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REGULATED NANOMATERIALS: 2006-2009

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REGULATED NANOMATERIALS: 2006-2009

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Also published in the Series of Safety of Manufactured Nanomaterials:

No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*

No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*

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No. 28, *Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories (2010)*

No. 29, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 8th Meeting of the Working Party on Manufactured Nanomaterials (2011)*

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The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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 **Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/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, World Bank and OECD. UNDP is an observer. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

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

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

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

This document is published under the responsibility of the Chemicals Committee of the OECD. It is intended to provide information on the outcomes and developments of the OECD programme on the safety of manufactured nanomaterials.

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OECD'S PROGRAMME ON THE SAFETY OF MANUFACTURED NANOMATERIALS

The OECD's Programme on the Safety of 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 Programme brings together more than 100 experts from governments and other stakeholders from: a) OECD Countries; b) non-member economies such as China, the Russian Federation, Singapore, South Africa, and Thailand; and c) observers and invited experts from UNITAR, FAO, 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 are being undertaken.

The Programme of Work is being implemented 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
- Environmentally Sustainable Use of Manufactured Nanomaterials

Each project is being managed by a steering group, which comprises members of the OECD Working Party on Manufactured Nanomaterials (WPMN), with support from the Secretariat. Each steering group implements its respective "operational plans", each with their specific objectives and timelines. The outputs of each project are then evaluated and endorsed by the WPMN, and subsequently by the OECD Chemicals Committee.

This document was prepared by the WPMN steering group five leading the project on Co-operation on Voluntary Schemes and Regulatory Programmes and was endorsed at the 8th meeting of the WPMN in March 2011.

More information about the work of the OECD's Programme on the Safety of Manufactured Nanomaterials, as well as OECD's publications regarding safety issues of nanomaterials, is available at 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

EXECUTIVE SUMMARY

1. One of the objectives of the WPMN project on Co-operation on Voluntary Schemes and Regulatory Programmes is to gather information on the nanomaterials notified under the various regulatory regimes in OECD jurisdictions to provide an indication of regulatory activity and trends over time.

2. This document presents the information obtained from the *Questionnaire on Regulated Nanomaterials: 2006-2009* issued August 27th, 2010. Responses received are summarised in the Tables (see Annexes). This document also provides a comparative analysis between the information provided by jurisdictions in the *Questionnaire on Regulatory Regimes for Manufactured Nanomaterials* (hereinafter "2008 Questionnaire") [1] and the responses from this *Questionnaire on Regulated Nanomaterials: 2006-2009*.

3. This report includes the analysis of the responses received on: i) general information regarding legislative updates and definitions (section I); ii) legislation (section II); iii) the types and number of nanomaterials that have been notified (proponent led notification) to various OECD jurisdictions as well as the triggers for notification and risk assessment results and risk management measures (section III); iv) the types and number of nanomaterials that have been notified (not proponent led notification) to various OECD jurisdictions as well as the triggers for notification, risk assessment results and risk management measures (section IV); and v) a comparative analysis of the results from the 2008 Questionnaire/report and this questionnaire/report (section V).

4. Seventeen (17) responses were received from seven (7) jurisdictions[2] for legislation covering chemical substances and/or products including industrial chemicals, pesticides, fertilisers, agricultural compounds, food and food additives, pharmaceuticals and veterinary medicines. Other legislation reported includes those covering occupational health and safety, consumer products, control of major accidents, packaging and labelling.

5. 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. This is consistent with the responses of the 2008 Questionnaire.

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[1] A Questionnaire on Regulatory Regimes for Manufactured Nanomaterials was issued July 28, 2008. The results are available in the Report of the Questionnaire on Regulated Regimes, which was published in April 2010.

[2] The seven jurisdictions include Australia, Canada, Japan, Sweden, Switzerland, the United Kingdom and the United States. The European Commission (EC) reiterated and updated the comprehensive overview of EU-wide chemicals legislation in place within European Member States, provided in the 2008 questionnaire. As information remains largely unchanged, readers should direct themselves to the summary of the 2008 Questionnaire responses for this information. However, there are a number of sector specific pieces of EU legislation outside the direct scope of chemicals, biocides and plant protection legislation, within which nanomaterials are referred to. The Cosmetic Products Regulation is one such example which has been included here, recognising that international regulatory issues relating to this sector are addressed mainly under the International Cooperation on Cosmetics Regulation (ICCR).

6. Since the 2008 Questionnaire, there have not been any amendments to existing legislative regimes that would impact the regulation of nanomaterials or products containing nanomaterials with the exception of one[3]. However, there has been some advancement in the development of definitions for nanomaterials in several jurisdictions and it is anticipated that additional jurisdictions will be following suit in the near future. Of the two (2) jurisdictions that reported having a definition for nanomaterials during the period specified in the Questionnaire (2006-2009), a commonality lies in the 1-100 nm size range distinction as defining criteria.

7. Of the seven (7) jurisdictions that responded to the Questionnaire, three (3) jurisdictions have received submissions from companies regarding nanomaterials or products containing nanomaterials. Of the three (3) jurisdictions, two (2) have received notifications for nanomaterials under existing legislative regimes and one (1) received low volume exemption notices for the reported nanomaterials. The types of nanomaterials that have been notified are varied and range from carbon nanotubes to quantum dots. Respondents indicated that companies are reporting Commercialisation/Marketing and Industrial Use as the most frequent activities associated with the notified nanomaterials.

8. The international regulatory landscape has remained fairly consistent since the 2008 Questionnaire with the exception of one legislative amendment[4], one new legislation[5] and several advancements regarding definitions for nanomaterials. This report builds on the responses provided by delegations to the 2008 Questionnaire by summarising the nanomaterials being notified internationally and the legislative actions being taken by individual jurisdictions.

[3] Ordinance of 18 May 2005 on Protection against Dangerous Substances and Preparations in Switzerland (Annex I table 2).

[4] Ibid.

[5] The Food and Drugs Act in Canada (Annex I table 1)

SECTION I: SUMMARY OF RESPONSES RECEIVED ON LEGISLATIVE UPDATES AND DEFINITIONS

Legislative Updates (Annex I Table 1 and Table 2)

9. Of the seventeen (17) legislations reported, a single (1) source of legislation underwent an amendment that affected the regulation of nanomaterials. The amendment was a change in the volume trigger for notification.

10. Although not reported in the questionnaire, a new regulation on cosmetic products, including provisions related to nanomaterials, was adopted in the European Union on November 30th, 2009. The regulation will become applicable on July 11th, 2013.

11. Provisions related to nanomaterials include:

- Nanomaterials, like any other substance, may only be used if they are safe;
- Ingredients in the nano-form must be indicated in the list of ingredients and followed by the word "nano" in brackets;
- Manufacturers are obliged to notify the European Commission of cosmetics containing nanomaterials six months prior to the placing on the market of the product, in order to allow it to request a safety assessment, in the case of a concern;
- A sector-specific definition of nanomaterials is provided, in order to clearly identify which materials need to be labelled and notified. Such definition, however, can easily be amended to adapt it to technical and scientific progress and definitions subsequently agreed at the international level.

