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Number 19

ANALYSIS OF INFORMATION GATHERING INITIATIVES ON MANUFACTURED NANOMATERIALS

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No. 19

ANALYSIS OF INFORMATION GATHERING INITIATIVES ON MANUFACTURED NANOMATERIALS

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2009

Also published in the Series of Safety of Manufactured Nanomaterials:

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

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

No. 3, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)*

No. 4, *Manufactured Nanomaterials: Programme of Work 2006-2008 (2008)*

No. 5, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials(2008)*

No. 6, *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme(2008)*

No. 7, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 4th Meeting of the Working Party on Manufactured Nanomaterials(2008)*

No. 8, *Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials(2009)*

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No.10, *Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials(2009)*

No.11, *Emission Assessment for the Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance(2009)*

No.12, *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009)*

No. 13, *Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (2009)*

No. 14, *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme (2009)*

No. 15, *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (2009)*

No. 16*, Manufactured Nanomaterials: Work Programme 2009-2012 (2009)*

No. 17, *Current Developments in Delegations and other International Organisations on the Safety of Manufactured Nanomaterials- Tour de Table (2009)*

No. 18, *Manufactured Nanomaterials: Roadmap for Activities during 2009 and 2010 (2009)*

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The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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

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

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

FOREWORD

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

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

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

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

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THE WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

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

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

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

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

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

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

6. This document was prepared by the WPMN steering group 5 leading the work on co-operation on voluntary schemes and regulatory programmes. The Working Party endorsed the Analysis of Information Gathering Initiatives (Section I) at its 4th meeting. The Table of Comparison (Section II), which served as the basis for this analysis, was further updated with inputs from Canada, Germany and the United States. This table was endorsed at the 5th meeting of the Working Party.

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

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

[3] Trade Union Advisory Committee to OECD.

PROJECT ON CO-OPERATION ON VOLUNTARY SCHEMES AND REGULATORY PROGRAMMES

7. The project on **Co-operation on Voluntary Schemes and Regulatory Programmes** was established to achieve two objectives with respect to information gathering schemes:

- To identify common elements of the various information gathering initiatives, in place or planned, which encourage industry and other entities to submit existing information and data and/or generate new data on risk assessment and risk management of nanomaterials; and

- To develop considerations and recommendations for approaches and elements to implement effective information gathering schemes.

8. In order to achieve these objectives, the project proceeded in several stages beginning with the compilation of information on current and planned information gathering schemes, followed by organization of the available information into various categories to facilitate comparison, and concluded with the development of recommendations and considerations. Delegations were invited to provide input and update information at each stage.

9. This document is the analysis of current and proposed information gathering initiatives for manufactured nanomaterials (Section I). It includes a number of considerations and recommendations which should be considered in developing an information gathering initiative. The document also includes a table which compares current information gathering schemes (Section II). Information provided through this table served as a basis of the analysis of information gathering initiatives. In addition, the table was further updated with inputs from Canada, Germany and the United States. These updates were no longer considered by the analysis.

10. It is expected that the Table of Comparison (Section II) be updated when new information on current or additional initiatives become available.

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

EXECUTIVE SUMMARY

12. One of the objectives of the WPMN project on Co-operation on Voluntary Schemes and Regulatory Programmes is to submit suggestions to member countries on approaches and elements to consider in information gathering initiatives for manufactured nanomaterials.

13. The current document presents the *analysis of Information Gathering Initiatives* (Section I) which analyzes the similarities and differences identified in current or proposed information gathering initiatives on manufactured nanomaterials. This document concludes with a number of considerations and recommendations to countries which are considering launching voluntary or mandatory information gathering schemes.

14. The analysis includes the following information elements that should be considered in an information gathering initiative: use pattern; physical and chemical properties; life cycle information; fate; human health toxicity; ecotoxicity; and risk management measures.

15. The *Table of Comparison on Information Gathering Schemes: Manufactured Nanomaterials* (Section II) summarises the information on the Information Gathering Schemes launched by Australia, Canada, Denmark, Germany, Ireland, the United Kingdom and the United States. This table served as the basis for the *analysis of Information Gathering Initiatives.*

16. It is worth noting that the table was further updated with new information from Canada, Germany and the United States, which was not taken into account by the analysis. Nevertheless, this new information did not bring any required changes in the analysis. It is expected that the table be updated as new information on current or new initiatives becomes available.

