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REPORT OF THE QUESTIONNAIRE ON REGULATORY REGIMES FOR MANUFACTURED NANOMATERIALS

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REPORT OF THE QUESTIONNAIRE ON REGULATORY REGIMES FOR MANUFACTURED NANOMATERIALS

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The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and 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 the 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 (http://www.oecd.org/ehs).

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

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, UNEP, UNIDO, UNITAR, WHO and OECD. The World Bank and UNDP are observers. 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.

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. 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. This programme 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.

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THE WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

The Working Party on Manufactured Nanomaterials [1] was established in 2006 to help member countries efficiently and effectively address the safety challenges of nanomaterials. OECD has a wealth of experience in developing methods for the safety testing and assessment of chemical products.

The Working Party brings together more than 100 experts from governments and other stakeholders from: a) OECD Countries; b) non-member economies such as Brazil, China, the Russian Federation, Singapore and Thailand; and c) observers and invited experts from UNITAR, FAO, IOMC, UNEP, WHO, ISO, BIAC[2], TUAC[3], and environmental NGOs.

Although OECD member countries appreciate the many potential benefits from the use of nanomaterials, they wished to engage, at an early stage, in addressing the possible safety implications at the same time as research on new applications is being undertaken.

The Working Party is implementing its work through specific projects to further develop appropriate methods and strategies to help ensure human health and environmental safety:

- OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities;
- Safety Testing of a Representative Set of Manufactured Nanomaterials;
- Manufactured Nanomaterials and Test Guidelines;
- Co-operation on Voluntary Schemes and Regulatory Programmes;
- Co-operation on Risk Assessment;
- The Role of Alternative Methods in Nanotoxicology;
- Exposure Measurement and Exposure Mitigation; and
- Co-operation on the Environmentally Sustainable Use of Nanotechnology.

Each project is being managed by a steering group, which comprises members of the WPMN, with support from the Secretariat. Each steering group implements its respective "operational plans", each with their specific objectives and timelines. The results of each project are then evaluated and endorsed by the entire WPMN.

More information about the work of the WPMN, as well as publications and updates on efforts of governments and other stakeholders to address safety issues of nanomaterials is available at http://www.oecd.org/env/nanosafety.

[1] Updated information on the OECD's Programme on the Safety of Manufactured Nanomaterials is available at: www.oecd.org/env/nanosafety

[2] The Business and Industry Advisory Committee to the OECD

[3] Trade Union Advisory Committee to OECD

PROJECT ON CO-OPERATION ON VOLUNTARY SCHEMES AND REGULATORY PROGRAMMES

The project on **Co-operation on Voluntary Schemes and Regulatory Programmes** was established to achieve two objectives with respect to regulatory regimes:

- To identify applicable (current and proposed) regulatory regimes and how they address information requirements, hazard identification, exposure mitigation, risk assessment and risk management measures for manufactured nanomaterials; and

- To gather information on the nanomaterials notified under the various regulatory regimes to provide an indication of regulatory activity and trends over time.

In order to achieve these objectives, the project is been implemented in several stages. As a first step, a compilation on information on Regulatory Regimes for Manufactured Nanomaterials was prepared and then analysed. This allowed to identify key features in legislations that provide regulatory oversight of nanomaterials and their products.

This report includes the analysis of: i) the responses received on general information on objectives of the legislation and activities addressed by the legislations (section I); ii) the responses on pre-market registration or notification, assessment and management of substances (section II); iii) the responses received on registration/notification, assessment, and management of substances already in commerce (section III), and iv) those legislative features identified in this survey, for consideration when amending or drafting legislation for the regulatory oversight of nanomaterial and their products (section IV). The responses to the questionnaire provided by delegations are compiled in the Annexes of this report.

A follow-up survey is expected to identify the types and number of nanomaterials notified under the different regulatory regimes to be conducted to provide statistics on the notifications received by individual jurisdictions on nanomaterials. It is expected that by collecting this information, trends relating to commercial activity or changes in legislative requirements and oversight be seen.

This report was prepared by the WPMN steering group 5 leading the work on co-operation on voluntary schemes and regulatory programmes. The Working Party endorsed this report in November 2009.

EXECUTIVE SUMMARY

One of the objectives of the WPMN project on Co-operation on Voluntary Schemes and Regulatory Programmes is to identify applicable (current and proposed) regulatory regimes and how they address information requirements, hazard identification, exposure mitigation, risk assessment and risk management measures for manufactured nanomaterials.

The current document presents the information obtained from the WPMN Questionnaire on Regulatory Regimes for Manufactured Nanomaterials issued July 28, 2008. Responses received are summarized in the Tables (see Annexes).

Twenty-four responses were received from nine jurisdictions for Legislations covering a wide variety of chemical substances and/or products including industrial chemicals, pesticides, fertilizers, agricultural compounds, fuels and fuel additives, food and food additives and veterinary medicines. Other Legislations reported included those covering occupational health and safety, consumer products, control of major accidents and labelling and packaging. Although a wide variety of sectors are represented in the data obtained, it is noted that responses from the industrial chemical sector were in the majority for those Legislations reporting pre-market and/or post-market registration/notification and assessment.

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. Since nanomaterials and products containing nanomaterials are currently being regulated under existing Legislations, and given the qualitative nature of the survey itself, the results of this analysis have been limited to identifying the number of legislations with various features that may be of use in the registration/notification and assessment of nanomaterials. Readers are cautioned that the features mentioned may not be relevant for all Legislative mandates, nanomaterials or products, and that response from the industrial chemical sector dominate.

Of the twenty-four (24) Legislations reported, fourteen (14) have pre-market registration/notification and assessment of substances. Of these fourteen (14), seven (7) represent the industrial chemical sector, three (3) represent the agricultural sector, two (2) represent the labelling sector, one (1) represents the occupational health and safety sector and one (1) represents the fuel and fuel additives sector. Of these fourteen (14) Legislations, eight (8) do not have trigger quantities for registration/notification, allowing these jurisdictions to assess nanomaterials imported, manufactured, used or disposed of in any quantity. The other six (6) Legislations however, do have trigger quantities ranging from 10-1000 kg/year. Depending on the substance identification and conditions of manufacturing, registration/notification based on trigger quantities may present a problem for these jurisdictions wanting to assess nanomaterials when it is manufactured, imported, used or disposed of at quantities below the trigger volume for registration/notification.

Of the fourteen (14) Legislations reported to have pre-market registration/notification and assessment of substances, ten (10) were reported to have a tiered or graduated assessment approach based on volumes, substance type[4] and/or substance hazard. The presence of a tiered or graduated assessment approach that can be based on substance type is promising for jurisdictions planning to amend their Legislations to include specific provisions for nanomaterials.