Formal or Working Definitions for Nanomaterials/Nanotechnology (Annex I Table 3 and Table 4)

12. During the period specified by the Questionnaire (2006-2009), the majority of jurisdictions reported not having a formal or working definition for nanomaterials with the exception of two (2) jurisdictions[6] that reported having a definition for nanomaterials. In both cases, the definitions are fairly general, not specific to a particular source of legislation, and can be utilised to support the administration of various legislative and regulatory regimes. A commonality can be drawn between the definitions in that they each utilise a nanomaterial size range of 1-100 nanometres as part of the defining criteria.

13. It should be noted that Australia reported not having a working or formal definition in place during the period specified by the Questionnaire (2006-2009). However, new administrative procedures, including a working definition for industrial nanomaterials, for the notification and assessment of industrial nanomaterials were published in October 2010 by the National Industrial Chemicals and Assessment Scheme (NICNAS) and will be effective in January 2011. Additionally, the United States is developing

[6] The jurisdictions are Canada and the United States (Annex I table 3).

rules under their Toxic Substances Control Act (TSCA) that will propose a definition of nanoscale materials for purposes of identifying materials subject to each rule under TSCA.

14. Although not reported in this questionnaire, in April 2009, the European Parliament called for the "introduction of a science-based definition of nanomaterials in Union legislation as part of nano-specific amendments to existing regulations"[7]. In preparing the response, the European Commission provided a draft recommendation for public consultation that includes a definition for nanomaterials that is intended to determine when a material should be considered as a nanomaterial for legislative and policy purposes in the European Union. The definition is intended to be used as "an overarching, broadly acceptable reference term for any Union communication or legislation addressing nanomaterials". The final adoption of the Recommendation is expected in 2011.

Legislation Submitted in Previous Questionnaire (Annex I Table 5)

15. In the 2008 Questionnaire, twenty-four (24) responses were received from nine jurisdictions (9) as compared to seventeen (17) responses from seven (7) jurisdictions. The European Union (two pieces of legislation previously reported) and New Zealand (two pieces of legislation previously reported) did not participate in this questionnaire.

16. The United States reported five (5) additional legislations in the 2008 Questionnaire, dealing with, among other things, occupational health and safety, consumer products, food, drugs and cosmetics. They were not reported in this questionnaire.

17. Canada and the European Commission reported additional legislation in this questionnaire that was not reported in the 2008 Questionnaire.

[7] European Commission, 2010. Draft Commission Recommendation on the Definition of the Term "Nanomaterial". http://ec.europa.eu/environment/consultations/pdf/recommendation_nano.pdf

SECTION II: SUMMARY OF RESPONSES RECEIVED ON LEGISLATION

Substances/Products Regulated Under or Excluded from Legislation and Purpose of Legislation (Annex II Table 6 and 7)

18. Table 6 of Annex II provides an overview of the substances/products regulated under or excluded from the reported legislations and Table 7 outlines the purpose of each legislation.

19. It can be noted that most reported legislation is intended to regulate chemicals, although the authority exists to regulate nanomaterial substances and/or products that contain nanomaterials.

Activities Targeted by Legislation (Annex II Table 8)

20. Fifteen (15) of seventeen (17) legislations are reported to target usage and thirteen (13 of 17) legislations are reported to target both manufacturing and importation. Ten (10 of 17) legislations have been reported to target commercialisation/marketing, seven (7 of 17) target disposal/waste and one (1 of 17) targets other activities (research and development).

21. The majority of legislation reported in the questionnaire targets usage, manufacturing and importation; whereas disposal/waste and other activities are targeted to a lesser extent.

Objectives of Legislation (Annex II Table 9)

22. The objectives of most legislation were reported to address consumer protection (15 of 17) and environmental protection (13 of 17). Market regulation and worker protection were identified as objectives in both nine (9) of seventeen (17) legislations. Two (2) legislations have other objectives including public protection from work activities and protection of the public within an area likely to be affected by a major accident/hazard. There are no legislations that address the objective of innovation/competitiveness enhancement. This is fairly consistent with the objectives reported in the original Questionnaire.

Volume Trigger for Notification (Annex II Table 10)

23. The volume trigger for notification for the majority of legislations (4 of 17) is reported to be ≥ 1000 kg/year. Two (2) of seventeen (17) legislations have a notification volume trigger of ≥ 0 kg/year and three (3) have ≥ 100 kg/yr. Additionally, three (3) legislations are reported to be product based and, therefore do not rely on a volume trigger for notification. Responses were not provided for five (5) legislations and this may suggest the inapplicability of the volume trigger.

Legislation End Use Application (Annex II Table 11)

24. The majority of legislations have end use applications associated with consumers (14 of 17) and industrial use (13 of 17). Food and drug end use applications are reported for the least amount of legislations (7 of 17).

Requirements for Proponents to Notify Nanomaterials under Legislation (Annex II Table 12)

25. Of the seventeen (17) legislations reported, proponents are required to notify nanomaterials under three (3) legislative regimes. Therefore, the majority of legislation in OECD jurisdictions does not have specific requirements for proponents to notify nanomaterials.

SECTION III: SUMMARY OF RESPONSES RECEIVED ON NON-CONFIDENTIAL BUSINESS INFORMATION ON NOTIFIED NANOMATERIALS

Information Regarding Nanomaterials within the 1-100 nm Size Range (Annex III Table 13)

Number of Companies/Institutions Reporting Nanomaterials

26. Four (4) of seventeen (17) legislations have received submissions from companies/institutions regarding nanomaterials. One (1) legislation has pending applications from four (4) different companies to register pesticides containing nanomaterials. Of the four (4) legislations that have received submissions, one (1) has received report from three (3) companies reporting nanomaterials under new chemical exemption categories (< 100 kg/yr) and not as notification for assessment.

27. Overall, among all respondents, a total of approximately fifty-four (54) different companies, four (4) of which have pending applications, have reported nanomaterials under four (4) different legislations. These legislations include Australia's Industrial Chemicals Notification and Assessment Act, Canada's Canadian Environmental Protection Act, 1999, the United States' Toxic Substances Control Act and the Federal Insecticide, Fungicide and Rodenticide Act.

Number of Different Nanomaterials Reported between January 2006 and December 2009

28. A total of ninety-three (93) different nanomaterials have been reported under four (4) different legislations (listed above), of which, twelve (12) different nanomaterial substances have been reported for low volume exemption categories (< 100 kg/yr).

Information Regarding Nanomaterials outside the 1-100 nm Size Range (Annex III Table 14)

29. None of the respondents indicated receiving report, from companies/institutions, of nanomaterials outside the 1-100 nm size range for the reported legislation.

Number of Companies/Institutions that have Reported Activities with the Nanomaterials Reported in the Questionnaire (Annex III Table 15)

30. Of the three (3) jurisdictions that have indicated receiving report of nanomaterials under specific legislation, the one (1) legislation that received report for low volume exemptions could not provide information as to the nature of the activities associated with the nanomaterials in question.

31. The greatest amount of companies reported Commercialisation/Marketing (48 companies) and Use (47 companies) as activities for the nanomaterials reported in the Questionnaire. The least amount of companies reported Import (19 companies) as an activity for the nanomaterials reported in the Questionnaire.

Data Collected Through Notification under Specific Legislation

32. Canada and the United States have indicated receiving data from companies/institutions through notification of nanomaterials, in the 1-100 nm size range, under the Canadian Environmental Protection Act (CEPA, 1999) and Toxic Substances Control Act (TSCA), respectively.