SECTION I. ANALYSIS OF INFORMATION GATHERING INITIATIVES

INTRODUCTION

18. One of the objectives of the WPMN project on Co-operation on Voluntary Schemes and Regulatory Programmes is to submit suggestions to member countries on approaches and elements to consider in information gathering initiatives for manufactured nanomaterials.

19. The current document presents an analysis of the similarities and differences identified in current or proposed information gathering initiatives. This document concludes with considerations and recommendations to countries which are considering launching such initiatives. These recommendations are applicable to voluntary or mandatory information gathering schemes.

20. Please note that these "considerations and recommendations" are suggestions offered to member countries. They have been established without pre-defined consequences for any regulatory or voluntary information gatherings mechanisms that member countries may undertake in the future.

21. The analysis includes a list of information elements that should be considered in an information gathering initiative.

INFORMATION GATHERING SCHEMES – SIMILARITIES AND DIFFERENCES

22. The United States, the United Kingdom, and Australia have information gathering schemes which target information on use patterns and physico-chemical properties as well as any other relevant information (for example, effects, fate and behaviour). All requested information is submitted on a voluntary basis.

A. STATED PURPOSE

- All aim to obtain information from industry to build a baseline of information. This information will inform the development or adequacy of regulatory programmes
- A few differences in level of detail describing other objectives
  - Promote implementation of risk assessment and risk management practices
  - Complement research efforts

B. TARGET RESPONDENTS

- US programme is most comprehensive targeting manufacturers, importers, processors, users, and researchers
- UK programme targeting manufacturers, importers, users. Researchers not targeted but their input is welcome
- Australian programme focussed on manufacturers and importers

C. STATED BENEFITS

- Promotes collaboration between government and industry
- Promotes continued corporate responsibility to ensure nanomaterials are introduced responsibly to markets
- Informs understanding of markets and based on real data
- Informs potential developments in risk assessment methodologies and risk management tools based on real data

D. DEFINITION / SCOPE OF PROGRAM

- Engineered nanomaterials
- US – at least one dimension between 1 and 100 nm
- UK – two or more dimensions up to 200 nm

E. TIMEFRAME

- UK has launched a two year programme (2006-2008) during which submissions can be made at any time
- US is proposing a two year programme during which submissions can be made at any time
- Australia originally called for responses within 6 weeks. Information was collected within 3 months.

F. GENERAL APPROACH

- Companies asked to report existing information
- No programme required generation of data
- US includes a more comprehensive second phase at which time data would be generated
- UK discourages generation of data requiring use of animals

G. TYPES OF DATA SOUGHT

- All request basic identification data:
  - Substance identification
  - Use and quantity of use
- US and UK provide guidelines for relevant data based on their respective substance notification data requirements:
  - Substance characterization
  - Physico-chemical properties
  - Effects
  - Fate and behaviour
  - Measurement and detection techniques
- US identifies some endpoints which are specific to nanomaterials (e.g., agglomeration)

H. CONFIDENTIALITY

- Australia allowed companies to claim information as confidential and subsequently published a summary of information available to the public.
- US will treat data as confidential as if submitted under TSCA
- UK will treat data as confidential unless otherwise stated and data owner will be consulted should information be requested under the Freedom of Information Act or the Environmental Information Regulations.

QUESTIONNAIRES – SIMILARITIES AND DIFFERENCES

Response to these surveys was voluntary. These surveys differ from the US, UK, and Australian initiatives in that they consist of a series of questions focusing mostly on use patterns or occupational safety issues. Germany, Denmark and Ireland have issued such a survey.

A. STATED PURPOSE

- Obtain information from industry on use patterns or occupational safety

B. TARGET RESPONDENTS

- Germany described the target participants as companies or institutions which produce, use, or process in quantities of >10 kg/yr
- Denmark targeted manufacturers. The project was carried out by a consultant. The questionnaire was developed in cooperation with laboratories involved in nanomaterials research and development
- Ireland does not specify

C. DEFINITION / SCOPE OF QUESTIONNAIRE

- Particles produced as powder
- Ireland and Denmark: one dimension less than 0.1 μm (100 nm)
- Germany: at least two dimensions less than 0.1 μm (100 nm)
- Germany also includes aggregates and agglomerates, but excludes fumes from soldering or metal, and diesel fumes
- Denmark covered engineered nanoparticles, nanofibres and nanoflakes.