[4] For example, chemical, polymer, or nanomaterial

Although none of the fourteen (14) Legislations with pre-market registration/notification and assessment of substances have specific information requirements for nanomaterials, nine (9) Legislations were reported to have a mechanism to require new information and/or testing for the assessment or as part of a risk management measure.

Of the twenty-four (24) Legislations reported, fifteen (15) have registration/notification, and/or assessment and/or management of substances already in commerce. Of these fifteen (15), eight (8) represent the industrial chemical sector, three (3) represent the agricultural sector, two (2) represent the worker protection sector, one (1) represents the labelling sector and one (1) represents the fuel and fuel additives sector. The ability to assess substances already in commerce is beneficial in order to be able to assess those nanomaterials which may not have received pre-market assessment, either because they exist below trigger quantities for pre-market assessment, or because their molecular composition is indistinguishable from their larger counterparts. The requirement to re-register whenever there is a change to the substance, hazard or classification is also beneficial if assessment is triggered because of the manufacture, import or use of the substance in a nano-sized form. Some registrations/notification and assessments are triggered by volume, which may limit the usefulness of these provisions for those nanomaterials imported, manufactured or used at low volumes.

Eleven (11) of fifteen (15) Legislations are reported to have an inventory of chemicals in commerce, but only the EU indicated that nanomaterials could be identified in the inventory when the properties of the nanomaterial results in a different hazard classification. The ability to distinguish nanomaterials from their larger counterparts with the same molecular composition would assist regulatory agencies with their assessments and help the public and workers identify which form of a substance is in use. As well, the inability to identify a nanomaterial from its larger counterpart also limits the usefulness of non-CBI registration, assessment and risk management information available to the public, workers and companies in the supply chain.

In conclusion, nanomaterials and their associated products are currently being regulated under existing Legislations in many countries. As the work and science of the various steering groups within the OECD WPMN progresses, various jurisdictions may wish to amend existing regulations, or develop new provisions for the regulation of nanomaterials and their products based on project findings. Section IV of this report presents a summary of legislative features identified in legislations currently providing regulatory oversight of nanomaterials and their products. It is noted that not every feature was present in every Legislation, nor is it assumed that every feature listed is relevant for all Legislations. It is further noted that the effectiveness of the identified Legislative features in protecting the environment and human health has not been determined.

SECTION I: SUMMARY OF RESPONSES RECEIVED ON BASIC INFORMATION (SECTION 1 OF THE QUESTIONNAIRE)

Objectives of the Legislations (Annex I Table 1)

The objective of most of the legislations identified was to address Consumer, Environmental and/or Worker Protection. Eleven (11) were identified with an objective of Market Regulation, two (2) have the objective of Innovation/Competitiveness Enhancement and six (6) were identified as having other objectives including data gathering and development, protection of the public within an area likely to be affected by a major accident, public protection from work activities, promotion of alternative test methods and protection of human/public health. Although not part of the Legislation, Japan indicated the existence of a guidance document on interim preventive measures against exposure to nanomaterials at manufacturing and handling sites, effective 2007.

Activities addressed by the Legislations (Annex II Table 2)

Activities addressed by the Legislations included Usage, Manufacturing, Importation, Commercialization/Marketing, and Disposal/Waste.

SECTION II: SUMMARY OF RESPONSES RECEIVED ON PRE-MARKET REGISTRATION OR NOTIFICATION, ASSESSMENT AND MANAGEMENT OF SUBSTANCES (SECTION 2 OF THE QUESTIONNAIRE)

Pre-market Registration/Notification of Substances (Annex II Table 3)

Fourteen (14) Legislations were reported to have pre-market notification and assessment. Seven (7) represent the industrial chemical sector, three (3) represent the agricultural sector, two (2) represent the labelling sector, one (1) represents the worker protection sector and one (1) represents the fuel and fuel additives sector. Of these fourteen (14) legislations, six (6) (from the industrial chemical and worker protection sectors) have trigger quantities for notification ranging from 10-1000 kg/year. Ten (10) were reported to have a tiered or graduated assessment approach based on either volumes and/or categories of substance type/hazard. Eight (8) were reported to have actual timelines for assessment ranging from 5-245 days, though some respondents indicated that the timeframe given was a service standard and not an actual legislated time frame. All fourteen (14) require data to be submitted with the pre-market registration/notification, and eleven (11) accept surrogate data.

General Data Requirements (Annex II Table 4)

All fourteen (14) Legislations require information on the Chemical Identification and the Physico-chemical Properties of the substance. With the exception of one (1) Legislation (representing the agricultural sector), they all also require information on Health Effects. With the exception of the two (2) Legislations representing the labelling sector, all of the remaining Legislation (12 of 14) require information on Material Characterization and Use and Volumes of Use. Eleven (11 of 14) require information on Environmental Effects. Eight (8 of 14) require information on Fate and Behaviour, noting that all three (3) Legislations in the labelling and worker protection sectors did not. Seven (7) Legislations require exposure information, most requiring the full set of exposure information listed (including worker, direct consumer, environment, and consumers through the environment), with the exception of the Legislation reported from the worker protection sector which only required exposure information on workers. Other information requirements were listed for five of the Legislations including application and use information, residue studies, information on the manufacturing site, efficacy data and information to justify polymers of low concern (number of reactive functional groups, number average molecular weight, functional group equivalent weight etc.).

Assessment Considerations (Annex II Table 5)

Pre-market assessment is mandatory for twelve (12) of the Legislations and the two (2) Legislations without a mandatory assessment process (both from the industrial chemical sector) have a risk assessment process that can be done on a "case-by-case" basis. Eleven (11) Legislations include an assessment of public health and safety, ten (10) include an assessment of environmental impacts, and eight (8) include an assessment of occupational health and safety. It should be noted that for the two (2) Legislations reported from the labelling sector, there is no assessment of occupational health and safety, public health and safety or environmental impacts.

Risk Management Options (Annex II Table 6)

Of the fourteen (14) Legislations with pre-market notification and assessment of substances, respondents indicated that risk management was mandatory for five (5) Legislations. Of the remaining nine (9) Legislations without mandatory risk management, six (6) have risk management that can occur on a case-by-case basis. No response was received for the other three (3) Legislations. Risk management tools included, conditions, prohibitions, additional testing or reporting requirements (2 Legislations), label and MSDS statements, restrictions on use, rejections of registration, regulation of the substance, and packaging, waste and disposal requirements. Most respondents declined to respond to the timelines for implementation of these measures, however two (2) respondents indicated the timelines for implementation were equivalent to the assessment period, and one (1) indicated that there were no Legislative timelines. Nine (9) of the Legislations require data to be submitted, five (5) require this when the information is not already available, two (2) require any information that the evaluators need to assess risk, and three (3) respondents indicated that data is (also) required to be generated depending on the results of the assessment.

