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REPORT OF THE QUESTIONNAIRE ON REGULATORY REGIMES FOR MANUFACTURED NANOMATERIALS 2010-2011

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

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

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FOREWORD

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

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

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

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I: 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. The current document presents the information obtained from the WPMN Questionnaire on Regulated Nanomaterials: 2010-2011 issued July 12, 2012. The findings (see Annexes for full responses) are summarized in this document.

3. The questionnaire contained four sections related to the oversight of nanomaterials in various OECD jurisdictions.

4. Section 1: Regulatory Updates (including enacted and pending actions). This section aimed to summarize information from respondents regarding regulatory updates with respect to activities under their programs. Respondents were invited to indicate if they had received nanomaterial notifications/submissions since 2009 and if so, identify the relevant legislation(s) and testing requirements. Respondents were also invited to comment on any future planned amendments to existing legislation.

5. Section 2: Definitions and/or Legal Approaches for Nanomaterials by Jurisdiction. This section aimed to summarize and compare the existing and proposed definitions for nanomaterials (e.g. regulatory, legislative, policy, etc.) in OECD jurisdictions. All jurisdictions, including those that have existing definitions for nanomaterials, were requested to include information regarding the key elements of regulatory definitions, policy definitions, and/or any other approaches to cover nanomaterials. Also, jurisdictions were invited to include any information about proposed work on a definition for nanomaterials.

6. Section 3: Regulatory Challenges. This section aimed to summarize the existing and anticipated challenges regarding the regulation of nanomaterials within OECD jurisdictions and the actions to address these identified challenges.

7. Section 4: Opportunities for Collaboration. This section aimed to summarize collaboration initiatives among member states and summarize the jurisdictions that sponsor expert workshops under the OECD WPMN.

8. Fourteen (14) responses were received from nine jurisdictions[1] for legislation covering chemical substances and/or products including industrial chemicals, therapeutics, foods and drugs, and biocides. Other legislation reported includes those covering occupational health and safety, consumer products, packaging and labelling.

9. There was agreement between the responses on utilizing existing regulatory frameworks to regulate nanomaterials. Some jurisdictions have developed reporting regimes specific to nanomaterials to gather information on uses and quantities. This finding is consistent with the past surveys of this steering group.

[1] The nine jurisdictions include Australia, Canada, Denmark, European Union, France, Germany, Italy, Netherlands and the United States.

10. Developing regulatory definitions still seems to be a fairly challenging issue for regulatory bodies; however, regulatory definitions have been developed and now are being used by some jurisdictions. All the definitions seem to be common in that they consider a 1-100nm size range, unique properties when outside of 1-100nm, both internal and external structure, and have addressed ways to differentiate between materials which are engineered nanomaterials and traditional chemicals which have nano-scale components by using percentage cut-offs. Challenges do remain due to the lack of an appropriate nomenclature system to differentiate nanomaterials from each other and their bulk and molecular forms. Discussions are underway within ISO TC/229 and IUPAC and at the domestic level to help develop a framework for nomenclature.

11. Challenges such as lack of appropriate test methodologies, information on uses of nanomaterials, and approaches to consider nano-relevant endpoints hinder the risk assessment and risk management process. Countries continue to work domestically by fostering research and internationally to work together to help address these challenges and reduce uncertainties in risk assessment and risk management.

12. Collaboration remains critical in progressing our understanding of nanomaterials as suggested by the many examples provided by respondents on international collaborations at the policy, regulatory, and research level (such as the OECD WPMN).

13. Since this is the final survey under the SG5 operational plan and with its merger now with steering group six on risk assessment approaches, this report recommends that sections 1-3 of this survey become standing items in the tour de table so that this information can continue to be updated and provide direction to the activities on risk assessment approaches and the other steering groups.

14. Lastly, the international regulatory landscape has significantly changed since the original questionnaire in 2008. Majority of jurisdictions are actively using existing frameworks to regulate nanomaterials, while there have been some developments on nano-specific reporting regimes (such as in France). Definitions, although a very challenging and uncertain issue in 2008 have also started to emerge and jurisdictions are now using regulatory and policy definitions to successfully identify nanomaterials. As can be seen from the responses in 2008 and now, the regulatory world of nanomaterials is now better informed and more focused with the increasing availability of scientific information on the safety implications of manufactured nanomaterials.

II: REGULATORY REGIMES: 2010-2011

Introduction

15. The OECD Programme on the Safety of Manufactured Nanomaterials 2009-2011: Operational Plans of the Projects outlines that Steering Group 5 is to complete a final questionnaire and report on Regulatory Regimes over the period of 2010-2011.

16. The previous two questionnaires have indicated that the regulatory landscape for nanomaterials has remained fairly consistent with jurisdictions relying on authorities under existing Legislation to regulate nanomaterials and products containing nanomaterials. However, there have been advancements in certain jurisdictions regarding the definition of nanomaterials. Based on these conclusions, Steering Group 5 has developed this questionnaire that requests information aiming to inform the current regulatory situation in most OECD jurisdictions.

Background

17. Prior to this current questionnaire, SG5 published two questionnaires and reports on regulatory regimes and regulated nanomaterials.

Questionnaire and Report on Regulatory Regimes for Manufactured Nanomaterials

18. This questionnaire, the first of three, was issued in July of 2008 and requested information on the various Legislations in use, during that period, to assess nanomaterials. The main purpose of this original regulatory regimes questionnaire was to identify applicable (current and proposed) regulatory regimes and how they address information requirements related to hazard identification, exposure assessment and mitigation, risk assessment and risk management measures for manufactured nanomaterials. In 2008, information was submitted by various jurisdictions concerning a variety of legislations relevant to nanomaterials.

19. The *Report on Regulatory Regimes for Manufactured Nanomaterials* was finalized in 2009 and was declassified in April 2010. The main conclusions of the report were that none of the respondents reported having Legislation specific to nanomaterials and most respondents indicated that existing authority in current Legislation is sufficient to regulate substances that are nanomaterials, or products containing nanomaterials.

Questionnaire and Report on Regulated Nanomaterials: 2006-2009

20. This questionnaire, the second of three, was issued in August of 2010 and was created as a follow-up questionnaire to the original issued in 2008. The focus of this questionnaire was to update the status of Legislation and gather information on the types and number of nanomaterials notified and/or assessed in various OECD jurisdictions, between January 1, 2006 and December 31, 2009, in order to obtain a snapshot of the regulatory landscape and commercial activity during that time period. The Questionnaire was intended to also collect additional non-confidential business information on the nanomaterials notified, such as the trigger for notification and risk assessment results. The initial intent

was to continue repeating this survey over time to observe trends relating to changes in commercial activity and Legislative requirements.

21. The *Report on Regulated Nanomaterials: 2006-2009* was published in December of 2011. Similar to the previous report, the main conclusions were that jurisdictions reported not having Legislation specific to nanomaterials, but indicated that the authority to regulate nanomaterials and products containing nanomaterials exists in current Legislation. Jurisdictions also provided information on the types of nanomaterials notified which helped inform the OECD WPMN Sponsorship research project. Overall, since the original questionnaire in 2008, the regulatory landscape has remained fairly consistent with the exception of one legislative amendment and advancements in several jurisdictions were in the process of developing of definitions for nanomaterials.

Questionnaire and Report on Regulated Nanomaterials: 2010-2011

22. This questionnaire, the third of three, contained four sections that are related to the oversight of nanomaterials in various OECD jurisdictions. The survey is meant to cover a period of 2010-2011; however, due to delays some information contained in this document is more recent.

23. Section 1: Regulatory Updates (including enacted and pending actions). This section aimed to summarize information from respondents regarding regulatory updates within their respective jurisdictions since December of 2009. Respondents that responded to the previous questionnaires regarding a specific Legislation were able to include any updates that affected the regulation of nanomaterials. Moreover, for specific notified nanomaterials, respondents were able to provide information regarding the testing recommended, testing required and testing information received related to the regulatory risk assessment of the nanomaterial.

24. Section 2: Definitions and/or Legal Approaches for Nanomaterials by Jurisdiction. This section aimed to summarize and compare the existing and proposed definitions for nanomaterials (e.g. regulatory, legislative, policy, etc.) in OECD jurisdictions. All jurisdictions, including those that have existing definitions for nanomaterials, were requested to include information regarding the key elements of regulatory definitions, policy definitions, and/or any other approaches to cover nanomaterials. Also, jurisdictions were invited to include any information about proposed work on a definition for nanomaterials.

25. Section 3: Regulatory Challenges. This section aimed to summarize the existing and anticipated challenges regarding the regulation of nanomaterials within OECD jurisdictions and the actions to address these identified challenges.

26. Section 4: Opportunities for Collaboration. This section aimed to summarize collaboration initiatives among member states and summarize the jurisdictions that sponsor expert workshops under the OECD WPMN.

III: SUMMARY OF RESPONSES

Section 1: Regulatory Updates (Including Enacted and Pending Actions)

Notification/Report/Assessment of Nanomaterials (Annex 1 – Table 2 and 3)

27. Consistent with the last surveys of SG5, WPMN members continue to receive notifications and regulate nanomaterials under their existing legislative and regulatory frameworks. France is the only WPMN member country which has initiated nano-specific regulatory action through its mandatory reporting requirements (use and quantity information) at ≥100g annual quantities. This reporting threshold is lower than those used by other countries under existing regimes. It will be important to observe, within the WPMN, whether this threshold better represents volumes of nanomaterials.

Amendments affecting the Regulation of Nanomaterials (Annex 1 – Table 3)

28. The European Union (EU) has made a number of nano-specific regulatory amendments to their regulations. The European Commission adopted on 18 October 2011 a Recommendation on the definition of Nanomaterial (EC/696/2011). The definition is intended to be used for regulatory and policy purposes and was addressed to the EU Member States, Institutions and Agencies. Since its adoption it has been integrated in to several pieces of EU legislation, been used by the French authorities in their national nanomaterial registry and by the European Chemicals Agency (ECHA) in their implementation of REACH. ECHA has also updated its guidance on safety data sheets, information requirements and safety assessment with respect to nanomaterials (available on the web). The EU has also updated the 'Biocidal Products Directive', and changed to a Biocidal Products Regulation (528/2012) under which the approval of an active substance will not include the nanomaterial form unless nanomaterials have been specifically assessed for their environmental and human health risks. Biocides containing that information will have to be labelled and cannot benefit from the simplified authorisation procedure. Specific requirements have been introduced in Regulations covering cosmetic products (Regulation No 1223/2009) and Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Similarly on 18 December 2013 a proposal has been made to the co-legislators in the European Union on rules applicable to novel food. In addition a number of concrete decisions on 'Eco-labelling' contain specific considerations regarding nanomaterials (2011/383/EU, 2011/381/EU).