Activities and Volumes Reported (Annex III Table 16)

33. All nanomaterials that have been notified under CEPA, 1999 and TSCA, are within the 1-100 nm size range and are reported to have industrial uses, with two (2) nanomaterial types having consumer use as well.

34. To date, the majority of notified nanomaterials are carbon nanotubes (between 23 and 33), including both multi-walled and single-walled.

35. All the companies that notified nanomaterials in Canada reported volumes of 10-100 kg/yr. In the United States, one (1) company reported a volume of > 1000 kg/yr (400,000 kg/yr for titanium dioxide with an organic shell). The volumes reported under each legislation can be attributed to the volume trigger associated with the legislation.

Data Provided by Companies/Institutions (Annex III Table 17)

36. With the exception of two (2) companies, each company that provided data through notification of a nanomaterial supplied information on the physical and chemical properties of the nanomaterial. Companies provided the least amount of information on fate and exposure, ecotoxicity data and human toxicity data.

37. Almost all companies reported having risk management measures in place for the notified nanomaterials reported in the Questionnaire.

Risk Assessment and Risk Assessment Conclusions (Annex III Table 18)

38. For each of the notified nanomaterials reported in the Questionnaire, a pre-market assessment was completed.

39. For the majority of the notified nanomaterials reported in the Questionnaire that were subject to a pre-market assessment, suspicion of toxicity or risk was identified for uses that led to exposure to human health and/or the environment.

Risk Management and Future Notification Obligations (Annex III Table 19)

40. Jurisdictions are using risk management to limit exposures and releases by adopting Significant New Activities (SNAcs) and Significant New Use Rules (SNURs). This means that the use of a nanomaterial is permitted under certain conditions and a notification is required when there is intent for a different use.

SECTION IV: SUMMARY OF OTHER ANALYSIS: NON-PROPONENT LED ASSESSMENTS

Information Collected for Nanomaterials ***(with 1, 2 or 3 dimensions in the 1-100 nm size range)*** (Annex IV Table 20 and Table 21)

41. One respondent indicated that a non-proponent led assessment was conducted for a single nanomaterial intended for consumer use. Assessment information on fate and exposure, physical and chemical data, human toxicity data and ecotoxicity data was collected. The assessment conclusion was a recommendation for conditional registration and a screening level risk assessment was used as a risk management tool.

SECTION V: COMPARATIVE ANALYSIS AND CONCLUSION

42. The 2008 Questionnaire and the *Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials* were intended 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. The report of the 2008 Questionnaire concluded that nanomaterials and their associated products are being regulated under existing legislation in many OECD jurisdictions. This report furthers this conclusion by outlining the various OECD jurisdictions that have received notifications, between 2006 and 2009, for nanomaterials and their associated products, the number and various types of notified nanomaterials and the regulatory actions taken by individual jurisdictions.

43. For the most part, the regulatory landscape for nanomaterials has not changed since the 2008 Questionnaire. OECD jurisdictions are still relying on existing legislation to regulate nanomaterials and products containing nanomaterials. Amendments to existing legislation have been minimal; one respondent reported an amendment affecting the regulation of nanomaterials. However, there has been progress in several jurisdictions with regards to the development of definitions for nanomaterials.

44. There was discrepancy between the number of respondents in the 2008 Questionnaire and this Questionnaire. Twenty-four (24) responses from nine (9) jurisdictions were received for legislation in the 2008 Questionnaire as compared to seventeen (17) responses from seven (7) jurisdictions in this Questionnaire. Many jurisdictions reported the same legislations as the 2008 Questionnaire with the exception of Canada and the United States.

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

Table 1. Legislative Updates.

Country	Name of Legislation	Original Regulatory Regimes Survey Completed?	Amendments Affecting Regulation of Nanomaterials?
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	Yes	No
Canada	The Canadian Environmental Protection Act, 1999	Yes	No
Canada	The Fertiliser Act	Yes	No
Canada	The Food and Drugs Act	No	No
Canada	The Pest Control Products Act	Yes	No
European Commission	The Cosmetic Products Regulation[8]	No	Yes
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	Yes	No
Japan	Industrial Safety and Health Law	Yes	No
Sweden	Swedish Environmental Code (1998:808)	Yes	No
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	Yes	No
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	Yes	Yes (Table 2)
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	Yes	No
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	Yes	No
United Kingdom	The Biocidal Products Directive 98/8/EC	Yes	No
United Kingdom	Management of Health and Safety at Work Regulations 1999	Yes	No
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	Yes	No
United States	Toxic Substances Control Act (TSCA)	Yes	No
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	Yes	No

[8] Although not reported in the Questionnaire, the Cosmetic Products Regulation was adopted in the European Union in November 2009 and will be applicable in July 2013.

Table 2. Legislative Amendments since November 2008 that Affect the Regulation of Nanomaterials.

Country	Legislation	Amendment
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	The volume trigger for notification has been changed from 10 kg/yr to 1000 kg/yr.

Table 3. Formal or Working Definitions for Nanomaterials/Nanotechnology by Jurisdiction.

Country	Definition Exists?	Definition Specific to Legislation or Jurisdiction?	Formal or working definition for nanomaterials?	Context
Australia	No[9] (Table 4)		Working	Administration of Legislative and Regulatory Frameworks
Canada	Yes (Table 4)	Jurisdiction	Working	General
European Commission	Yes[10] (Table 4)	Legislation (Cosmetic Products Regulation)		Specific to the Cosmetic Products Regulation
Japan	No			
Sweden	No			
Switzerland	No			
United Kingdom	No			
United States TSCA	No[11]			
United States FIFRA	Yes (Table 4)			General
Total	3			

[9] During the period specified for this Questionnaire (2006-2009), Australia did not have a formal or working definition for nanomaterials. However, new administrative processes for the notification and assessment of industrial nanomaterials, to be effective in January 2011, were published in October 2010 by the National Industrial Chemicals and Assessment Scheme (NICNAS). The new administrative processes include a working definition for industrial nanomaterials.

[10] Although not reported in the questionnaire, the Cosmetic Products Regulation was adopted in the European Union in 2009 and will be applicable in July 2013.

[11] The Environmental Protection Agency (EPA) is developing three rules under TSCA that will propose a definition of nanoscale materials for purposes of identifying the materials subject to each rule.

Table 4. Definition of Nanomaterial/Nanotechnology by Jurisdiction.

Country	Definition
Australia	These new administrative arrangements will be effective from 1 January 2011. They will apply to any new chemical that falls under the following working definition of 'industrial nanomaterial': *"… industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"* [Notes to the working definition: • intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials • 'unique properties' refers to chemical and/or physical properties that are different because of its nanoscale features as compared to the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications. • aggregates and agglomerates are considered to be nanostructured substances • where size distribution shows 10% or more of a substance (based on number of particles) is at the nanoscale, NICNAS will consider this substance to be a nanomaterial for risk assessment purposes.] http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2010oct_whole.pdf
Canada	Health Canada considers any manufactured product, material, substance, ingredient, device, system or structure to be nanomaterial if: • It is at or within the nanoscale in at least one spatial dimension, or; • It is smaller or larger than the nanoscale in all spatial dimensions and exhibits one or more nanoscale phenomena. For the purposes of this definition: The term "nanoscale" means 1 to 100 nanometres, inclusive; The term "nanoscale phenomena" means properties of the product, material, substance, ingredient, device, system or structure which are attributable to its size and distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and, The term "manufactured" includes engineering processes and control of matter and processes at the nanoscale. http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/draft-ebauche-eng.php
European Commission	The Cosmetic Products Regulation. The regulation defines a nanomaterial as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm."
United States	The EPA works within the general framework of the National Nanotechnology Initiative's definition which states that "Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometres, where unique phenomena enable novel applications." http://www.nano.gov/html/facts/whatIsNano.html

Table 5. Legislation Submitted in the 2008 Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (not Provided for this Questionnaire).