Access to Information (Annex II Table 7)

Of the fourteen (14) Legislations with pre-market notification and assessment of substances, all of the Legislations but one(1) (from the industrial chemical sector), had provisions for confidentiality of information submitted, and of those that had provisions for confidentiality, all but one (1) had criteria and processes used to review confidential business information (CBI) claims. All but one (1) of the Legislations had provisions for public and worker access to at least some registration information. Most was non-CBI by request only, for five (5) legislations non-CBI information was published or disclosed by the applicant. Assessment information was accessible under all but four (4) of the Legislations almost exclusively by request with only non-CBI information being released, however, under four (4) legislations, some of the assessment information was available through a public inventory. Under only one (1) Legislation was this information not available to the public, but available to the worker. At least some of the Risk Management Information is available to the public in eleven (11) of the Legislations, for four (4) Legislations, respondents indicated the available information is in the form of product labels and MSDS sheets, four (4) respondents indicated information is published and three (3) indicated non-CBI only by request. Finally, respondents for all but one (1) of the Legislations (for which there was no response) indicated that risk management information is available to workers. Five (5) respondents indicated “yes”, without additional clarification, three (3) responded with product labels and MSDS sheets, two (2) indicated published information and the rest, three (3), indicated by request of non-CBI only.

SECTION III: SUMMARY OF RESPONSES RECEIVED ON REGISTRATION/NOTIFICATION, ASSESSMENT, AND MANAGEMENT OF SUBSTANCES ALREADY IN COMMERCE (SECTION 3 OF THE QUESTIONNAIRE)

Registration/Notification of Substances already in Commerce (Annex III Table 8)

Of the fifteen (15) Legislations analysed for Section 3 of the Questionnaire, nine (9) reported to have mandatory provisions for registration/notification of substances already in commerce, one (1) had non-mandatory provisions for registration, four (4) had no provisions for registration including both Legislations from the occupational health and safety sector, and one (1) reported not applicable. The conditions required for registration varied. For five (5) Legislations registration is mandatory for all products, for two (2) Legislations registration is required for products classed as dangerous or hazardous or subject to registration under REACH (as of 2010). Two (2) Legislations require registration for all products imported or manufactured in quantities exceeding either 100 kg /yr or 1000 kg/yr and for one (1) Legislation with non-mandatory registration; registration is required when authorities are aware of an increased risk of adverse health and/or environmental effects. For each of the ten (10) Legislations with provisions for registration, registration requires updates when there is a major change or amendment to the product or change in hazard classification. Two (2) Legislations also reported regular updates either every two or five years.

Ten (10) Legislations were reported to require the submission of information on the existing substance, or requires testing to be conducted; including two (2) Legislations for which there are no provisions for registration/notification, but information may be requested as part of a provision to require assessment of substances already in commerce. For four (4) of these Legislations, information/testing is required on request.

Respondents indicated that eleven (11) Legislations have an inventory of chemicals in commerce, with almost all of them updated on an as needed basis. Only the EU reported that nanomaterials could be identified in the inventory if their hazard classification differs from the bulk form.

Assessment of Substances already in Commerce (Annex III Table 9)

Of the fifteen (15) Legislations analysed under Section 3 of the Questionnaire, thirteen (13) Legislations have provisions for assessment of substances already in commerce, and one (1) reported that assessment was conducted on a voluntary basis. For those respondents that listed conditions triggering assessment, they included all products/substances (listed for 3 of 14 Legislations), high risk substances (2 of 14 Legislations), when gaps exist in health effects data, when new data becomes available/change to product/re-registration (3 of 14 Legislations) or when there are gaps in health effects data (one Legislation). The four (4) Legislations that have trigger quantities for registration were all from the industrial chemical sector, three (3 of 4) indicating trigger volumes of either 100 kg/yr or 1000 kg/yr.

A tiered or graduated approach to assessment was listed for five (5) Legislations and the timeline for assessment ranged from none, 65-245 days (1 Legislation), up to 6 months (2 Legislations) up to 12 months (1 Legislation), 24 months (1 Legislation), by 2010 (or up to 2020) (2 Legislations). For one (1) Legislation it was indicated that the timelines for assessment varied depending on the assessment type, and the last one indicated that the assessment must be completed by the employer before work begins with a

hazardous substance. For nine (9) of the Legislations reported to conduct assessments of substances already in commerce, there is an obligation to conclude an assessment that has been initiated. Data is required to be submitted under ten (10) Legislations, nine (9) permit surrogate data.

General Data Requirements for Legislations requiring the submission of data for the assessment of substances already in commerce (Annex III Table 10)

General Data Requirements were reported for ten (10) Legislations and all but four (4) Legislations required all of the data points listed.

Assessment Considerations for Legislations with provisions for assessment of substances already in commerce (Annex III Table 11)

Of the fourteen (14) Legislations with assessment provisions for (or voluntary assessment of) substances already in commerce, eleven (11) were reported to have mandatory assessment. The three (3) Legislations without mandatory assessment were from the industrial chemical sector. The assessments conducted under all fourteen (14) of the Legislations include public health and safety, all of the Legislations with the exception of the two (2) representing the occupational health and safety sector assess environmental impacts, and ten (10) assess occupational health and safety.

Risk Management Options for the Legislations with provisions for assessment of substances already in commerce (Annex III Table 12)

Of the fourteen (14) Legislations with assessment provisions for substances already in commerce, eight (8) were reported to have mandatory risk management measures. The risk management tools available included regulatory development, performance agreements, codes of practice, guidelines, planning notices, label statements, prohibition of certain use patterns/restrictions on use, refusal to register, packaging requirements, workplace exposure controls, risk and safety phrases on MSDS, controls on waste disposal, controls on discharge emissions, and request for additional data. No response was received for most of the Legislations regarding the timelines for implementation of risk management tools, however those listed included none, 3.5 years for regulatory development, prior to use by employer, prior to marketing, timeline varies with volumes and properties of substance, and timeline is mandated when a request for additional data is made.

Ten (10) Legislations were reported to have criteria that the government must meet to impose risk management measures. No elaboration on the criteria was indicated for six (6) of the Legislations, three (3) of the Legislations were reported to require a safety concern/meet a definition of toxic, and one (1) was reported to require risk management measures as long as they are reasonably practicable and the cost to implement is not grossly disproportionate to the risk.

Access to Information/Confidentiality of information for Legislations with provisions for registration/notification and/or assessment of substances already in commerce (Annex III Table 13)

Of the fifteen (15) Legislations reported to have registration/notification and/or assessment of substances already in commerce, responses were received from eleven (11) Legislations, indicating that provisions for confidentiality exist. All but one (1) of these has a criteria and process to review CBI claims.