29. In addition, Germany is planning to introduce nano-relevant requirements for their Ecolabel Blue Angel. As already mentioned, France has a nano-specific reporting regime to gather use and quantity information for nanomaterials ≥100g. Similar to France, Belgium is considering and Denmark has amended relevant legislations to ensure that relevant authority to establish a nanoproduct database as well as compel reporting to this database for domestic producers and importers of nanoproducts. Lastly, Australia has issued a working definition of nanomaterials for regulatory purposes and provided administrative guidelines for nanoforms of new industrial chemicals.

Information Recommendations/Requirements/Received (Annex 1 – Table 4)

30. In terms of information requirements, there was consistency between all the respondents on the type of information required to conduct nano-relevant assessments. Differences exist between when these requirements are triggered, which is due to the differences in regulatory authorities and regimes in individual countries. Nonetheless, all respondents require physical-chemical, ecotoxicology and human health testing (acute and/or chronic when appropriate) to make safety determination. Canada, under the Canadian Environmental Protection Act, 1999 (CEPA) has received nano-specific test data.

Planned Amendments (Annex 1 – Table 5)

31. Almost all respondents, with the exception of the US are considering ways to amend or provide clarification to their regulations for manufactured nanomaterials. Since this is the last OECD-WPMN survey on the regulatory regimes, it is important to be aware of these new regulatory amendments and clarifications.

32. It is recommended that a specific section be added to the Tour de Table document to request regulatory updates on regulatory regimes from OECD WPMN member countries.

Section 2: Definitions and/or Legal Approaches for Nanomaterials by Jurisdiction

Definitions (Annex II – Tables 6, 7 and 10)

33. All respondents define nanomaterials in a similar manner or have similar thoughts on what elements a nanomaterial definition should include. For example, all responses included a 1-100nm size range for nanomaterials (also referred to as nano-objects; additional discussion may be needed to explore how size is reported, i.e., by mass or particle number), and identified exceptions to this size range due to unique properties. In addition, there was also agreement in the responses on the definition addressing both external and internal nano structures. Of note is that most responses acknowledge that certain traditional chemicals may also have nano-object components and that a percentage cut-off is needed to differentiate these from engineered nanomaterials. For example, Australia considers a substance to meet its nanomaterial definition when the material includes 10% or more of number of particles, while the EU uses a 50% cut-off. Other respondents identified the need for such a threshold to differentiate between engineered nanomaterials and traditional chemicals.

34. Many of the respondents indicated that, within their respective country, a nanomaterial definition may be developed or refined in the future (*Annex II – Table 10)*. As mentioned previously it is important to be aware of these developments to increase consistency across WPMN members.

35. It is recommended that a section be added to the Tour de Table document to request updates on definitions from OECD WPMN member countries.

Differentiating Between Nano and Bulk (Annex II – Table 8)

36. There were some differences noted in how countries are differentiating nanomaterials from bulk forms. For example, Canada's CEPA chemicals program currently uses only a size-based cut-off (1-100nm), while the Canadian Food and Drug Act is interested in the different properties that nanomaterials may have that are not observable in the bulk forms and in individual atoms and molecules. Other countries rely on their nanomaterial definitions to differentiate nanomaterials from their bulk forms, because these definitions can indicate which substances are likely to behave differently than their bulk and molecular counterparts. The EU definition makes no distinction between manufactured or other origins of the nanomaterial except for the Regulation on Food Information for Consumers (1169/2011/EU) which refers to "intentionally produced materials"; it is the size alone that determines if it is a nanomaterial. However, in the Regulation on Cosmetics Products it has been specified that only nanomaterials that are bio-persistent and non-soluble are subject to the special provisions.

Differentiating Between Nano within the Same Class (Annex II – Table 9)

37. According to the responses, countries have not found a consistent way to differentiate nanomaterials within the same class (due to a lacking nomenclature and uncertainties in physical-chemical properties). This seems to be done on a case-by-case basis. For example, nanomaterials of the same class,

but with different surface modifications are assessed differently due to the differences in chemical make-up. However, it is unclear if any of the regulatory regimes can currently differentiate between different shapes of the same nanomaterial of the same size. Some information on this is available in the ECHA IUCLID User Manual for Nanomaterials – which facilitates submitting nanomaterial information under REACH for registration. It is expected as countries become more mature in their experiences with manufactured nanomaterials, they will be able to better differentiate the relevant forms of nanomaterials of the same class.

Section 3: Regulatory Challenges

Nomenclature (Annex III – Table 11)

38. Respondents have indicated that the lack of a nomenclature system continues to pose challenges in regulating nanomaterials within their respective jurisdictions. Without an appropriate nomenclature system for nanomaterials, many countries are unable to differentiate nanomaterials from each other and from bulk/molecular forms. However, domestic and international work has begun to address this challenge. For example, under ISO TC/229, a joint ISO-International Union on Pure and Applied Chemistry (IUPAC) has been initiated to develop a chemical-based nomenclature system, the EU has initiated a call for research proposals for the development of a systematic framework for naming of nanomaterials, and the US Environment Protection Agency is working with its Chemical Abstract Service (CAS) to develop a nomenclature system for carbon nanotubes.

Hazard Identification (See Annex III – Table 12)

39. The majority of hazard-associated challenges identified by respondents are associated with the need for appropriate test methodologies for the characterization and measurement of nanomaterials in different environmental and human health tests. Respondents continue to foster relevant research capacity domestically and internationally, including discussions within the OECD WPMN projects, to help address physical-chemical and methodology related challenges (e.g., engagement in the WPMN test guideline amendments). Of note is that the US has identified challenges with regards to whether hazard identification methods are applicable to nanomaterials broadly or to classes of nanomaterials. This is significant because identifying which methods are relevant to which nanomaterials or classes of nanomaterials will allow regulatory bodies to better focus testing requirements. This is the premise of the WPMN Expert Workshop being planned in the US for 2014.

Health and Safety (See Annex III – Table 13)

40. In terms of health and safety challenges associated with occupational exposure prevention and control of nanomaterials, many of the responses indicated that current domestic guidelines and regulations are being used for nanomaterials, with additional guidance and/or outreach needed to inform relevant stakeholders of nano-specific challenges. Almost all responding countries support ongoing research to inform on safety in occupational settings, while the EU is developing specific guidance for employers and workers involved in nano-related activities. In addition, SafeWork in Australia has developed the Work Health and Safety Assessment Tool for handling engineered nanomaterials and is also working on developing methods for nanomaterials exposure measurement to be used by industrial hygienists.

Risk Assessment Methodologies(See Annex III – Table 14)

41. The primary risk assessment challenges identified in the responses were associated with: (a) the lack of specific test methods for manufactured nanomaterials; (b) uncertainties on how to adapt existing regulations and guidelines to nanomaterials; (c) lacking foundational scientific information on extrapolations within classes of nanomaterials, and between traditional chemicals and nanomaterials; and

(d) lacking risk assessment methodologies on how to use nano-relevant endpoints in risk assessments (such as using the increased specific surface area as a predictor of hazard). All responding countries are supporting relevant projects domestically and internationally to help inform on these challenges (e.g., working together under the WPMN Steering Group on Regulatory Regimes and Risk Assessment Approaches).

Risk Management and Nanomaterials in Commerce (See Annex III – Table 15)

42. To better manage risks associated with nanomaterials, responding countries highlighted challenges associated with: (a) knowledge of use profiles of nanomaterials; and (b) lack of test methods to mitigate exposures. To better inform risk management, countries are currently engaged in the development of nano-registries (e.g., France, Denmark, German UBA report on a European register for products containing nanomaterials), regulatory instruments (e.g., the EPA rule under the Toxic Substances Control Act to gather information on the uses of nanomaterials or the EU intention to revise the information requirements in REACH Annexes for nanomaterials), and various tools (e.g., web platforms and stakeholder discussions) to increase knowledge on the risk management of manufactured nanomaterials.

Research (See Annex III – Table 16)

43. All responding countries indicated that research activities are being supported domestically and internationally to help reduce gaps in risk assessment and risk management of manufactured nanomaterials. For example, the EU identified the following challenges in their 2013 Work Program: (1) Safety in nanoscale production and products; (2) Nanomaterials safety assessment: Ontology, database(s) for modeling and risk assessment; (3) Development of a systematic framework for naming and assessing safety of the next generations of nanomaterials being developed for industrial applications; and (4) Development of methods and standards supporting the implementation of the Commission recommendation for a definition of nanomaterial. To support these challenges, the NANoREG projects, along with other projects have been initiated. Countries are also relying on more global projects to help reduce uncertainties in risk assessments, such as the OECD WPMN Sponsorship program, towards which contributing countries have spent a lot of research funds. Research continues to evolve as challenges and uncertainties with risk assessments and risk management changes and becomes better informed.

Impact of Regulatory Actions on Innovation and Economic Growth (See Annex III – Table 17)

44. None of the responses identified any negative impacts of regulatory actions associated with manufactured nanomaterials on innovation and economic growth. All responses indicated that there is a strong level of existing stakeholder outreach and consultation process, or a review process to assess impacts of regulatory changes to ensure that innovation is not hindered, while protecting the environment and human health.

Labelling/Communication of Nanomaterials (See Annex III – Table 18)

45. Responses on labelling/communication of nanomaterials indicated that countries are only in the preliminary stages of discussing the needs for labelling and its impacts on the marketplace and are either reviewing current strategies or commissioning reviews on regulatory aspects of nanomaterials, including labelling. In the EU there are labelling requirements introduced for Cosmetic products (1223/2009), Biocidal products (528/2012) and food (1169/2011). The European Commission has proposed to the co-legislators a Regulation on Labelling of medical devices COM(2012)542.

Section 4: Opportunities for Collaboration

46. All responding countries are working collaboratively, either domestically, bilaterally or internationally under groups such as the OECD WPMN to address environment and human health safety implications of manufactured nanomaterials. Many countries continue to sponsor expert workshops, e.g., the WPMN Expert workshops on test guidelines for nanomaterials, and it is anticipated that those countries which do not sponsor these meetings would still actively participate in them.

Section 5: Next Steps

47. From the responses received, it can be concluded that countries continue to use and adapt their existing legislative and regulatory frameworks to regulate nanomaterials. New legislations, such as the France nano registry are important initiatives to provide marketplace penetration of manufactured nanomaterials. Some commonalities in definitions have also started to emerge, for example, a percentage cut-off to differentiate between engineered nanomaterials and traditional chemical substances which may contain some nano-sized particles. In addition, the 1-100nm size range has become fairly consistent across all definitions.