Country	Name of Legislation
European Commission	Classification, Labelling and Packaging of Substances and Mixtures Regulation
European Commission	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
New Zealand	Agricultural Compounds and Veterinary Medicines Act, 1977
New Zealand	Hazardous Substances and New Organisms Act, 1996
United States	Occupational Safety and Health Act of 1970
United States	Consumer Product Safety Act
United States	Clean Air Act
United States	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA)
United States	Federal Food and Drug and Cosmetic Act

ANNEX II: RESPONSES RECEIVED ON LEGISLATION (SECTION 2 OF THE QUESTIONNAIRE)

Table 6. Substances/Products Regulated under or Excluded from Legislation.

Country	Name of Legislation	Description of Substances/Products Regulated	Description of Substances/Products Excluded
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	Industrial chemicals according to the ICNA Act 1989 are varied and cover, for example, dyes, solvents, adhesives, plastics, laboratory chemicals, paints, as well as chemicals used in cleaning products and cosmetics and toiletries.	Medical devices and therapeutic goods, pesticides and veterinary medicines, chemicals added to food and chemicals in food packaging.
Canada	The Canadian Environmental Protection Act, 1999	Commercial and industrial substances and substances regulated under the F&DA including food, pharmaceuticals, natural health products, cosmetics and medical devices.	Manufactured items, wastes, transient reaction intermediates, mixtures, impurities, incidental reaction products, substances occurring in nature and substances listed on the Domestic Substances List.
Canada	The Fertiliser Act	Fertiliser (nutrients) and supplement (substances other than fertilisers that improve the physical condition of soils or plant growth) products. Products can include farm fertilisers, micronutrients, lawn and garden products as well as supplements such as water holding polymers, microbial inoculants, and composts.	Commercial and industrial substances, pesticides, products regulated under the Food and Drugs Act, feeds and seeds.
Canada	The Food and Drugs Act	Food, pharmaceuticals, natural health products, cosmetics and medical devices.	Commercial and industrial substances, pesticides, fertilisers, feeds and seeds.
Canada	The Pest Control Products Act	All products used for pest control.	Commercial and industrial substances, products regulated under the Food and Drugs Act, fertilisers, feeds and seeds.
European Commission	The Cosmetic Products Regulation	"'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;" "'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;"	

Country	Name of Legislation	Description of Substances/Products Regulated	Description of Substances/Products Excluded
		"In view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 to technical and scientific progress and to definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3)."	
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	The term "chemical substance" as used in this Act means a chemical compound obtained by causing chemical reactions to elements or compounds.	A radioactive substance, any specified poison prescribed in paragraph #) of Article 2 of the Poisonous and Deleterious Substances Control Act, etc.
Japan	Industrial Safety and Health Law	A "chemical substance" shall be defined as an element or a compound.	No response.
Sweden	Swedish Environmental Code (1998:808)	Substances, mixtures and articles.	None (-)
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	Substances, mixtures and articles.	None (-)
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	All chemicals and chemical products.	Foodstuff, feedstuff, cosmetics, medical products, biocides, plant protection agents and waste.
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	Applies to all employers with undertakings that use hazardous substances or where those substances may be present.	Lead and asbestos. Also, where the substance is hazardous to health solely by virtue of its radioactive, explosive or flammable properties, or solely because it is at a high or low temperature or a high pressure.
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	Chemicals.	Cosmetics and medicines among others.

Country	Name of Legislation	Description of Substances/Products Regulated	Description of Substances/Products Excluded
United Kingdom	The Biocidal Products Directive 98/8/EC	Biodical products: "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise to exert a controlling effect on any harmful organisms by chemical or biological means."	Non-biocidal uses of products and active substances.
United Kingdom	Management of Health and Safety at Work Regulations 1999	Covers all work activities.	
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	Dangerous substances, such as chlorine, liquefied petroleum gas, explosives and arsenic pentoxide which can cause serious damage/harm to people and/or the environment.	
United States	Toxic Substances Control Act (TSCA)	Chemical substances.	Foods, drugs, cosmetics, pesticides, alcohol, tobacco, firearms and nuclear material.
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	Sale and distribution of pesticides and biocides.	Certain uses, such as chemical sterilants that are covered by the US Food and Drug Administration.

Table 7. Purpose of Legislation.

Country	Name of Legislation	Purpose
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	Through the ICNA Act, 1989, NICNAS regulated the introduction, through manufacture or importation, of industrial chemicals into Australia. NICNAS undertakes risk assessments and makes recommendations for safe use under the national OHS, public health and environment frameworks. State and Territory agencies regulate and control the use of industrial chemicals.
Canada	The Canadian Environmental Protection Act, 1999	The CEPA 1999 is aimed at preventing pollution and protecting the environment and human health while contributing to sustainable development.
Canada	The Fertiliser Act	The Fertilizers Act requires that all regulated fertilizer and supplement products must be effective and safe for humans, plants, animals, and the environment.
Canada	The Food and Drugs Act	The F&DA and the Regulations govern the sale and advertisement of the products that fall under the purview of the Act in order to ensure their safety and prevent deception. The Act also sets out the labelling requirements for food.
Canada	The Pest Control Products Act	The purpose of the Act is to ensure that all pesticides in Canada will not cause harm to human health, future generations or the environment.
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their	To establish a system to evaluate, before manufacture or import, whether or not new chemical substances have properties such as persistence, and to implement necessary regulations with respect to the manufacture, import, use, etc in order to prevent environmental pollution caused by chemical

Country	Name of Legislation	Purpose
	Manufacture)	substances that are persistent and pose a risk of impairing human health or interfering with the inhabitation and/or growth of flora and fauna.
Japan	Industrial Safety and Health Law	The purpose of this Act is to secure, the safety and health of workers in workplaces, as well as to facilitate the establishment of comfortable working environment.
Sweden	Swedish Environmental Code (1998:808)	To protect human health and the environment from chemical hazards.
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	To protect human health and the environment from chemical hazards.
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	This legislation determines and assesses the dangers and risks that substances and preparations may pose to human life and health and to the environment, the conditions under which substances and preparations that may endanger people or the environment are placed on the market, the handling of substances and preparations that may endanger people or the environment, as well as the way in which data relating to substances and preparations is processed by the enforcement authorities.
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	The legislation implements the requirements of the EU Chemical Agents Directive. It requires employers to assess health risks from dangerous substances and put in place control measures to protect their workers.
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	CHIP requires the supplier of a dangerous chemical to identify the hazards (dangers) of the chemical, give information about the hazards to their customers and to package the chemical safely.
United Kingdom	The Biocidal Products Directive 98/8/EC	To harmonise the European market for biocidal products and their active substances so that once a product is authorised in one Member State under the Directive that authorisation can be recognised in the other Member States; To provide a high level protection of people, animals and the environment.
United Kingdom	Management of Health and Safety at Work Regulations 1999	Umbrella legislation covering all work activities.
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	The legislation implements EC Directives 96/82/EC and 2003/105/EC (Seveso II). It aims to control major-accident hazards involving dangerous substances and thereby provide protection for people and the environment. The main duties (on operators of major hazard sites and local authorities) relate to control and mitigation measures for individual major hazard sites and not national registration, assessment etc arrangements for the substances themselves.
United States	Toxic Substances Control Act (TSCA)	Assess and manage risks from chemical substances.
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	EPA may register (license for sale and distribution) a pesticide only if the use of the pesticide does not cause unreasonable adverse effects on the environment.