D. TYPES OF QUESTIONS

- General questions about the company
  - Industrial sector
  - Volume of handling
  - Number of employees
- Specific questions about the nanomaterials
  - Nanomaterial class

- Primary size
- Nature of handling (e.g., production, use, release)
- Analytical methods
- Exposure mitigation practices

- The Irish and Danish surveys also requested any available information on physico-chemical properties, toxicity data, and ecotoxicity data. The German survey requested only health effects information.

E. CONFIDENTIALITY

- The German questionnaire was made anonymous (collection of information by industry association) with general conclusions made public.
- Denmark treated the information submitted as confidential.

CONSIDERATIONS AND RECOMMENDATIONS

23. The overall objectives of information gathering initiatives are:

- To provide governments with as comprehensive and representative an understanding as possible of what manufactured nanomaterials are in, or soon to enter, commerce, in what quantities and by which companies; for what applications they are being used or anticipated to be used; and the extent of risk-relevant information on them that is available, so that governments can take appropriate actions and decisions to meet information needs and address potential risks; and
- To maximize the amount of information available to the public, while protection information that is legitimately considered confidential, in order to increase the public's and stakeholders' ability to meaningfully engage in discussions and decisions concerning such materials.

24. The following considerations and recommendations are offered to help ensure that information gathering initiatives achieve these objectives, and should be implemented in a manner consistent with these objectives.

1. The Information gathering initiative should include deadlines that reflect the time needed to gather information being requested and identify the next steps.

25. In the case of voluntary submission of data, deadlines should be considered for: a) companies agreeing to volunteer; b) companies providing the requested information, c) government evaluating the viability of the program, and d) government assessing and acting on the information.

26. Too long a deadline (years) before respondents manifest themselves will create uncertainty as to what information will be submitted and when it will be submitted. Shorter deadlines (2 to 6 months) should be considered for information which is already available and use pattern data submission. Longer deadlines should be considered when respondents will generate information.

2. In the case of voluntary information gathering initiatives, authorities should clearly indicate how they intend to measure progress and the success of the programme, when and how they will be assessed, and the steps that will be taken if objectives are not met.

27. A clear message from authorities on their expectations with regard to measuring progress and success should be an incentive for participation.

28. Incentives should be considered to increase response to voluntary initiatives. For instance, industry can be offered to describe their regulatory needs which will be taken into consideration in the development of regulations.

3. Consideration should be given to supplementing voluntary initiatives with mandatory reporting.

29. Authorities should consider mandatory information gathering to obtain basic use pattern information such as who is manufacturing or importing nanomaterials, what nanomaterials are being manufactured or imported, in what quantities and what are the current or expected uses as well as toxicological and risk-related information readily available.

30. This information will, among other things, allow a meaningful assessment of a voluntary program to gather more extensive information.

4. Authorities should require respondents to submit all available information on any nanomaterial they include in the initiative.

31. Such a requirement would preclude the possibility of selective reporting and encourage submission of information on all major nanomaterials a company produces. It would reassure authorities and the public that all available information is collected.

5. The information sought in information gathering initiatives should clearly be delineated.

32. Clear indications should be given as to what information is sought. Respondents should be requested to indicate whether they are: a) providing the information, b) not providing it because they do not have it, or c) not providing it because they do not wish to divulge it (in the last case, respondents should indicate why they have declined to provide the information).

33. As comprehensive a set of relevant parameters as possible should be delineated. There should also be a request to provide any information that is relevant to the objectives of the program even if it is specified in the request. More details as to the information elements that should be requested are provided in Annex A.

6. Authorities should make clear that they intend to act on any information they receive that indicates a risk with respect to human health or the environment.

34. Information should not be collected for information purposes only. It should be indicated that any necessary risk management action will be taken if the information submitted indicates a risk. This is necessary to build public confidence and ensure that appropriate action is taken to address identified issues.

7. Authorities should indicate at the outset what specific types of information submitted by companies are eligible for protection as confidential business information.