48. Several regulatory challenges with nanomaterials were highlighted by respondents, including the need for appropriate test methodologies and approaches to apply endpoints in risk assessments and risk management. The merger of Steering Group 5 and Steering Group 6 will help ensure that these approaches are developed in a way that feeds directly into regulatory risk assessment and management activities. Further, responding countries also continue to support and initiate research projects to help address risk assessment challenges and uncertainties and share this information internationally.

49. Lastly, maintaining current knowledge on regulatory regimes in various jurisdictions is important for the WPMN as it will continue to inform priorities and direction. *It is recommended that the Sections 1-3 of this survey be included as items of the Tour de Table to more efficiently keep up to date on the various regulatory activities among OECD WPMN member countries.* This information will be useful to inform the work of the WPMN as a whole and will help focus risk assessment projects.

IV.ANNEXES

Annex I: Responses Received on Regulatory Updates (Section 1 of the Questionnaire)

Table 1. Legislation/Agencies by Country[2].

Country	Agencies
Australia	NICNAS- Industrial Chemicals Notification and Assessment Scheme
	TGA- Therapeutic Goods Administration
	SafeWork Australia- Occupation health and safety and standard setting body for workplace chemicals
Canada	Canadian Environmental Protection Act (1999) (CEPA) 1. New Substances Notification Regulations (2005)
	Food and Drugs Act (F&DA) 1. Medical Devices Regulations 2. Food and Drug Regulations 3. Natural Health Products Regulations
Denmark	The Danish Chemicals Act
European Union[3]	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EC No 1907/2006)
	Classification, Labelling and Packaging (CLP) Regulation (EC No 1272/2008/EC)
	Biocides Directive / Biocidal Products Regulation (EU) 528/2012) (applicable from 1 September 2013)
France	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national

[2] In this document when reference is being made to the 'European Union' it implies that the legislation is applicable in all the 28 EU Member States, also those Member States who are not Party to the OECD. In addition, some EU Member States provided separate responses to the survey to highlight domestic strategies. Responses from EU Member States which referenced EU Regulations were removed for clarity since these were included as part of the EU response.

[3] The European Union has legislation in place with specific provisions for nanomaterials as regards Regulation on Cosmetic Products (Regulation No 1223/2009), Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. On 18 December 2013 a proposal has been made to the co-legislators in the European Union on rules applicable to novel food. In addition a number of concrete decisions on 'Eco-labelling' containing specific considerations regarding nanomaterials have been made. These legal acts are not further described in the response to this questionnaire.

Germany	2001/83/EC
United States	Toxic Substances Control Act (TSCA)

Table 2. Notification/Report/Assessment of Nanomaterials.

Country	**Notification/Report and/or Assessment of Nanomaterials?**	**Name of Legislation under which Nanomaterials were Notified/Reported/Assessed**
Australia	Yes	Industrial Chemicals (Notification and Assessment) Act 1989 (NICNAS)
	Yes	Therapeutic Goods Act 1989 and Therapeutic Goods Regulations 1990 (TGA)
Canada	Yes	Canadian Environmental Protection Act (1999)
	Yes	Food and Drugs Act (F&DA)
Denmark	No	
European Union	Yes	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EC No 1907/2006)
	Yes	Classification, Labelling and Packaging (CLP) Regulation (EC No 1272/2008/EC)
	No	Biocides Directive
France	Yes	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national.
Germany	Yes	2001/83/EC
United States	Yes	Toxic Substances Control Act (TSCA)

Table 3. Legislative Amendments.

Country	**Amendments Affecting Regulation of Nanomaterials ?**	**Legislation**	**Description**
Australia	No		NICNAS has issued a working definition of nanomaterials for regulatory purposes and administrative guidelines for nanoforms of new industrial chemicals.

Canada	No	CEPA (1999)	Although no specific legislative or regulatory amendments are being planned in Canada, further clarity on regulatory requirements with respect to nanomatrials is provided in the form of an Advisory Note.
	No	F&DA	
Denmark	Yes		The Danish Chemicals Act has been amended in 2013 to ensure that the Danish Minister of Environment has the necessary authorizations to write a ministerial order with detailed rules on the establishment of a Danish nanoproduct database (i.e. a database on mixtures and articles containing or releasing nano materials) – as well as a reporting duty to this database for producers and importers of nanoproducts for the Danish market. The Amendment Act was passed in the Danish Parliament on 12. March 2013, and the Danish Environmental Protection Agency is presently working on the detailed ministerial order, which is expected to come into force in the beginning of 2014. The Danish nanoproduct database will not cover medical equipment, pharmaceutical products, food, food contact materials, feeds (all of which are not covered by the Chemicals Act) and pesticides, biocides and cosmetics (where there is EU-regulation with regard to nano)
European Union	Yes	REACH	Annex II of REACH has been amended (note: with no specific reference to nanomaterial) to better address e.g. physico-chemical parameters also related to nanomaterial characterisation. Respective ECHA guidance on Safety Data Sheets (with reference to nanomaterial) has been made available via the web[4]. Furthermore, an update to the ECHA guidance on Information Requirements and Chemical Safety Assessment (IR-CSA) with respect to nanomaterials has been issued and made available via the web. Technical guidance for IUCLID 5.2 has also been provided that outlines best practices to document information on nanomaterials in IUCLID[1]. In IUCLID nanomaterials can be reported as different nanoforms under REACH registration and C&L.
	No	CLP Regulation	
	Yes	Biocides Directive	The current legal framework regarding the placing on the market of biocidal products, the 'Biocidal Products Directive' has been revised and will be replaced as of 1 September 2013 by the new 'Biocidal Products Regulation'. Under the new Regulation, the approval of an active substance will not include the nanomaterial form unless nanomaterials have been specifically assessed as regards the risks to the environment and to health. Biocides containing nanomaterial will have to be labelled with that information and cannot benefit from the simplified authorisation procedure.
France	Yes	Déclaration	This Legislation is specific to nanomaterials

[4] http://echa.europa.eu/regulations/nanomaterials

		obligatoire des nanomatériaux manufacturés mis sur le marché national	Code de l'Environnement - partie législative, Livre V : Prévention des pollutions, des risques et des nuisances, Titre II : Produits chimiques, biocides et substances à l'état nanoparticulaire, Chapitre III : Prévention des risques pour la santé et l'environnement résultant de l'exposition aux substances à à l'état nanoparticulaire, Articles L523-1 à L523-5 (créé par l'Article 185 de la Loi n° 2010-788 du 12 juillet 2010) ; Code de l'Environnement - partie réglementaire : Article R523-12 à D523-22 (créé par les articles 1 et 2 du Décret n°2012-232 du 17 février 2012) ; Arrêté du 6 août 2012 relatif au contenu et aux conditions de présentation de la déclaration annuelle des substances à l'état nanoparticulaire, pris en application des articles R. 523-12 et R. 523-13 du code de l'environnement. Voir le site Internet R-Nano.fr : Déclaration des substances à l'état nanoparticulaire : https://www.r-nano.fr/ voir Zone de documentation règlementaire; voir Tutoriel - Document d'aide aux utilisateurs déclarants : https://www.r-nano.fr/download?fileId=297196f0-7262-4dbc-a734-e2410d8f8307 An English version of this site does exist but the main parts are only in French.
Germany	Yes		This Legislation is specific to nanomaterials Regulation (EU) No 528/2012 of the European parliament and of the council of 22 May 2012 concerning the making available on the market and use of biocidal products According to Article 6 (6) of Regulation (EC) No 66/2010 the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. In the recently enacted product group criteria (e.g. all-purpose cleaners and sanitary cleaners (Commission Decision 2011/383/EU), lubricants (Commission Decision 2011/381/EU)) it was introduced that the proof that substances do not meet the criteria for these classifications shall be specific to the particular form of the substance, i.e. need also to be specific for nanoforms. The assessment and verification criteria refer as minimum data requirement to Annex VII of REACH (standard information requirements for substances manufactured or imported in quantities of 1 ton or more). For product groups which may contain nanomaterials (like lubricants) it is planned that such

			requirements are also introduced in the criteria for the German Ecolabel Blue Angel. However for nanomaterials it needs to be referred as minimum data requirement to Annex VIII of REACH (standard information requirements for substances manufactured or imported in quantities of 10 tons or more).
Italy	No		
United States	No		

Table 4. Recommended Testing Information for Notified/Reported Nanomaterials.

Country	Legislation	Recommended Testing	Required Testing for Industrial Chemicals	Received Testing
Australia	NICNAS	-	As a minimum requirement particle size information (primary particle size and number-weighted size distribution) will be required in the following cases: - where the chemical is an industrial nanomaterial - where it can be anticipated or there is uncertainty that the chemical could be a nanomaterial and exposure to human health or the environment is expected based on use scenarios AND -The chemical is introduced as a solid/powder or as a dispersion and is insoluble (e.g. water insolubility < 1 mg/L); and/or known to be biopersistent. In addition to the particle size information, the following additional data, above that which is normally required for bulk chemicals under a particular notification category may also be requested (where applicable) under certain circumstances. - method of production	-