Table 8. Activities Targeted by Legislation.

Country	Name of Legislation	Activity Targeted by Legislation					
		Manufacturing	Importation	Commercialisation/ Marketing	Usage	Disposal/Waste	Other
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	●	●		●	●	● R&D
Canada	The Canadian Environmental Protection Act, 1999	●	●		●		
Canada	The Fertiliser Act		●	●			
Canada	The Food and Drugs Act	●	●	●			
Canada	The Pest Control Products Act	●	●	●	●		
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	●	●		●		
Japan	Industrial Safety and Health Law	●	●		●		
Sweden	Swedish Environmental Code (1998:808)	●	●	●	●	●	
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	●	●	●	●		
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)			●	●		
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	●			●	●	
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	●	●	●	●		
United Kingdom	The Biocidal Products Directive 98/8/EC		●	●	●		

Country	Name of Legislation	Activity Targeted by Legislation					
		Manufacturing	**Importation**	**Commercialisation/ Marketing**	**Usage**	**Disposal/Waste**	**Other**
United Kingdom	Management of Health and Safety at Work Regulations 1999	●			●	●	
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	●			●	●	
United States	Toxic Substances Control Act (TSCA)	●	●	●	●	●	
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)		●	●	●	●	
Total		**13/17**	**13/17**	**10/17**	**15/17**	**7/17**	**1/17**

Table 9. Objectives of Legislation.

Country	Name of Legislation	Objective of the Legislation					
		Market Regulation	Innovation/ Competitiveness Enhancement	Environmental Protection	Worker Protection	Consumer Protection	Other
Australia	Industrial Chemicals (Notification and Assessment) Act (INAC) 1989			●	●	●	
Canada	The Canadian Environmental Protection Act, 1999			●		●	
Canada	The Fertiliser Act	●		●	●	●	
Canada	The Food and Drugs Act	●				●	
Canada	The Pest Control Products Act	●		●		●	
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	●		●		●	
Japan	Industrial Safety and Health Law				●		
Sweden	Swedish Environmental Code (1998:808)	●		●		●	
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	●		●		●	
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)			●		●	

Country	Name of Legislation	Objective of the Legislation					
		Market Regulation	**Innovation/ Competitiveness Enhancement**	**Environmental Protection**	**Worker Protection**	**Consumer Protection**	**Other**
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)				●		
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					●	Public protection from work activities
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)			●	●	● By a major accident	Protection of the public within an area likely to be affected
United States	Toxic Substances Control Act (TSCA)			●	●	●	
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	●		●	●	●	
Total		**9/17**	**0/17**	**13/17**	**9/17**	**15/17**	**2/17**

Table 10. Volume Trigger for Notification.

Country	Name of Legislation	Volume Trigger for Notification						
		≥ 0 kg//yr	≥ 1kg/yr	≥ 10 kg/yr	≥ 100 kg/yr	≥ 1000 kg/yr	≥ 10 000 kg/yr	Other
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989				•			
Canada	The Canadian Environmental Protection Act, 1999				•			
Canada	The Fertiliser Act							No trigger-product based
Canada	The Food and Drugs Act							No trigger-product based
Canada	The Pest Control Products Act							No trigger-product based
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)					•		
Japan	Industrial Safety and Health Law				•			
Sweden	Swedish Environmental Code (1998:808)					•		
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)					•		
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)					•		
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	No response						
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	No response						

Country	Name of Legislation	Volume Trigger for Notification						
		≥ 0 kg/yr	≥ 1kg/yr	≥ 10 kg/yr	≥ 100 kg/yr	≥ 1000 kg/yr	≥ 10 000 kg/yr	Other
United Kingdom	The Biocidal Products Directive 98/8/EC	No response						
United Kingdom	Management of Health and Safety at Work Regulations 1999	No response						
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	No response						
United States	Toxic Substances Control Act (TSCA)	•						
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	•						
Total		**2/17**	**0/17**	**0/17**	**3/17**	**4/17**	**0/17**	**3/17 product based**

Table 11. Legislation End Use Application.

Country	Name of Legislation	End Use Application						
		Industrial Use	Food and Drug	Consumer	Research and Development	Cosmetic	Pesticide	Agricultural
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	●		●	●	●		
Canada	The Canadian Environmental Protection Act, 1999	●	●	●	●	●		
Canada	The Fertiliser Act			●				●
Canada	The Food and Drugs Act		●	●		●		●
Canada	The Pest Control Products Act						●	
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	●						
Japan	Industrial Safety and Health Law	●						
Sweden	Swedish Environmental Code (1998:808)	●		●		●	●	
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	●		●			●	
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	●		●	●			
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	●	●	●	●	●	●	●
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	●	●	●	●	●	●	●

Country	Name of Legislation	End Use Application						
		Industrial Use	**Food and Drug**	**Consumer**	**Research and Development**	**Cosmetic**	**Pesticide**	**Agricultural**
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 Hazard Regulations 1999 (amended 2005)	●	●	●	●	●	●	●
United States	Toxic Substances Control Act (TSCA)	●		●				
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)			●	●		●	●
Total		**13/17**	**7/17**	**14/17**	**9/17**	**9/17**	**9/17**	**8/16**

Table 12. Requirements for Proponents to Notify Nanomaterials under Legislation.

Country	Name of Legislation	Requirements for proponents to notify nanomaterials?	Comments
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	Yes	A proponent must notify if a chemical substance is a new chemical substance not already on the AICS. As of 1 January 2011, certain exemption categories are restricted for nanoforms of new chemicals. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is currently exploring options for notification requirements for nanoforms of existing chemicals.
Canada	The Canadian Environmental Protection Act, 1999	Yes	
Canada	The Fertiliser Act	No	
Canada	The Food and Drugs Act	No	
Canada	The Pest Control Products Act	No	
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	No	
Japan	Industrial Safety and Health Law	No	
Sweden	Swedish Environmental Code (1998:808)	No	
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	No	
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	No	
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	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 Hazard Regulations 1999 (amended 2005)	No	
United States	Toxic Substances Control Act (TSCA)	Yes	A proponent must notify if a chemical substance is a new chemical substance not already on the TSCA Inventory. The EPA also plans to propose additional reporting requirements for new and existing nanomaterials in early 2011.
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	No	
Total		**3 Yes/17**	

ANNEX III: NON-CONFIDENTIAL BUSINESS INFORMATION ON NOTIFIED NANOMATERIALS (PROPONENT INITIATED NOTIFICATION) (SECTION 3 OF THE QUESTIONNAIRE)

Table 13. Summary Information Regarding Reported Nanomaterials within 1-100 nm Size Range.

