



Information from Industry on Applied Nanomaterials and their Safety

Background Paper on Experiences
with Reporting Mechanisms

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1. Introduction

Public authorities are currently faced with the regulatory challenge of striking a balance between the opportunities presented by the development of nanomaterials and, at the same time, the need to ensure public health and safety and protection of the environment. In order to develop appropriate legislation, the knowledge basis of public authorities on these manufactured nanomaterials needs to be improved. In light of the gaps in information in relation to market penetration and the potential risks associated with nanomaterials, a number of countries have developed specific reporting initiatives. These initiatives aim at providing governments with the information they require to determine whether current legislation is adequate and at informing debate on whether additional legislation is required.

This background paper reviews the various reporting mechanisms that have been adopted by or are under construction within EU Member States, as well as examples of non-EU mechanisms (Canada, the US, Australia and Japan). It then draws some comparisons between the approaches adopted, addressing such issues as: who is asked to report; information to be reported; data management; incentives; administrative burden and availability of information to the public. The report concludes with an assessment of the success or failure of the schemes in meeting their stated objectives.

2. Reporting Systems for Nanomaterials in EU Member States

This section outlines the approaches taken in EU Member States to gather information on nanomaterials on the market. These include a trial voluntary reporting system in the UK, a legislative proposal for a mandatory system in France, and one-time voluntary surveys carried out in Germany, Ireland and Denmark.

United Kingdom

In September 2006, the UK Department for Environment, Food and Rural Affairs (DEFRA) established a voluntary reporting system for Manufactured Nanomaterials. The system is a 2-year trial initiative for industry and research organisations to provide information relevant to understanding the potential risks posed by engineered nanoscale materials. During the 2-year trial, thirteen data submissions were received, eleven from industry and 2 from academia. The scheme remains ongoing in that additional submissions are welcome. As of June 2009, DEFRA was reviewing the scheme in order to determine a suitable way forward for the voluntary reporting system, including the development of possible options expected to fall under the umbrella of the REACH Regulation.¹

France

During the 2007 Environment Roundtable (*Grenelle de l'environnement*) initiated by President Sarkozy, it was stressed that better knowledge of nanomaterials and of nanomaterial containing products on the market was necessary in order to assess potential risks and to take precautionary measures if needed. An existing voluntary reporting mechanism under the French Agency for Environmental and Occupational Health Safety (*Agence française de sécurité sanitaire de l'environnement et du travail*) has not proven to be successful due to the low number of respondents.

¹ Department for Environment, Food and Rural Affairs (DEFRA). UK Voluntary Reporting Scheme for Engineered Nanoscale Materials, February 2008. Available at <http://www.defra.gov.uk/environment/quality/nanotech/documents/vrs-nanoscale.pdf>.

With these considerations in mind, the French government has proposed legislation that would establish a mandatory reporting system for manufacturers and importers placing nanomaterials and nanomaterial-containing products on the French market. As of September 2009, the proposal for a mandatory reporting mechanism was still under discussion in the National Assembly.

If the new legislation is adopted, Article L.523-1 of the Environment Code will require information on quantities and uses of the nanomaterials as well as the identity of the professional users – information that was also sought under the existing voluntary mechanism. More detailed requirements will be covered by an implementing decree that has not yet been drafted.

The legislative impact study for the proposed Article L.523-1 argues that a mandatory reporting system is needed for two reasons, firstly because REACH registration does not cover substances produced in quantities of less than one ton per year, and secondly because there are currently no specific obligations to report information on nanomaterials at the EC level.²

Denmark

In 2007 the Danish Environmental Protection Agency published the results of a survey of nanotechnological consumer products carried out primarily on the basis of interviews and questionnaires to Danish companies placing such products on the Danish market.³

Germany

In 2006, the Federal Institute for Occupational Health and Safety (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin*) jointly with the Association of the Chemical Industry (*Verband der Chemischen Industrie*) launched a voluntary survey in order to have a better understanding of the activities involving the handling of nanomaterials. The questionnaire contained a ‘general part’ with general cross-product questions and a ‘specific part’ with product-specific questions on individual nanomaterials. The questionnaire was sent to a total of 656 companies; 217 companies responded, a return rate of 33%.⁴