			- medium identity - medium conditions (identity and concentration of stabilizers, ionic strength and ionic composition) - shape - crystalline phase - agglomeration/aggregation state - composition (purity/impurities) - surface area - surface charge - surface chemistry (such as coatings and modifications) - toxicity data will be requested on a case-by-case basis These additional data requirements will be determined on a case by case basis and are subject to variation as new knowledge regarding toxicity of nanomaterials is developed.	
	TGA	Consistent with the legislation	Consistent with the legislation	Consistent with the legislation
	SafeWork	-	-	-
Canada	CEPA (1999)	Acute toxicity testing (oral, dermal and/or inhalation) skin irritation skin sensitisation repeated dose toxicity (oral and inhalation) *in vitro* mutagenicity *in vitro* clastogenicity *in vivo* genotoxicity The average particle size and the particle size distribution are requested during the	Dependent on import/manufacture volume-ranged from Acute toxicity testing to the full suite quoted in (a) above. Under CEPA 1999, testing is required for all new substances, including nanomaterials, in a tiered manner according to the quantity to be manufactured or imported. This testing may include: phys-chem data, ecotoxicology, mammalian toxicology, mutagenicity and skin irritation/sensitization tests.	Acute oral toxicity acute inhalation toxicity skin irritation *in vitro* skin and eye irritation skin sensitization repeated dose toxicity (inhalation and oral) *in vitro* mutagenicity *in vitro* clastogenicity *in vivo* genotoxicity

		risk assessment process.	Information specific to nanomaterials has been required in Significant New Activity (SNAc) Notices, such as: agglomeration (aggregation) state, shape, surface area and surface charge of the substance, water solubility, and leachability (as appropriate).	Acute ecotox endpoints, leaching studies, industrial release information, physical-chemical characterization
	F&DA	In order to identify and assess potential risks and benefits (where applicable) of nanomaterials, the Department may require the following types of information, when relevant: Manufacturing methods; Critical Process Parameters (CPP) (Note: not required for foods) Quality of the product; Critical Quality Attributes (CQA) (Note: not required for foods) Quality of Nanomaterial; Critical Material Attributes (CMA): Characteristics, and physical chemical properties of the nanomaterial such as: composition, identity, purity, morphology, structural integrity, catalytic or photo-catalytic activity, particle size/size distribution, electrical/mechanical/optical properties, surface-to-volume ratio, chemical reactivity, surface area/chemistry/charge/structure/shape,	None	None

		water solubility/dispersibility, agglomeration/aggregation (or other properties), and descriptions of the methods used to assign these determinations; Toxicological, eco-toxicological, metabolism and environmental fate data that may be both generic and specific to the nanomaterial if applicable; and, Risk assessment and risk management strategies, if considered or implemented. Future guidance documents that are specific to regulatory program areas will be developed in a manner that is in accordance with the unique parameters of program-specific legislative and regulatory authorities.		
Denmark	The Danish Chemicals Act	-	-	-
European Union	REACH	Tiered information requirements of the REACH registration of 1 t/y or more are as reported in the OECD-WPMN Questionnaire 2008. The information requirements can be fulfilled via non-testing or testing approaches under the obligatory data sharing regime between registrants of the same substance. Staggered timelines apply for registration of phase-in substances (including their forms); while for non-phase-in substances the registration is a	Under REACH the information requirements can be fulfilled via non-testing or testing approaches, with animal testing the last option. The requirements differ (for example, depending on tonnages placed on the market), but include parameters such as: - PhysicoChemical - Toxicological - Ecotoxicological - environmental fate and behaviour Specific advice on how to comply with the	The information on the registration of high volume, CMR and/or PBT/vPvB (>100 t/y) phase-in substances (including their forms) is made available via the ECHA website. Compliance checks and evaluation of the Testing Proposals are an on-going process.

		precondition for the market access. (see below)	above general provisions specifically for nanomaterials has been made available on ECHA's web site since April 2012: http://echa.europa.eu/regulations/nanomaterials	
	CLP	This refers to available information generated on the basis of non-testing or testing.	This refers to available information generated on the basis of non-testing or testing approaches. Further testing may be required in certain cases on physic-chemical parameters.	See ECHA CL Inventory.
	Biocides Directive	-	-	-
France	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national	-Méthode d'identification des **impuretés** : Fluorescence X ; ICP/OES ; ICP/MS ; connaissance du procédé ; HPLC ; GC ; CE ; RNM ; FT-IR ; Autre + Ligne directrice de test à préciser ; -Méthode de détermination de la **taille** : MET ; MEB ; AFM ; Autre + Ligne directrice de test à préciser ; -Méthode de détermination de la **distribution** : DLS ; Diffraction laser ; Sédimentation sous champ terrestre ; Sédimentation centrifuge ; Raman (NTC) ; Autre + Ligne directrice de test à préciser ; -Méthode de détermination de la **taille moyenne des agrégats (**ordre de grandeur ou intervalle) avec écart type : saisie libre + Ligne directrice de test à préciser ; -Méthode de détermination de la **taille des agglomérats** avec écart type : saisie	-	-

		libre + Ligne directrice de test à préciser ; Méthode de la **caractérisation de la forme** : MET ; MEB ; AFM ; Autre + Ligne directrice de test à préciser ; -Méthode de détermination de la **surface spécifique** : BET avec azote ; Calcul à partir MET/ME ; SAXS ; Autre ; -Méthode utilisée pour l'**analyse de l'état cristallin** est obligatoirement la diffraction X + Ligne directrice de test à préciser ; -Méthode utilisée pour l'**analyse de la charge surfacique** est obligatoirement la zétamétrie + Ligne directrice de test à préciser. Voir aussi Tutoriel - Document d'aide aux utilisateurs déclarants : https://www.r-nano.fr/download?fileId=297196f0-7262-4dbc-a734-e2410d8f8307		
Germany	Regarding 2001/83/EC	Citation from assessment report "In case the trigger value of 10 ng/L of ferumoxytol is exceeded, a full Phase II environmental risk assessment has to be supplied. However, as the active ingredient ferumoxytol is not a standard small molecule drug, a special study design will be necessary and not all of the base set studies can be readily performed with the active ingredient. Therefore the	See Recommended Testing	None of the recommended/required testing was received. CHMP declared available guidance "to be not applicable" in that case.

		applicant is asked to seek regulatory advice on conducting the required studies. In case the applicant identifies problems related to the nature of the active ingredient when conducting the standard OECD studies, a detailed report, e.g. compiled from information available on fate and effects of the active ingredient in the environment could be supplied (references would need to be attached as full text). Especially of interest is the question whether potentially excreted particles retain their nanosize. Reasons for not conducting the Phase II base set studies should also be justified."		
United States	TSCA	An algal toxicity study	EPA has issued requirements in consent orders triggering certain testing after an aggregate production volume or specified time period. Testing required included a 90-day chronic inhalation study, physical/chemical properties such particle size distribution, dustiness testing, and thermogravimetric analysis, workplace monitoring, and mobility in soil. For carbon nanotubes EPA has also required data on their structure such ring size, hexagonal array orientation, axis alignment, deformities, and nanotube length.	Two 90 day inhalation studies, workplace monitoring, and physical chemical properties for several substances including particle size distribution, dustiness testing and carbon nanotube structural data.

Table 5. Planned Amendments to Existing Legislation.

Country	**Legislation**	**Planned Amendment**
Australia	NICNAS	Australia is reviewing its regulatory framework for industrial chemicals for its ability to manage the risks from their nano-forms. This work is progressing in consultation with stakeholders. No definitive proposals for

		legislative amendments have yet been agreed
	TGA	None planned
	SafeWork	-
Canada	CEPA (1999)	None planned
	F&DA	None planned
Denmark	The Danish Chemicals Act	The Danish Chemicals Act has been amended in 2013 to ensure that the Danish Minister of Environment has the necessary authorizations to write a ministerial order with detailed rules on the establishment of a Danish nanoproduct database (i.e. a database on mixtures and articles containing or releasing nano materials) – as well as a reporting duty to this database for producers and importers of nanoproducts for the Danish market. The Amendment Act was passed in the Danish Parliament on 12. March 2013, and the Danish Environmental Protection Agency is presently working on the detailed ministerial order, which is expected to come into force in the beginning of 2014. The Danish nanoproduct database will not cover medical equipment, pharmaceutical products, food, food contact materials, feeds (all of which are not covered by the Chemicals Act) and pesticides, biocides and cosmetics (where there is EU-regulation with regard to nano)
European Union	REACH	According to the Commission Communication on the Second Regulatory Review of Nanomaterials, the REACH regulation forms the best framework for the risk management of nanomaterials when they occur in substances and mixtures, but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013. The forthcoming impact assessment of possible amendments to some of the REACH Annexes (to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations) will address the specific requirements.
	CLP	None planned
	Biocides Directives	The current legal framework regarding the placing on the market of biocidal products, the 'Biocidal Products Directive' has been revised and will be replaced as of 1 September 2013 by the new 'Biocidal Products Regulation'. Under the new Regulation, the approval of an active substance will not include the nanomaterial form unless nanomaterials have been specifically assessed as regards the risks to the environment and to health. Biocides containing nanomaterial will have to be labelled with that information and cannot benefit from the simplified authorisation procedure.
France	-	Des discussions sont en cours au niveau européen sur l'encadrement réglementaire des substances à l'état nanoparticulaires. Différentes options sont envisagées dont la création d'un registre européen. Plusieurs Etats Membres et

		représentants du Parlement Européen considèrent qu'une réglementation spécifique devrait être développée.
Germany	-	Together with the BfR and BAuA UBA proposed a concept how to amend REACH legislation regarding nanomaterials. The concept was presented on EU technical level and will be published soon at the agencies websites.
Italy	Yes	A national regulatory scheme aimed at gathering basic information on nanomaterials manufactured, imported and put on the Italian market on their own or contained in mixtures or articles and eventually manufactured or used in R&D is under development. The draft project is now under public consultation among national experts and stakeholders.
United States	No	

Annex II: Definitions and/or Legal Approaches for Nanomaterials by Jurisdiction (Section 2 of the Questionnaire)

Table 6. Working or Formal Definitions for Nanomaterials by Jurisdiction.

Country	Legislation	Definition
Australia	NICNAS	NICNAS 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 a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial. For TGA the general international definition is accepted. For SafeWork the ISO definition is accepted and used in Safe Work Australia's model Codes of Practice for (a) Workplace Labelling and (b) Preparation of Safety Data Sheets (SDS)

		http://www.safeworkaustralia.gov.au/sites/swa/model-whs-laws/model-cop/pages/model-cop
	TGA	None
	SafeWork	None
Canada	CEPA (1999) F&DA	The Acts and Regulations administered by Health Canada have no explicit reference to nanomaterial at this time. Health Canada uses existing legislation and regulations to mitigate the potential health risks of nanomaterials and help realize their health benefits. According to the "Policy Statement on Health Canada's Working Definition for Nanomaterials", Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be nanomaterial if: a. It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or; b. It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena. For the purposes of this definition: i. The term "nanoscale" means 1 to 100 nanometres, inclusive; ii. The term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and, iii. The term "manufactured" includes engineering processes and the control of matter. Available at this website: http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php This Working Definition targets drugs, biologics, medical devices, natural health products, food and food packaging, pesticides, new and existing substances (industrial and consumer chemicals and polymers), consumer products and cosmetics. The Working Definition also targets the Workplace Hazardous Materials Information System, which is coordinated by Health Canada to promote the safety of workers who handle nanomaterials and products containing nanomaterials. This Working Definition is not written in regulations; rather it is applied within existing legislative and regulatory frameworks across the Department to support the assessment of nanomaterials and to provide assistance to manufacturers and other stakeholders in meeting their respective statutory obligations. Its key objective is to identify nanomaterials for

		information gathering.
Denmark	The Danish Chemicals Act	Denmark will use the definition of nanomaterials in the Commission Recommendation no. 696 of 18. October 2011 in the ministerial order on the establishment of the nanoproduct database. Denmark has as yet (March 2013) no formal working definition for nanoproducts. Such a definition is needed for the nanodatabase which is mentioned under section 2.
European Union	European Commission Recommendation on the definition of Nanomaterial REACH CLP Regulation Biocides Directive	The EU definition is an overarching one whose scope may be further determined via its application in specific legislation. For example in some cases it may only be of legislative relevance to address a smaller group of nanomaterials than those covered by the size depend definition e.g. by narrowing the scope. This is the case in the Biocidal Products Regulation that does not cover 'incidental' nanomaterials. Such precisions do not alter the definition of nanomaterial *per se*, only the number of nanomaterials under that definition subject to specific requirements. The EU definition in full: A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials. http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm To note, it has already been included in the abovementioned Biocides legislation and work is on-going with a view to build-in the definition in other EU level legislation such a Regulation on Cosmetics Products and Regulation on Food Information to Consumers (EU) 1169/2011. Until amended the definition in the Food Regulation reads: "engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