35. A practical approach would be to apply existing legal requirements that govern confidentiality and public access to information in the country where the initiative is undertaken. To the extent possible, occupational health and safety information should be made available to the public.

8. Authorities should identify clearly how information collected under the initiative will be made public.

36. Such an approach will create transparency and avoid misunderstandings on how the information will be reported. It is also important for respondents to understand which information will be made public, whether sensitive information will be aggregated to avoid confidential information issues and in what circumstances reporting will take place.

9. Information gathering initiatives should capture the broadest possible scope of nanomaterials and applications.

37. The working definition of nanomaterials adopted by the Working Party should be used. Consideration should be given to including not only "free" nanomaterials or nanoparticles but other nanomaterial-derived or nanoparticle-containing materials that have the potential to release "free" nanomaterials at various stages of their lifecycle.

10. The information gathering initiative should include companies and research institutions conducting R&D on nanomaterials particularly pre-commercialization R&D.

38. While it may be difficult or inappropriate to seek information on materials very early in the development cycle, there are several reasons why inclusion of at least the advanced R&D activities is warranted:

- First, there are occupational exposures to consider: there is a pressing need to understand material handling and risk management practices used in R&D settings.
- Second, these activities represent a critical stage in all current and future nanomaterial development. Gaining an understanding of materials in the later stages of development will help identify upcoming applications.
- Third, restricting information gathering to those materials already in commercial production and use will also limit the ability to begin to understand and delineate the potential risks, as well as information needs and risk management needs for the full range of materials soon to be entering commerce.

11. Authorities should consider provisions for updates to submitted information.

39. Information submitted under gathering schemes may become out of date or redundant in light of further research and/or developments. Authorities need to consider means to ensure they possess the most up to date information such as requiring data owners to update their submission when new information becomes available or by periodically approaching respondents to ascertain their latest information.

12. Companies and institutions participating to the initiative should be reminded of the importance of having appropriate personnel respond to the information request.

40. It is important that people fully familiar with the topics identified in the request provide the information to ensure that complete and accurate information is submitted. For example, scientific personnel may be best suited to respond to technical questions regarding the chemistry of a nanomaterial.

13. Authorities should consider providing tools to respondents to facilitate their response.

41. Such tools include a standard response form, the use of multiple choice questions, and appropriate explanations and instructions. Electronic data submission should also be considered.

14. Authorities should ensure appropriate communication of the information gathering initiative.

42. Authorities should consider how the information gathering initiative will be brought to the attention of potential respondents. There may be a need to identify industry associations that are able to publicize the initiative and help develop appropriate communication tools to reach the maximum number of potential respondents.

INFORMATION ELEMENTS

43. The following information elements should be considered in an information gathering initiative.

Use Patterns

- Quantities imported, manufactured, processed and associated applications/uses

Physical and Chemical Properties

- Physical form and particle size distribution
- Surface area measurements and predictions
- Extent of heterogeneity of the material, and the amount and identity of any impurities or contaminants

Life Cycle Information

- Means of handling transportation storage, disposal, etc.
- Pathways for potential release and exposure at each stage of the lifecycle of the nanomaterial or product containing the nanomaterial
- Any available monitoring information or data on worker exposure or environmental releases

Fate

- Biological fate and behaviour such as biokinetics and ADME (adsorption, distribution, metabolism and elimination) data
- Identity of biological or environmental breakdown products
- Bioaccumulation potential and distribution among environmental media (fugacity)
- Information on stability, weathering, erosion, etc.

Human Health Toxicity

- Data from acute and chronic toxicity studies

Ecotoxicity

- Data from acute and chronic toxicity studies

Risk Management Measures

- Risk management measures currently in place such as health surveillance, monitoring, engineering controls and use of personal protective equipment
- Effectiveness of engineering controls and use of personal protective equipment
- Any risk management measure that needs to be taken throughout the life cycle of the nanomaterials
- Any information or report submitted to other regulatory agencies or other countries
- Any information required to be submitted to workers or customers such as material safety data sheets or labelling

For all reported information elements, in addition to the data values themselves the methods by which they were generated should also be reported.

SECTION II. TABLE OF COMPARISON ON INFORMATION GATHERING SCHEMES: MANUFACTURED NANOMATERIALS

44. This table summarises the information on the Information Gathering Schemes (voluntary or mandatory) launched by Australia, Canada, Denmark, Germany, Ireland, the United Kingdom and the United States.