Ireland

In 2006, the Health and Safety Authority (HSA) launched an internet public stakeholder consultation on nanotechnology using a questionnaire to collect information on the nature of nanomaterials produced or imported in Ireland (chemical identity, quantities, particle sizes, methods by which nanomaterials are identified, potential hazards, exposure scenarios). The questionnaire was publicly available on the HSA website for a period of six weeks. Responses were received from nanomaterials companies as well as companies active in the following sectors: electronics, pharmaceutical and medical devices. According to a public official the response rate was low.⁵

It is also worth noting that at the EU level DG Enterprise and Industry has carried out a preliminary assessment of nanomaterials on the market for CASG Nano.⁶ The assessment compiled information from various data providers, Internet sources and research projects, and categorized nanomaterials according to their stage of development.

² Information gathered via an interview with a French official, September 2009.

³ F. Stuer-Lauridsen, A. Kamper, P. Borling, G. Petersen, S. Foss Hansen & A. Baun. *Survey of nanotechnological consumer products*. Danish Environmental Protection Agency, 2007.

⁴ Exposure to Nanomaterials in Germany: Results of the Corporate Survey of the Federal Institute for Occupational Health and Safety (BauA) and the Chemical Industry Association (VCI). Available at <http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/survey.pdf>.

⁵ Information on the Irish survey provided by the Health and Safety Authority, October 2009.

⁶ The subgroup of REACH Competent Authorities on nanomaterials.

3. Reporting Systems for Nanomaterials in Non-EU Countries

Several initiatives have been taken outside the EU to gather information on nanomaterials. These include a voluntary reporting scheme in the United States, a planned one-time mandatory information call-down in Canada and one-time surveys in Australia and Japan.

United States

At the beginning of 2008, the US Environmental Protection Agency (USEPA) introduced the voluntary Nanoscale Materials Stewardship Programme (NMSP). The NMSP comprises two sub-programs, the Basic Program and the In-Depth Program. Under the Basic Program, the NMSP requests manufacturers, importers, processors or users to submit data on engineered nanoscale materials. Under the In-Depth Program, USEPA invites participants to work with the Agency on a plan for developing more detailed data on representative nanoscale materials over a longer time frame. The objective of this Stewardship Program is to take a first step in assisting the EPA to assess the potential risks of engineered nanomaterials.

An Interim Report on the NMSP issued by the USEPA reported that, as of December 2008, 29 companies or associations had submitted information covering 123 nanoscale materials under the Basic Program, and four companies had agreed to participate in the In-Depth Program. The NMSP was considered useful in that the USEPA had indeed advanced its knowledge base in this area. However, it was noted that nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based and some 90 per cent of the different nanoscale materials likely to be commercially available were not reported under the Basic Program⁷.

Canada

The Canadian government has announced plans to launch a mandatory information gathering survey on nanomaterials on the basis of the 1999 Canadian Environmental Protection Act (CEPA). Notices issued under Section 71 of CEPA are applicable to those persons (e.g., individuals, companies, institutions, etc.) described in the notice, and response is mandatory. The persons to whom the notice applies must make efforts to answer the questions by providing information to which they ought to have reasonable access. Responding companies may submit with their information a request that it be treated as confidential.

The Section 71 information gathering survey for nanomaterials is expected to require manufacturers and importers of nanomaterials, as well as research and development institutes, to report quantity, usage and chemical data to the government, including any available toxicological and monitoring information. This one-time reporting requirement is intended to gather information deemed necessary for improved decision-making with respect to possible regulatory development. The mandatory scheme is expected to be launched sometime in the autumn of 2009.⁸

Australia

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has the mission to deliver safe and sustainable use of chemicals via integrated regulation of industrial chemicals introduced to Australia. As part of this mission and to gain a better understanding of the nanomaterials

⁷ Nanoscale materials Stewardship Program Interim Report, January 2009, U.S. Environmental Protection Agency Office of Pollution Prevention and Toxic. Available at: <http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf>

⁸ Information on the probable mandatory survey in Canada collected from interviews with Canadian public officials.

on the Australian market, NICNAS undertook a Voluntary Call for Information (VCI) in 2006 concerning nanomaterials and their intended applications. Around 20 companies answered the survey, giving information on 21 different types of nanomaterials.