		(i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material; Until amended the definition in the Cosmetics Regulation reads: “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;
France	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national	" Substance à l'état nanoparticulaire ” : substance telle que définie à l'article 3 du règlement (CE) n° 1907/2006, fabriquée intentionnellement à l'échelle nanométrique, contenant des particules, non liées ou sous forme d'agrégat ou sous forme d'agglomérat, dont une proportion minimale des particules, dans la distribution des tailles en nombre, présentent une ou plusieurs dimensions externes se situant entre 1 nm et 100 nm. Cette proportion minimale peut être réduite dans des cas spécifiques lorsque cela se justifie pour des raisons tenant à la protection de l'environnement, à la santé publique, à la sécurité ou à la compétitivité. Elle est précisée par un arrêté conjoint des ministres chargés de l'environnement, de l'agriculture, de la santé, du travail et de l'industrie. Par dérogation à cette définition, les fullerènes, les flocons de graphène et les nanotubes de carbone à paroi simple présentant une ou plusieurs dimensions externes inférieures à 1 nm sont à considérer comme des substances à l'état nanoparticulaire. Aux fins de cette définition, les termes " particule ”, " agglomérat ” et " agrégat ” sont définis comme suit : a) On entend par " particule ” un fragment de matière possédant des contours physiques bien définis ; b) On entend par " agrégat ” une particule constituée de particules fortement liées ou fusionnées ; c) On entend par " agglomérat ” un amas de particules ou d'agrégats faiblement liés dont la surface externe globale correspond à la somme des surfaces de ses constituants individuels. " Substance à l'état nanoparticulaire contenue dans un mélange sans y être liée ” : substance à l'état nanoparticulaire incorporée intentionnellement dans un mélange dont elle est susceptible d'être extraite ou libérée dans des conditions normales ou raisonnablement prévisibles d'utilisation ;
Germany	Yes	EU COM Recommendation: natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an

		aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials. For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows: — 'particle' means a minute piece of matter with defined physical boundaries, — 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components, — 'aggregate' means a particle comprising strongly bound or fused particles For human pharmaceuticals a more inclusive definition was discussed at EMA in 2010 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2009/12/event_detail_000095.jsp&mid=WC0b01ac058004d5c3).
Italy	No	
United States	No	

Table 7. Summary of key elements for a definition of nanomaterials as identified by countries.

Country	**Legislation**	**Key Elements in a Definition for Nanomaterials**
Australia	NICNAS	NICNAS – Key elements that should be included in a regulatory definition are included in the working definition above. This enables regulatory effort to be directed to substances that require assessment.
	TGA	-
	SafeWork	-
Canada	CEPA (1999)	Size/Dimensions: It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or; 'Unique' Nanoscale properties: It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena or % by number in the nano-scale Scope and targeted and intended use should be included: For example, HCs Working Definition targets drugs, biologics, medical devices, natural health products, food and food packaging, pesticides, new and existing
	F&DA	

		substances (industrial and consumer chemicals and polymers), consumer products and cosmetics. Working Definition also targets the Workplace Hazardous Materials Information System, which is coordinated by Health Canada to promote the safety of workers who handle nanomaterials and products containing nanomaterials. It is to be applied across all of these program areas in Health Canada to support the assessment of nanomaterials and to provide assistance to manufactures and other stakeholders in meeting their respective statutory obligations, pursuant to applicable Acts and Regulations.
Denmark	The Danish Chemicals Act	In order to establish a mandatory registration of nanoproducts a number of elements related to the product are needed. These include the following elements: - Threshold for release of (free) nanomaterials - Threshold for the amount of nanomaterial in the product
European Union		Existing definition.
France	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national	Définition faite pour les besoins de la Déclaration oligatoire des nanomatériaux manufacturés mis sur le marché national. Les éléments clés de la définition permettent l'identification univoque de la substance à l'état nanoparticulaire.
Germany	-	Size, number based size distribution with certain percentage of nano-fraction, should have a minimum threshold nanoscale.
United States	TSCA	A definition of a nanomaterial could include elements of size less than 100 nanometers, distribution in sizes around the mean size, consideration different morphology or shapes, e.g., spheres, rods, ellipsoids, cylinders, needles, wires, fibers, cages, hollow shells, trees, flowers, rings, tori, cones, or sheets and consideration of coatings. A definition would be used to identify materials subject to specific information requests.

Table 8. How jurisdictions differentiate between Nanomaterials and their bulk forms.

Country	**Legislation**	**Differentiation Between Nanomaterials and Their Bulk Forms**
Australia	NICNAS	For industrial chemicals, by use of the working definition above.

	TGA	For therapeutic goods Australia doesn't differentiate on safety grounds, however quality (Good Manufacturing Practice) has to be guaranteed.
	SafeWork	SafeWork differentiates based on the ISO definition. For work health and safety (WHS) purposes, hazard classification is based on properties, irrespective of size.
Canada	CEPA (1999)	Determination of primary particle size Particle size
	F&DA	Health Canada's current interest mainly lies with determining what potentially unfamiliar or different properties and their effects may be evident in nanomaterials that are not observable in the "bulk" form, and are different from the properties of individual atoms and molecules. Many biological substances, structures and processes are at the nanoscale. Materials that either naturally exist within the nanoscale size range, or exhibit nanoscale properties/phenomena in nature will not automatically be re-classified as nanomaterials (e.g. naturally occurring chemical or biological molecules like nucleic acids/DNA/proteins, micro-organisms or cell structures like flagella or ribosomes, etc). Health Canada currently regulates some biotechnology-based health products, and at this time, Health Canada has no reason to reconsider those products as nanomaterials if they simply fall within the nanoscale. However, an example where a natural macromolecule would be considered to be a nanomaterial is the class of Ribonucleic acid (RNA) nanostructures designed specifically to achieve higher order structures, and ultimately, increased functionality.
Denmark	The Danish Chemicals Act	We use commission recommendation 696 when possible.
European Union		Through application of the European Commission Recommendation on the definition of Nanomaterial or other definitions applicable in EU law.
France	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national	par application de la définition.
United States	TSCA	Particle size and particle size distribution.

Table 9. How jurisdictions differentiate between nanomaterials within the same size class.

Country	Legislation	Differentiation Between Nanomaterials Within the Same Size Class
Australia	NICNAS	NICNAS currently assesses each nanomaterial on its merits. Criteria for distinguishing substances within the same size class have yet to be developed.
	TGA	-
	SafeWork	SafeWork uses hazard classification that is based on properties.
Canada	CEPA (1999)	Chemical name, manufacturing methods, notifier description (TEM, size distributions, etc.) Particle size, presence of coatings/surface modifications.
	F&DA	No differentiation is made
Denmark	The Danish Chemicals Act	No formal differentiation
European Union	REACH) (EC No 1907/2006)	At present there is no legally defined single way of differentiating between different forms or grades of the same nanomaterial. Under REACH it is a responsibility for firms to demonstrate safe use of substances. It is therefore inferred that due consideration is given to the hazard and risk profile of all the forms and grades of the substance also when several of these forms or grades are nanomaterials. Due to the many factors that influence and determine hazards from one nanoform or grade to another these considerations are currently subject to specific considerations that must be made and documented case-by-case. Much the same applies pursuant to the CLP Regulation. It should be noted that by February 2014 no nanoform has been listed pursuant to the Regulation on Biocidal Products. Nevertheless it is clear that some of the same considerations as under REACH apply when it comes to listing active ingredients on the positive list. Like for other forms or grades of substances, when nanomaterial forms are positive listed it must be described and named in a way ensuring that the data supporting the inclusion exactly matches the description. So far these considerations take place on a case-by-case basis. .
	CLP Regulation	
	Biocides Directive	
France	Déclaration obligatoire des nanomatériaux manufacturés mis sur le marché national	Par application de la définition et par indication des caractéristiques permettant l'identification de la substances à l'état nanoparticulaire. Voir Tutoriel - Document d'aide aux utilisateurs déclarants : "**6 Identité de la substance, champs à renseigner**", pages 9 à 20: https://www.r-nano.fr/download?fileId=297196f0-7262-4dbc-a734-e2410d8f8307

Germany	-	Different coatings, sizes, shapes, size distributions, crystal modifications.
United States	TSCA	Nanomaterials of the same size class could be differentiated based on particle size distribution, morphology or shape, coating, and volume specific surface area.

Table 10. Whether jurisdictions plan to develop a definition for nanomaterials in the future.

Country	**Legislation**	**Yes**	**No**	**Uncertain at This Time**
Australia	NICNAS			
	TGA			
	SafeWork			
Canada	CEPA (1999)			
	F&DA			
Denmark	The Danish Chemicals Act	We anticipate that we need a definition of the nanoproducts for which registration to the Danish Nanoproduct database is needed.		
European Union	-		A Definition exists already.	
France	-			
Germany	-		Will be involved in the discussion on EU level for amendment of the EU COM Recommendation in 2014.	
Italy		The EU COM foresees to update the recommended definition within 2014 according to new scientific and technical developments. It is envisaged to implement the recommended definition by EU COM in any relevant national regulatory regimes.		

United States	TSCA	EPA is developing regulations specific to nanomaterials under TSCA that would define the nanomaterials subject to that regulation. The regulation would require information about the manufacturing, processing and use of certain types of nanoscale materials.		

Annex III: Regulatory Challenges (Section 3 of the Questionnaire)

Table 11. Nomenclature for Nanomaterials.