45. The table presents a range of information on information gathering schemes on manufactured nanomaterials by country: date in which the information gathering scheme was issued; timeframe; development approach; purpose; definition/scope of program; targeted respondents; operational cost; stated benefits; participation incentives; nature of questions; types of data sought; confidentiality; communication; results to date; comments on program; experience; as well as other remarks.

COUNTRIES 1 TO 4	**AUSTRALIA (Voluntary survey)**	**CANADA (Proposed mandatory scheme)**	**DENMARK (Voluntary survey)**	**GERMANY (Voluntary survey)**
Date Request Issued	Published in Australia Chemical Gazette February 7, 2006; deadline for submission March 17, 2006	Projected launch: Spring, 2009	29 March to 26 April 2007	Published May 2006
Timeframe	Completed October 2006	4 month response time	Completed	Completed
Development Approach		Multi-stakeholder (government, industry, academia, public interest groups) consultation (September 2007) to obtain feedback on effective information gathering approaches followed by regular discussions with stakeholders	Danish EPA surveyed manufacturing of nanomaterials. The project was carried out by a consultant who developed a questionnaire in close co-operation with 6 labs that perform research and development of new nanomaterials	Workshop (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Federal Institute of Occupational Safety and Health, Federal Environmental Agency) "Assessment on synthetic nanomaterials at workplaces and in the environment" (October 2005)
Purpose	Obtain information to focus efforts to ensure the adequacy of the regulatory scheme (NICNAS)	Obtain information to conduct preliminary risk assessments on nanomaterials in Canadian commerce and to gather information to inform the development of a regulatory framework for nanomaterials	Collect information on type and quantities of nanomaterials produced and the production methods	Obtain information on worker protection during the production and handling of engineered nanomaterials
	Collect information on industrial uses, cosmetics and personal care products and quantities imported or manufactured	Collect information on use patterns (including volumes), physical and chemical properties, fate, toxicity data and stewardship practices for nanomaterials already in commerce	Collect information on consumer and environmental risks including waste disposal treatment and ecotoxicity	Identification of focal points regarding nanomaterials and risk management measures
			Collect information on practices to prevent or reduce potential risks and the need	

COUNTRIES 1 TO 4	**AUSTRALIA (Voluntary survey)**	**CANADA (Proposed mandatory scheme)**	**DENMARK (Voluntary survey)**	**GERMANY (Voluntary survey)**
			for guidance including what type of guidance that is needed	
Definition / Scope of Program	Specifically engineered materials with at least one dimension less than 100 nm.	Principally including nanomaterials that are deliberately engineered to have one or more spatial dimensions in the range of 1 to 100 nm	Engineered nanoparticles, nanofibres and nanoflakes with at least one dimension smaller than 100 nm	Engineered nanoparticles produced as powder with at least two dimensions are smaller than 0.1 micrometers.
Reporting year	Targeted import and manufacture during 2005 and 2006	Nanomaterials imported or manufactured in 2008		
Inclusions	Nanomaterials or products (mixtures) containing nanomaterials	Graphene, single or multi-walled carbon nanotubes; fullerene with 60 carbon atoms or more; quantum dots; dendrimers; imported food or feed packaging containing nanomaterias.		Aggregates and agglomerates
Exclusions	Nanomaterials outside the scope of NICNAS (i.e., therapeutic goods, food or food additives, agricultural or veterinary chemicals)	Carbon Black ; Organic pigments; Biological materials; Polymers, unless intentionally manufactured to exhibit the novel properties characteristic at the nanometre scale; Naturally occurring nanomaterials; Imported manufactured items.		Fumes from soldering or metal and diesel fumes
Targeted Respondents	Manufacturers, importers	Manufacturers, importers, research and development.	All companies that may produce or apply nanomaterials. The Danish Industry has provided a list of companies that may be relevant. Other companies	Companies/institutions which produce, use or process products with nanomaterials

COUNTRIES 1 TO 4	**AUSTRALIA (Voluntary survey)**	**CANADA (Proposed mandatory scheme)**	**DENMARK (Voluntary survey)**	**GERMANY (Voluntary survey)**
			known by the Danish EPA or the consultant have also been approached.	
Volume trigger		Annual Import or production >1 kg		Annual use of >10 kg
Operational Cost		No monetary cost. Time invested to prepare the requests: one person-year	Approximately 300.000 DKr. Cost for Danish EPA	No dollar costs noted, only manpower
			Companies are requested to use approximately 2 to 3 hours to fill in the questionnaire	
Stated Benefits	***For government:*** Gain an understanding of which industrial nanomaterials are on the market or close to commercialization	***For government:*** Gain the opportunity to assess toxicity; gain an understanding of the Canadian market. Obtain a snapshot of the current market including volumes of use. Obtain readily available toxicological data.	Knowledge on the type of nanomaterials produced, the production methods and the size of the production is valuable for the Danish EPA, contributing to the international development of regulation of nanomaterials.	Identifying focuses
	Provide focus for addressing adequacy of NICNAS regulatory schemes		Knowledge on the practices to prevent or reduce potential risks and the need for guidance including what type of guidance is valuable for the Danish EPA to develop guidance to the companies if needed.	Deduction of commonly used risk management measures
	Develop links with industry to aid future dialogue in regulatory review		Participants were provided the opportunity to describe their regulatory needs which the Danish EPA would take into consideration during the development of regulations.	Review on actual uses of nanomaterials

COUNTRIES 1 TO 4	**AUSTRALIA (Voluntary survey)**	**CANADA (Proposed mandatory scheme)**	**DENMARK (Voluntary survey)**	**GERMANY (Voluntary survey)**
Participation Incentives		Legal obligation to respond.		
Nature of Questions	General questions relating to the company. Specific questions related to the material	General questions relating to the company. Specific questions related to the material	A general part on issues related to the company, production methods, working environment, disposal, etc. A specific part related to each nanomaterial.	General questions relating to the company. Specific questions related to the material. Information on occupational exposure and risk mitigation
Types of Data Sought				
Company Identification	Company name, location	Company name, location Industrial code	Sector, Type of products, Number of employees	Company name, location
Material Identification	Chemical name, trade name, formula, CAS# if available	chemical name, trade name, formula, CAS# if available	Name of material, type of material, CAS# if possible	Class of nanomaterials in use
Material Characterization		Any available information on primary shape; average size; size distribution; structure.	Aggregation, size of particles, surface area; The weight percentage of material in the final product	Size of primary particles
Use Pattern Information	Estimate of total quantity (kg/yr) imported and/or manufactured (raw or in products). Industrial uses, uses available to the public	Estimate of total quantity (kg/yr) imported and/or manufactured. Known or predicted uses.	Production volume and handling volume by employees (as product, within process or as by-product)	Nature of handling (produce, use, release, etc.)
Fate and Exposure Information		**Any** information available	Type of measurements of exposure performed; level of exposure during further treatment, use, or disposal of product	Occupational monitoring; Nature of any occupational exposure; Exposure mitigation practices
Physico-Chemical Properties		**Any** available information relating to the SG3 list of properties	Whether the material is a powder, suspended in liquid or in a solid matrix	None
Human Toxicity Data		Any toxicological information or data available	Data availability and data source on health risks	Available information on health effects
Ecotoxicity Data		Any toxicological information or data available	Data availability and data source on ecotoxicity risks	None
Other Data		Any available stewardship practices	Type of process, Research/development/produ	

COUNTRIES 1 TO 4	**AUSTRALIA (Voluntary survey)**	**CANADA (Proposed mandatory scheme)**	**DENMARK (Voluntary survey)**	**GERMANY (Voluntary survey)**
			ction, number of employees that works with nanomaterials, education, Use of guidelines	
			Personal protection equipment, feeling of safety	
			Waste disposal, pre-treatment, type of waste, Emission from production facilities,	
			Information to customers on products, further treatment of product, Whether guidance or regulation needed and if yes, what type	
Confidentiality	Companies can claim commercial information to be confidential. Summary of information published.	Companies can claim commercial information to be confidential. Summary of information expected to be published.	The information will be treated confidentially.	The questionnaire was anonymised by the German Chemical Association
Communication	Summary report published on NICNAS website (January 2007)	It is expected that a summary report will be published	Project report by the end of 2007	The results of the survey have now been published. In German: Tätigkeiten mit Nanomaterialien in Deutschland - Ergebnisse der BAuA/VCI-Fragebogenaktion (in: Gefahrstoffe - Reinhaltung der Luft 10/2007, S. 419-424) In English: http://www.baua.de/nn_43190/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Survey.pdf? on the BAuA-Webpage presentation

COUNTRIES 1 TO 4	**AUSTRALIA (Voluntary survey)**	**CANADA (Proposed mandatory scheme)**	**DENMARK (Voluntary survey)**	**GERMANY (Voluntary survey)**
				of first conclusions was given at VCI-workshop nanomaterials at the workplace in April 2007
Results to Date	Approximately 21 types of nanomaterials identified			
	15 companies import; 4 companies manufacture; 4 companies formulate			
	Highest volume of use 10,000-50,000 tonnes/year; over half are used at less than 1 tonne/year: 4 are used at less than 0.1 tonnes/year			
Comments on Program Experience	Received limited response in timeframe provided; following up directly with some sectors (e.g., cosmetics, surface coatings) and contacted companies where published information on nanomaterials are reported to be in use		Some companies and laboratories have committed to analyse their practices to prevent or reduce potential risks	A follow up survey is being considered
Other Remarks		Does not replace existing legislative obligations in Canada		

Countries 5 to 7	**IRELAND (Voluntary survey)**	**UNITED KINGDOM (Voluntary reporting scheme)**	**UNITED STATES (Voluntary reporting scheme)**
Date Request Issued	June – September 2006	On-going; launched September 2006	Launched January 2008
Timeframe	Completed	2 year program duration	Proposal for a 2 year program duration
		On-going review of scheme as information is collected and as a result of legislative developments	Regular reviews during 2 year period
		Formal review every 6 months	Final evaluation at end of 2 year period
		Final review and evaluation after 2 years	
Development Approach	The Health and Safety Authority (HAS) participates in a European Commission Working Group which has developed an action plan on nanomaterials. The questionnaire was developed to contribute to this work.	Result of Regulatory Impact Assessment and given as best option to address issue quickly and at minimal cost and burden to both industry and government; Full public consultation August 2006	Broad stakeholder meeting (June 2005, Sept 2005) for public input to voluntary program proposal; Scientific peer consultation (October 2006 and September 2007); Public meeting (August 2007)
Purpose	To gain some information on the nature and extent of the use of nanomaterials in Irish industry.	Obtain existing data from industry	Build a baseline of information on engineered nanoscale chemical substances
		Complement research efforts	Promote implementation of risk assessment and risk management practices
		Inform on development of any necessary control measures	
Definition / Scope of Program	Engineered nanoparticles produced as powders. Particle dimension smaller than 0.1 µm	Specifically engineered materials that have two or more dimensions up to 200 nm	Materials that are produced as a result of a manufacturing process with one or more dimensions between 1 and 100 nm
Reporting year		Current year (2006 to 2008)	Current or material soon to be commercialized
Inclusions	Aggregates and agglomerates. Nanomaterials which are researched, produced, used or released by the company	Focus on free nanomaterials because identified has having greater potential for environmental exposure	Does not preclude naturally-occurring or un-intentionally-produced nanoscale materials that may inform for the purposes of the program

Countries 5 to 7	**IRELAND (Voluntary survey)**	**UNITED KINGDOM (Voluntary reporting scheme)**	**UNITED STATES (Voluntary reporting scheme)**
Exclusions			
Targeted Respondents		Manufacturers, importers, users. Not targeting research, but input would be welcomed	Manufacturers, importers, processors, users, researchers (but not if only at research stage or with speculative or uncertain future applications)
Operational Cost			
Stated Benefits		***For government:***	***For participants:***
		Low cost approach; build evidence quickly	Responsible technology development
		For participants:	Opportunity to help develop best ways of evaluate and addressing potential risks
		Discussions informed by real data	Shared learning experience
		Demonstration of corporate responsibility, responsible development	
		Sharing of good practice	
Participation Incentives			Participation incentives suggested by stakeholders: Feedback on submissions from the EPA to companies
			No need for repeat submission under TSCA except for data requirements not previously submitted under voluntary program
			Authority for promotional purposes so that companies can demonstrate involvement in the program
			EPA will work to promote harmonization with notification requirements among federal agencies and internationally
			EPA will provide assistance on regulatory matters to smaller companies

