaborate on issues pertaining to environmental fate and transport.

Figure 13. Importance of environmental fate and transport issues, depicted by (a) country responses and (b) issue.

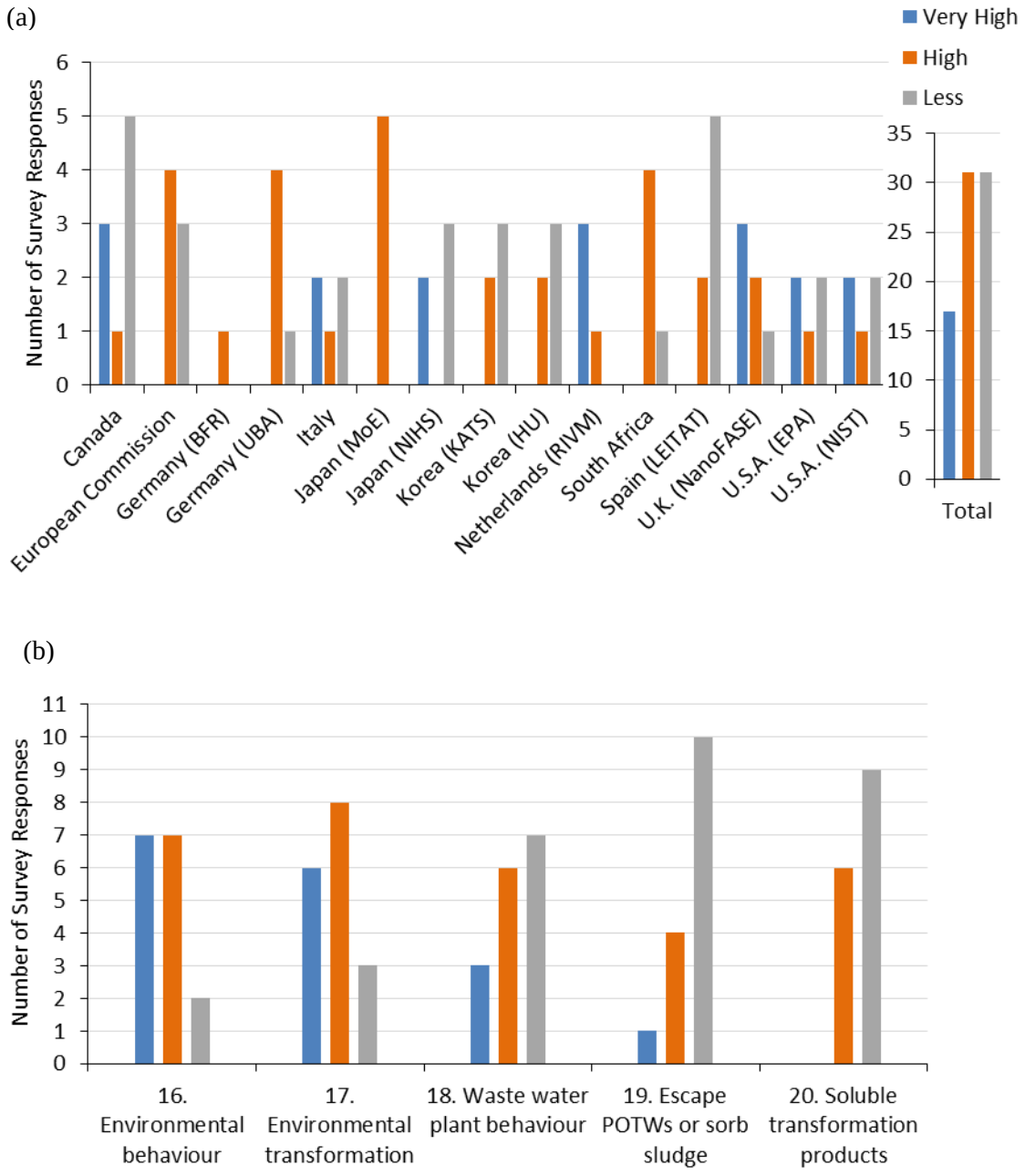


Figure 14. Data availability of environmental fate and transport issues, depicted by (a) country responses and (b) issue.

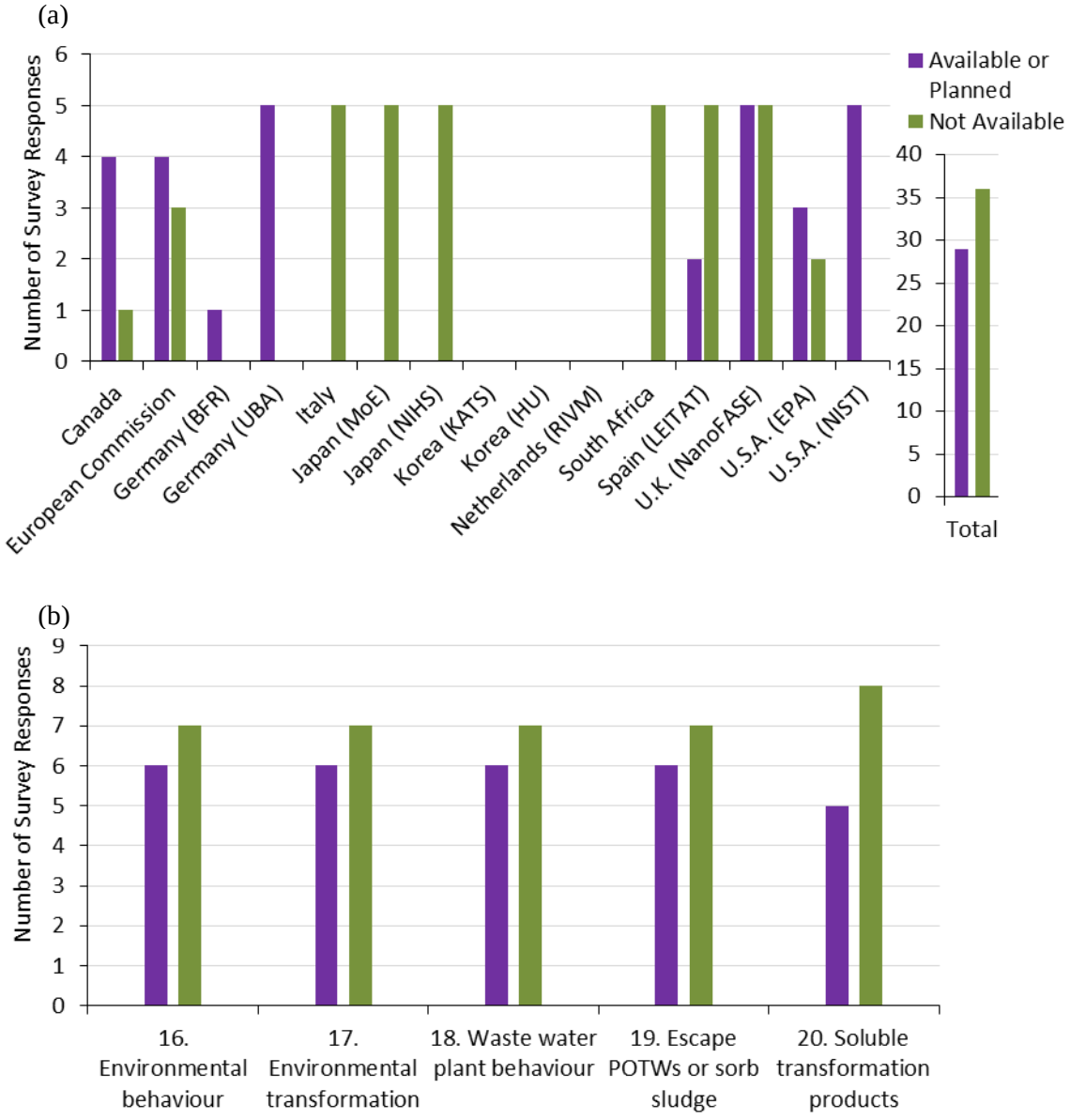
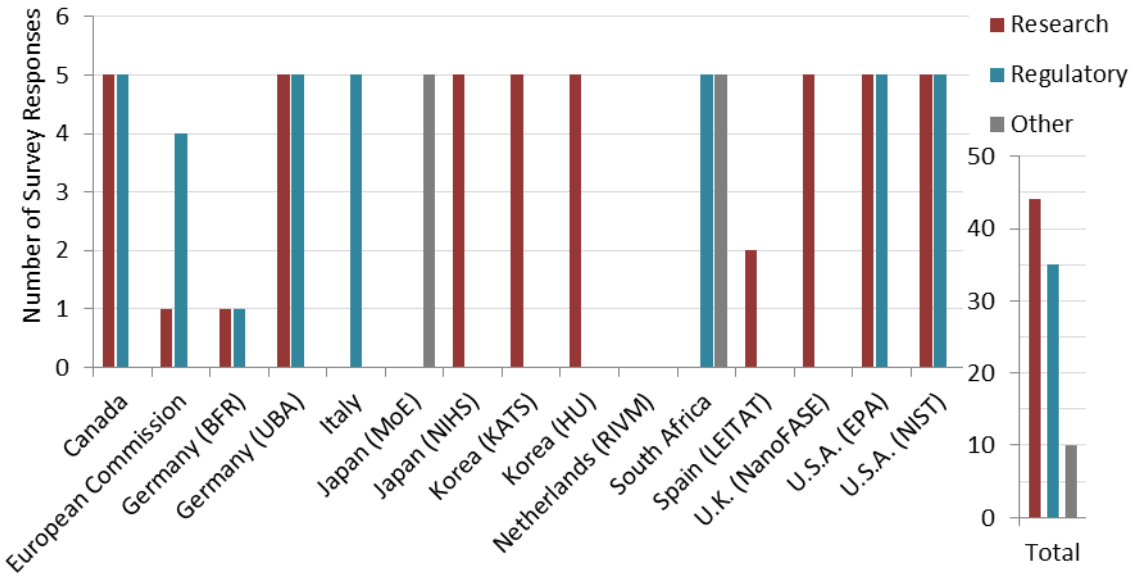
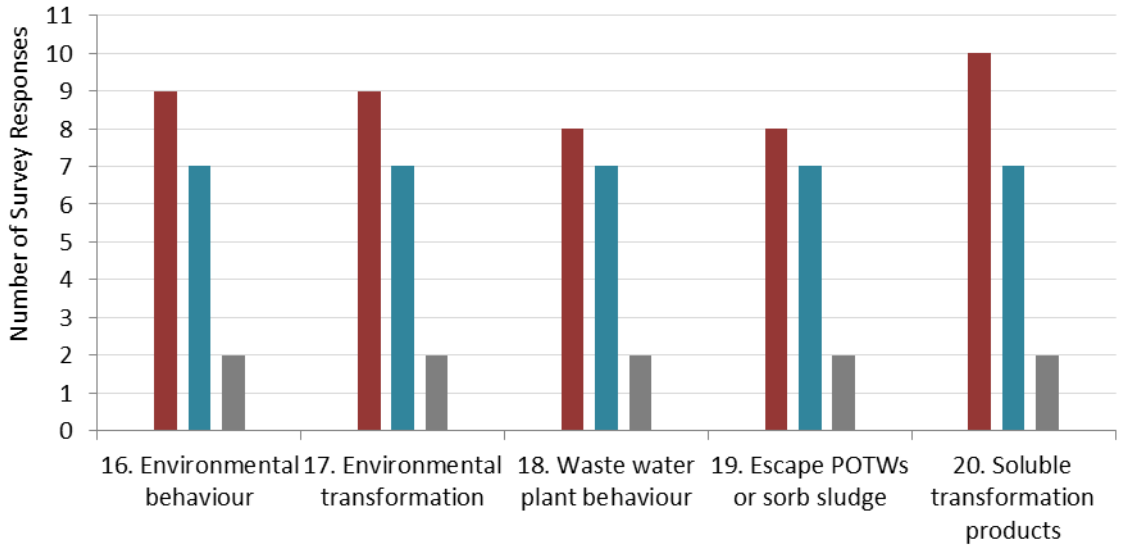