In 2008 NICNAS extended this VCI to include nanomaterials at the research and development stage as well as categories of physico-chemical and toxicological data held on each nanomaterial (though actual data is not to be submitted nor new data generated). Information gathered also included their volumes and how they are used in industry and public sector research. Businesses and public sector researchers were encouraged to participate in the VCI to assist NICNAS in developing appropriate regulatory processes to manage any risks posed by nanomaterials.⁹

Japan

The Ministry of Economy, Trade and Industry (METI) organised an expert meeting in March 2009 in order to gather information on six targeted nanomaterials (carbon nanotubes, carbon black, titanium dioxide, fullerenes, zinc oxide, silicon dioxide). These six substances account for 99% of the production volume of nanomaterials produced in Japan. The information was provided by the industrial organisations concerned and mainly dealt with the characteristics of the targeted nanomaterials, their use, the production volume and the exposure and emission prevention measures taken.¹⁰

An earlier survey conducted by the METI on safety handling of nanomaterials at manufacturing sites and research laboratories reviewed existing good practices both in domestic and overseas sites.¹¹ Finally, the Ministry of the Environment established the 'Investigative Commission on Fundamental Surveys on the Environmental Impact of Nanomaterials' which has been conducting reviews on safety measures and methods for safety assessment of nanomaterials since June 2008.¹²

4. Recommendations from the OECD Working Party on Manufactured Nanomaterials

The OECD Working Party on Manufactured Nanomaterials (WPMN) is the main forum at the international level for the coordination of regulatory activities relating to nanomaterials. It was established in 2006 to help member countries address the safety challenges of nanomaterials efficiently and effectively.

The WPMN has collated information about its members' activities regarding voluntary reporting and surveys. The subsequent report explains the pros and cons of different schemes, including the considerable constraints faced by some schemes as well as successful approaches. The WPMN has developed a number of recommendations for information gathering initiatives, including the following:

⁹ Australian Government Gazette No.C10, 7 October 2008 Industrial Nanomaterials Voluntary Call for information 2008. At: http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2008oct_whole.pdf

¹⁰ The Expert Meeting on Safety Measures for Nanomaterials Manufactures etc. Report (unofficial translation), Ministry of Economy, Trade and Industry (METI), March 2009, Japan. Available at: http://www.meti.go.jp/policy/chemical_management/files/The%20Expert%20Meeting%20on%20Safety%20Measures%20for%20Nanomaterial%20Manufactures%20etc.pdf

¹¹ OECD Paper: Current Developments in Manufactured Nanomaterials in Japan. Available at <http://www.oecd.org/dataoecd/46/54/40464609.pdf>

¹² The Expert Meeting on Safety Measures for Nanomaterials Manufactures etc. Report (tentative translation), Ministry of Economy, Trade and Industry (METI), March 2009, Japan. Available at http://www.meti.go.jp/policy/chemical_management/files/The%20Expert%20Meeting%20on%20Safety%20Measures%20for%20Nanomaterial%20Manufactures%20etc..pdf

1. The information gathering initiative should include deadlines that reflect the time needed to gather information being requested and identify the next steps;
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;
3. Consideration should be given to supplementing voluntary initiatives with mandatory reporting;
4. Authorities should require respondents to submit all available information on any nanomaterial they include in the initiative;
5. The information sought in information gathering initiatives should clearly be delineated;
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;
7. Authorities should indicate at the outset what specific types of information submitted by companies are eligible for protection as confidential business information;
8. Authorities should identify clearly how information collected under the initiative will be made public;
9. Information gathering initiatives should capture the broadest possible scope of nanomaterials and applications;
10. The information gathering initiative should include companies and research institutions conducting R&D on nanomaterials particularly pre-commercialization R&D;
11. Authorities should consider provisions for updates to submitted information;
12. Companies and institutions participating to the initiative should be reminded of the importance of having appropriate personnel respond to the information request;
13. Authorities should consider providing tools to respondents to facilitate their response;
14. Authorities should ensure appropriate communication of the information gathering initiative.