Country	Legislation	Challenge	Action
Australia	NICNAS	Consistency with international nomenclature	Engagement with standards setting bodies such as ISO
	TGA	The variation and potential change as the technology advances	Follow scientific rationale for processes and provide supportive role with International bodies
	SafeWork		
Canada	CEPA (1999)	Lack of a specific nomenclature system for nanomaterials limits our ability to appropriately distinguish between nanomaterials and nanomaterials and their bulk counterparts. The INCI name, International Nomenclature Cosmetic Ingredient, is mandatory for ingredient labelling of cosmetic products. INCI does not have a specific naming system to identify for nanomaterial ingredients.	Participation in ISO TC 229 and work with IUPAC to develop nomenclature systems for classes of nanomaterials.
	F&DA	-	-
Denmark	The Danish Chemicals Act	Apart from the general challenges related to nomenclature of nanomaterials, which DK shares with the rest of EU, DK is not facing specific challenges regarding nomenclature of nanomaterials.	No actions in this area

European Union		Nomenclature, or the naming of individual nanomaterials, is a significant issue from a regulatory perspective. Nomenclature permits us to distinguish one nanomaterial from another. It also provides specificity when taking risk management actions, such that an entire class is not implicated by an adverse risk outcome of a single nanomaterial. Like the IUPAC nomenclature for the classical substances the invented nomenclature for nanomaterials should have the international acceptance.	International activity: ISO Technical Committee 229 – JWG1 for Terminology and Nomenclature undertakes activities relating to the Nomenclature for nanomaterials. Nomenclature discussions began in Jan 2008. A Technical Report outlining nomenclature considerations and priorities (ISO/TR 14786:2014 Nanotechnologies -- Considerations for the development of chemical nomenclature for selected nano-objects) was released in 2014. There is close collaboration of JWG1 with IUPAC (Union of Pure and Applied Chemistry) and it was agreed that nomenclature activities will be published through IUPAC approval process. Commission Activity: A call for research proposals addressing the development of a systematic framework for naming and assessing safety of the next generations of nanomaterials has been published (see section 3.f)
Germany	-	n/a	n/a
United States	TSCA	There is not a nomenclature system for carbon nanotubes. There is not an agreed upon system for identifying or differentiating distinct materials for the same chemical substance, i.e. how do you identify two distinct forms of titanium dioxide with different particle size distributions and what constitutes a different particle sized distribution.	EPA is working with Chemical Abstract Services to develop a nomenclature system for carbon nanotubes.

Table 12. Hazard Identification (e.g. methods to characterize nanomaterials, testing methods used, accessibility and affordability of current methods for hazard identification, etc.)

Country	**Legislation**	**Challenge**	**Action**
Australia	NICNAS		Request data such as particle size measurements for any submitted toxicity tests

	TGA	Framework development	Continually monitor development and assess in light of local legislation
	SafeWork	Under Work Health and Safety (WHS) Regulations, manufacturers & importers are required to classify hazardous chemicals. It is difficult for small & medium businesses to do this	Model codes of practice recommend that Safety data Sheets (SDS) & workplace labels should be provided for nanomaterials
Canada	CEPA (1999)	Extrapolation between nanomaterials (i.e., choosing the appropriate surrogate) Validity of testing methods and analytical tools to detect, characterize and measure nanomaterials	Participating in international forums such as the WPMN, Expert Meetings, and ISO TC/229 to support the generation and synthesis of appropriate science. Support domestic research to help minimize challenges in hazard identification.
	F&DA	Nanomaterial-based products under the F&DA (i.e. nanomedicines) can be associated with a broad spectrum of toxicities that are dependent on the nanoparticle properties (e.g. size, surface charge and solubility). However, there is currently no specific guidance document available for nanomedicines. Nanoparticle properties can significantly impact the PK profile/biodistribution of nanomedicines resulting in safety concerns. The components of the nanomedicines can also interact with the immune system and may trigger unique immunogenicity/immunotoxicity profile. Animals are generally not predictive of immunological responses for biologics (however, it may not be the case if the nanomedicine is a chemical drug), it is likely that immunological studies for nanomedicines should be carried out in human clinical trials. Long term studies may be required for a nanomaterial that persist and accumulated in particular tissues for an extended period of time.	
Denmark	The Danish Chemicals Act	Apart from the general challenges related to Hazard identification of nanomaterials, which DK shares with the rest of EU, DK is not facing specific challenges	As a part of the national action plan for “better control of nanomaterials” DK is running a series of projects aimed at assessing the use, exposure, hazards

		regarding nomenclature of nanomaterials	and risks of nanomaterials in consumer products and the environment. Under this initiative, specific subprojects aim at addressing challenges related to hazard identification.
European Union		Development of methodologies appropriate to nanomaterials, as applicable	The approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, adapted to the specificities of nanomaterials and in accordance with not least the OECD Recommendation on safety testing of nanomaterials and the guidance note on sample preparation and dosimetry. Changes to the compulsory minimum information requirements for substances are currently being revised specifically for nanomaterials, see table 5 above.
Germany		Method adaptation for nanomaterials regarding ecotoxicology and environmental fate for regulatory testing, nanospecific testing strategy; grouping of nanomaterials, characterisation of nanomaterials; comparability of test results	Funding of research
United States	TSCA	Whether current hazard identification methods are applicable to nanomaterials or classes of nanomaterials. Is there adequate and accurate characterization of nanomaterials that have been tested? Are there any new metrics to identify or quantify hazards of nanomaterials or classes of nanomaterials? Methods that are applicable to subgroups of nanoscale materials so that more targeted assessments can be done?.	EPA continues to conduct/sponsor research on risk assessment and exposure prevention of nanomaterials or classes of nanomaterial, work with other US Federal Agencies that are developing data (for example worker exposure and exposure prevention methods developed by the National Institute for Occupation Safety and Health), and other projects such as the OECD testing program for nanomaterials to develop needed data to answer questions summarized in paragraphs B through D. However, there is not sufficient information to refine these methodologies for classes of nanoscale materials. This has impacts on our available regulatory management tools.

Table 13. Health and Safety (e.g. regulations regarding occupational exposure prevention and control of nanomaterials, etc.)

Country	Legislation	Challenge	Action
Australia	NICNAS	Consider suitable personal protective equipment when making recommendations for safe use of nanomaterials	-
	TGA	-	-
	SafeWork	Limited information on hazards. Limited emissions & exposure measurement capability. Only small number of workplace exposure standards in place for nanomaterials.	Organisations advised to take precautionary approach in choosing workplace controls where information on hazards associated with nanomaterials is limited.
Canada			-
	F&DA	F&DA Veterinary Drugs Due to the lack of a comprehensive understanding of the effects of nanomaterials on human, animal and environmental health, the Veterinary Drugs Directorate has not yet established a comprehensive occupational health and safety policy. Moreover, occupational health and safety is a shared responsibility between the federal and provincial governments in Canada. At this time, there is no conclusive evidence linking exposure of nanomaterials from veterinary drugs or food sources to negative impact on human health. Additional research is necessary before a definitive policy approach can be taken.	F&DA Veterinary Drugs Veterinary drugs including those that contain nanomaterials are regulated by the Food and Drugs Act and the Food and Drug Regulations. These provide the Veterinary Drugs Directorate with the authority to regulate the human health and safety aspects of veterinary drug products. The Regulations cover the aspects of the manufacturing, human and animal safety and efficacy assessment, and post-market surveillance of veterinary drug products including those containing nanomaterials. The latter products are subject to the same rigorous assessments as non-nanomaterial-containing veterinary drug products.
Denmark	The Danish Chemicals Act	Even though there at present are no identified health and safety issues/risks it is a challenge to identify possible health and safety issues.	A series of research initiatives are covering this area.
European Union		Implementation of appropriate Health and Safety Legislation	The review of relevant EU Health and Safety legislation to be carried out by 2014 (it is dependent on the completion of a study report expected for

			2013) should allow for more clarity on whether the current EU Occupational Safety and Health (OSH) legal framework needs adaptions to the existing EU legal instruments, whether new ones will be in order or what other mechanisms may help achieve the objective of protecting workers from potential nanomaterial related risks. Until then, the Commission believes that it is important that the guidance is developed as quickly as possible that may assist employers and workers tackle better any possible, and obviously identified, risks likely to be posed by nanomaterials in the workplace. Such Guidance is being developed in parallel to the study report mentioned and should be available by 2013.
Germany	-	n/a	n/a
United States	TSCA	Whether current methods for estimating and preventing exposures to workers, consumers, and the environment are applicable to nanomaterials or classes of nanomaterials. Are there any new metrics to identify or quantify exposures of nanomaterials or classes of nanomaterials?	EPA continues to conduct/sponsor research on risk assessment and exposure prevention of nanomaterials or classes of nanomaterial, work with other US Federal Agencies that are developing data (for example worker exposure and exposure prevention methods developed by the National Institute for Occupation Safety and Health), and other projects such as the OECD testing program for nanomaterials to develop needed data to answer questions summarized in paragraphs B through D. However, there is not sufficient information to refine these methodologies for classes of nanoscale materials. This has impacts on our available regulatory management tools.

Table 14. Risk Assessment Methodologies.

Country	**Legislation**	**Challenge**	**Action**
Australia	NICNAS	To build technical capacity in the	Making use of the best scientific evidence available for risk based

		identification of potential hazards and in risk assessment methodology, processes and practices to ensure that it makes appropriate recommendations about risk mitigation	assessment of the impacts of the new technology on human health and the environment, including the ability to review decisions as new scientific evidence becomes available
	TGA	Understanding the risk resulting from nanomaterials/drugs. How does it differ from same material at non-nano size?	Develop current risk assessment processes to be able to detect changes in toxicological activity attributable purely to nano size
	SafeWork	Limited information on hazards. Limited emissions & exposure measurement capability	Work health and safety assessment tool for handling engineered nanomaterials published by Safe Work Australia.http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/at201008workhealthandsafetyassessmenttoo . Safe Work Australia is working with the Australian Institute of Occupational Hygienists (AIOH) to develop nanomaterials exposure measurement procedure for routine use by hygienists.
Canada	CEPA (1999)	Materials characterization (differentiating one material from another- which material are we assessing) Appropriate test methods to measure different p-chem, fate, and effects endpoints Risk assessment approaches	Our understanding of risk assessments of nanomaterials is still evolving. Nanomaterials regulated under the industrial chemicals program employ a precautionary approach (i.e., exposure is typically mitigated), and nano-relevant information is requested whenever appropriate to conduct more informed risk assessments. Canada also continues to work in international projects, such as the international life sciences institute NanoRelease project aimed at developing methods to quantify releases of nanomaterials from solid matrices. Canada is also part of the Regulatory Cooperation Council (RCC) Nanotechnology Initiative with the United States. Under this project, Canada and the US are developing a classification scheme for nanomaterials to inform on the utilization of analogue/read-across, developing frameworks and common assumptions to better inform risk assessments, and mining public and confidential use information to increase marketplace knowledge of nanomaterials.