Figure 15. Framework of environmental fate and transport issues, depicted by (a) country responses and (b) issue.

(a)



(b)



Category 5: Exposure Assessment (Direct and Indirect)

59. The importance of issues relating to direct and indirect exposure assessment for consumer and environmental exposure to manufactured nanomaterials was assessed via questions 21 through 29 of the survey (Appendix A). Overall, issues in this category were denoted by survey respondents as being of high or very high importance. Countries which indicated issues in this category as being of higher relative importance included Spain, Germany and the Netherlands (Figure 16a). When the survey responses were divided by question, two issues emerged as the most important in this category: exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials (***Issue 25***), and accurate exposure measurements of nanomaterials in various environmental media (***Issue 26***) (Figure 16b,c). Most survey respondents indicated that issues in this category were relevant to consumer exposure compared to environmental exposure (data not shown).

60. Although many countries (eleven of fourteen responding organizations) indicated that data were available, most also identified a significant lack of available data pertaining to exposure assessment (Figure 17a). Information on data availability varied considerably between survey issues in this category (Figure 17b,c). The survey data indicate that available or planned data exist most often for information pertaining to exposure pathways which can be evaluated (***Issue 23***), routes of exposure with which to assess consumer and environmental exposure (***Issue 24***) and exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials (***Issue 25***). Conversely, no data were available for the number of consumers, including children potentially exposed to nanomaterials during the use of an article or product (***Issues 21*** and ***22***). Data were also lacking for environmental and consumer exposure measurements, leaching from products and emissions from consumer products and articles (***Issues 26 – 29***). Within the responses showing a lack of data for these issues, it was indicated that data are less available for consumer exposure than for environmental exposure (data not shown).

61. The type of exposure assessment data available OECD countries is predominantly in the form of research. For example, Korea (ATS and HU) has ongoing research projects related to each issue in this category. Furthermore, research related to exposure pathways, routes of exposure, acute exposure measurements in various environmental media, as well as data on leaching and emission from consumer articles and products (***Issues 23, 24, 26, 28, 29***, respectively) is ongoing in Spain and planned in the U.K. Canada has also completed case studies on routes of exposure and exposure models. The European Commission and Germany (BfR) both have completed research and methods/models/databases/tools which will generate data on exposure models to be used in characterizing consumer and environmental exposure to nanomaterials (***Issue 25***). Moreover, the European Commission has completed and ongoing data development while Germany (BfR) has completed case studies that relate to exposure models (***Issue 25***). Citations and further information provided by countries on available or planned data are available in Appendix C.

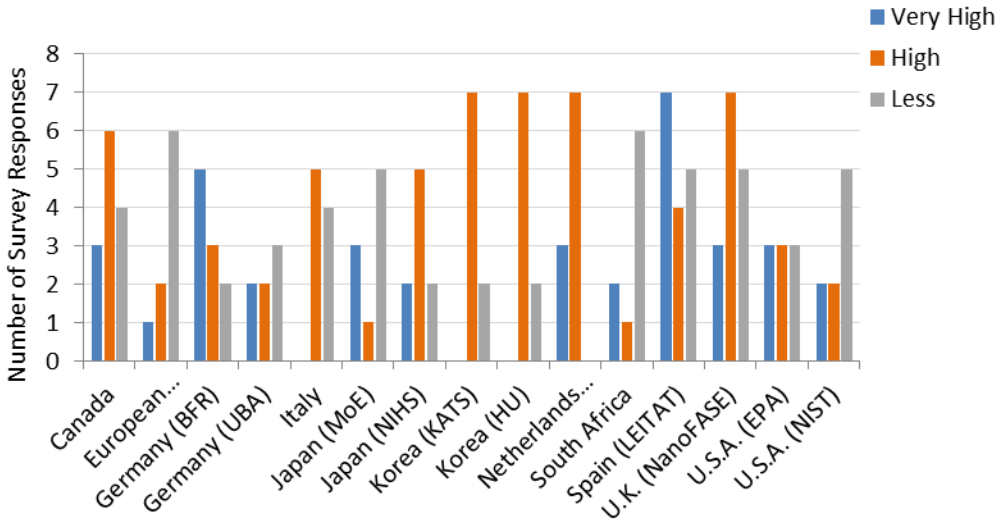
62. Most organizations indicated that exposure assessment data was being developed for or used by both regulatory and research frameworks (Figure 18a). However, some organizations (i.e., Japan (NIHS), Korea (KATS and HU), Spain, and the U.K.) identified research as being the only framework of relevance for exposure assessment. For this reason, the research framework appears to be slightly more important than the regulatory framework. No clear differences were noted when the survey data were divided according to issue (Figure 18b,c). Overall, information pertaining to direct and indirect exposure assessment for consumer and environmental exposure to manufactured nanomaterials appears to be a topic of importance for most OECD countries.