5. Who is asked to report?

Each reporting mechanism studied above requires or will require information from a range of respondents (from the manufacturers of nanomaterials to the processors of waste containing nanomaterials). However, as is shown in the table below, the targeted respondents differ significantly from a reporting mechanism to another. The Australian VCI has the widest range of addressees followed by the UK voluntary reporting system and the US NMPS. The Australian VCI and the UK voluntary reporting system are the only ones that request some information from the processors of waste streams containing nanomaterials.

It is also worth noting that few reporting mechanisms (the US NMPS, the Australian VCI, the German voluntary survey) require information from processors of nanomaterials.

	US	CAN	JPN	AUS	IE	DE	FR	UK	DK
Manufacturers	√	√	√	√	√	√	√	√	√
Processors	√			√		√			
Importers	√	√		√			√	√	
Placing on the market				√			√		
Users	√		√		√	√		√	√
R&D	√	√		√	√		√	√	
Waste processors				√				√	

6. Information to be reported under these mechanisms

The table below presents the data requested under each of the mechanisms. Most reporting schemes request information on the identification of nanomaterials, their uses, the quantities produced and their potential to penetrate cell membranes and on exposure and risk management.

Information	US	CAN ¹³	JPN ¹⁴	AUS	IE	DE	FR ¹⁵	UK	DK
Identification									
CAS# (if possible)		√		√	√			√	√
Formula	√	√		√					
Chemical name	√	√	√	√	√	√		√	√
Structure	√	√		√					
Potential to penetrate cell membranes									
Shape [particle, fibre, etc.]	√	√		√				√	
Size range		√		√	√	√		√	√
Persistence									
Aggregation potential				√				√	√
Composition								√	
Water solubility	√			√				√	
Toxicity					√ ¹⁶				
Surface area				√				√	√
Release of component				√				√	
Reactivity								√	
Exposure and risk management	√	√	√	√	√	√		√	√
Uses	√	√	√	√		√	√	√	√
Quantities	√	√	√	√	√	√	√	√	√

The two voluntary schemes currently in force, the UK voluntary reporting system and US NMSP, have both developed an indicative set of information to be submitted. The amount of information specifically mentioned and requested under both schemes differs remarkably. The UK voluntary reporting system provides a very comprehensive checklist of information that can be submitted, while the US EPA Basic Programme requests information on fewer topics. Though the UK authorities mentioned at various instances that the list of types of data to submit was merely indicative, it is now

¹³ Information taken from the OECD Working Party on Manufactured Nanomaterials, Report on Project five: Cooperation on Voluntary Schemes and Regulatory Programmes. Note that as of September 2009, Canada had not yet launched its one-time mandatory information call-in.

¹⁴ Note that information in English about the Japanese survey is scarce.

¹⁵ To be confirmed, since the proposed legislation has not yet been adopted in France.

¹⁶ The Irish survey asked for any information available on the potential hazards associated with nanomaterials.

considered that the number of questions requesting data in detail could have had a discouraging effect on participants.

At this stage, the French authorities were not able to specify the data that would be requested under the proposed mandatory mechanism apart from the quantities, the uses of the nanomaterials and the identity of the professional users. The precise content of the data required will be fixed by a decree to be issued later in the regulatory process.

The 2008 Australian VCI provides an exhaustive list of questions (around 100) covering information on the business involvement with nanomaterials of respondents, chemical identity, physical and chemical properties, environmental fate and ecotoxicological data, human toxicological data and use information.¹⁷ The result of this voluntary survey has not yet been published. To compare, the German voluntary questionnaire only provides 17 questions that are mainly focusing on aspects of worker protection during the production and handling of nanomaterials. The Irish and the Danish survey requested even less detailed information.

It is worth noting that almost all voluntary reporting mechanisms, either existing or under construction, require or request respondents only to submit readily available information. Only the USEPA's In-Depth Programme, which has a longer time frame than the Basic Program, seeks to have participants voluntarily develop data (including testing, if needed), with USEPA support.