For the most part, the public, workers and companies in the supply chain all have access to the same non-CBI registration, assessment and risk management information either by request or through a public inventory/registry for all Legislations reported. Two (2) Legislations were reported to not allow access to assessment information to anyone, and the one (1) Legislation that requires the assessment to be conducted by the employer, only has information available to the workers.

Finally, of the fifteen (15) Legislations analyzed in this section, seven (7) indicated that companies in the supply chain have information obligations towards their suppliers (indicated with an asterisk in the last column of Table 13).

SECTION IV: SUMMARY OF LEGISLATIVE FEATURES IDENTIFIED IN THIS SURVEY

Responses from the questionnaire provided valuable insight into how current regulatory regimes attempt to address the notification, assessment and management of nanomaterials and their products. A list of key features present in one or more of the Legislations examined in this report, is provided below. It should be noted that the mandates of the Legislations examined in this report were quite varied, and not every feature identified below was necessarily relevant, or present in all Legislations.

a. The ability to distinguish different forms of substances from their larger counterparts in chemical inventories when their hazard classification differs;
b. Consistent regulatory coverage to address nanomaterials employed in the full range of regulatory uses (e.g., for classification and labelling, industrial, pesticidal, agricultural, or consumer product uses);
c. Assessments that address risks to human health, workers, consumers, and the environment;
d. Triggering assessments prior to importation, manufacture, use or waste disposal activities;
e. Registration or notification, assessment and management of both new nanomaterials and nanomaterials already in commerce, as well as reporting updates within regular intervals or in case of significant changes;
f. Registration or notification and assessment of nanomaterials without or with very low minimum trigger quantities, to account for materials that are used at low volumes.
g. Tiered or graduated assessment approach based on volumes, substance type and/or substance hazard;
h. Use of nano-specific information requirements, including physical-chemical properties, material characterization, health effects, environmental effects, environmental fate and behaviour, use pattern information, and exposure information, (including worker, direct consumer, environment, and consumers through the environment);
i. Ability to request additional information and/or testing either during the assessment or as part of a risk management measure;
j. Authority to undertake control actions where necessary including rejections of registration, conditions on use, prohibitions, additional testing or reporting requirements, labelling and Safety Data Sheet statements, packaging requirements, performance agreements, codes of practice, guidelines, and workplace exposure controls;
k. Authority for companies in the supply chain to have information obligations towards their suppliers;
l. Guidance on preventative measures against exposure and release of nanomaterials at manufacturing and handling sites; and
m. Provisions for confidentiality, processes to review confidentiality claims, and access by the public, workers and companies in the supply chain to non-confidential information.

It is noted that while these key features have been summarized here, their effectiveness in enabling risk assessors and risk managers to effectively protect the environment and human health, as it relates to nanomaterials, has not been determined.

ANNEX I: RESPONSES RECEIVED ON BASIC INFORMATION (SECTION 1 OF THE QUESTIONNAIRE)

Table 1. Objective of the Legislation

Country	Name of Legislation	Provisions specific to Nano-materials?	Objective of the Legislation					
			Market Regulation	Innovation	Environmental Protection	Worker Protection	Consumer Protection	Other
Australia	Industrial Chemicals Notification and Assessment Act, 1989	No			●	●	●	
Canada	Canadian Environmental Protection Act, 1999	No			●		●	
Canada	Fertilizers Act	No	●		●	●	●	
Canada	Pest Control Products Act	No		●	●	●	●	
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	No	●		●	●	●	

Country	Name of Legislation	Provisions specific to Nano-materials?	Objective of the Legislation					
			Market Regulation	Innovation	Environmental Protection	Worker Protection	Consumer Protection	Other
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	No	●	●	●	●	●	●
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	No	●		●		●	
Japan	Industrial Safety and Health Law	No				●		
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	No	●				●	
New Zealand	Hazardous Substances and New Organisms Act, 1996	No			●	●	●	
Sweden	Environment Code; The Chemical Products and Biotechnical Organisms Ordinance	No			●		●	●

Country	Name of Legislation	Provisions specific to Nano-materials?	Objective of the Legislation					
			Market Regulation	Innovation	Environmental Protection	Worker Protection	Consumer Protection	Other
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	No	●		●	●	●	
United Kingdom (Great Britain)	Control of Substances Hazardous to Health Regulations	No				●		
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	No	●		●	●	●	
United Kingdom	The Biocidal Products Directive 98/8/EC	No	●		●	●	●	
United Kingdom	Management of Health and Safety at Work Regulations, 1999	No				●		●
United Kingdom	Control of Major Accident Hazards Regulations, 2005	No			●	●		●
United States	Toxic Substances Control Act	No	●		●	●	●	●
United States	Occupational Safety and Health Act of 1970	No				●		
United States	Consumer Product Safety Act	No					●	
United States	Clean Air Act	No			●			

Country	Name of Legislation	Provisions specific to Nano-materials?	Objective of the Legislation					
			Market Regulation	Innovation	Environmental Protection	Worker Protection	Consumer Protection	Other
United States	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and The Resource Conservation and Recovery Act (RCRA)	No			●			
United States	Federal Food and Drug and Cosmetic Act*	No	●				●	
United States	Federal Insecticide, Fungicide and Rodenticide Act	No	●		●	●	●	●

* Legislation addresses marketing requirements for products that may contain nanomaterials. Accordingly, it is not addressed in the other appendices to this report. It is listed here as a potential source of information and mechanism for collaboration relevant to regulation of the use of nanomaterials.

Table 2. Activity Addressed by the Legislation

Country	Name of Legislation	Activity addressed by Legislation				
		Manufacturing	Importation	Commercialization/Marketing	Usage	Disposal/Waste
Australia	Industrial Chemicals Notification and Assessment Act, 1989	●	●		●	●
Canada	Canadian Environmental Protection Act, 1999	●	●			
Canada	Fertilizers Act		●	●		
Canada	Pest Control Products Act	●	●	●	●	●
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	●	●	●	●	
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	●	●	●	●	●
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	●	●		●	
Japan	Industrial Safety and Health Law	●	●		●	
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	●	●		●	

Country	Name of Legislation	Activity addressed by Legislation				
		Manufacturing	Importation	Commercialization/Marketing	Usage	Disposal/Waste
New Zealand	Hazardous Substances and New Organisms Act, 1996	●	●		●	●
Sweden	Environment Code; The Chemical Products and Biotechnical Organisms Ordinance	●	●	●	●	●
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	●	●	●	●	
United Kingdom (Great Britain)	Control of Substances Hazardous to Health Regulations	●			●	●
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	●	●	●	●	
United Kingdom	The Biocidal Products Directive 98/8/EC		●	●	●	
United Kingdom	Management of Health and Safety at Work Regulations, 1999	●			●	●
United Kingdom	Control of Major Accident Hazards Regulations, 2005	●			●	●

Country	Name of Legislation	Activity addressed by Legislation				
		Manufacturing	**Importation**	**Commercialization/Marketing**	**Usage**	**Disposal/Waste**
United States	Toxic Substances Control Act	●	●	●	●	●
United States	Occupational Safety and Health Act of 1970	●	●	●	●	●
United States	Consumer Product Safety Act				●	
United States	Clean Air Act	●	●	●	●	
United States	CERCLA and RCRA					●
United States	Federal Food and Drug and Cosmetic Act*	●	●	●	●	
United States	Federal Insecticide, Fungicide and Rodenticide Act	●	●	●	●	●

* Legislation addresses marketing requirements for products that may contain nanomaterials. Accordingly, it is not addressed in the other appendices to this report. It is listed here as a potential source of information and mechanism for collaboration relevant to regulation of the use of nanomaterials.