	F&DA		
Denmark	The Danish Chemicals Act	Risk assessment may not be possible due to lack of data and uncertainty that regular risk assessment methods for chemicals are suitable for nanomaterials.	As a part of the national action plan for "better control of nanomaterials" DK is running a series of projects aimed at assessing the use, exposure, hazards and risks of nanomaterials in consumer products and the environment. Under this initiative, specific subprojects aim at addressing risk assessment methodology.
European Union	-	Ensuring the development of appropriate risk assessment methodologies.	The European Chemicals Agency (ECHA) works with the EU Member State experts and other stakeholders to ensure appropriate risk assessment methodologies are used and communicates the requirements (text on Guidance, Helpdesks, training workshops and webinars etc). While the REACH regulation applies to nanomaterials, there are no particular requirements for nanomaterials and it may not have been clear to registrants how to address nanomaterials in their registration dossiers submitted by the 2010 deadline. ECHA has been working with industry, stakeholder groups, member states and the Commission to provide clarity to registrants to enable them to demonstrate safe use of their substances in all forms under REACH. Guidance updates based on the outcome from the REACH Implementation Projects on Nanomaterials concerning information requirements, exposure assessment and risk management and characterisation of nanomaterials were published in 2012 [http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment]. ECHA has convened a Nanomaterial Working Group (NMWG) which is an informal advisory group consisting of experts form Member States, the European Commission, ECHA and accredited stakeholders organisations [http://echa.europa.eu/regulations/nanomaterials]. The activities of the NMWG formally started in January 2013, and 3 meetings or webex were organized in 2013. At the latest meeting in October 2013, subgroups discussed characterisation of NMs and grouping/read-across for NMs. ECHA has also coordinated the GAARN project (Group

			Assessment of Already Registered Nanomaterials) to assess current registrations for representative nanomaterials with their respective registrants. The purpose of GAARN has been to build a consensus in an informal setting on best practices in assessing and managing the safety of nanomaterials under the REACH regulation The project also aimed at drawing practical lessons from the exercise, develop best practices for assessment and reporting in the registration file under REACH, also in a more generalized manner where possible. ECHA has been actively involved in projects related to nanomaterials under the REACH regulation (REACH implementation projects on substance identity, information requirements and exposure assessment (RIP-oNs 1-3); NANOSUPPORT with DG JRC. ECHA is also organising training and webinars on an on-going basis to improve understanding of the issues relevant for nanomaterial hazard assessment.
Germany		Adapt existing guidelines for environmental risk assessment; qualitative and quantitative exposure assessment in the environment; development of analytic equipment	Committee activities
United States	TSCA	Are current risk assessment methodologies applicable to nanomaterials or classes of nanomaterials?	EPA continues to conduct/sponsor research on risk assessment and exposure prevention of nanomaterials or classes of nanomaterial, work with other US Federal Agencies that are developing data (for example worker exposure and exposure prevention methods developed by the National Institute for Occupation Safety and Health), and other projects such as the OECD testing program for nanomaterials to develop needed data to answer questions summarized in paragraphs B through D. However, there is not sufficient information to refine these methodologies for classes of nanoscale materials. This has impacts on our available regulatory management tools.

Table 15. Risk Management and Nanomaterials in Commerce (e.g. register for nanomaterials or products containing nanomaterials, labelling of products containing nanomaterials, etc.)

Country	Legislation	Challenge	Action
Australia	NICNAS	Making appropriate risk management recommendations to protect health and safety of people and the environment	Reviewing the ability of its existing regulatory framework to deliver an efficient and effective response to the new technology and adopting measures to protect public health and safety and the environment where best available scientific evidence is insufficient to support the safety of the product/chemical.
	TGA	The Therapeutic Goods legislation requires that the labelling of medicines, including sunscreens, must declare the identity and quantities of active ingredients in the product. The legislation does not require that the labelling declare the particle size of the ingredients	Use current Advertising Code principles for nano-materials and assessment of the strengths and limitations of this approach
	SafeWork	Establishing appropriate risk management methods for range of nanomaterials and applications for workplaces	Safe Work Australia has published a guide to safe handling & use of carbon nanotubes. Provides two options for two risk management: 1. With detailed hazard identification & exposure assessment 2. Using Control Banding approach http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/safe-handling-nanotubes General guide for safe handling of nanomaterials to be produced by June 2013
Canada	CEPA (1999)	Knowledge of use profiles of industrial nanomaterials; lack of specificity in risk management measures given the overall lack of information and nomenclature systems for nanomaterials	Under the RCC, Canada and the US are gathering information on the uses of industrial nanomaterials in the two countries.
	F&DA	--	-
Denmark	The Danish	It is a challenge to get a better picture of actual	Denmark is establishing a nanoproduct database, cf. the answer to

	Chemicals Act	the number, types and use of products on the Danish market containing or releasing nano materials. The information is necessary for an evaluation of whether the contents of nanomaterials in the nanoproducts on the Danish market pose a risk for consumers and the environment in Denmark.	question 2 in section 1.
European Union		Ensuring appropriate levels of labelling and communication are undertaken.	The Commission will create a web platform with references to all relevant information sources, including registries on a national or sector level, where they exist. A first version mainly based on links to available information will be put on line as soon as possible. The Commission will assist in the elaboration of harmonised data formats, to improve exchange of information. In parallel, the Commission will be launching an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes. Product specific labelling requirements exist for cosmetic products, biocidal products and food stuff where substances (or ingredients as the case may be) that are nanomaterials must be marked in the ingredient list with a bracket containing the word (nano).
Germany		transparency on nanomaterials in products and possible exposure to human and environment	UBA published a "Concept for a European Register of Products Containing Nanomaterials" (June 2012) (http://www.umweltbundesamt.de/chemikalien/publikationen/information_concept_nanoregister_npr_e.pdf)
United States	TSCA	Identifying nanomaterials in commerce and their potential risks	EPA has been developing a rule under TSCA to gather more information on the uses of nanomaterials in commerce and the available hazard and exposure data for those nanomaterials.

Table 16. Research (e.g. research to support science risk-based regulatory decisions.)

Country	Legislation	Challenge	Action
Australia	NICNAS	The depth & extent of relevant current research to support risk assessment	Follow literature and develop internal skills to target regulatory issues
	TGA	The depth & extent of relevant current research to support risk assessment	Follow literature and develop internal skills to target regulatory issues
	SafeWork	Safe Work Australia's Nanotechnology WHS Program – Focus areas of research, see http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/pages/aboutnano Ensure nanotechnology is covered appropriately within the Work Health and Safety Regulatory Framework Improve understanding of the hazardous properties of engineered nanomaterials Assess the effectiveness of workplace controls in preventing exposure to engineered nanomaterials Develop procedures for detecting and measuring emissions exposure in workplaces	Published research reports, see http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/quicksearchresults?PublicationType=Research reports Human Health Hazard Assessment and Classification of Carbon Nanotubes Measurements of Particle Emissions from Nanotechnology Processes, with Assessment of Measuring Techniques and Workplace Controls Brief Review on Health Effects of Laser Printer Emissions Measured as Particles Nanoparticles from Printer Emissions in Workplace Environments Durability of carbon nanotubes and their potential to cause inflammation Engineered Nanomaterials: Feasibility of establishing exposure standards and using control banding in Australia Engineered Nanomaterials: Investigating substitution and modification options to reduce potential hazards Developing Workplace Detection and Measurement Techniques for Carbon Nanotubes An Evaluation of MSDS and Labels associated with the use of Engineered Nanomaterials Engineered Nanomaterials: Evidence on the effectiveness of workplace controls to prevent exposure Engineered Nanomaterials: a review of the toxicology and

			health hazards
Canada	CEPA (1999)	- foster domestic and international capacity to generate research on risk assessment priorities and needs - applying research findings to nanomaterial risk assessments - using research on nanomaterials to extrapolate to other nanomaterials -	- Canada is actively supporting domestic and international research projects to help inform risk assessments.
	F&DA	Filling knowledge gaps	F&DA - HC is conducting laboratory research to study the effects of lipid nanoparticles on the thermal stability of various recombinant proteins with the aim of identifying determinants of susceptibility to unintended deleterious interactions.
Denmark	The Danish Chemicals Act	Communication between regulators and scientist	The Danish Environmental Protection Agency is running a national network for researchers, regulators, industry, NGO's and other stakeholders. This network meets biannually.
European Union		1. While toxicity data is continuously becoming available, their relevance to regulators is often unclear or unproven. It is necessary to provide legislators with a set of tools for risk assessment and decision making for the short to medium term, by gathering data and performing pilot risk assessment, including exposure monitoring and control. 2. To establish techniques for modelling relationships between nanoparticle properties and toxicity. 3. *Challenges identified for the 2013 Work Programme:* • Safety in nanoscale production and products • Nanomaterials safety assessment: Ontology,	1.Challenge addressed in the WP2012 Work programme. The selected project, NANoREG, will start in the Q1- 2013. NANoREG should: (i) provide answers and solutions from existing data, complemented with new knowledge, (ii) Provide a tool box of relevant instruments for risk assessment, characterisation, toxicity testing and exposure measurements of MNMs, (iii) develop, for the long term, new testing strategies adapted to innovation requirements, (iv) Establish a close collaboration among authorities, industry and science leading to efficient and practically applicable risk management approaches for MNMs and products containing MNMs. NANoREG will streamline its activities with the WPMN Sponsorship Programme.

		database(s) for modelling and risk assessment • Development of a systematic framework for naming and assessing safety of the next generations of nanomaterials being developed for industrial applications • Development of methods and standards supporting the implementation of the Commission recommendation for a definition of nanomaterial	2. Challenge addressed in the WP2012 Work programme. Five selected projects (Mod-ENP-Tox, PreNanoTox, NanoPuzzles, MembraneNanoPart, MODERN) to start on 01/01/2013. 3.Selection of research proposals on-going and to be finalized in Q2-2013. Selected projects to start end 2013/early 2014.
Germany		nano-ecotoxicology short and long term, behaviour in environmental compartments; comparability of results	funding of research
Italy		To foster dialogue between scientists, regulators and industries in order to take science based regulatory decisions while taking into consideration industrial development and innovation of NMs.	Italy is participating with 5 partners to the Consortium of FP7 Large-scale integrating project with title "A common European approach to the regulatory testing of nanomaterials" – NANoREG, started on 1 March 2013.
United States	TSCA	**Identifying specific research given the uncertainties with challenges described paragraphs a through e above.**	**EPA continues to conduct and sponsor research on test methods and environmental detection of nanomaterials.**

Table 17. Impact of Regulatory Actions on Innovations and Economic Growth.