7. Data management

With all reporting mechanisms reviewed, government authorities were in charge of collecting and managing the information submitted by the respondents. In the UK, the information was collected and managed by DEFRA, and in the US, by USEPA. This information could in some cases be shared with other governmental departments or bodies. Other options for data management, such as the outsourcing to external companies, have not been used, although some government officials considered the option to be interesting. Note however that the Danish survey was contracted to a consulting company and that the German survey was jointly organised by a government authority, the Federal Institute for Occupational Health and Safety (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin*) and a private organisation, the Association of the Chemical Industry (*Verband der Chemischen Industrie*).

8. Incentives

Under the UK voluntary reporting system, attention was given to the fact that participation in a voluntary mechanism would demonstrate corporate social responsibility and provide the opportunity for companies to develop responsibly and to share good practice. A similar approach to incentives was followed under the USEPA program. The Danish survey also highlighted the importance of companies being able to describe their regulatory needs and thus inform and influence governmental decisions through a demonstration of corporate social responsibility.

¹⁷ Australian Government Gazette No.C10, 7 October 2008. Industrial Nanomaterials Voluntary Call for information 2008. Available at: http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2008oct_whole.pdf.

9. Administrative burden

No detailed reactions were obtained from government officials on the administrative burden created for companies through the voluntary reporting mechanisms. It is nevertheless important to take into consideration that many players on the nanomaterials market are small start-up businesses.

10. Availability of information to the public versus commercial confidentiality

Striking the right balance between providing the public with information concerning safety and security in relation to nanomaterials and protecting sensitive business information can be difficult. In the development of the reporting mechanisms described above, governments have aimed to maximise the amount of information received whilst simultaneously ensuring that the general public is not excluded from receiving potentially important information.

It should be noted that most countries have specific legislation on access to information which obliges government bodies to make certain information publicly available, even while recognising that certain commercially sensitive information should not be disclosed.

The USEPA treats data under the NMSP as confidential, similar to information submitted under the Toxic Substance Control Act (TSCA), which allows chemical manufacturers, processors and distributors to claim information submitted to the EPA as confidential. Under TSCA, the USEPA must then protect such data (e.g. trade secrets or financial information) from unauthorized disclosure. The UK also treats the data submitted under the voluntary reporting system as confidential unless otherwise stated. If information is requested under the Freedom of Information Act or the Environmental Information Regulations, data owners will first be consulted.

With regard to Canada's pending mandatory information call-in on nanomaterials, Article 300 of the 1999 CEPA allows companies to claim the information submitted as commercial and to be kept confidential, although a non-confidential summary of information is likely to be published.

In France, one of the Environment Code's most important principles is to make information concerning public health and environmental protection publicly available. Since the mandatory reporting scheme on nanomaterials and its implementing measures have not yet been enacted, it is not yet known how much of the specific information to be submitted will be disclosed to the public, and how much will be protected on the basis of commercial confidentiality.

Under the Australian VCI all information that is submitted by respondents is considered to be confidential unless stated otherwise. With regard to the German survey, the questionnaire was anonymous and the name of the companies did not appear in the final result paper.

11. Success or failure?

Overall, the UK voluntary reporting system has not been considered as a great success as only 13 responses have so far been received. However, it should be noted that this response rate is estimated to represent approximately 20-25% of concerned companies in the UK. Government officials also confirm that they have obtained a number of very detailed responses in addition to responses relating to substances of concern. As such, progress has been made in understanding some substances on the UK market. Options for increasing participation rates currently under consideration include

simplification of the reporting form and the introduction of additional incentives in relation to corporate social responsibility.

The surveys carried out by Germany and Ireland also had quite low response rates.

Australia has not yet published the result of its voluntary survey and in Japan available data is not sufficient to assess the success of such an initiative.

In its interim report of January 2009, the USEPA considered the voluntary NMSP to be successful. However, in December 2008, the USEPA had only received 29 submissions covering 123 nanoscale materials, which it recognised as representing only a small fraction of the products currently under development or on the market in the US. Furthermore, it regretted that it had been unable to fill a number of environmental health and safety information gaps. In September 2009, a USEPA official indicated that the NMSP will be shut down at its conclusion in early 2010, and is likely to be replaced by a mandatory scheme.¹⁸

¹⁸ Remarks made by Steve Owens, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, U.S Environmental Protection Agency, at the Conference on Transatlantic Regulatory Co-operation: Securing the Promise of Nanotechnologies, London, 10 September 2009.