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ENVIRONMENT DIRECTORATE
CHEMICALS COMMITTEE

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Working Party on Manufactured Nanomaterials

CO-OPERATION ON VOLUNTARY SCHEMES AND REGULATORY PROGRAMMES: PROGRESS REPORT AND NEXT STEPS

7th Meeting of the Working Party on Manufactured Nanomaterials taking place at OECD Conference Centre in Paris, France on 7-9 July 2010, starting at 10h00 on the first day.

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English - Or. English

The project ***Co-operation on Voluntary Schemes and Regulatory Programmes*** was established at the 2nd Working Party on Manufactured Nanomaterials (WPMN) together with an operational plan [ENV/CHEM/NANO(2007)9]. The project is being implemented by a steering group (SG5) led by Canada, which includes delegates from: France, Germany; Japan; Netherlands; Switzerland; United Kingdom; United States; European Commission; the Russian Federation; BIAC; TUAC; and Environmental NGOs.

This report has been prepared by SG5 for consideration by the WPMN. It presents progress achieved in implementing the project since the 6th WPMN. The report includes an update on: i) the Follow-up Questionnaire: Information Gathering Schemes; ii) the Questionnaire on Regulated Nanomaterials: 2006-2009; iii) an update on the information sharing database and the collaborative workspace; and iv) publications since the 6th WPMN.

In addition, this document presents the draft *Questionnaire on Regulated Nanomaterials: 2006-2009* (See Annex I) including two embedded excel tables-summary of data collected (Appendix 3 and 4) as well as the original *Questionnaire on Regulatory Regimes for Manufactured Nanomaterials* which was issued in 2008 (See Annex II).

ACTION REQUIRED: ***The WPMN is invited to:***

i) take note of progress achieved;

ii) provide specific inputs to the draft Questionnaire on Regulated Nanomaterials: 2006-2009(Annex I) and agree it be circulated amongst delegations in September; and

iii) agree to the next steps as proposed.

PROGRESS REPORT OF PROJECT FIVE: CO-OPERATION ON VOLUNTARY SCHEMES AND REGULATORY PROGRAMMES

Progress achieved since the 6th meeting of the WPMN

Background

1. This project examines various national voluntary reporting schemes and regulatory programmes to assess the safety of manufactured nanomaterials. Its primary objectives are: i) to finalise a report on the regulatory regimes which will summarise the information requirements, hazard identification, risk assessment and exposure mitigation/risk management features; ii) to gather information on the lessons learned from jurisdictions which have completed information gathering initiatives, and summarize non-CBI information and statistics on nanomaterials reported, to provide insight of global market activity; iii) to gather information on the nanomaterials notified under the various regulatory regimes for the periods 2006-2009 and 2010-2011, to provide an indication of regulatory activity/trends over time; iv) to establish, on a pilot basis, a collaborative workspace to allow delegations to exchange information; v) to secure member participation in the *Information Sharing database*.

2. The SG5 draft operational plan for 2009-2012 was approved with amendments at the last WPMN and finalised by the Steering Group shortly after the meeting. Based on the agreed operational plan [ENV/JM/MONO(2010)11] the expected outputs for the period 2009-2012 include:

- A report summarising the information gathered and lessons learned from the various information gathering initiatives that have been completed (draft report to be completed).
- A report on current and proposed regulatory regimes and how they address information requirements, hazard identification, risk assessment and exposure mitigation/ risk management of nanomaterials [published in April as ENV/JM/MONO(2010)12].
- A report summarising the nanomaterials that have been notified/assessed under the various regulatory regimes for the periods 2006-2009 and 2010-2011 (questionnaire drafted, see Annex).
- Establishment of a collaborative workspace for information exchange (underway).
- An up-to-date Information Sharing Database (underway).

Follow-up Questionnaire: Information Gathering Schemes

3. As agreed at the 6th WPMN, SG5 has moved forward on the follow-up Questionnaire: Information Gathering Schemes. The survey was finalized in January 2010 and released to the WPMN for response by March 30, 2010. Inputs received from several jurisdictions have been compiled and summarised into a draft report, one for Part A (lessons learned) and one for Part B (non-CBI data).