Country	**Legislation**	**Challenge**	**Action**
Australia	NICNAS	To ensure any regulatory action is the best way to proceed after considering other non-regulatory options and to minimise burden on industry whilst ensuring safe use of nanomaterials for people and the environment.	The Australian government has in place a process to assess impact of any proposed regulatory change.
	TGA	Avoid stifling safe development	Engage with clients to understand their needs
	SafeWork	-	-
Canada	CEPA (1999)	How to obtain the necessary information on nanomaterials, and how to regulate them in a manner that does not prevent them	Consult with industry on proposed approaches. Focus information requests and requirements.

		from offering their many benefits to society.	
	F&DA	-	-
Denmark	The Danish Chemicals Act	The reporting obligation for Danish importers and manufacturers of nanoproducts to the Danish nanoproduct database (cf. the answer to question 2 in section 1) will be an administrative burden on Danish companies – of which a large portion is small and medium sized companies. An impact assessment has been made in order to estimate the administrative burdens. It shows that all the relevant companies presently have very little information about the nanomaterials in their products (in fact many do not know whether they import nanoproducts or not). The companies therefore have to find out first whether they import or manufacture nanoproducts - and secondly the companies that find that they have products to report will have to spend time obtaining the necessary information. The companies fear that both exercises will be time consuming and that they will be required to report commercial confidential information, they therefore also fear that the reporting obligations to the Danish nanoproduct database will hamper innovation and economic growth.	Danish Environmental Protection Agency will develop guidelines to help the companies assess in a speedier manner whether they manufacture or import nanoproducts. Furthermore, the reporting obligation will be limited to more basic information about the nanoproducts, which also means that less (or no) commercial confidential information will have to be reported. Finally, products containing carbon black or titanium dioxide as the only nanomaterial will be exempted from the reporting obligation. It is possible that other groups of products may be exempted from the reporting obligation.
European Union		Nanotechnology has been identified as a key enabling technology (KET) providing the basis for further innovation and new products.[5] In its Communication 'A European strategy for Key Enabling Technologies – A bridge to growth and jobs'[6] the Commission has outlined a single strategy for KETs, including nanotechnology, built upon three pillars: technological research, product demonstration and competitive manufacturing activities.	The applicable legislation must ensure a high level of health, safety and environmental protection. At the same time, it should permit access to innovative products and promote innovation and competitiveness. The regulatory environment affects time to market, marginal cost structure and allocation of resources, especially for SMEs. It also creates new business opportunities and contributes to consumer and investor confidence in the technology. International collaboration in particular with our trade partners can stimulate the development and

5 http://ec.europa.eu/enterprise/sectors/ict/key_technologies/kets_high_level_group_en.htm

6 http://ec.europa.eu/enterprise/sectors/ict/files/kets/act_en.pdf

			commercialization of nanotechnology-enabled applications and industries.
Germany	-	n/a	n/a
United States	TSCA	Protecting human health and the environment while allowing commercialization of new nanomaterials.	EPA has allowed most nanomaterials reported as new chemical substances to be commercialized but with restrictions to prevent exposures and environmental releases that could result in potential risks. However, the tools do not exist to do targeted assessments for classes of nanomaterials which impact the regulatory actions we take.

Table 18. Labelling/Communication of Nanomaterials (e.g. public labelling for market use, level of labelling detail, materials information systems, labels/waste handling, etc.)

Country	**Legislation**	**Challenge**	**Action**
Australia	NICNAS	Does not administer a labelling code, separate regulatory schemes operate for marketing/labelling of products	Examine advertising Code for its applicability to nanomaterials
	TGA	The Therapeutic Goods legislation requires that the labelling of medicines, including sunscreens, must declare the identity and quantities of active ingredients in the product. The legislation does not require that the labelling declare the particle size of the ingredients. Challenge is to understand how the current advertising code can provide appropriate information in an understandable way	Model codes of practice recommend that SDS & workplace labels should be provided while information is being gathered for classification
	SafeWork	Limited hazard information	-
Canada	CEPA (1999)	Labelling of nanomaterials has not been considered under CEPA 1999 to date.	
	F&DA	-	-
Denmark	The Danish Chemicals Act	N/A	N/A

European Union		See response in table 15 above.	
Germany		transparency on nanomaterials in products and possible exposure to human and environment	UBA published a "Concept for a European Register of Products Containing Nanomaterials" (June 2012) (http://www.umweltbundesamt.de/chemikalien/publikationen/information_concept_nanoregister_npr_e.pdf)
United States	TSCA	EPA has received questions and public comments that nanomaterials should be labelled	EPA's response has been that labelling requirements would be used only be to identify potential risks.

Annex IV: Opportunities for Collaboration (Section 4 of the Questionnaire)

Table 19. Collaboration with Other Countries regarding the Regulation of Nanomaterials.

Country	Legislation	Yes	No
Australia	NICNAS	NICNAS works unilaterally (through OECD WPMN) and bilaterally (through Memoranda of Understanding with counterpart agencies in Canada, USA, Europe and New Zealand) on the regulation of industrial chemicals, including nanomaterials. NICNAS is in close contact with its counterparts overseas through the OECD Working Party on Manufactured Nanomaterials, as well as directly with the US EPA, Canadian Departments of Health and Environment, and with the NZ EPA.	
	TGA		
	SafeWork	SafeWork participates in ISO TC229, OECD WPMN, NanoRelease, WHO Collaborating Centres nanotechnology project and Informal bilateral liaisons with other countries' WHS agencies.	
Canada	CEPA (1999)	The New Substances Program is involved in various international activities, including:	
	F&DA	1) International Organization for Standardization (ISO) Technical Committee (TC) 229 on Nanotechnologies 2) Organisation for Economic Co-operation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) and Working Party on Nanotechnology (WPN) 3) Canada-US Regulatory Cooperation Council (RCC)	

		4) International Cooperation on Cosmetic Regulation (ICCR) – 2 Reports have been published a) Criteria and Methods of Detection for Nanomaterials in Cosmetics: http://www.fda.gov/downloads/InternationalPrograms/HarmonizationInitiatives/UCM235485.pdf b) Methods for Characterization of Nanomaterials in Cosmetics http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/iccr5_char_nano_en.pdf 5) International Regulators Nanotechnology Working Group 6) International Life Sciences Institutes (ILSI) – NanoRelease Food Additive Project 7) NanoLyse In addition, for veterinary drugs, Health Canada collaborates with other regulatory agencies in USA, Europe, Australia, etc in the regulation of non-nanomaterial products and substances and would do the same for substances that are, or products containing nanomaterials.	
Denmark	The Danish Chemicals Act	Denmark has an ongoing contact and dialogue with France in particular, but also Belgium, Italy in order to learn about the design of their initiatives regarding databases and the regulation behind this database. Further we collaborate with the other Nordic Countries (Sweden, Norway, and Finland) on a contribution on nanosilver to the OECD-sponsorship programme. Janeck Scott-Fordsman (JSF@dmu.dk) is project leader on this initiative.	
European Union	-	The European Union places high priority on cooperating with other countries and international organisations as regards the safe use of nanomaterials. This means an active engagement in the work of the OECD WPMN in all parts of its work programme, in the Test Guidelines Programme (WNT) as well as in relevant standardisation activities under the auspices of ISO and CEN. The European Union is also supportive to the work going on in the context of SAICM and UN-GHS.	
France	-	Pays de L'Union Européenne, Belgique, Italie, Pays-Bas, pour la Déclaration des substances à l'état nanoparticulaire présentent sur le marché national.	
Germany	-	OECD, EU, IUPAC, SAICM	
Italy	-	Participation to the European dialogue for proposing adaptions for NMs of existing legislation on chemicals. Participation to an EU Member States task force with the aim of harmonizing the scheme to be used for national registries on NMs.	
United States	TSCA	The US and Canada have been exchanging information pertaining to nanomaterial risk assessment and risk management under a bilateral activity called the Regulatory Cooperation Council (RCC) to increase regulatory transparency and coordination between both countries. The US and Australia have shared information on the risk assessment and risk management of a	

		nanomaterial that was notified in both countries. The US and the European Commission have exchanged information on issues related to definitions, risks assessment and risk management of nanomaterials.	

Table 19. Expert Workshop Sponsorship.

Country	**Legislation**	**Yes**	**No**
Australia	NICNAS		
	TGA	Workshop with NICNAS, FSANZ, Office of Chemical Safety in 2010	
	SafeWork	Nanotechnology WHS Symposium (September 2010)	
Canada	CEPA (1999)	The Workshop on the Human and Environmental Risk Assessment of Nanomaterials convened by Health Canada and Environment Canada (March 24-26, 2010) provided an open forum for detailed dialogue on nanomaterials among science evaluators, research scientists and regulators. The Workshop was attended by 25 experts from Australia, Canada, Europe, Korea and the United States of America. In addition, seven observers attended the Workshop. Regulatory Cooperation Council with the United States	
	F&DA	***F&DA -Foods*** Health Canada will be hosting a Joint NanoLyse/NanoRelease Workshop to discuss methods and safety of nanomaterials and share information from the respective projects. NanoLyse is an EU research consortium to develop methods of analysis for engineered nano-materials in foods and NanoRelease is an International Life Sciences Institute lead initiative to develop of analytical methods, alimentary canal models for uptake of engineered nano-materials and review of regulatory issues.	
Denmark	The Danish Chemicals Act		
European Union	-	Europe-wide collaboration within groups consisting of representatives from Member States and key stakeholders is undertaken. The subgroup of thee Competent Authorities for REACH and CLP on nanomaterials	

		(CASG-nano) and ECHA Nanomaterials Working Group.	
France	-		
Germany	-	OECD Expert Meeting on Environmental Fate and Ecotoxicology of Nanomaterials (January 29.-31. 2013, Berlin, Germany)	
United States	TSCA	As part of RCC activity the US and Canada will conduct public workshops with knowledgeable stakeholders on issues related to assessment and regulation of nanomaterials.	

[1] http://echa.europa.eu/view-article/-/journal_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated