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# UK Voluntary Reporting Scheme for engineered nanoscale materials

Department for Environment, Food and Rural Affairs  
Nobel House  
17 Smith Square  
London SW1P 3JR  
Telephone 020 7238 6000  
Website: <http://www.defra.gov.uk>

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Information about this publication and further copies are available from:

Chemicals and Nanotechnologies Division

Defra

Area 2A

Nobel House

17 Smith Square

London SW1P 3JR

Tel: 020 7238 1577

Fax: 020 7238 1602

E-mail: [nano.technology@defra.gsi.gov.uk](mailto:nano.technology@defra.gsi.gov.uk)

This document is also available on the Defra website.

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# 1 Introduction and Summary

- 1 The Government is aiming to develop appropriate controls in respect of any risks to the environment and human health from free engineered nanoscale materials. In order to move towards appropriate controls, there is a need to build evidence on potential risks. This Voluntary Reporting Scheme is one strand of the Government's approach to gathering this evidence.<sup>1</sup>
- 2 We would like to receive data on manufactured nanomaterials from anyone involved in their manufacture or use and anyone involved in nanoscience research or managing wastes consisting of engineered nanoscale materials. Information on the type of data we would welcome is set out in Chapter 2 and in "Nanomaterials: Hazards and risks to health and the environment: A supplementary guide for the UK Voluntary Reporting Scheme", which can be downloaded from the Defra Nanotechnologies website.
- 3 We do not necessarily require or expect commercially sensitive business information to be submitted to the Voluntary Reporting Scheme. Although the data reporting form allows information on a broad range of characteristics and properties to be entered, we understand that it may only be possible to provide limited data to the scheme. The scheme aims to provide an indication of those nanomaterials which are currently in development or production. Even basic details, such as the identity of an engineered nanomaterial, are helpful in building up this picture, which will inform high-level policy decisions and enable our effort and resources to be focused in areas which are relevant to the UK's current nano manufacturing and research base. It is not intended that individual risk assessments will be made on nanomaterials submitted to the scheme.
- 4 The scheme will work alongside the Government's programme of scientific research, to help develop a better understanding of the properties and characteristics of engineered nanoscale materials, so enabling potential hazard, exposure and risk to be considered. Building an evidence base in this way will allow for a more informed debate about the nature of appropriate controls. It will also lead to appropriate controls in the shortest time frame giving a predictable regulatory environment for all.
- 5 The scheme, which is voluntary and does not replace existing legislation, is intended to run from September 2006 to September 2008.
- 6 This scheme is being run by the Department for Environment, Food and Rural Affairs, working with other Government departments and agencies, the Scottish Executive, the National Assembly for Wales and Northern Ireland Administration.

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<sup>1</sup> More information on the Government's approach can be found on Defra's nanotechnologies web pages at: <http://www.defra.gov.uk/environment/nanotech/index.htm>

## 1.1 How to provide data to the scheme

- 7 The data reporting form contains an INDICATIVE set of data, and any data field completed within this would be welcomed. It is not expected that all of the data fields will be completed. A glossary of terms and acronyms is provided in the Annex to this document.
- 8 Forms, completed as appropriate, should be sent to:  
Mr David Lovell  
Department for Environment, Food and Rural Affairs  
Chemicals and Nanotechnologies Division  
Area 2A  
Nobel House  
17 Smith Square  
London SW1P 3JR  
  
Tel: 020 7238 1577  
Fax: 020 7238 1602 E-mail: david.lovell@defra.gsi.gov.uk
- 9 We welcome both electronic and postal submissions, though electronic is preferred.
- 10 This document is on the Department for Environment, Food and Rural Affairs website at:  
<http://www.defra.gov.uk/environment/nanotech/policy/index.htm>

## 1.2 Scheme administrator

- 11 If you would like help with queries or require further information about this scheme please contact:  
Steve Morgan 020 7238 1580  
John Garrod 020 7238 1576

## 2 Operation of the Scheme

12 The reporting scheme is entirely voluntary. The data obtained from the scheme will be reviewed regularly. We will upgrade the scheme as we develop our understanding of both how it is working and the data that is of most value. The scheme will run for two years. At the end of this period, it will be fully evaluated together with the findings of the Government's research programme on potential risks, and the Secretary of State for Environment, Food and Rural Affairs will take a decision on future direction.