ANNEX II: RESPONSES RECEIVED ON PRE-MARKET REGISTRATION OR NOTIFICATION, ASSESSMENT AND MANAGEMENT OF SUBSTANCES (SECTION 2 OF THE QUESTIONNAIRE)

Table 3. Pre-Market Registration/Notification, Assessment and Management of Substances

Country	Name of Legislation	Pre-market Notification	Pre-market Assessment	Trigger quantities	Exemptions	Tiered or Graduated Approach	Timelines for Assessment	Is Data Required?	Is Surrogate Data Permitted
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	Yes	>100 kg/yr	Yes	Yes	90 days; 14-28 days for permits	Yes	Yes
Canada	Canadian Environmental Protection Act, 1999	Yes	Yes	100-1000 kg/yr	Yes	Yes	5-75 days	Yes	Yes
Canada	Fertilizers Act	Yes	Yes	No	Yes	No	195-245 days	Yes	Yes
Canada	Pest Control Products Act	Yes	Yes	No	Yes	Yes	No response	Yes	Yes

Country	Name of Legislation	Pre-market Notification	Pre-market Assessment	Trigger quantities	Exemptions	Tiered or Graduated Approach	Timelines for Assessment	Is Data Required?	Is Surrogate Data Permitted
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	Yes	No	Yes	Yes	Must be complete before being placed on market	Yes	Yes
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes	> 1 tonne/yr	Yes	Yes	2010, 2013, 2018 for phase in substances	Yes	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	Yes	Yes	>100 kg/yr	Yes	Yes	Must be complete before import or manufacture	Yes	No
Japan	Industrial Safety and Health Law	Yes	Yes	>100 kg/yr	Yes	Yes	Must be complete before import or manufacture	Yes	No
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	Yes	Yes	No	Yes	Yes	40 or 70 days	Yes	Yes
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	No	Yes	No response	40 or 100 days	Yes	No Response

Country	Name of Legislation	Pre-market Notification	Pre-market Assessment	Trigger quantities	Exemptions	Tiered or Graduated Approach	Timelines for Assessment	Is Data Required?	Is Surrogate Data Permitted
Switzer-land	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Yes	>10 kg/yr	Yes	Yes	None	Yes	Yes
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	Yes	N/A	No	Yes	Yes	Prior to being placed on market	Yes	Yes
United States	Toxic Substances Control Act	Yes	Yes	No	Yes	No	90 days	Yes	Yes
United States	Clean Air Act	Yes	Yes	No	Yes	No	6 months to assess plus 6 months to request additional testing	Yes	Yes

N/A: Not applicable

Table 4. General Data Requirements for the 14 Legislations with Pre-Market Registration/Notification

Country	Name of Legislation	Chemical ID	Material Characterization	Use and Volumes of Use	Exposure Information				Physico-chemical properties	Health Effects	Environmental Effects	Fate and Behaviour	Other
					Workers	Direct Consumer	Environment	Consumers thru the environment					
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Canada	Canadian Environmental Protection Act, 1999	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
Canada	Fertilizers Act	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Canada	Pest Control Products Act	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	No	No	No	No	No	No	Yes	Yes	Yes	No	No
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes
Japan	Industrial Safety and Health Law	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	Yes	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	NR	NR

Country	Name of Legislation	Chemical ID	Material Characterization	Use and Volumes of Use	Exposure Information				Physico-chemical properties	Health Effects	Environmental Effects	Fate and Behaviour	Other
					Workers	Direct Consumer	Environment	Consumers thru the environment					
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	Yes	No	No	No	No	No	No	Yes	Yes	Yes	No	No
United States	Toxic Substances Control Act	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
United States	Clean Air Act	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	No	NR

NR: No response

Table 5. Assessment Considerations for the 14 Legislations with Pre-market Assessment

Country	Name of Legislation	Is assessment mandatory?	If no, can it be case-by-case?	Includes occupational health and safety?	Includes public health and safety?	Includes environmental impacts?
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	N/A	Yes	Yes	Yes
Canada	Canadian Environmental Protection Act, 1999	Yes	N/A	No	Yes	Yes
Canada	Fertilizers Act	Yes	Yes for exempt products	Yes	Yes	Yes
Canada	Pest Control Products Act	Yes	N/A	Yes	Yes	Yes
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	N/A	No	No	No
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes	Yes	Yes	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	Yes	N/A	No	Yes	Yes
Japan	Industrial Safety and Health Law	Yes	N/A	Yes	No	No
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	Yes	N/A	No	Yes	No
New Zealand	Hazardous Substances and New Organisms Act, 1996	No	Yes	Yes	Yes	Yes
Switzer-land	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	No	Yes	Yes	Yes	Yes
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	Yes	N/A	No	No	No
United States	Toxic Substances Control Act	Yes	N/A	Yes	Yes	Yes
United States	Clean Air Act	Yes	N/A	No	Yes	Yes

N/A: Not applicable

Table 6. Risk Management Options for the 14 Legislations with Pre-market Assessment

Country	Name of Legislation	Is risk management mandatory?	If no, can it be done on a case-by-case basis?	Risk management tools available	Timelines for implementation	Requirement to develop new information?
Australia	Industrial Chemicals Notification and Assessment Act, 1989	No	Yes	Hazard Classification, labelling, packaging requirements, restrictions on use, waste disposal/discharge restrictions	None	Yes, if existing data is not available to address information requirements, or as a requirement following outcome of assessment
Canada	Canadian Environmental Protection Act, 1999	No	Yes	Condition, Prohibitions, Additional testing	30-75 days	Yes, if existing or surrogate data is not available to address information requirements
Canada	Fertilizers Act	No	Yes	Label statements, prohibit certain use patterns	No response	Yes, if not pre-existing
Canada	Pest Control Products Act	Yes	N/A	Label requirements, restrictions on use, rejection of registration	No response	Yes, any information needed to support registration
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	No response	No response	No response	No response	Yes, tests required for physical hazards when data is not available
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	N/A	Classification and Labelling, MSDS, restrictions	No response	Yes, any information needed to support registration
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	No	No response	No response	No response	No