63. Although some information is available on routes of exposure, exposure scenarios, and exposure models, there is an apparent lack of information on how consumers and children are exposed to nanomaterials during the use of nanomaterial containing products. It is recommended that, where possible, countries that have gathered a significant amount of information in this area (e.g., Korea and

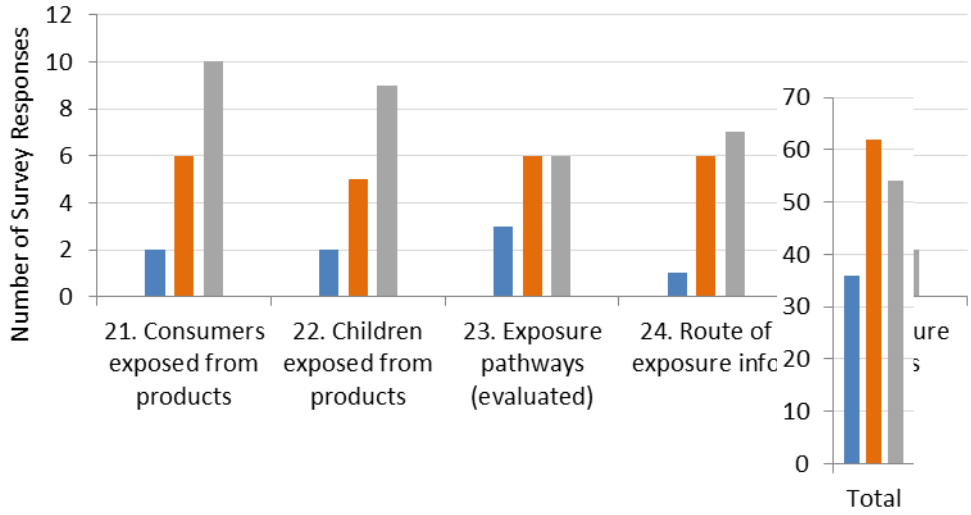
Spain) collaborate and share information on direct and indirect exposure assessment with those countries that are most interested in these issues.

Figure 16. Importance of exposure assessment issues, depicted by (a) country responses (b,c) issue

(a)



(b)



(c)

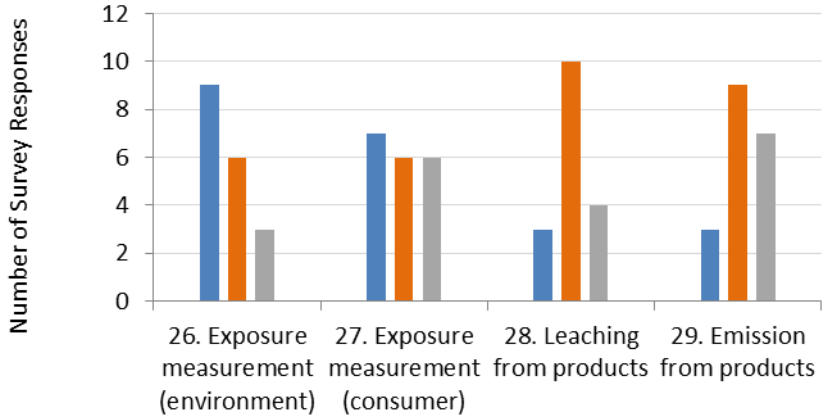
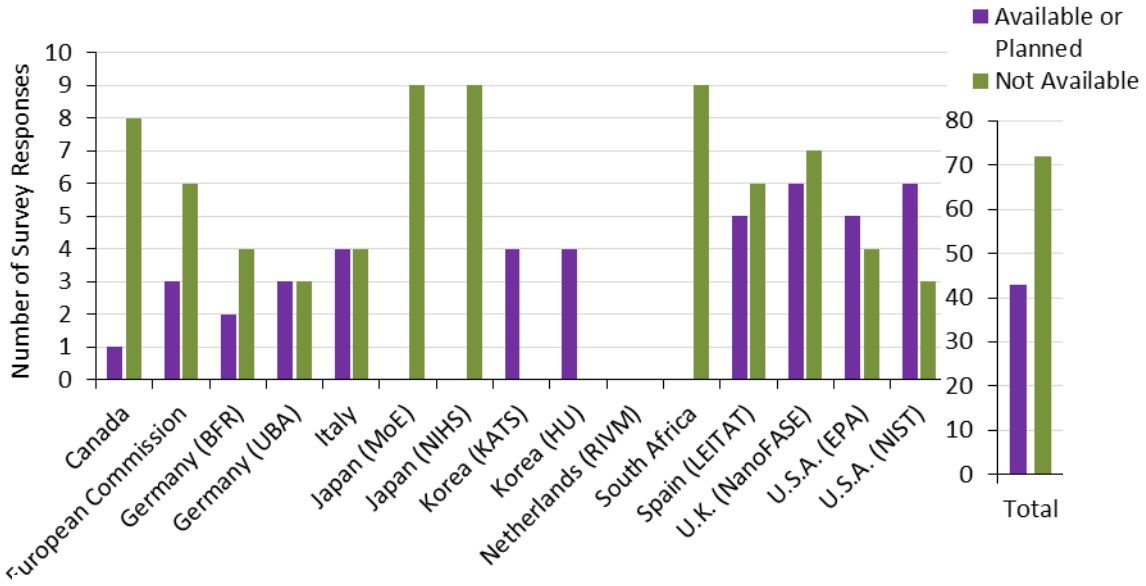
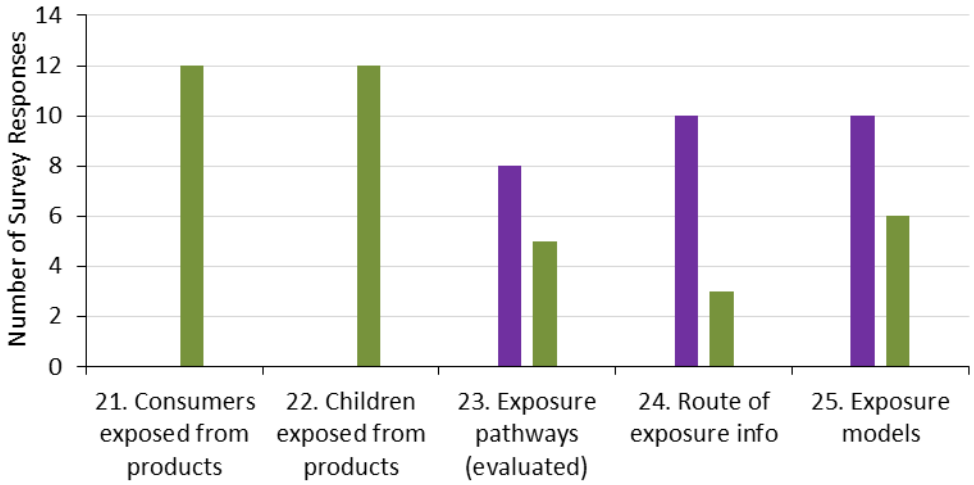


Figure 17. Data availability of exposure assessment issues, depicted by (a) country responses and (b,c) issue

(a)



(b)



(c)

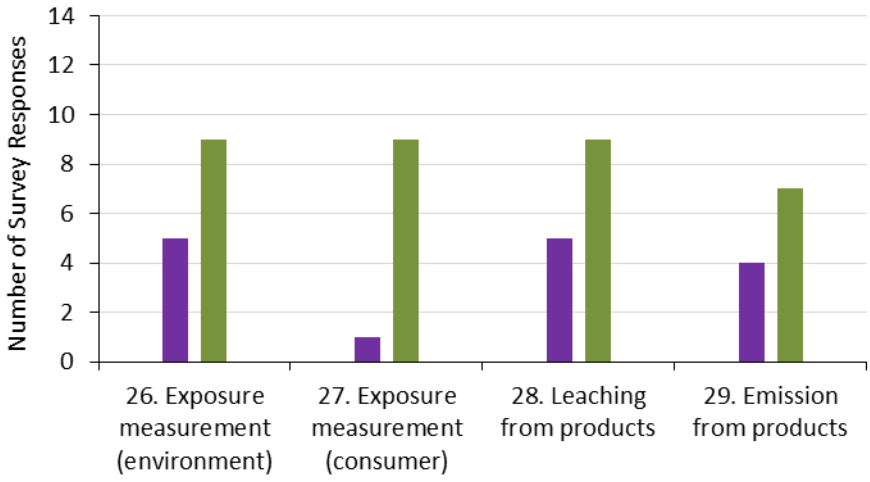
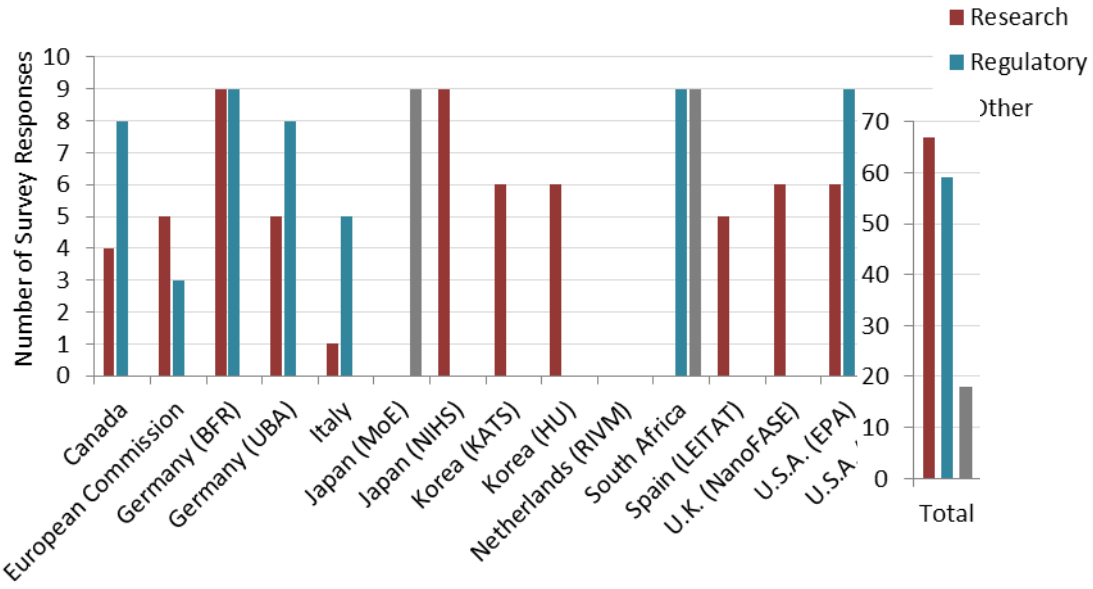
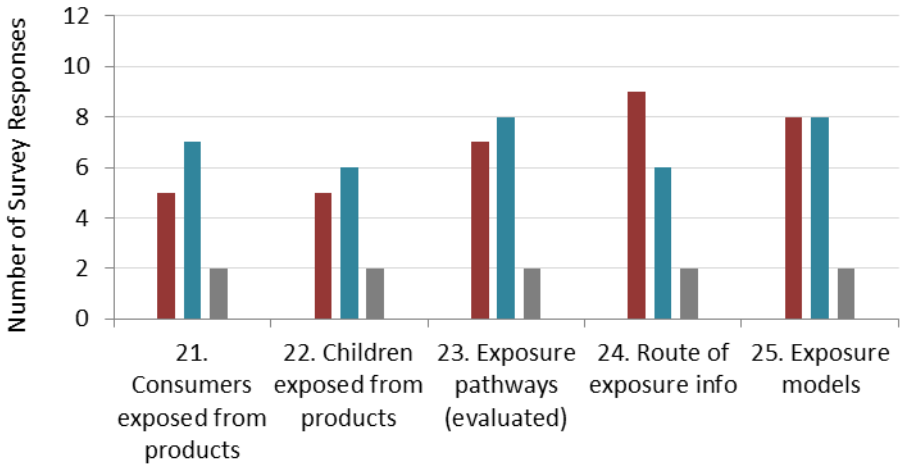