Country	Name of Legislation	How many companies/institutions have reported nanomaterials under this Legislation?	How many different nanomaterials have been reported under this Legislation between January 1, 2006 and December 31, 2009?
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	3[12]	12[13]
Canada	The Canadian Environmental Protection Act, 1999	Between 1 and 10	Between 1 and 8
Canada	The Fertiliser Act	Not Applicable (N/A)	N/A
Canada	The Food and Drugs Act	N/A	N/A
Canada	The Pest Control Products Act	N/A	N/A
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	N/A	N/A
Japan	Industrial Safety and Health Law	N/A	N/A
Sweden	Swedish Environmental Code (1998:808)	N/A	N/A
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	N/A	N/A
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	N/A	N/A
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	N/A	N/A
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	N/A	N/A
United Kingdom	The Biocidal Products Directive 98/8/EC	N/A	N/A

[12] Three companies have reported nanomaterials under new chemical exemption categories (<100kg/yr), not as notification for assessment.

[13] Twelve substances have been reported for low volume exemption categories, identified as “nano” between the years of 2006-2009.

Country	Name of Legislation	How many companies/institutions have reported nanomaterials under this Legislation?	How many different nanomaterials have been reported under this Legislation between January 1, 2006 and December 31, 2009?
United Kingdom	Management of Health and Safety at Work Regulations 1999	N/A	N/A
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	N/A	N/A
United States	Toxic Substances Control Act (TSCA)	37	72
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	Pending applications, from 4 different companies, to register pesticides containing nanoscale materials.	Received applications for 1 nanomaterial; however, there are several forms of this nanomaterial.
Total		**~ 54**	**~ 93**

Table 14. Summary Information Regarding Reported Nanomaterials Outside 1-100 nm Size Range.

Country	Name of Legislation	How many companies/institutions have reported nanomaterials under this Legislation?	How many different nanomaterials have been reported under this Legislation between January 1, 2006 and December 31, 2009?
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989	N/A	N/A
Canada	The Canadian Environmental Protection Act, 1999	N/A	N/A
Canada	The Fertiliser Act	N/A	N/A
Canada	The Food and Drugs Act	N/A	N/A
Canada	The Pest Control Products Act	N/A	N/A
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	N/A	N/A
Japan	Industrial Safety and Health Law	N/A	N/A
Sweden	Swedish Environmental Code (1998:808)	N/A	N/A
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	N/A	N/A
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	N/A	N/A
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	N/A	N/A
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	N/A	N/A
United Kingdom	The Biocidal Products Directive 98/8/EC	N/A	N/A
United Kingdom	Management of Health and Safety at Work Regulations 1999	N/A	N/A
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	N/A	N/A
United States	Toxic Substances Control Act (TSCA)	N/A	N/A
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	N/A	N/A
Total		**0/17**	**0/17**

Table 15. Number of Companies/Institutions that have Reported Activities with Nanomaterials

Country	Name of Legislation	Activities reported					
		Commercialisation/ Marketing	Import	Manufacture	Use	Disposal	Other
Australia	Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989						Not enough information to answer
Canada	The Canadian Environmental Protection Act, 1999	10	9	1	10	None	None
Canada	The Fertiliser Act	N/A	N/A	N/A	N/A	N/A	N/A
Canada	The Food and Drugs Act	N/A	N/A	N/A	N/A	N/A	N/A
Canada	The Pest Control Products Act	N/A	N/A	N/A	N/A	N/A	N/A
Japan	Chemical Substances and Control Law (previously Act on the Evaluation of Chemical Substances and Regulation of their Manufacture)	N/A	N/A	N/A	N/A	N/A	N/A
Japan	Industrial Safety and Health Law	N/A	N/A	N/A	N/A	N/A	N/A
Sweden	Swedish Environmental Code (1998:808)	N/A	N/A	N/A	N/A	N/A	N/A
Sweden	The Chemical Products and Biotechnical Organisms Ordinance (2008:245)	N/A	N/A	N/A	N/A	N/A	N/A
Switzerland	Ordinance of 18 May 2005 On Protection Against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)	N/A	N/A	N/A	N/A	N/A	N/A
United Kingdom	Control of Substances Hazardous to Health Regulations (COSHH)	N/A	N/A	N/A	N/A	N/A	N/A
United Kingdom	Chemicals Hazard Information and Packaging for Supply Regulations 2002	N/A	N/A	N/A	N/A	N/A	N/A
United Kingdom	The Biocidal Products Directive 98/8/EC	N/A	N/A	N/A	N/A	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
United Kingdom	Control of Major Accident Hazard Regulations 1999 (amended 2005)	N/A	N/A	N/A	N/A	N/A	N/A
United States	Toxic Substances Control Act (TSCA)	37	9	28	37	37	0[14]
United States	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	1	1	2	None	None	None
Total		**48**	**19**	**31**	**47**	**37**	**0**

[14] None of the 72 nanoscale materials reported to EPA under TSCA identified a specific consumer use for the nanoscale materials. Other than chemical intermediates, most of the applications described such as paints, coating, structural or mechanical reinforcements, batteries, and other conductive applications could be found in consumer products where the nanoscale material was bound of encapsulated in some type of composite, resin, or coating.

Table 16. Summary Data Collected, by Jurisdiction, through Notification under Specific Legislation (activities and volumes reported).

Country	Name of Legislation	Identity of nanomaterial	NM within 1-100 nm? (Y/N)	Explain if you answered no in the previous column.	# of companies reporting activities	All use codes[15] for this NM	# of companies reporting <10 kg/yr	Use codes for <10 kg/yr	# of companies reporting 10-100 kg/yr	Use codes for 10-100 kg/yr	# of companies reporting 100-1000 kg/yr	Use codes for 100-1000 kg/yr	# of companies reporting >1000 kg/yr	Use codes for >1000 kg/yr
Canada	CEPA 1999	Surface modified silica	Y		Between 1 and 10	2,4			Between 1 and 10					
		Inorganic phosphate	Y		Between 1 and 10	2			Between 1 and 10	2				
		Carbon nanotube	Y		Between 1 and 10	2			Between 1 and 10	2				
		Organic	Y		Between 1 and 10	2,4			Between 1 and 10	2,4				
United States	TSCA	Multi Walled CNT 19 substances	Y		13	2								
		Single Walled CNT 4 substances	Y		4	2								
		Fullerenes 4 substances: (5,6) Fullerene-C60-Ih (5,6) Fullerene-C70-D5h(6) (5,6) Fullerene-C84-D2 (5,6) Fullerene-C84-D2d	Y		1	2								
		Functionalised Fullerenes 4 substances	Y		2	2								
		Other Carbon allotrope and carbon allotrope derivatives 12 substances	Y		3	2								

[15] Use codes: 1- Research and Development, 2- Industrial Use, 3- Food and Drug, 4-Consumer Use, 5- Cosmetics, 6- Pesticide, 7- Agricultural and 8- Other.

Country	Name of Legislation	Identity of nanomaterial	NM within 1-100 nm? (Y/N)	Explain if you answered no in the previous column.	# of companies reporting activities	All use codes[15] for this NM	# of companies reporting <10 kg/yr	Use codes for <10 kg/yr	# of companies reporting 10-100 kg/yr	Use codes for 10-100 kg/yr	# of companies reporting 100-1000 kg/yr	Use codes for 100-1000 kg/yr	# of companies reporting >1000 kg/yr	Use codes for >1000 kg/yr
		Metal or metal oxides with an organic shell 10 substances	Y		4	2								
		Silica or silica compounds with an organic shell 9 substances	Y		3	2								
		Titanium dioxide with an organic shell 3 substances	Y		3	2							1 400,000 kg/yr	
		Organic compounds 5 substances	Y		5	2								
		Quantum dots 2 substances	Y		2	2								

Table 17. Summary Data Collected, by Jurisdiction, through Notification under Specific Legislation (data provided by companies).