Country	Name of Legislation	Is risk management mandatory?	If no, can it be done on a case-by-case basis?	Risk management tools available	Timelines for implementation	Requirement to develop new information?
Japan	Industrial Safety and Health Law	No	Yes	No response	No response	No
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	Yes	N/A	No response	No response	Yes, if more information to assess risk is needed
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	Labelling information, packaging, workplace exposure controls, use restriction	No response	No
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	N/A	Risk and Safety phrases on MSDS and product packaging	At the time of Marketing	Yes, depending on market volume and results of risk assessment
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	No response	No response	No response	No response	No
United States	Toxic Substances Control Act	No	Yes	Any step necessary to prevent or control unreasonable risk. Additional reporting for Significant New Use Rule (SNUR)	Within 90 day review period	No, but can request new information for significant new use rule (SNUR)
United States	Clean Air Act	No	Yes	Regulate the fuel or fuel additive	No response	Yes, unless small business exemption applies

N/A: Not applicable

Table 7. Access to Information/Confidentiality for the 14 Legislations with Pre-market Assessment

Country	Name of Legislation	Provisions for confidentiality?	Criteria and Process to review CBI claims?	Access to Registration Information?		Access to Assessment Information?		Access to risk management information?	
				Public	Worker	Public	Worker	Public	Worker
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	Yes	Yes, non-CBI published	Yes	Yes, non-CBI published	Yes	Yes, MSDS, labels, standards	Yes, MSDS, labels
Canada	Canadian Environmental Protection Act, 1999	Yes	Yes	By request non-CBI only	By request non-CBI only	By request non-CBI only	By request non-CBI only	Yes, published	Yes, published
Canada	Fertilizers Act	Yes	Yes	By request non-CBI only	By request non-CBI only	By request non-CBI only	By request non-CBI only	By request, non-CBI and info on product labels	By request, non-CBI and info on product labels
Canada	Pest Control Products Act	Yes	Yes	Yes non-CBI in public registry	Yes, non CBI in public registry	Yes non-CBI in public registry	Yes, non-CBI in public registry	Yes, non-CBI in public registry	Yes, non-CBI in public registry

Country	Name of Legislation	Provisions for confidentiality?	Criteria and Process to review CBI claims?	Access to Registration Information?		Access to Assessment Information?		Access to risk management information?	
				Public	Worker	Public	Worker	Public	Worker
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	Yes	Yes, class and label in public inventory	Yes	Yes, class and label in public inventory	No	No	Yes, on label and MSDS
European Union	Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)	Yes	Yes	Yes, non-CBI published	Yes	Yes, non-CBI published	Yes	Yes, non-CBI published	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	Yes	No	Yes, name only	Yes	No	No response	No response	No response
Japan	Industrial Safety and Health Law	No	No	Yes, name only	Yes	No	Yes	No	Yes
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977	Yes	Yes	Yes, on request, non -CBI	Yes, on request, non-CBI	Yes, on request, non -CBI	Yes, on request, non-CBI	Yes, on request, non-CBI	Yes, on request, non-CBI
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	Yes, applicant disclosed	Yes, on request	Yes, non CBI	Yes, on request	Yes, published	Yes, on request
Switzer-land	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Yes	Yes, non CBI	Yes	No	No	Yes, MSDS info	Yes

Country	Name of Legislation	Provisions for confidentiality?	Criteria and Process to review CBI claims?	Access to Registration Information?		Access to Assessment Information?		Access to risk management information?	
				Public	Worker	Public	Worker	Public	Worker
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations, 2002	Yes	Yes	No	No	No	No	Yes, MSDS and product labels	Yes, MSDS and product labels
United States	Toxic Substances Control Act	Yes	Yes	Yes, non CBI on request	Yes, non CBI on request	Yes, non CBI on request	Yes, non CBI on request	Yes, non CBI on request	Yes, non CBI on request
United States	Clean Air Act	Yes	Yes	Yes, non CBI on request	Yes, same as public	Yes	Yes, same as public	Yes, summary and analysis	Yes, same as public

CBI: Confidential Business Information

ANNEX III: RESPONSES RECEIVED ON REGISTRATION/NOTIFICATION, ASSESSMENT, AND MANAGEMENT OF SUBSTANCES ALREADY IN COMMERCE (SECTION 3 OF THE QUESTIONNAIRE)

Table 8. Registration/Notification of Substances already in Commerce

Country	Name of Legislation	Provisions for Registration?	Is Registration Mandatory?	Does Registration require updates?	Is information or testing required?	Is there an inventory of chemicals in commerce?	Is the inventory updated regularly?	Can nanomaterials be identified in this inventory?
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	No	Yes, new data, adverse effects, changes to volumes, use pattern, method of manufacture	Yes, if a health or environmental concern exists	Yes	Yes, monthly	No
Canada	Canadian Environmental Protection Act, 1999	No	N/A	N/A	Yes on request	Yes	No, on an as needed basis. Currently preparing for more routine updating	No

Country	Name of Legislation	Provisions for Registration?	Is Registration Mandatory?	Does Registration require updates?	Is information or testing required?	Is there an inventory of chemicals in commerce?	Is the inventory updated regularly?	Can nanomaterials be identified in this inventory?
Canada	Fertilizers Act	Yes	Yes, every 2 years	Yes, every 2 years or if a major amendment is made to the product	Yes, may be required	No	N/A	No
Canada	Pest Control Products Act	Yes	Yes, for all products	Yes, renewed every 5 years, re-evaluated every 15 years, and when there is a change to the product	Yes, on request	Yes	Yes	N/A
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	Yes, as of 2010	Yes, when hazard classification changes	Yes, for physical hazards if info is not already available	Yes if hazardous or registered under REACH	No, on an as needed basis	Yes

Country	Name of Legislation	Provisions for Registration?	Is Registration Mandatory?	Does Registration require updates?	Is information or testing required?	Is there an inventory of chemicals in commerce?	Is the inventory updated regularly?	Can nanomaterials be identified in this inventory?
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes, if imported or manufactured > 1 tonne per year	Yes, any change in status, composition, quantities, new uses, new data, new classification, updates on safe use, change to CBI	Yes, if greater than 1 tonne/year	Yes	Yes, on an as needed basis	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture	No	No	Yes	No	Yes	Yes, five years from the completion of the assessment period	No
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	Yes, if new use pattern or new information becomes available on adverse effects	No response	Yes	Yes, no timeframe reported	No
Sweden	Environment Code; The Chemical Products and Biotechnical Organism Ordinance	Yes	Yes, if imported or manufactured > 100 kg annually	Yes, volumes, change in use or hazard classification	Yes, if doubt that the hazard classification is correct	Yes	Yes, yearly	No