Figure 18. Framework of exposure assessment issues, depicted by (a) country responses and (b,c) issue.

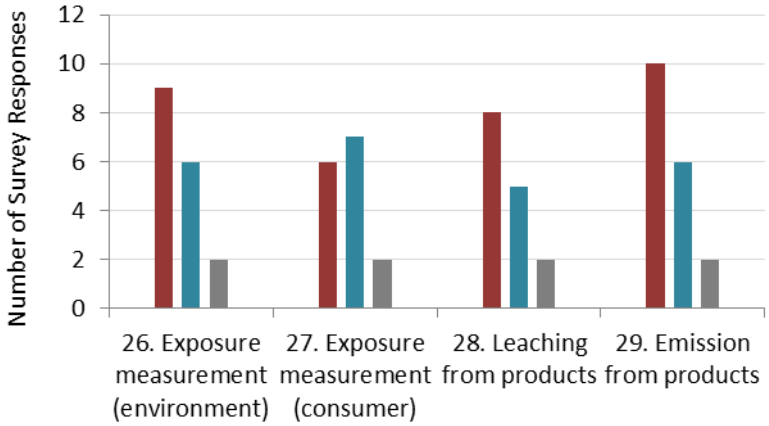
(a)



(b)



(c)



Category 6: Exposure Control and Mitigation

64. Exposure control and mitigation, as it pertains to consumers and the environment, was the topic of survey questions 30 through 33 (Appendix A). Only the European Commission and the Netherlands identified the issues in this category to be exclusively of high or very high importance (Figure 19a). When survey responses were divided by question, the issue of effectiveness of controls for mitigating environmental exposure to nanomaterials (***issue 30***) emerged as the most important issue in this category (Figure 19b); however, compared to issues in Categories 1 through 5, this issue was considered significantly less important.

65. The survey data indicate significant gaps in knowledge for issues relating to exposure control and mitigation. The vast majority of respondents, representing eleven of fifteen countries, indicated that data were not available (Figure 20a), with the exception of Korea (KATS and HU) and Spain. There was slightly more information on mitigating consumer exposure (***Issues 32*** and ***33***) versus environmental exposure (***Issues 30*** and ***31***) (Figure 20b).

66. The survey data indicate that information pertaining to exposure control and mitigation is developed for or used by both regulatory and research frameworks. Overall, the regulatory framework was slightly more relevant, though considerable differences were observed across countries (Figure 21a). Only the U.S.A (EPA and NIST) indicated equal relevance of regulatory and research frameworks (Figure 21a). Some countries indicated that the data was to be developed or used exclusively in a regulatory context (e.g., Canada, Germany, Italy and Japan), whereas research was identified as the more relevant framework for the European Commission, Spain and Korea. South Africa indicated exposure and control mitigation data as being developed and used by industry and regulatory frameworks, and Japan indicated that this information was being gathered via the ministry's study. No clear differences were noted when the survey data were divided according to the question (Figure 21b).

67. Only two countries submitted information pertaining to the type of available data in this category. Consistent with the other broad categories, Korea (ATS and HU) reported ongoing research, case studies, data development, methods/models/ databases/tools for all issues in this category. The only other respondent was Spain who reported planned and ongoing research and case studies on various controls for mitigating environmental exposure to nanomaterials and their effectiveness (***Issues 30*** and ***31***, respectively). Spain also reported planned data development on the efficacy of controls for environmental exposure mitigation (***Issue 30***). Citations and further information provided by countries on available or planned data are available in Appendix C.

68. Overall, the survey data indicate that information pertaining to exposure control and mitigation, as it pertains to consumers and the environment, is considered less important compared to issues in other categories. Moreover, issues in this category have significant data gaps. In the future, it is possible that issues in this category may become more important, and a need for this type of information will be identified, as data becomes available in other areas. However, given the core mandate of OECD on exposure measurement and mitigation, this may be an area that could benefit from more discussion within the OECD WPMN.

Figure 19. Importance of exposure control and mitigation, depicted by (a) country responses (b) issue

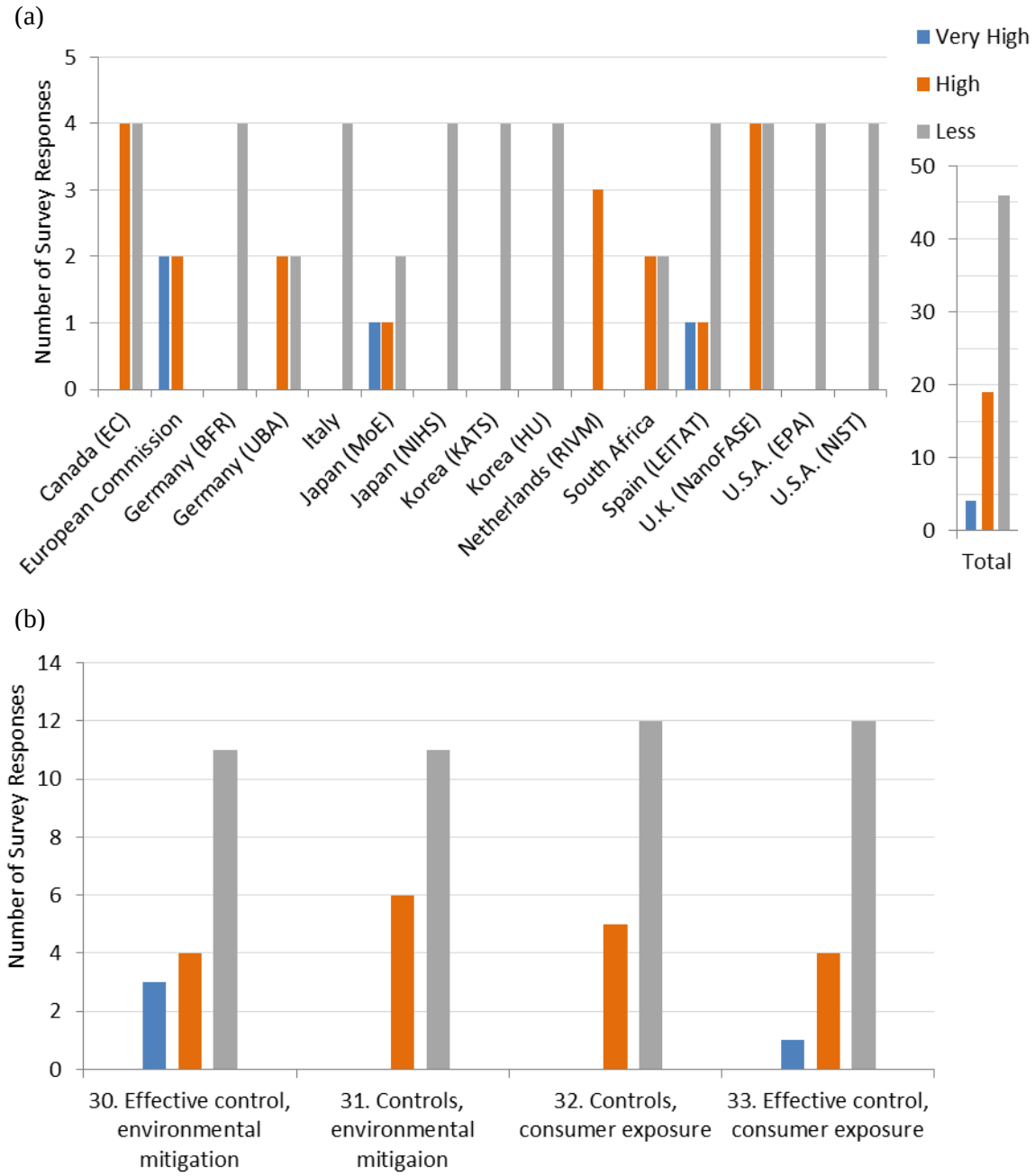
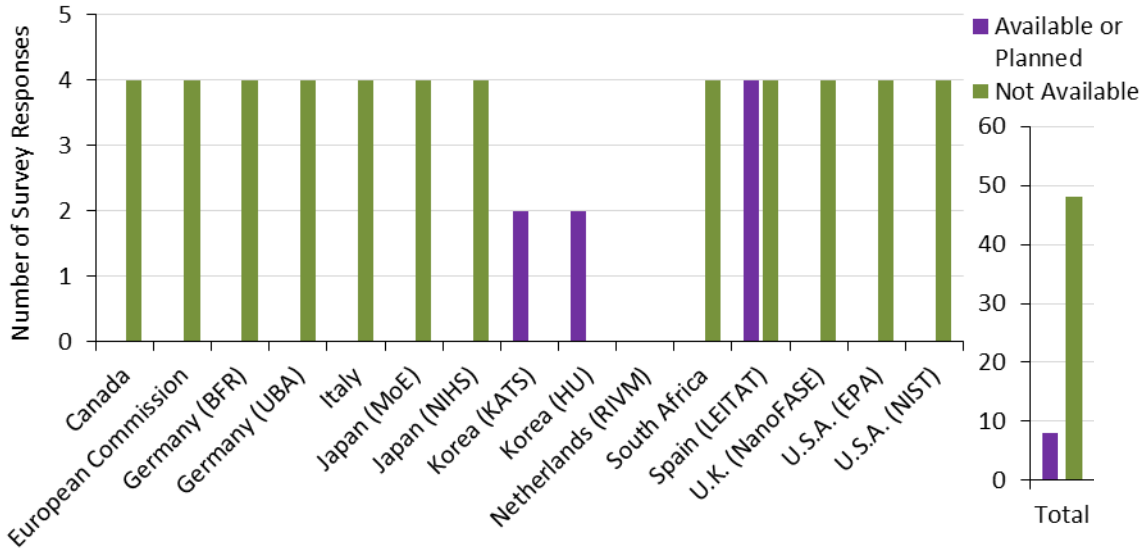


Figure 20. Data availability of exposure control and mitigation issues, depicted by (a) country responses and (b) issue

(a)



(b)

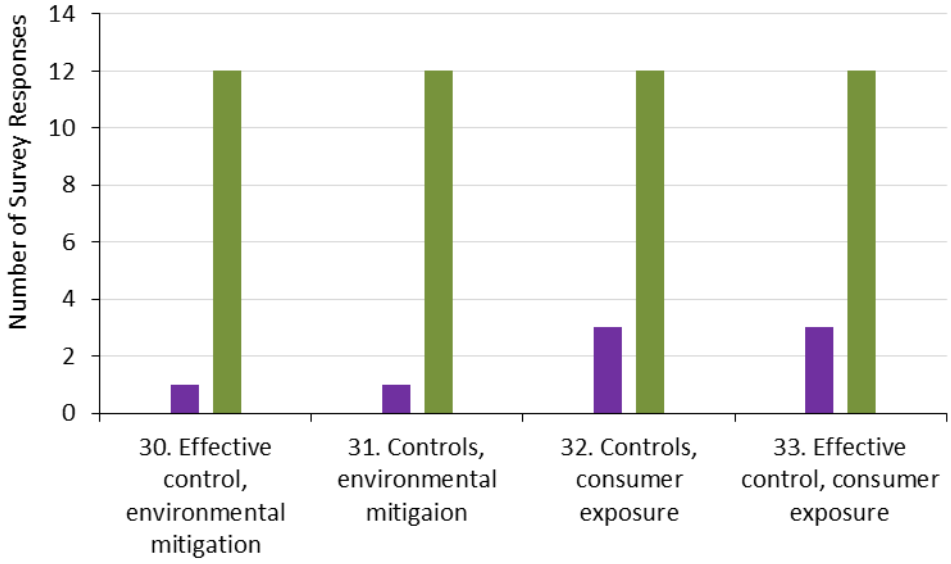
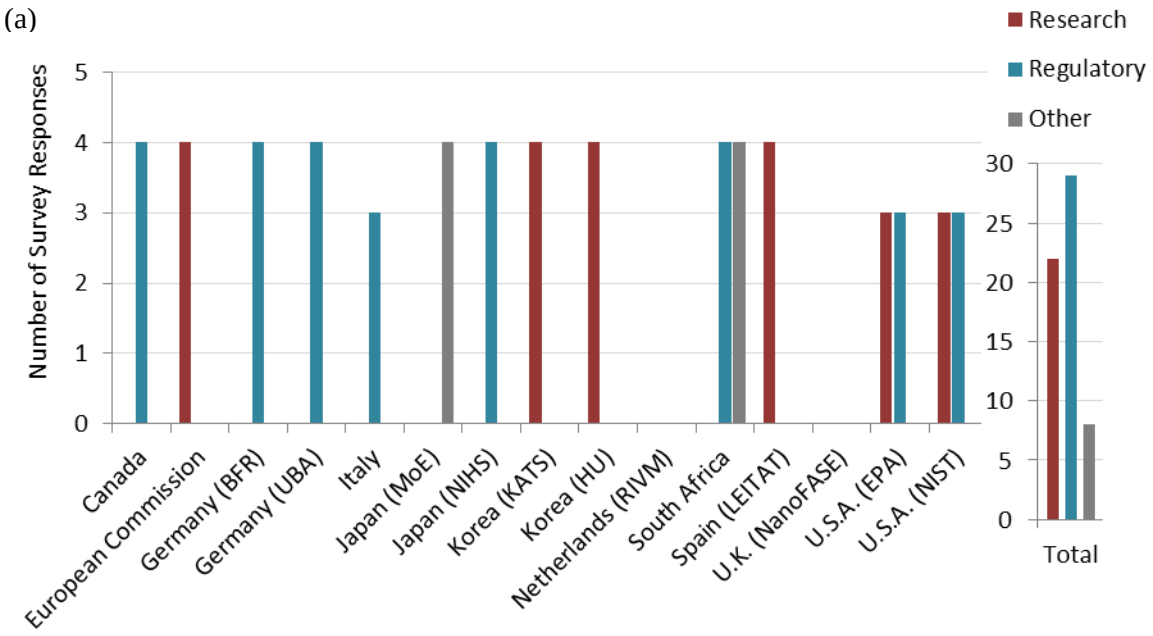
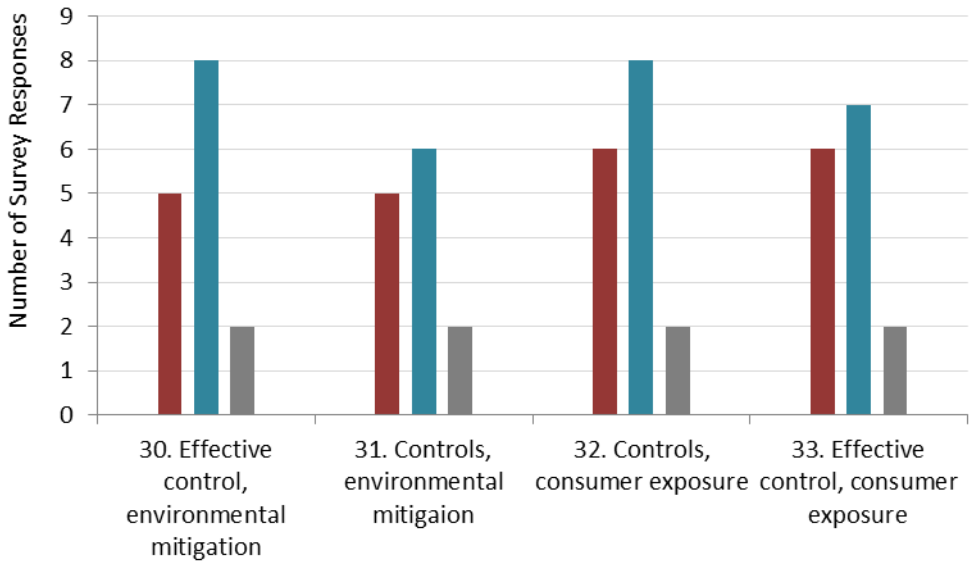


Figure 21. Framework of exposure control and mitigation issues, depicted by (a) country responses and (b) issue

(a)



(b)



APPENDIX A: SURVEY FORM

COMPILATION OF AVAILABLE INFORMATION AND DATA USED FOR ASSESSING CONSUMER AND ENVIRONMENTAL EXPOSURES TO MANUFACTURED NANOMATERIALS

INSTRUCTIONS

In **Section 1** of the survey, participants are requested to provide information on the importance of, availability of data, and framework for generation of issues identified in 6 categories. If issues are considered to relate predominantly to consumer or environmental exposure assessment, this should be reflected by filling the Box with either "C" or "E". If the issue is important to both human and ecological exposure assessment, both "C" and "E" should be indicated. This may also facilitate collection of contributions from different authorities within one delegation.

- Importance:
  You consider the issue as very high – high – less importance for consumer or environmental exposure assessment of nanomaterials. Please note that scoring as "very high" and "high" is limited to a maximum of 6 and 12 issues, respectively. Scoring should also take into account the degree to which an issue is "specific" to nanomaterials. This does not exclude the possibility that issues are priorised which relate to both, nano- and non-nanomaterials.

- Data availability:
  Indicate whether you expect relevant information required to develop guidance on this issue from other sources to be available or planned, or to not be available in significant amounts.

- Inter-relationship:
  Please list other Important Issues which you consider to be related and which may be addressed in the same project in order to reduce the overall number of projects and pool resources. A linkage analysis shall be prepared as part of the survey report.

- Potential contribution to OECD projects:
  Members are also invited to self-identify as volunteers to lead, to participate or contribute to specific OECD projects. Members will also have an opportunity to volunteer to lead or participate after the results of the survey have been compiled.

Section 2 of the survey provides an opportunity to indicate the type of available information, and the status of the information or data (e.g., completed, ongoing, or planned), and can also be used to indicate any "horizontal" activity which is considered to support the development of specific guidance on the nanomaterial consumer and/or environmental exposure assessment and/or control methodology.

Section 3 of the survey may be used to provide additional descriptive information requested in the survey, if additional space is needed.

TABLE DESCRIPTION

Column I

- Lists all discrete issues identified for consideration by OECD.

Columns II and III

- Participants are invited to check the appropriate box. If checking a "data available" box you are invited to provide additional information and references below (Section 2).

Column IV (Section 1)

- Participants are invited to provide check the appropriate box related to the program under which the data or information is being developed or used. If the "other" box is selected, please provide additional information in Section 2.

Column V (Section 1)

- Participants are invited to indicate whether they would like to volunteer to lead specific projects related to the issue or can otherwise contribute resources. This includes contributions such as drafting, initial peer-review or expert consultation. This column can also be used to indicate linkages between topics.

EXAMPLE:

Name / Contact person: Cathy Fehrenbacher Affiliation: U.S. EPA
Delegation: United States of America E-mail address:
fehrenbacher.cathy@epa.gov

Section 1 – Characterization of Importance, Data Availability and Willingness to Volunteer

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
Material Characterization Relevant to Consumer and Environmental Exposure								
1	Name of the nanomaterial which accurately reflects the substance and impurities	☐C ☐E ☐Both	☐C ☐E ☐Both	☐C ☐E X Both	☐C ☐E X Both	☐C ☐E ☐Both	☐Research XRegulatory ☐Other (describe)	3, 4
2	Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, etc.	☐C ☐E X Both	☐C ☐E ☐Both	☐C ☐E ☐Both	☐C ☐E ☐Both	☐C ☐E X Both	☐Research XRegulatory ☐Other (describe)	1, 3, 4, 16-20, 23,24,25,26,28, 29, 30,31,32
3	Concentrations of nanomaterials in the products/formulations	☐C ☐E ☐Both	☐C ☐E ☐Both	☐C ☐E X Both	☐C ☐E X Both	☐C ☐E ☐Both	☐Research XRegulatory ☐Other (describe)	1, 3, 4, 16-20, 23-26,28-32, 33-36
4	Physical form of nanomaterials in products and articles	☐C ☐E ☐Both	☐C ☐E X Both	☐C ☐E ☐Both	☐C ☐E ☐Both	☐C ☐E X Both	☐Research XRegulatory ☐Other	1, 3, 4, 16-20, 23-26, 28-32, 33-36

Section 1 - Characterization of Importance, Data Availability and Willingness to Contribute to Future Work

In Section 1 of the survey, please indicate the importance of the data or information, characterize its availability, and indicate the type of program or framework under which the data is used. If additional space is needed to provide descriptive information, please provide that information in Section 3 of the survey form. Finally, indicate any linkages between the issues and whether you would like to volunteer to lead or contribute to future work related to the issue.

Name / Contact person: Affiliation:
Delegation: E-mail address:

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
Material Characterization Relevant to Consumer or Environmental Exposure								
1	Name of the nanomaterial which accurately reflects the substance and impurities	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □ Other (describe)	
2	Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, surface area, density, dustiness, etc.)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
3	Concentrations of nanomaterials (bound or unbound) in the products/formulations	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

[1] Scoring as "very high" is limited to a maximum of 6 issues.

[2] Scoring as "high" is limited to a maximum of 12 issues.

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
4	Physical form of nanomaterials (bound and unbound) in products and articles	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
	Production, Use, and Market							
5	Information on manufacturing and processing into product or article	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
6	Information on current and anticipated production/import quantities	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
7	Information on current and potential uses, including consumer goods	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
8	Market share information for uses, including consumer goods	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
9	Information on use of nanomaterials in products used by children	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
Releases to the Environment (Direct, Indirect, and via Consumer Use)								
10	Information on sources of nanomaterials released from manufacture and processing	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
11	Information on frequency, duration, and magnitude of release from manufacture and processing	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
12	Information of nanomaterials released from the use of articles and products into the environment	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
13	Information on frequency, duration, and magnitude of release from use of the nanomaterial itself into the environment	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
14	Applicability of OECD emission scenarios (ESDs) for nanomaterials	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
15	OECD emission scenarios (ESDs) under development for nanomaterials	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
	Environmental Fate and Transport							
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).	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
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.	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
18	Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate.	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
19	Test data to determine whether releases of nanomaterials escape the POTWs or sorb to sludge.	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
20	Test data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs.	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
Exposure Assessment (Direct and Indirect) for Consumer and Environmental Exposure to Manufactured Nanomaterials								
21	Information on the number of consumers potentially exposed to nanomaterials during use of an article or product	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
22	Information on the number of children potentially exposed to nanomaterials during use of an article or product	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
23	Information on exposure pathways for nanomaterials which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
24	Information on the routes of exposure (inhalation, ingestion, dermal) to nanomaterials with which to assess consumer and environmental exposure	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
25	Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
26	Accurate exposure measurements of nanomaterials in various environmental media	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
27	Accurate exposure measurements for consumers exposed to nanomaterials	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
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)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

	I	II - Importance			III – Data Availability		IV - Framework	V – Linkages; Volunteer
	ISSUE	very high[1]	high[2]	less	Available or Planned	Not Available	Research, Regulatory, Other	Identify linkages; Volunteer to lead or contribute
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)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
Exposure Control and Mitigation, as it Pertains to Consumers and Environment								
30	Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
31	Information on controls for mitigating environmental exposure to nanomaterials (if available, please describe)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
32	Information on controls for mitigating consumer exposure to nanomaterials (if available, please describe)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	
33	Information on effectiveness of controls for mitigating consumer exposure to nanomaterials (if available, please describe)	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ C □ E □ Both	□ Research □ Regulatory □Other (describe)	

Section 2 - Characterization of Type of Information, Data, etc., including Citation

In Section 2 of the survey, please describe any planned or ongoing data development, research, case studies, methods, databases, tools or models which pertain to consumer and/or environmental exposure assessment. If additional space is needed to provide descriptive information, please provide that information in Section 3 of the survey form. If final documents, methods, models, or tools are available, please provide a complete citation or URL.

Name / Contact person: Affiliation:
Delegation: E-mail address:

	I	II - Type of Available Information, Data, etc.				III - Citation
	ISSUE	**Data Development**	**Research**	**Case Studies**	**Methods/Models/Databases/Tools**	**Please provide citation or URL**
Material Characterization Relevant to Consumer or Environmental Exposure						
1	Name of the nanomaterial which accurately reflects the substance and impurities	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
2	Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, etc.	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
3	Concentrations of nanomaterials in the products/formulations	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
4	Physical form of nanomaterials in products and articles	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
Production, Use, and Market						
5	Information on manufacturing and processing into product or article	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
6	Information on current and anticipated production/import quantities	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
7	Information current and potential uses, including consumer goods	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	

	I	II - Type of Available Information, Data, etc.				III - Citation
	ISSUE	**Data Development**	**Research**	**Case Studies**	**Methods/Models/Databases/Tools**	**Please provide citation or URL**
8	Market share information for uses, including consumer goods	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
9	Information on use of nanomaterials in products used by children	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
Releases to the Environment (Direct, Indirect, and via Consumer Use)						
10	Information on sources of nanomaterials released from manufacture and processing	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
11	Information on frequency, duration, and magnitude of release from manufacture and processing	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
12	Information of nanomaterials released from the use of articles and products into the environment	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
13	Information on frequency, duration, and magnitude of release from use into the environment	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
14	Applicability of OECD emission scenarios (ESDs) for nanomaterials	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
15	OECD emission scenarios (ESDs) under development for nanomaterials	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	

Environmental Fate and Transport						
16	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).	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
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.	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
18	Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate.	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
19	Test data to determine whether releases of nanomaterials escape the POTWs or sorb to sludge.	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
20	Test data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs.	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
Exposure Assessment (Direct and Indirect) for Consumer and Environmental Exposure to Manufactured Nanomaterials						
21	Information on the number of consumers potentially exposed to nanomaterials during use of an article or product	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
22	Information on the number of children potentially exposed to nanomaterials during use of an article or product	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	

23	Information on exposure pathways which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
24	Information on the routes of exposure (inhalation, ingestion, dermal) with which to assess consumer and environmental exposure	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
25	Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
26	Accurate exposure measurements of nanomaterials in various environmental media	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
27	Accurate exposure measurements for consumers exposed to nanomaterials	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
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)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
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)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
Exposure Control and Mitigation, as it Pertains to Consumers and Environment						
30	Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
31	Information on controls for mitigating environmental exposure to nanomaterials (if available, please describe)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	

32	Information on controls for mitigating consumer exposure to nanomaterials (if available, please describe)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	
33	Information on effectiveness of controls for mitigating consumer exposure to nanomaterials (if available, please describe)	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	□ Completed □ Ongoing □ Planned	

Section 3 – Additional Information on Sections 1 and 2

Section 3 of the survey form is provided in case additional space is needed to provide descriptive information related to Sections 1 or 2 of the survey form.

Name / Contact person: Affiliation:
Delegation: E-mail address:

Section 2 – Characterization of Type of Information, Data, etc., including Citation

	I	**II**
	ISSUE	**Additional Descriptions (relevant to Sections 1 or 2 of the Survey Form)**
Material Characterization Relevant to Consumer or Environmental Exposure		
1	Name of the nanomaterial which accurately reflects the substance and impurities	
2	Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, etc.	
3	Concentrations of nanomaterials in the products/formulations	
4	Physical form of nanomaterials in products and articles	
Production, Use, and Market		
5	Information on manufacturing and processing into product or article	
6	Information on current and anticipated production/import quantities	
7	Information current and potential uses, including consumer goods	
8	Market share information for uses, including consumer goods	
9	Information on use of nanomaterials in products used by children	
Releases to the Environment (Direct, Indirect, and via Consumer Use)		
10	Information on sources of nanomaterials released from manufacture and processing	
11	Information on frequency, duration, and magnitude of release from manufacture and processing	
12	Information of nanomaterials released from the use of articles and products into the environment	
13	Information on frequency, duration, and magnitude of release from use into the environment	
14	Applicability of OECD emission scenarios (ESDs) for nanomaterials	

	I	II
	ISSUE	**Additional Descriptions (relevant to Sections 1 or 2 of the Survey Form)**
15	OECD emission scenarios (ESDs) under development for nanomaterials	
Environmental Fate and Transport		
16	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).	
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.	
18	Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate.	
19	Test data to determine whether releases of nanomaterials escape the POTWs or sorb to sludge.	
20	Test data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs.	
Exposure Assessment (Direct and Indirect) for Consumer and Environmental Exposure to Manufactured Nanomaterials		
21	Information on the number of consumers potentially exposed to nanomaterials during use of an article or product	
22	Information on the number of children potentially exposed to nanomaterials during use of an article or product	
23	Information on exposure pathways which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other)	
24	Information on the routes of exposure (inhalation, ingestion, dermal) with which to assess consumer and environmental exposure	
25	Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials	
26	Accurate exposure measurements of nanomaterials in various environmental media	
27	Accurate exposure measurements for consumers exposed to nanomaterials	
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)	
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)	

	I	II
	ISSUE	**Additional Descriptions (relevant to Sections 1 or 2 of the Survey Form)**
Exposure Control and Mitigation, as it Pertains to Consumers and Environment		
30	Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)	
31	Information on controls for mitigating environmental exposure to nanomaterials (if available, please describe)	
32	Information on controls for mitigating consumer exposure to nanomaterials (if available, please describe)	
33	Information on effectiveness of controls for mitigating consumer exposure to nanomaterials (if available, please describe)	

APPENDIX B: LINKAGES BETWEEN SURVEY ISSUES

The bottom/left of the table (red shading) indicates the number of countries that identified a linkage between issues, where the intensity of red shading is proportional to the number of countries that identified a linkage. The top/right of the table (blue shading) indicates the relatedness between each of the six broad categories, where the intensity of the shading is proportional to the number of countries that identified linkages between the categories (normalized for the number of issues in each category). Categories are noted in orange. Issue numbers are noted in yellow.

		1				2					3						4					5									6			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
1	1	/																																
	2	4	/																															
	3	2	3	/																														
	4	4	5	4	/																													
2	5	1	1	2	2	/																												
	6	1	1	0	1	1	/																											
	7	1	0	0	0	1	2	/																										
	8	1	0	0	0	1	1	3	/																									
	9	1	0	0	0	0	0	5	5	/																								
3	10	3	2	0	0	5	2	1	0	0	/																							
	11	3	2	1	0	4	2	1	0	0	6	/																						
	12	4	4	5	5	1	1	4	1	1	2	2	/																					
	13	4	4	5	4	1	1	4	1	1	2	2	4	/																				
	14	1	1	1	1	4	1	1	1	1	4	3	4	4	/																			
	15	1	1	0	1	4	1	1	0	0	5	4	5	5	4	/																		
4	16	2	4	1	3	1	1	1	1	1	4	4	6	3	1	1	/																	
	17	2	4	1	3	1	1	1	1	1	3	3	3	1	0	0	5	/																
	18	2	4	1	2	1	1	1	1	1	2	2	2	1	0	0	4	2	/															
	19	2	4	1	2	1	1	1	1	1	2	2	2	1	0	0	4	2	4	/														
	20	2	4	1	2	1	1	1	1	1	3	3	2	1	0	0	5	3	2	2	/													
5	21	1	0	1	1	0	1	4	2	2	1	1	2	1	0	0	1	0	0	0	0	/												
	22	1	0	1	1	0	1	4	2	3	1	1	2	1	0	0	1	0	0	0	0	4	/											
	23	1	2	2	2	1	1	2	2	2	2	2	4	4	0	0	3	2	2	2	3	1	2	/										
	24	1	2	2	2	0	0	2	2	2	2	1	4	3	0	0	2	1	1	1	1	1	2	4	/									
	25	0	3	2	2	1	3	4	2	2	2	2	2	2	0	0	2	2	2	2	2	3	1	5	4	/								
	26	3	5	2	3	1	1	2	2	2	2	2	2	2	0	0	2	2	2	2	2	1	1	3	2	6	/							
	27	3	5	2	3	0	0	2	2	2	1	1	2	1	0	0	2	1	1	1	1	1	1	3	2	5	1	/						
	28	3	5	5	5	0	0	2	2	2	1	1	2	1	0	0	2	0	1	0	0	1	1	2	1	4	4	4	/					
	29	3	5	5	5	0	0	2	2	2	1	1	2	1	0	0	1	0	0	0	0	1	1	2	1	5	4	4	3	/				
6	30	1	2	1	2	2	1	1	1	1	2	2	2	1	0	0	2	1	1	1	1	0	0	1	0	0	2	1	1	1	/			
	31	1	2	1	1	2	1	1	1	1	2	2	2	1	0	0	2	1	1	1	1	0	0	1	0	0	0	0	0	0	1	/		
	32	1	2	1	1	2	1	1	1	1	2	2	2	1	0	0	1	0	0	0	0	1	1	2	1	1	2	3	2	2	0	1	/	
	33	1	2	1	1	2	1	1	1	1	2	2	2	1	0	0	1	0	0	0	0	1	1	2	1	1	2	3	2	1	0	1	2	/

APPENDIX C: CITATIONS AND REFERENCES BY ISSUE

Category 1. Material Characterization		
Issue	**Organization**	**Citations/References**
1. Name of the nanomaterial which accurately reflects the substance and impurities	U.S. NIST	Numerous standards completed by ASTM E56 and ISO TC 229
2. Material characterization (e.g. purity, particle size, shape, aggregation/agglomeration potential, etc.	U.S. NIST	Numerous standards completed by ASTM E56 and ISO TC 229
	Italy	FP7-NanoReg
	Canada	RCC (http://nanoportal.gc.ca/default.asp?lang=En&n=5A56CB00-1), Government funded/supported research
3. Concentrations of nanomaterials in the products/formulations	U.S. NIST	Ongoing work at NIST to develop protocols to make and quantify ENM concentrations in polymer nanocomposites and a thread with AgNPs
	Canada	Government funded/supported research
4. Physical form of nanomaterials in products and articles	U.S. NIST	Ongoing work at NIST to measure the form of CNTs in polymer composites
	Canada	Government funded/supported research
Category 2. Production, Use, and Market		
6. Information on current and anticipated production/import quantities	Canada	S.71 survey results (http://www.chemicalsubstanceschimiques.gc.ca/plan/resources/s71-eng.php#nanomaterials)
Category 3. Releases to the Environment		
Issue	**Organization**	**Citation**
10. Information on sources of nanomaterials released from manufacture and processing	U.S. EPA	http://www.epa.gov/oppt/nano/nano-fact-sheet.html

12. Information of nanomaterials released from the use of articles and products into the environment	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)
	Canada	Government funded/supported research
	Germany, UBA	Several projects dealt with the release of NM from products: Nanosilver from textiles: e.g. Benn TM, Westerhoff P (2008), DOI: 10.1021/es7032718 Blaser SA, Scheringer M, Macleod M, Hungerbuhler K (2008), DOI: 10.1016/j.scitotenv.2007.10.010, Danish Ministry of the Environment (2012), URL: http://www2.mst.dk/Udgiv/publications/2012/06/978-87-92903-31-0.pdf, Geranio L, Heuberger M, Nowack B (2009), DOI: 10.1021/es9018332
	Korea, Hoseo Univ. & KATS	Kim E, Lee JH, Kim JK, Lee GH, Ahn K, Park JD, Yu IJ. 2015a. Case study on risk evaluation of silver nanoparticle exposure from antibacterial sprays containing silver nanoparticles, J of Nanomaterials, Article ID 346586. Kim E, Lee JH, Kim JK, Lee GH, Ahn K, Park JD, Yu IJ. 2015b. Case study on risk evaluation of printed electronics using nanosilver ink. Nanoconvergence, in press
13. Information on frequency, duration, and magnitude of release from use into the environment	U.S. EPA	https://www.epa.gov/tsca-screening-tools/interim-approaches-assessing-and-controlling-workplace-releases-and-exposures
	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)

Category 4. Environmental Fate and Transport		
Issue	**Organization**	**Citation**
16. 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).	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)
	Canada	Government funded/supported research
	Germany, UBA	Publications on fate of NM in (mainly) aquatic media exists. More research is needed with respect to ground water, sediment and air. Reviews highlighting current knowledge, scientific progress and gaps are e.g: Cornelis, G., et al., 2014. Fate and Bioavailability of Engineered Nanoparticles in Soils: A Review. Critical Reviews in Environmental Science and Technology. 44. Wagner, S., et al., 2014. Spot the difference: engineered and natural nanoparticles in the environment--release, behavior, and fate. Angew Chem Int Ed Engl. 53, 12398-419.
	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)
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.	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)
	Canada	Government funded/supported research

18. Test data to determine how the nanomaterials behave in waste water treatment plants, including the expected removal rate.	U.S. EPA	OECD Test Guidlines project "Development of a Draft Test Guideline for Nanomaterial Removal vai Soprtion Duriing 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).
	Canada	Government funded/supported research
	Germany, UBA	e.g. Kaegi, R., et al., 2011. Behavior of metallic silver nanoparticles in a pilot wastewater treatment plant. Environ Sci Technol. 45, 3902-8. Walser, T., et al., 2012. Persistence of engineered nanoparticles in a municipal solid-waste incineration plant. Nat Nanotechnol. 7, 520-4
20. Test data to determine whether natural organic matter and sunlight lead to soluble transformation products if nanomaterials escape the POTWs.	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) Exemplary citation on interaction of NM with complex matrices: Von der, Kammer. F., et al., 2010. Assessment of the physico-chemical behavior of titanium dioxide nanoparticles in aquatic environments using multi-dimensional parameter testing. Environ.Pollut. 158, 3472-3481. Von der Kammer, F., et al., 2012. Analysis of engineered nanomaterials in complex matrices (environment and biota): general considerations and conceptual case studies. Environ Toxicol Chem. 31, 32-49.

Category 5. Exposure Assessment		
Issue	**Organization**	**Citation**
23. Information on exposure pathways which can be evaluated (ingestion, inhalation dermal, soil, air, water, food chain, fish ingestion, drinking water, other)	U.S. EPA	https://www.epa.gov/tsca-screening-tools/interim-technical-guidance-assessing-screening-level-environmental-fate-and
	Canada	RCC (http://nanoportal.gc.ca/default.asp?lang=En&n=5A56CB00-1)
24. Information on the routes of exposure (inhalation, ingestion, dermal) with which to assess consumer and environmental exposure	U.S. EPA	http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=499980
	Canada	RCC (http://nanoportal.gc.ca/default.asp?lang=En&n=5A56CB00-1),, S.71 (http://www.chemicalsubstanceschimiques.gc.ca/plan/resources/s71-eng.php#nanomaterials)
25. Exposure models for use in characterizing or estimating consumer and/or environmental exposure to nanomaterials	Italy	SUN–EU FP7Project
	EU	https://www.consexponano.nl/ http://pubs.acs.org/doi/abs/10.1021/es500548h http://cordis.europa.eu/project/rcn/197194_en.html
	Germany, BfR	Migration Modelling from food contact materials: - Duncan T & Pillai, K (2015) Release of Engineered Nanomaterials from Polymer Nanocomposites: Diffusion, Dissolution, and Desorption; ACS Appl. Mater. Interfaces, 2015, 7 (1), pp 2–19, doi: 10.1021/am5062745 - Bott J, Störmer A, and Franz R, 2014. A comprehensive study into the migration potential of nano silver particles from food contact polyolefins. In: Chemistry of Food and Food Contact Materials: From production

	to plate. Benvenuto M A, Ahuja S, Duncan T V, Noonan G, Roberts-Kirchhoff E. Eds: ACS Symposium Series 1159, American Chemical Society, Washington DC, US. doi:10.1021/bk-2014-1159.ch005 - Bott J, Störmer A, and Franz R; Migration of nanoparticles from plastic packaging materials containing carbon black into foodstuffs; Food Additives & Contaminants: Part A, 2014, 31 (10) pp 1769-1782, doi: 10.1080/19440049.2014.952786 - Bott J, Störmer A, and Franz R; A model study into the migration potential of nanoparticles from plastics nanocomposites for food contact; Food Packaging and Shelf Life, 2014, 2 (2) pp 73-80, doi:10.1016/j.fpsl.2014.08.001
	Exposure Modelling/tools: - NANEX Project, 7th Framework programme, Project No 247794, http://www.nanex-project.eu - Environmental project No. 1636, 2015; Exposure assessment of nanomaterials in consumer products; Sub-report no. 1 from the project "Consumer exposure and risk assessment of nanomaterials in products on the Danish market"; http://mst.dk/service/publikationer/publikationsarkiv/2015/mar/exposure-assessment-of-nanomaterials-in-consumer-products (http://www2.mst.dk/Udgiv/publications/2015/01/978-87-93283-57-2.pdf)
	Environmental modelling: - Environmental project No. 1639, 2015; Nanomaterials in the Danish environment - Modelling exposure of the Danish environment to selected nanomaterials http://mst.dk/service/publikationer/publikationsarkiv/2015/mar/nanomaterials-in-the-danish-environment
Germany, UBA	e.g. Scheringer Working Group, ETH Zürich e.g. Praetorius, A., Scheringer, M., Hungerbühler, K., 2012. Development of Environmental Fate Models for Engineered Nanoparticles—A Case Study of TiO2 Nanoparticles in the Rhine River. Environmental Science & Technology 46, 6705-6713.

26. Accurate exposure measurements of nanomaterials in various environmental media	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
27. Accurate exposure measurements for consumers exposed to nanomaterials	Italy	SUN–EU FP7Project
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)	Italy	SUN–EU FP7Project
	Germany, BfR	Duncan T (2015) Release of Engineered Nanomaterials from Polymer Nanocomposites: the Effect of Matrix Degradation; ACS Appl. Mater. Interfaces, 2015, 7 (1), pp 20–39, doi: 10.1021/am5062757
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	U.S EPA	http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/9146/report/0
	Canada	ILSI NR

Category 6. Exposure Control and Mitigation

Issue	**Organization**	**Citation**
30. Information on effectiveness of controls for mitigating environmental exposure to nanomaterials (if available, please describe)	Italy	SUN-EU FP7 Project