Country	Name of Legislation	Identity of nanomaterial	# of companies providing info on fate and exposure	# of companies providing info on phys chem. properties	# of companies providing human toxicity data	# of companies providing ecotoxicity data	# of companies reporting risk management in place
Canada	CEPA 1999	Surface modified silica	0	All	0	0	0
		Inorganic phosphate	0	All	0	0	0
		Carbon nanotube	0	All	All	All	All
		Organic	0	All	All	All	All
United States	TSCA	Multi Walled CNT 19 substances	1	13	6	2	13
		Single Walled CNT 4 substances	0	4	0	0	4
		Fullerenes 4 substances: (5,6) Fullerene-C60-Ih (5,6) Fullerene-C70-D5h(6) (5,6) Fullerene-C84-D2 (5,6) Fullerene-C84-D2d	0	1	0	0	1
		Functionalised Fullerenes 4 substances	0	2	0	0	2
		Other Carbon allotrope and carbon allotrope derivatives 12 substances	0	3	0	0	3
		Metal or metal oxides with an organic shell 10 substances	1	4	0	0	4
		Silica or silica compounds with an organic shell 9 substances	0	3	0	0	3
		Titanium dioxide with an organic shell 3 substances	0	3	0	0	3
		Organic compounds 5 substances	0	5	0	0	5
		Quantum dots 2 substances	No response	0	1	0	2

Table 18. Summary Data Collected, by Jurisdiction, through Notification under Specific Legislation (risk assessment).

Country	Name of Legislation	Identity of Nanomaterial	Pre-market assessment complete? (Y/N)	Post-market assessment complete?	Assessment Conclusions
Canada	CEPA 1999	Surface modified silica	Y	N	The substance is not suspected of being "toxic" under CEPA, 1999. However, there is a suspicion that a significant new activity (SNAc) may result in the substance becoming "toxic" under CEPA, 1999. A SNAc is considered an alternative use or other activity that results in or may result in: i) a significantly greater quantity or concentration of the substance in the environment and/or ii) a significantly different manner or circumstances of exposure to the substance.
		Inorganic phosphate	Y	N	The substance is not suspected of being "toxic" under CEPA, 1999. However, there is a suspicion that a significant new activity (SNAc) may result in the substance becoming "toxic" under CEPA, 1999. A SNAc is considered an alternative use or other activity that results in or may result in: i) a significantly greater quantity or concentration of the substance in the environment and/or ii) a significantly different manner or circumstances of exposure to the substance.
		Carbon nanotube	Y	N	The substance is not suspected of being "toxic" under CEPA, 1999. However, there is a suspicion that a significant new activity (SNAc) may result in the substance becoming "toxic" under CEPA, 1999. A SNAc is considered an alternative use or other activity that results in or may result in: i) a significantly greater quantity or concentration of the substance in the environment and/or ii) a significantly different manner or circumstances of exposure to the substance.
		Organic	Y	N	Under assessment
United States	TSCA	Multi Walled CNT 19 substances	Y		Potential Unreasonable Risk from PMN. Will not present an unreasonable risk under conditions described in the exemption notice.
		Single Walled CNT 4 substances	Y		Same as Multiwalled Carbon Nanotubes.
		Fullerenes 4 substances: (5,6) Fullerene-C60-Ih	Y		Potential Unreasonable Risk from PMN.

Country	Name of Legislation	Identity of Nanomaterial	Pre-market assessment complete? (Y/N)	Post-market assessment complete?	Assessment Conclusions
		(5,6) Fullerene-C70-D5h(6) (5,6) Fullerene-C84-D2 (5,6) Fullerene-C84-D2d			
		Functionalised Fullerenes 4 substances	Y		Potential Unreasonable Risk from PMN.
		Other Carbon allotrope and carbon allotrope derivatives 12 substances	Y		Potential Risk if used differently from PMN. Will not present an unreasonable risk under conditions described in the exemption notice.
		Metal or metal oxides with an organic shell 10 substances	Y		Potential Unreasonable Risk from PMN. Potential Risk if used differently from PMN. Will not present an unreasonable risk under conditions described in the exemption notice.
		Silica or silica compounds with an organic shell 9 substances	Y		Potential Risk if used differently from PMN. Will not present an unreasonable risk under conditions described in the exemption notice.
		Titanium dioxide with an organic shell 3 substances	Y		Potential Unreasonable Risk from PMN. Will not present an unreasonable risk under conditions described in the exemption notice.
		Organic compounds 5 substances	Y		Potential Unreasonable Risk. Risk if used differently from PMN. No unreasonable risk. Will not present an unreasonable risk under conditions described in the exemption notice
		Quantum dots 2 substances	Y		Will not present an Unreasonable Risk under conditions described in the exemption notice.

Table 19. Summary Data Collected, by Jurisdiction, through Notification under Specific Legislation (risk management and future notification obligations).

Country	Name of Legislation	Identity of Nanomaterial	Risk Management	Any future Notification Obligations
Canada	CEPA 1999	Surface modified silica	A significant new activity is any activity involving the substance in quantities greater than 10 kilograms per calendar year, other than for use as a component of a waterborne industrial coating, or a waterborne wood floor coating applied by the consumer by roller or squeegee where, once cured, the substance will become part of the solid matrix. A significant new activity is any activity involving the substance in quantities greater than 10 kilograms per year, other than for use as a component of industrial coatings for polycarbonate, polyester, polymethylmethacrylate and polyethyleneterephthalate substrates where, once cured, the substance will become part of the solid matrix. (a) the use of the substance in a quantity greater than 10 kg per calendar year in products that are intended for use by or for children; (b) the use of the substance in a quantity greater than 10 kg per calendar year other than for use as a component in ultraviolet or electron beam curable coatings when they are applied to products in an industrial setting; or (c) the use of the substance in a quantity greater than either 10 000 kg per calendar year or an accumulated total of 50 000 kg as a component in ultraviolet or electron beam curable coatings when they are applied to products in an industrial setting. A significant new activity is an activity that involves: (a) the use of the substance as a defoaming agent in wastewater treatment or fermentation or paper manufacturing processes in quantities equal to or greater than 1 000 kilograms per calendar year, where the substance is engineered to contain particles between 1 to 100 nanometres particle size range; or	Under Risk Management, a person that proposes a significant new activity for these substances shall provide to the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, the information outlined in the initial Notice.