Country	Name of Legislation	Provisions for Registration?	Is Registration Mandatory?	Does Registration require updates?	Is information or testing required?	Is there an inventory of chemicals in commerce?	Is the inventory updated regularly?	Can nanomaterials be identified in this inventory?
Switzer-land	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Yes, if classed as dangerous	Yes, if change in classification	No	Yes	Yes, continuously as needed	No
United Kingdom (Great Britain)	Control of Substances Hazardous to Health Regulations (COSHH)	No	No	No	No	No	N/A	No
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	Yes, before marketing begins	Yes, any significant change	Yes, existing and new	No	N/A	N/A
United Kingdom	Management of Health and Safety at Work Regulations 1999	N/A	N/A	N/A	N/A	N/A	N/A	N/A
United States	Toxic Substances Control Act	No	N/A	N/A	Yes, on request	Yes	Yes, as needed	No
United States	Clean Air Act	Yes	Yes, all	Yes, change to notifier, substitutions of additives, changes to composition, development of new data	Yes, when data gap exists	Yes	Yes, as needed	No

N/A: Not applicable

Table 9. Assessment of Substances Already in Commerce

Country	Name of Legislation	Are there provisions for assessment?	Trigger Quantities	Tiered or graduated approach?	Timelines for assessment	Obligation to conclude assessment	Is data required	Is surrogate data permitted?
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes, on a priority basis, based on health or environmental concern	Yes	Yes, they can be for hazard, public health risk or environmental risk only, or a full risk assessment	No mandatory timelines for preparing draft report, but legislative timeframes apply to finalizing assessment	Yes	Yes	Yes
Canada	Canadian Environmental Protection Act, 1999	Yes, if existing, high human exposure, or if persistence or bioaccumulative concerns with toxicity or where Ministers give priority for assessment	N/A	Yes, partially based on volumes	By 2010 for substances catagorized as high priority, by 2020 for medium priority or within 5 years of being added to the Priority Substance List	Yes	Some required. Additional voluntary submission strongly encouraged	Yes
Canada	Fertilizers Act	Yes, for product	No	No	65-245 day	Yes	Yes	Yes

Country	Name of Legislation	Are there provisions for assessment?	Trigger Quantities	Tiered or graduated approach?	Timelines for assessment	Obligation to conclude assessment	Is data required	Is surrogate data permitted?
		re-registration or major change to product			service standard			
Canada	Pest Control Products Act	Yes, if claimed to be a Pest control product	No	Yes	24 month service standard, timelines will be determined on a case by case basis. There have not been any registrations of a nanomaterial yet.	Yes	Yes, for registration	Yes
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	No	Yes	By 2010 for substances and 2015 for mixtures	No	Yes	Yes

Country	Name of Legislation	Are there provisions for assessment?	Trigger Quantities	Tiered or graduated approach?	Timelines for assessment	Obligation to conclude assessment	Is data required	Is surrogate data permitted?
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes, > 1 tonne per year	Yes	Non-phase in substances, 6 months	Yes	Yes	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	No, done voluntarily	Yes, > 1 tonne per year	N/A priority assigned by import/manufacture volume	No response	No	No	No
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	No response	No response	Varies depending on assessment type	Yes	Yes	Yes
Sweden	Environment Code; The Chemical Products and Biotechnical Organism Ordinance	No response	Yes > 100 kg per annum	No response	No response	No response	No response	No response
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes, if poses a potential risk or is the target of an international program on existing substances	No	No	No	No	Yes	Yes
United	Control of	Yes, by	No response	No response	Before work	N/A	N/A	N/A

Country	Name of Legislation	Are there provisions for assessment?	Trigger Quantities	Tiered or graduated approach?	Timelines for assessment	Obligation to conclude assessment	Is data required	Is surrogate data permitted?
Kingdom (Great Britain)	Substances Hazardous to Health Regulations (COSHH)	employer			begins with a hazardous substance			
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	No	N/A	Up to 12 months	Yes	Yes	No response
United Kingdom	Management of Health and Safety at Work Regulations 1999	Yes to determine controls to protect workers and public	No response	No	No	Yes	N/A	No response
United States	Toxic Substances Control Act	Yes, as new data becomes available	N/A	N/A	No	No	N/A	N/A
United States	Clean Air Act	Yes, when gaps exist in health-effects data	No	No	6 months to assess, additional 6 months to identify data needed	Yes	Yes	Yes

N/A: Not applicable

Table 10. General Data Requirements for 10 Legislations requiring data to be submitted for the assessment of substances already in commerce

Country	Name of Legislation	Chemical ID	Material Characterization	Use and Volumes of Use	Exposure Information				Physico-chemical properties	Health Effects	Environmental Effects	Fate and Behaviour	Other
					Workers	Direct Consumer	Environment	Consumers thru the environment					
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	NR
Canada	Canadian Environmental Protection Act, 1999	NR	NR	Yes	NR	NR	NR	NR	NR	NR	NR	NR	Yes
Canada	Fertilizers Act	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Canada	Pest Control Products Act	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	No	No	No	No	No	No	Yes	Yes	Yes	No	No
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
United States	Clean Air Act	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	No	NR

NR: No response

Table 11. Assessment Considerations for 14 Legislations with provisions for (or voluntary) assessment of substances already in commerce

Country	Name of Legislation	Is assessment mandatory?	Includes occupational health and safety?	Includes public health and safety?	Includes environmental impacts?
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	Yes	Yes	Yes
Canada	Canadian Environmental Protection Act, 1999	Yes	No	Yes	Yes
Canada	Fertilizers Act	Yes	Yes	Yes	Yes
Canada	Pest Control Products Act	Yes	Yes	Yes	Yes
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	No	Yes	Yes
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes	Yes	Yes
Japan	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture	No	No	Yes	Yes
New Zealand	Hazardous Substances and New Organisms Act, 1996	Yes	Yes	Yes	Yes
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	No	Yes	Yes	Yes
United Kingdom (Great Britain)	Control of Substances Hazardous to Health Regulations	Yes	Yes	Yes	NR
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	Yes	Yes	Yes
United Kingdom	Management of Health and Safety at Work Regulations 1999	Yes	Yes	Yes	No
United States	Toxic Substances Control Act	No	Yes	Yes	Yes
United States	Clean Air Act	Yes	No	Yes	Yes

NR: No response

Table 12. Risk Management Options for the 14 Legislations with provisions for (or voluntary) assessment of substances already in commerce

Country	Name of Legislation	Is risk management mandatory?	Risk management tools available	Timelines for implementation	Criteria that the government must meet to impose RM measures?
Australia	Industrial Chemicals Notification and Assessment Act, 1989	No	Hazard classification, labelling, packaging, restriction on use and supply, controls for waste disposal or discharge emissions	None	Yes, no elaboration given
Canada	Canadian Environmental Protection Act, 1999	Yes, if considered toxic	Regulation, performance agreements, codes of practice, guidelines, planning notices, prohibition	3.5 years for regulation development and implementation	Yes, substance must meet the definition of toxic in section 64 of CEPA and be published on Toxic Substances List
Canada	Fertilizers Act	Yes	Label statements, prohibit certain use patterns, refusal to register	No response	Yes, there must be a safety concern
Canada	Pest Control Products Act	Yes	Label requirements, conditions on use, rejection of registration	No response	Yes, no elaboration given
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	No	No response	No response	No
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Classification, labelling, MSDS, restrictions	Varies with volumes and properties of substance	Yes, no elaboration given
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	No	No response (voluntary assessment, no provisions)	No response (voluntary assessment, no provisions)	No response (voluntary assessment, no provisions)
New Zealand	Hazardous Substances and New Organisms Act, 1996	No response	Label statements, packaging requirements, workplace exposure controls, use restriction	No response	Yes, criteria listed in HSNo Act

Country	Name of Legislation	Is risk management mandatory?	Risk management tools available	Timelines for implementation	Criteria that the government must meet to impose RM measures?
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Risk and safety phrases on MSDS and product packaging, restriction of certain substances/application	Prior to marketing	Yes, no elaboration given
United Kingdom (Great Britain)	Control of Substances Hazardous to Health Regulations	Yes	Employer must put in place practicable measures to protect health of employees including training, surveillance	Prior to use by employer	N/A assessment conducted by employer
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	No response	No response	No response
United Kingdom	Management of Health and Safety at Work Regulations, 1999	Yes	Not specified in Legislation	No response	Yes, measures must be reasonably practicable and must be implemented unless cost is grossly disproportionate to risk
United States	Toxic Substances Control Act	No	If unreasonable risk, take steps to prevent or control risks. May require submission of data	None, if request for data, timeline is mandated in request	Yes, no elaboration given
United States	Clean Air Act	No	Regulate fuel or fuel additive	No response	Yes, if determined that there is a risk to public health or welfare

Table 13. Access to Information/Confidentiality for the 15 Legislations with registration/notification and/or assessment of substances already in commerce

Country	Name of Legislation	Provisions for confidentiality	Criteria and Process to review CBI claims?	Access to Registration Information?			Access to Assessment Information?			Access to risk management information?		
				Public	Worker	Company in supply chain	Public	Worker	Company in supply chain	Public	Worker	Company in supply chain
Australia	Industrial Chemicals Notification and Assessment Act, 1989	Yes	Yes	Yes, non-CBI published	Yes	Yes	Yes, non-CBI published	Yes	Yes	Yes, MSDS, labels, standards	Yes	Yes
Canada	Canadian Environmental Protection Act, 1999	Yes	Yes	By request non-CBI only	By request non-CBI only	By request non-CBI only	By request non-CBI only	By request non-CBI only	By request non-CBI only	Yes, published	Yes, published	Yes, published
Canada	Fertilizers Act	Yes	Yes	Yes	Same as public	Same as public	No	No	No	No	Yes	Yes
Canada	Pest Control Products Act	Yes	Yes	Yes non-CBI in public registry	Yes, non-CBI in public registry	Yes, non-CBI in public registry	Yes, non-CBI in public registry	Yes, non-CBI in public registry	Yes, non-CBI in public registry	Yes non-CBI in public registry	Yes, non-CBI in public registry	Yes*, non-CBI in public registry
European Union	Classification, Labelling and Packaging of Substances and Mixtures Regulation	Yes	Yes	Yes, class, label, notifier in public inventory	Yes	Yes	Yes, hazard classification in public inventory	No	No	No	Yes through product labels	Yes* through product labels

Country	Name of Legislation	Provisions for confidentiality	Criteria and Process to review CBI claims?	Access to Registration Information?			Access to Assessment Information?			Access to risk management information?		
				Public	Worker	Company in supply chain	Public	Worker	Company in supply chain	Public	Worker	Company in supply chain
European Union	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	Yes	Yes	Yes, non CBI publicly available	Yes, through employer	Yes	Yes, non-CBI publicly available	Yes, through employer	Yes	Yes, non-CBI publicly available	Yes, through employer	Yes*
Japan	Act on the Evaluation of Chemical Substances and Regulation of their Manufacture	Yes	No	Yes, volume only	Yes	Yes	Yes, biodegradation, bioaccumulation, toxicity to health and environmental	No response	No response	No response	No response	No response
New Zealand	Hazardous Substances and New Organisms Act, 1996	NR	NR	Yes, summary on effects in public register	Yes	Yes	NR	Yes	Yes	NR	Yes	Yes*
Sweden	Environment Code; The Chemical Products and Biotechnical Organism Ordinance	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Country	Name of Legislation	Provisions for confidentiality	Criteria and Process to review CBI claims?	Access to Registration Information?			Access to Assessment Information?			Access to risk management information?		
				Public	Worker	Company in supply chain	Public	Worker	Company in supply chain	Public	Worker	Company in supply chain
Switzerland	Chemicals Ordinance/Ordinance on Risk Reduction related to Chemical Products	Yes	Yes	Yes, non CBI	Yes	Yes	No	No	No	Yes	Yes	Yes
United Kingdom (Great Britain)	Control of Substances hazardous to Health Regulations	NR	NR	NR	NR	NR	NR	Yes from employer	NR	NR	Yes from employer	NR
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	Yes	Yes, non CBI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*
United Kingdom	Management of Health and Safety at Work Regulations, 1999	NR	NR	NR	NR	NR	Yes, if non CBI	Yes	Yes	Yes, if non CBI	Yes	Yes*
United States	Toxic Substances Control Act	Yes	Yes	N/A	N/A	N/A	Yes, non CBI versions on request	Yes	Yes	Yes, full disclosure	Yes	Yes*

Country	Name of Legislation	Provisions for confidentiality	Criteria and Process to review CBI claims?	Access to Registration Information?			Access to Assessment Information?			Access to risk management information?		
				Public	Worker	Company in supply chain	Public	Worker	Company in supply chain	Public	Worker	Company in supply chain
United States	Clean Air Act	Yes	Yes	Yes, non CBI	Yes, same as public	Yes, same as public	Yes	Yes, same as public	Yes, same as public	Yes, summaries and analysis	Yes, same as public	Yes, same as public

NR: No response

N/A: Not applicable

* indicates companies in the supply chain have information obligations towards their suppliers