Countries 5 to 7	**IRELAND (Voluntary survey)**	**UNITED KINGDOM (Voluntary reporting scheme)**	**UNITED STATES (Voluntary reporting scheme)**
Nature of Questions	General questions relating to the company , specific questions related to the material		***Basic Program:*** Report existing information (characterization, use, exposure, risk management practices) ***In-depth program:*** Data development and generation
Types of Data Sought			
Company / Activity Identification	Primary industrial sector, volume of handling, Number of employees	Source, manufacturing process,	
Material Identification		Chemical identity (CAS#, name, composition)	Chemical identify (name, formula, structure, reactants, impurities, etc.)
Material Characterization	Nanomaterial class, Primary size (1D or 2D), Analytical methods used	Dimensions and shape, size range, prediction of surface area	Properties specific to nanoscale materials (e.g., crystal structure, agglomeration state)
Use Pattern Information	Type of process used	Uses, including downstream users'	Quantities produced or imported, process description, commercial availability
Fate and Exposure Information	Material Safety Data Sheets	Exposure pathways, environmental fate, behaviour and interactions (e.g., reaction with other substances)	lifecycle overview. Fate and transport
Physico-Chemical Properties	If available, provide details	Based on properties found in the Notification of New Substances (NONS) form including*:* Water solubility and stability Flammability, ignition and explosion potential (occupation safety) Agglomeration/aggregation and deglomeration / disaggregation properties	Based on properties found on standard Premanufacture Notice (PMN) including: Physical state Solubility in water or other solvents Spectra Octanol/water partition coefficient
Human Toxicity Data	If available, provide details	Based on toxicity data found in the Notification of New Substances (NONS) form, for example*:* Inhalation, dermal toxicity Data derived from non-animal test methods (e.g., in vitro, (Q)SARs)	Health effects

Countries 5 to 7	**IRELAND (Voluntary survey)**	**UNITED KINGDOM (Voluntary reporting scheme)**	**UNITED STATES (Voluntary reporting scheme)**
Ecotoxicity Data	If available, provide details	Based on ecotoxicity data found in the Notification of New Substances (NONS) form, for example*:* Effects on organisms, degradation	environmental effects
Other Data	Exposure mitigation practices	Statement on benefits of applications	Bioaccumulation/ biomagnification
		Measurement and detection techniques	Biodegradation
		Current risk management practices	risk management practices (occupational and consumer)
Confidentiality		Data to be treated as confidential unless otherwise indicated	Data to be treated as confidential as it would be under TSCA
Communication		Quarterly reports published (December 2006, April 2007, July 2007)	Notices posted on the Federal Register, Reports and other documents posted online http://www.epa.gov/oppt/nano/#stewardship
		Communication with government, industry, academia and civil society groups through the Nanotechnologies Stakeholder Forum	Overview of Issues for Public discussion and Consideration by NPPTAC (9/21/05)
		Public engagement through the Nanotechnology Engagement Group	Concept Paper for the Nanoscale Materials Stewardship Program under TSCA
			TSCA Inventory Status of Nanoscale Substances – General Approach
Results to Date		July 2007 - 9 responses (7 industry, 2 academia)	May 2007 – 3 submissions and 10 additional commitments by companies for submissions
		October 2007 - no additional responses	December 2008 – 29 responses covering 123 nanoscale materials. An additional 7 commitments to participate.
			EPA released an interim report on January 12, 2009.

Countries 5 to 7	**IRELAND (Voluntary survey)**	**UNITED KINGDOM (Voluntary reporting scheme)**	**UNITED STATES (Voluntary reporting scheme)**
Comments on Program Experience		Mention to Industry that lack of complete data package should not deter submission of data	
Other Remarks		Does not replace existing legislative obligations	Does not replace existing legislative obligations
		Discouraged generation of additional testing requiring use of animals	On-going development of regulatory measures including definitions, SNURs, and how to apply different sections of TSCA
		Dynamic situation: data package will change as understanding grows	Data elements requested are based on the data requirements under TSCA
		Have developed a suggested data package with extensive data and endpoints to guide potential reporters	