4. The draft report has been sent to the responding countries[1] for confirmation of the data. Deadline for inputs have been given to these delegations until June 21, 2010 to review their data in the report and provide feedback. It is expected that once completed, the report will be disseminated to SG5 for comments.

[1] Australia, Canada, Czech, Denmark, Germany, Ireland, Japan, United Kingdom and the United States.

Following a comment period of one month, the draft report is expected to be finalized and circulated to the WPMN for declassification by written procedure.

Questionnaire on Regulated Nanomaterials: 2006-2009

5. As agreed at the 6th WPMN, the Questionnaire on Regulated Nanomaterials: 2006-2009, which focuses on information obtained through legislation, was prepared by Canada and further revised by SG5. The final draft is presented as an Annex.

6. The WPMN is invited to provide their comments and amend as appropriate.

7. SG5 expects to finalise the Questionnaire during the summer for release in September 2010 amongst delegations.

8. The WPMN is invited to agree that this Questionnaire be circulated, and to provide their responses in September.

Other progress

9. SG5 agreed to use the new WPMN's IT collaborative platform[2] to collect the data handled for the pilot Information Sharing Database. This Information Sharing Database allows delegations to identify contact persons responsible for the assessment of particular nanomaterials and to exchange information on manufactured nanomaterials. Information provided by delegations will be put into the Information Sharing Database. Delegations are invited to provide their information as soon as possible. In addition, delegations completing *the Regulated Nanomaterials Questionnaire 2006-2009* will be invited to indicate whether the non-CBI data provided can be used to populate this Information Sharing Database.

10. With regard to SG5 *Collaborative Workspace*, a list of possible topics for discussion including risk assessment and risk management will be developed. This activity will be led by the US in collaboration with Canada and the EC. The discussion will be held through the new WPMN's collaborative platform.

11. As agreed at the 6th WPMN, SG5 discussed the possibility of addressing two exposure-related projects identified by SG8: i) Analyze adequacy of MSDS for nanomaterials and provide recommendations; and ii) compare available regulations used to determine whether a substance that contains a nanomaterial is hazardous. During discussions among SG5, it was noted that the MSDS related project is already addressed by ISO/TC 229, and as for the second project, it was noted that information related to it might already be covered by the regulatory regimes survey that is underway.

Publications

12. Since the 6th WPMN, two documents have been finalized and declassified: i) the document Analysis of Information Gathering Initiatives on Manufactured Nanomaterials [ENV/JM/MONO(2009)45]; and ii) the Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials [ENV/JM/MONO(2010)12].

[2] The platform was launched in February 2010

ANNEX I. DRAFT QUESTIONNAIRE ON REGULATED NANOMATERIALS: 2006-2009

13. This Annex is the draft *Questionnaire on Regulated Nanomaterials: 2006-2009*. The WPMN is invited to amend as appropriate. The WPMN is also invited to agree that this Questionnaire be circulated amongst the WPMN delegations in September and to respond to it by the time agreed.

Introduction

14. The Questionnaire on Regulated Nanomaterials: 2006-2009 is intended to collect information on the types and number of nanomaterials that have been notified to various OECD jurisdictions between January 1, 2006 and December 31, 2009. This Questionnaire is also intended to collect additional non-confidential business information available on the nanomaterials notified, such as the trigger for notification and risk assessment results. By repeating this survey over time, trends relating to commercial activity or changes in Legislative requirements and/or oversight may be seen. It is noted that under some Legislations, risk assessments and management by a jurisdiction may have occurred in the absence of a requirement for a proponent to "notify" information. Details regarding this kind of Legislation and the nanomaterials for which a risk assessment has been conducted can also be reported here.

Background

15. This Questionnaire is a follow-up survey to the original Regulatory Regimes Questionnaire conducted by SG5 in 2008 that requested information on the various Legislations currently in use to assess nanomaterials. The main purpose of the original regulatory regimes survey was to identify applicable (current and proposed) regulatory regimes and how they address information requirements related to hazard identification, exposure assessment and mitigation, risk assessment and risk management measures for manufactured nanomaterials. In 2008, information was submitted by various jurisdictions concerning a variety of Legislations relevant to nanomaterials. None of the respondents reported having Legislation specific to nanomaterials, however most respondents indicated that the authority to regulate substances that are nanomaterials, or products containing nanomaterials, exists in current Legislation. The Regulatory Regimes Report was finalized in 2009 and will be declassified in 2010. The report listed key features found to be present in one or more of the Legislations.

16. The focus of this new survey, to update the status of Legislation and gather information on the types and number of nanomaterials notified and/or assessed in various OECD jurisdictions, may enable the OECD to obtain a snapshot of the regulatory landscape and commercial activity over this time period. By repeating this survey over time, trends relating to changes in commercial activity and Legislative requirements may be seen.

Instructions:

17. Complete a separate questionnaire for each piece of Legislation under which a nanomaterial, or product containing a nanomaterial has been reported/notified. A few questions may be repeated from the original Regulatory Regimes Questionnaire in 2008. Respondents are welcome to reference any responses given in the original questionnaire where appropriate.

WPMN working Definition of a nanomaterial:

18. A nanomaterial, as discussed by the WPMN [ENV/CHEM/NANO/M(2007)1][3], is considered to be a nano-object or nanostructured material with one, two or three dimensions in the size range typically between 1nm and 100 nm. If your jurisdiction applies another definition for nanomaterial, please provide the data for all nanomaterials captured by your definition. When completing Section 1, indicate the definition you are using for nanomaterial. When completing the Excel table(s), you will be given the opportunity to indicate whether or not the substance you listed falls within or outside the size range of 1-100 nm.

19. Information specific to a nanomaterial will be collected through two Excel tables, with guidance being provided in Sections 3 and 4 of the Questionnaire and through the use of comments embedded in the Excel tables themselves. Also, Appendices 1 and 2 provide additional information for use when completing the Excel tables. Complete the Excel tables to the best of your knowledge based on the non-confidential information you have. Please note that your completed questionnaire(s) will be used as a source of information for the analysis and will not be published as such, nor will it/they be included in the final report. The final report will be a summary of all of the information collected.

20. In the final column of the Excel tables, you will be given the opportunity to indicate for each substance, whether or not certain information from each Excel table can be used to populate the Pilot Information Sharing Database on the OECD website. The purpose of the Information Sharing Database is to allow different jurisdictions to identify contact persons within another jurisdiction responsible for the assessment of a particular nanomaterial. This contact information will enable delegations to exchange information on a bilateral basis. If you feel it is necessary to contact a particular person or company in advance of completing this final column of the Excel table, and do not have time to do so in advance of completing this questionnaire, leave the final column blank, and this information can be completed at a later date.

[3] As discussed at the 2nd meeting of the WPMN, in agreeing to the working definition of nanomaterials WPMN notes that the term should not be considered a definition in the strictest sense of the word and does not constitute an official OECD definition. For practical purposes, it is more closely akin to a working scope.

QUESTIONNAIRE ON REGULATED NANOMATERIALS: 2006-2009

Table of Contents

COUNTRY:

SECTION 1: LEGISLATION

1. Name of the Legislation under which nanomaterials were notified/reported/assessed between 2006-2009 (please complete a separate questionnaire for each Legislation):

2. Was the original Regulatory Regimes Survey, issued by SG5 in 2008, completed for this Legislation?

☐ Yes ☐ No

If no, would you be willing to complete the original Regulatory Regimes Survey? ☐ Yes ☐ No
If yes, the survey is attached[4].

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atoryRegimes May 2(

3. Has this Legislation undergone any amendments since November 2008 that would affect the regulation of nanomaterials?

☐ Yes ☐ No ☐ This Legislation is specific to nanomaterials

If yes, please describe:

4. Does this Legislation, or does your jurisdiction have one or more formal or working definitions for nanomaterials?

☐ Yes ☐ No

If yes, what is (are) the definition(s) used in your jurisdiction for nanomaterial (and if more than one, please specify the context, for example regulatory purposes vs. research funding purposes)?

Please provide any additional comments here:

[4] For convenience, the survey is available as Annex II

SECTION 2: DESCRIPTION OF SUBSTANCES/PRODUCTS REGULATED UNDER THIS LEGISLATION

1. Description of substances/products regulated by this Legislation:

click here to insert your response

2. Description of substance/products specifically excluded from this Legislation:

click here to insert your response

3. Purpose of the Legislation

4. Activity targeted (check all that apply):

☐ Manufacturing ☐ Importation

☐ Commercialization/Marketing ☐ Usage

☐ Disposal/Waste ☐ Other

5. Objective (check all that apply):

☐ Market Regulation ☐ Innovation/Competitiveness Enhancement

☐ Environmental Protection ☐ Worker Protection

☐ Consumer Protection ☐ Other please specify

6. Volume Trigger for Notification: ☐ ≥ 0 kg/yr ☐ ≥ 1 kg/yr ☐ ≥ 10 kg/yr

☐ ≥ 100 kg/yr ☐ ≥ 1 000 kg/yr ☐ ≥ 10 000 kg/yr Other please specify

7. End use Application (check all that apply): ☐ Research and Development

☐ Industrial Use ☐ Food and Drug ☐ Consumer Use

☐ Cosmetics ☐ Pesticide ☐ Agricultural

☐ Other please specify

8. Does your Legislation have the requirement for proponents to notify nanomaterials?

☐ Yes ☐ No

If no, complete Section 4. If yes, complete section 3, and also complete Section 4 if under your Legislation you have reviewed/assessed other nanomaterials (i.e. nanomaterials that were not "notified" by a proponent led notification).

SECTION 3: SUMMARY OF DATA COLLECTED

Depending on the definition your Legislation uses for nanomaterial, and on the information you have to report, you may be reporting only nanomaterials that fall within the 1-100 nm size range, or you may also have information on nanomaterials that fall outside this size range. If you only have information on nanomaterials within the 1-100 nm size range or you are unsure of the size range for the nanomaterials you are reporting, omit question 2. If you have information on nanomaterials that fall outside the range of 1-100 nm, please also complete question 2.

1. For nanomaterials with 1, 2 or 3 dimensions within the 1-100 nm size range:
a) How many companies/institutions have reported nanomaterials under this Legislation?

click here to insert your response

b) How many different nanomaterials have been reported under this Legislation between January 1, 1006 and December 31, 2009?

2. For nanomaterials with all dimensions outside the 1-100 nm size range:
a) How many companies/institutions have reported nanomaterials under this Legislation?

click here to insert your response ☐ Not applicable

b) How many different nanomaterials have been reported under your Legislation between January 1, 2006 and December 31, 2009?

☐ Not applicable

3. How many companies/institutions reported the following activities with the nanomaterials you are reporting in this Questionnaire?

Commercialization/Marketing **Import** **Manufacture**

Use **Disposal/Waste** **Other please specify**

4. Complete Excel table 1, providing non-confidential business information only. Leave blank any columns blank that are not relevant for your Legislation. When reporting the identity of the nanomaterials, please be as specific as possible. However, nanomaterials can be grouped categorically to avoid reporting confidential business information. See Annex 1 for a list of typical categories that you may wish to use. See Annex 2 for a list of use codes for use in completing columns D, F, H, J, and L of Excel Table 1. Comments are embedded with most column headings to provide additional guidance for completion of Excel table 1.

SECTION 3: SUMMARY OF DATA COLLECTED (CONTINUED)

5. Provide the following information you collected that was not included in Table 1 due to confidential business information (CBI) claims:

Number of nanomaterials notified but for which all information was listed as CBI:

6. Is there any other non-CBI information you collected that you would like to share?

☐ Yes ☐ No

If yes, please provide.

click here to insert your response

SECTION 4: SUMMARY OF OTHER ANALYSES

Complete this section for all nanomaterials that have been assessed/reviewed under your Legislation but were not included in Section 3 (i.e. a review was mandated/permitted by the Legislation but it was not initiated by a submission made by a proponent). If this section does not apply, check here and go to Section 5.

☐ **This section does not apply.**

Depending on the definition your Legislation uses for nanomaterial, and on the information you have to report, you may be reporting only nanomaterials that fall within the 1-100 nm size range, or you may also have information on nanomaterials that fall outside this size range. If you only have information on nanomaterials within the 1-100 nm size range or you are unsure of the size range for the nanomaterials you are reporting, omit question 2. If you have information on nanomaterials that fall outside the range of 1-100 nm, please also complete question 2.

1 a) How many nanomaterials with 1, 2 or 3 dimensions within the 1- 100 nm size range have been assessed under this Legislation between January 1, 2006 and December 31, 2009?

2. How many nanomaterials with all dimensions outside of the 1-100nm size range have been assessed under your Legislation between January 1, 2006 and December 31, 2009?

3. Complete Excel table 2, providing non-confidential business information only. Leave any columns blank that are not relevant for your Legislation. When reporting the identity of the nanomaterials, please be as specific as possible. However, nanomaterials can be grouped categorically to avoid reporting confidential business information. See Annex 1 for a list of typical categories that you may wish to use. See Annex 2 for a list of use codes for use in completing column D of Excel Table 2. Comments are embedded with most column headings to provide additional guidance for completion of the excel table.

SECTION 5: OTHER

1. **Please provide any other details, explanations or comments that you may have that will help to interpret the information that you provided.** click here to insert your response

Thank-you. This completes the Questionnaire. Please submit to the OECD WPMN secretariat by email: beobjeong.kim@oecd.org . If you have any questions while completing this form, please send them to the Chair of SG5, Greg Carreau (**greg.carreau@ec.gc.ca**) with a copy to the OECD Secretariat (beobjeong.kim@oecd.org).

21. The following appendices are Excel tables (Appendix 3 and 4) summarizing data collected through the questionnaire as well as categories of nanomaterials (Appendix 1) and use codes (Appendix 2) for use when completing the Excel tables.

APPENDIX 1: Suggested Categories of Nanomaterials for use (as applicable) when completing the excel table in Section 3 of the Questionnaire.

Please be as specific as possible when listing nanomaterials in the excel table, however, if necessary, in order to avoid providing confidential business information, they can be grouped categorically. Below are some categories that could be used, listed alphabetically.

Aluminium oxides
Carbon black
Cerium Oxide
Dendrimers
Fullerenes
Iron nanoparticles
Iron oxide
Multi-walled carbon nanotubes
Nanoclays
Pharmaceutical actives
Polystyrene
Quantum dots
Silicates
Silicic acids
Silicon dioxide
Silver nanoparticles
Single-walled carbon nanotubes
Titanium dioxide
Zinc oxide

APPENDIX 2: Use Codes for use (as applicable) when completing the excel table in Section 3 of the Questionnaire

1. Research and Development
2. Industrial Use
3. Food and Drug
4. Consumer Use
5. Cosmetics
6. Pesticide
7. Agricultural
8. Other

APPENDIX 3: Excel Table 1- Summary of Data Collected through Notification

Column	Items
A	Identity of Nanomaterial
B	Does this NM fall within the 1-100 nm size range? Y/N
C	Provide explanation if you answered No in Column B
D	Total # of companies reporting activities with this NM
E	List all Use Codes reported for this NM
F	# of Companies reporting < 10 kg/yr
G	Use codes reported for < 10 kg/yr
H	# of Companies reporting 10-100 kg/yr
I	Use codes reported for 10-100 kg/yr
J	# of Companies reporting 100-1000 kg/yr
K	Use codes reported for 100-1000 kg/yr
L	# of companies reporting > 1000 kg/y
M	Use codes reported for >1000 kg/yr
N	# of Companies providing info on fate and exposure
O	# of Companies providing info on phys-chem properties
P	# of Companies providing human toxicity data
Q	# of Companies providing ecotox data
R	# of Companies reporting Risk Management in place
S	Pre-Market Assessment Complete (Y/N)
T	Post-Market Assessment Complete (Y/N)
U	Assessment Conclusion
V	Risk Management
W	Any future notification obligations
X	Permission to use info in OECD database (Y/N)

APPENDIX 4: Excel Table 2- Summary of Data Collected by Jurisdictions for Assessment (Not Proponent-Led Notification)

Column	Items
A	Identity of Nanomaterial
B	Does this NM fall within the 1-100 nm size range? Y/N
C	Provide explanation if you answered No in Column B
D	List all Use Codes identified for this NM
E	Quantities in use kg/yr
F	Fate and exposure data (Y/N)
G	Phys-Chem Data (Y/N)
H	Human Toxicity Data (Y/N)
I	Ecotox Data (Y/N)
J	Assessment Conclusion
K	Risk Management Tools Used
L	Permission to use info in OECD database (Y/N)

ANNEX II. QUESTIONNAIRE ON REGULATORY REGIMES FOR MANUFACTURED NANOMATERIALS

22. The following is the original *Questionnaire on Regulatory Regimes for Manufactured Nanomaterials* issued in 2008. It is embedded Section 1-Question 2 of the Questionnaire on Regulated Nanomaterials: 2006-2009 (Annex I).

Introduction

23. The Questionnaire on Regulatory Regimes for Manufactured Nanomaterials is intended to identify applicable current and proposed regulatory regimes and how they address information requirements, hazard identification, exposure mitigation, risk assessment and risk management of manufactured nanomaterials. The questionnaire aims to collecting information on the regulation of the following fields: chemicals, consumer products, worker protection and waste management. If you feel that other legislations are also relevant, please also report them.

The questionnaire is divided into four main sections:

- Basic Information
- Pre-Market Registration / Notification, Assessment and Management of Substances
- Registration / Notification, Assessment, and Management of Substances Already in Commerce
- Other Remarks

24. The questionnaire consists of a series of Yes/No questions and is intended to be easy to complete. Fields which require completion are indicated by grey shading and drop down menus are provided for selection of standard responses. For selected fields, help information is available by pressing F1.

25. Please note that, in some countries, there might be several pieces of legislation governing different aspects of the safety of nanomaterials. Please complete one questionnaire for each piece of legislation.

Information to Respondents

26. The following provides guidance on how to respond to specific sections or questions in the questionnaire.

Section 1

27. The scope of the questionnaire is intended for legislation which may, in part or wholly, apply to risk assessment and management of manufactured nanomaterials. One questionnaire form should be

completed for each piece of legislation which may apply. Some sections and some specific questions may or may not be applicable to your legislation. If it is the case, please indicate so.

Sections 3, 4

Timelines for assessment (questions 11, 25a)

28. Timelines refer to the length of time required by the legislation to complete an assessment or to respond to a registration/notification.

Surrogate data (questions 13, 27)

29. Surrogate data refers to data for a substance similar to the registered/notified substance which is not reasonably expected to differ in physico-chemical, biochemical, or toxicological properties. For example, long alkyl chains with an additional methylene group (e.g., $C_{10}H_{22}$ to $C_{11}H_{24}$) would not be reasonably expected to exhibit significantly different properties from each other.

Timeframe for implementation (questions 16c, 30c)

30. The timeframe for implementation of a risk management tool refers to the time required by the legislation to execute risk management measures.

SECTION 1: Basic Information		
1.	**COUNTRY**	
2.	**LEGISLATION**	
2a.	**Name of legislation**	
2b.	**Current or planned (date)**	
2c.	**Administrative body(ies)**	
2d.	**Activity addressed by the legislation (check all that apply)**	☐Manufacturing ☐Importation ☐Importation ☐Commercialization / Marketing ☐Usage ☐Disposal / Waste
2e.	**Objective(s) of the legislation (check all that apply)**	☐Market Regulation ☐Innovation / Competitiveness Enhancement ☐Environmental Protection ☐Worker Protection ☐Consumer Protection ☐Other (please specify below)
Web link at which the legislation / regime can be found:		
3.	**Are there provisions specific to nanomaterials?**	**---**
3a.	**If yes, please identify provisions specific to nanomaterials**	
Additional clarifications / explanations:		
SECTION 2: Pre-Market Registration / Notification, Assessment and Management of Substances		
4.	**What is the enabling instrument / regulation?**	
5.	**Are there mechanisms for pre-market registration / notification of substances?**	**---**
Additional clarifications / explanations:		
6.	**Are there mechanisms for pre-market assessment of substances?**	**---**

Additional clarifications / explanations:		
7.	**Are there provisions specific to nanomaterials?**	**---**
7a.	**If yes, please identify provisions specific to nanomaterials**	
8.	**Are there trigger quantities for pre-market registration / notification?**	**---**
Additional clarifications / explanations:		
9.	**Are there exemptions or other exceptions from registration / notification?**	**---**
Additional clarifications / explanations:		
10.	**Does the assessment process use a tiered or graduated approach?**	**---**
Additional clarifications / explanations:		
11.	**What are the timelines for assessment?**	
12.	**Is data required to be submitted with registrations / notifications?**	**---**
13.	**Is surrogate data permitted?**	**---**
13a.	**If yes, what type of data is acceptable?**	
14.	**GENERAL DATA REQUIREMENTS**	
14a.	**Chemical identification**	**---**
14b.	**Material characterization**	**---**
14c.	**Use and volumes of use**	**---**
14d.	**Exposure information for:**	
14d.1	**Workers**	**---**
14d.2	**Consumers (direct exposure)**	**---**
14d.3	**The environment**	**---**
14d.4	**Consumers through the environment**	**---**
14e.	**Physico-chemical properties**	**---**
14f.	**Health effects**	**---**

14g.	**Environmental effects**	**---**
14h.	**Fate and behaviour**	**---**
14i.	**Other**	**---**
Additional clarifications / explanations:		
15.	**ASSESSMENT CONSIDERATIONS**	
15a.	**Is the assessment process mandatory?**	**---**
15b.	**If not mandatory, can the risk assessment be done on a "case-by-case" basis?**	**---**
15c.	**Does the assessment include occupational health and safety?**	**---**
15d.	**Does the assessment include public health impacts?**	**---**
15e.	**Does the assessment include environmental impacts?**	**---**
Additional clarifications / explanations:		
16.	**RISK MANAGEMENT OPTIONS**	
16a.	**Is the risk management mandatory?**	**---**
16b.	**If not mandatory, can the risk management be done on a "case-by-case" basis?**	**---**

16c.	**What risk management tools are available?**	**16c.**	**What is the timeframe for implementation of the tool?**
Additional clarifications / explanations:			

16d.	**Does the legislation require the development of new information?**	**---**
16e.	**If yes, what findings or conditions trigger this requirement?**	
17a.	**Are there provisions for confidentiality of information submitted?**	**---**
17b.	**Are there criteria and processes used to review confidential business information (CBI) claims?**	**---**
18.	**ACCESS TO INFORMATION**	

18a.	**Does the public have a right of access of registration information?**	**---**
	What is the nature of the information available?	
18b.	**Does the public have a right of access to assessment information?**	**---**
	What is the nature of the information available?	
18c.	**Does the public have a right of access to information to risk management information?**	**---**
	What is the nature of the information available?	
18d.	**Do workers have access to registration information?**	**---**
18e.	**Do workers have access to risk assessment information?**	**---**
18f.	**Do workers have access to risk management information?**	**---**
Additional clarifications / explanations:		
SECTION 3: Registration / Notification, Assessment, and Management of Substances Already in Commerce		
19.	**What is the enabling instrument / regulation?**	
20.	**Are there provisions for registration of substances already in commerce?**	**---**
20a.	**Is the registration process mandatory?**	**---**
20b.	**If yes, under what conditions is registration required?**	
20c.	**Does the registration of a substance require updates?**	**---**
20d.	**Under what conditions are updates required? (e.g., change in use or volume of use)**	
20e.	**Does the legislation require submission of information on existing substances or require testing to be conducted?**	**---**
20f.	**If yes, what findings or conditions must government meet to impose this requirement?**	

20g.	**Is there an inventory of chemicals in commerce?**	---
20h.	**Is the inventory updated on a regular basis?**	---
20i.	**If yes, how often is the inventory updated? (e.g. every year, every two years)**	
20j.	**Can nanomaterials in commerce be identified in this inventory?**	---
Additional clarifications / explanations:		
21.	**Are there provisions for assessment of substances already in commerce?**	---
21a.	**If yes, under what conditions is an assessment conducted?**	
Additional clarifications / explanations:		
22.	**Are there provisions specific for nanomaterials?**	---
22a.	**If yes, please identify provisions specific to nanomaterials**	
Additional clarifications / explanations:		
23.	**Are there trigger quantities for registrations?**	---
Additional clarifications / explanations:		
24.	**Does the assessment process use a tiered or graduated approach?**	---
Additional clarifications / explanations:		
25a.	**What are the timelines for assessment?**	
25b.	**Is there an obligation to conclude an assessment that has been initiated?**	---
26.	**Is data required to be submitted with notifications?**	---

27.	**Is surrogate data permitted?**	**---**
27a.	**If yes, what type of data is acceptable?**	
28.	**GENERAL DATA REQUIREMENTS (if applicable)**	
28a.	**Chemical identification**	**---**
28b.	**Material characterization**	**---**
28c.	**Use and volumes of use**	**---**
28d.	**Exposure information for:**	
28d.1	**Workers**	**---**
28d.2	**Consumers (direct exposure)**	**---**
28d.3	**The environment**	**---**
28d.4	**Consumers through the environment**	**---**
28e.	**Physico-chemical properties**	**---**
28f.	**Health effects**	**---**
28g.	**Environmental effects**	**---**
28h.	**Fate and behaviour**	**---**
28i.	**Other**	**---**
Additional clarifications / explanations:		
29.	**ASSESSMENT CONSIDERATIONS**	
29a.	**Is the assessment process mandatory?**	**---**
29b.	**Does the assessment include occupational health and safety?**	**---**
29c.	**Does the assessment include human health impacts?**	**---**
29d.	**Does the assessment include environmental impacts?**	**---**
Additional clarifications / explanations:		
30.	**RISK MANAGEMENT OPTIONS**	
30a.	**Is the risk management mandatory?**	**---**

30b.	**What risk management tools are available?**	**30c.**	**What is the timeframe for implementation of the tool?**

30d.	**Are there criteria that the government must meet in order to impose risk management measures?**		**---**
Additional clarifications / explanations:			
31a.	**Are there provisions for confidentiality of information submitted?**		**---**
31b.	**Are there set criteria and processes used to review confidential business information (CBI) claims?**		**---**
Additional clarifications / explanations:			
32.	**ACCESS TO INFORMATION**		
32a.	**Does the public have a right of access to information to registration information?**		**---**
	What is the nature of the information available?		
32b.	**Does the public have a right of access to assessment information?**		**---**
	What is the nature of the information available?		
32c.	**Does the public have a right of access to risk management information?**		**---**
	What is the nature of the information available?		
32d.	**Do workers have access to registration information?**		**---**
32e.	**Do workers have access to risk assessment information?**		**---**
32f.	**Do workers have access to risk management information?**		**---**
32g.	**Do companies down the supply chain have access to registration information?**		**---**
32h.	**Do companies down the supply chain have access to risk assessment information?**		**---**
32i.	**Do companies down the supply chain have access to risk management information?**		**---**
32j.	**Do companies in the supply chain have information obligations towards their suppliers?**		**---**
Additional clarifications/ explanations:			

SECTION 4: Other Remarks	
33.	**Please provide any additional remarks.**