Country	Name of Legislation	Identity of Nanomaterial	Risk Management	Any future Notification Obligations
			(b) the use of the substance in quantities greater than 10 kilograms per calendar year, other than for use as a defoaming agent in wastewater treatment or fermentation or paper manufacturing processes, where the substance is engineered to contain particles between 1 to 100 nanometres particle size range.	
		Inorganic phosphate	A significant new activity is any activity involving the substance in quantities greater than 10 kilograms per calendar year, other than for use as a component of printing inks for industrial printing activities where the substance is bound to the substrate.	Under risk management, a person that proposes a significant new activity set out in this Notice for this substance shall provide to the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, the following information: (a) a description of the proposed significant new activity in relation to the substance; (b) measurement of the particle size and particle size distribution of the substance; (c) for industrial activities where the particle size is determined to be between 1 and 100 nanometres, inclusively, in at least one dimension: (i) the information specified in item 7 of Schedule 4 of the New Substances Notification Regulations (Chemicals and Polymers), (ii) the information specified in item 8 of Schedule 5 to those Regulations, and (iii) the information specified in item 11 of Schedule 6 to those Regulations; and (d) for activities where the substance or products containing the substance could become available to consumers and the particle size is determined to be between 1 and 100 nanometres, inclusively, in at least one dimension:

Country	Name of Legislation	Identity of Nanomaterial	Risk Management	Any future Notification Obligations
				(i) the information specified in Schedule 6 to those Regulations, and (ii) the analytical information to determine the physical dimensions of the test substance for the duration of these tests.
		Carbon nanotube	2.(1) A significant new activity is any activity that involves: (a) the use of the substance in a quantity greater than 10 kg per calendar year: (i) in products that are intended for use by or for children, (ii) as a component in coatings that are applied industrially to consumer products that are not intended for use by or for children, or (iii) to industrially formulate a solid metallic consumer product that is not intended for use by or for children and, where applicable, further industrially process that product; (b) the use of the substance in a quantity greater than 100 kg per calendar year: (i) as a component in coatings that are applied industrially to products that are not intended for use by or for consumers, or (ii) to industrially formulate a solid metallic product that is not intended for use by or for consumers and, where applicable, further industrially process that product; (c) any other use of the substance in a quantity greater than 10 kg per calendar year other than its use to industrially formulate a rubber, plastic or any other solid polymeric product and, where applicable, further industrially process that product; or (d) the use of the substance in a quantity greater than either 1 000 kg per calendar year or an accumulated total of 5 000 kg to industrially formulate a rubber, plastic, or any other solid polymeric product and, where applicable, further industrially process that product. (2) Despite subitem (1), the activity where the substance is used to create a product that is to be exported before being sold or in any way transferred to the public and where the process involved in creating that product does not result in a release of more than 1 kg per day per site to the aquatic environment after wastewater treatment, is not a new activity.	Under risk management, a person that proposes a significant new activity set out in this Notice for this substance shall provide to the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, the following information: (a) a description of the proposed significant new activity in relation to the substance; (b) for a new activity described in subparagraphs 2(a)(ii) or (iii) or subparagraphs 2(b)(i) or (ii): (i) the information specified in Schedule 4 to the New Substances Notification Regulations (Chemicals and Polymers), (ii) all other information or test data concerning the substance that are in the possession of the person who proposes the significant new activity, or to which they have access, and that are relevant to determine whether the substance is toxic or capable of becoming toxic; (c) for a new activity described in subparagraph 2(a)(i) or paragraph 2(c), the information specified in Schedule 6 to those Regulations; (d) for a new activity described in paragraph 2(d), the information specified in Schedule 5 to those Regulations; (e) the analytical information to determine the length and diameter of the substance as produced and as administered in the health and ecological toxicity tests referred to in paragraphs (c) and (d); (f) the information describing the agglomeration/aggregation state, shape, surface area and surface charge of the substance as

Country	Name of Legislation	Identity of Nanomaterial	Risk Management	Any future Notification Obligations
			3. Despite paragraph 2(c), the use of the substance as a research and development substance, as this term is defined in subsection 1(1) of the New Substances Notification Regulations (Chemicals and Polymers), is not a new activity.	produced and as administered in the health and ecological toxicity tests referred to in paragraphs (c) and (d); and (g) the analytical information to determine the leachability potential of the substance from the product.
		Organic	Under assessment.	Under assessment.
United States	TSCA	Multi Walled CNT 19 substances	Consent order followed by SNUR (Significant New Use Rule). Limit exposures and releases based on PPE and controls described in the exemption notice.	Significant New Use Notification after SNUR is issued. Any changes of exposure or release controls.
		Single Walled CNT 4 substances	Same as multi walled CNTs.	Same as multi walled CNTs.
		Fullerenes 4 substances: (5,6) Fullerene-C60-Ih (5,6) Fullerene-C70-D5h(6) (5,6) Fullerene-C84-D2 (5,6) Fullerene-C84-D2d	Consent Order followed by SNUR.	Significant New Use Notification after SNUR is issued.
		Functionalised Fullerenes 4 substances	Consent Order followed by SNUR.	Significant New Use Notification after SNUR is issued.
		Other Carbon allotrope and carbon allotrope derivatives 12 substances	SNUR. Limit exposures and releases based on PPE and controls described in the exemption notice.	Significant New Use Notification after SNUR is issued. Any changes of exposure or release controls.
		Metal or metal oxides with an organic shell 10 substances	Consent Order followed by SNUR. SNUR. Limit exposures and releases based on PPE and controls described in the exemption notice.	Significant New Use Notification after SNUR is issued. Significant New Use Notification after SNUR is issued. Any changes of exposure or release controls.
		Silica or silica compounds with an organic shell 9 substances	SNUR. Limit exposures and releases based on PPE and controls described in the exemption notice.	Significant New Use Notification after SNUR is issued. Any changes of exposure or release controls.
		Titanium dioxide with an organic shell 3 substances	Consent Order followed by SNUR. Limit exposures and releases based on PPE and controls described in the exemption notice.	Significant New Use Notification after SNUR is issued. Any changes of exposure or release controls.
		Organic compounds 5 substances	Consent Order, SNUR, limit exposures and releases based on PPE and controls described in the exemption notice, and in one case no action taken.	Significant New Use Notification after SNUR is issued. Any changes of exposure or release controls.
		Quantum dots 2 substances	Limit exposures and releases based on PPE and controls described in the exemption notice.	Any changes of exposure or release controls.

ANNEX IV: SUMMARY OF OTHER ANALYSIS

Table 20. Summary of Data Collected for Nanomaterials (with 1, 2 or 3 dimensions in the 1-100 nm range) for Assessment/Review (not proponent led notification).

Country	Name of Legislation	How many companies/institutions have reported nanomaterials under this Legislation?	How many nanomaterials with all dimensions outside of the 1-100 nm size range have been assessed under this Legislation between January 1, 2006 and December 31, 2009?
United States	Federal Insecticide, Fungicide, and Rodenticide Act	None, all assessments are pending.	No response.

Table 21. Summary of Data Collected by Jurisdiction for Assessment (not proponent led notification).

Country	Name of Legislation	Identity of NM	NM Within 1-100 nm Size Range?	All Use Codes for NM	Quantities in Use kg/yr	Fate and Exposure Data (Y/N)	Phys-Chem Data (Y/N)	Human Tox Data (Y/n)	Ecotox Data (Y/N)	Assessment Conclusion	Risk Management Tools Used
United States	Federal Insecticide, Fungicide, and Rodenticide Act	Nanosilver	Y	4[16]		Y	Y	Y	Y	Recommendation for conditional registration.	Screening level risk assessment.

[16] Use codes: 1- Research and Development, 2- Industrial Use, 3- Food and Drug, 4-Consumer Use, 5- Cosmetics, 6- Pesticide, 7- Agricultural and 8- Other.