### 2.1 Focus of the Voluntary Reporting Scheme

13 For the purposes of the Voluntary Reporting Scheme, we will focus on engineered nanoscale materials that are free at any stage of a product's life-cycle.

14 The term 'life-cycle' refers to all phases in the life of a product. Specific life-cycle phases can vary depending on the type of product, but may include research, design, development, manufacture, import, supply, storage, transport, use or consumption, cleaning, decommissioning or dismantling, recycling and disposal, including what happens to the product after disposal.

15 Nanoscale materials are defined as having two or more dimensions up to 200nm. This definition, and thus the focus of the scheme, will be reviewed throughout the duration of the scheme, responding to the ongoing work of British Standards Institute (BSI), European Committee for standardisation (CEN), and International Organisation for Standardisation (ISO). However, we would still be interested in receiving data on engineered nanoscale materials falling outside this limit if deemed relevant to providing valuable information on potential risks.

16 We would like to receive data from any company or organisation manufacturing or using nanomaterials and anyone involved in nanoscience research or managing wastes consisting of engineered nanoscale materials.

17 In summary, the focus of the scheme is materials that:

- are deliberately engineered (i.e. not natural or unintentional by-products of other processes);
- have two or more dimensions broadly in the nanoscale; and
- are 'free' within any environmental media at any stage in a product's life-cycle.

### 2.2 Data submission

18 The suggested reporting form can be downloaded from the Defra Nanotechnologies website as a PDF file, onto which data may be directly entered. A Microsoft Word version of the form can also be obtained by contacting Defra (contact details are given at paragraph 8 of this guidance). It should be noted that although we recommend using the reporting form, data will be accepted in any format.

19 It is preferred that information be reported electronically as far as possible.

20 Information may be provided indirectly via a third party, such as a trade association, if preferred.

21 With regard to the commercial confidentiality of any data provided, we agree to:

- (a) treat any information provided to us in confidence unless expressly given permission by the data owner to do otherwise;

- (b) consult the person who provided information should that information be subject to a request under the provisions of the Freedom of Information Act or the Environmental Information Regulations. Defra may be obliged to provide information, upon such a request, to third parties.

## 2.3 Type of data

- 22 The type of data that is of interest includes information on material characterisation, hazard, use and exposure potential, risk management practices and the techniques used. **It should be emphasised that the intention is to encourage the submission of existing data and that we do not require generic data and data relating to any material in its 'bulk' form.**
- 23 Companies and organisations are not expected to generate additional data solely for the purpose of the scheme. It is also important to point out that we recognize the difficulties that currently exist with respect to animal testing and that **we wish to discourage scheme participants from generating any additional data that would require animal testing.** It is expected that many companies will be unable to supply all of the information outlined in the data reporting form. The lack of a complete package of data should not deter companies from reporting under the scheme.
- 24 Physico chemical and toxicology data must be provided by someone with an appropriate technical background and who is familiar with the nanomaterial.
- 25 It should also be noted that the data considered as desirable in order to determine the hazard, exposure and risk of engineered nanoscale materials is likely to change as our understanding of what is appropriate develops. The data outlined in the data reporting form and accompanying guidance is a starting point. In particular, some of the standard tests for bulk chemicals may not be relevant for nanoscale materials. However, in the absence of robust alternatives, the existing tests offer an appropriate starting point. These issues are currently the subject of expert discussion and debate in the UK and internationally.
- 26 Guidance on completion of the VRS data reporting form is provided in "Nanomaterials: Hazards and risks to health and the environment: A supplementary guide for the UK Voluntary Reporting Scheme", which can be downloaded from the Defra Nanotechnologies website.
- 27 To ensure that data is being compared appropriately it is important that we know how you arrived at specific data. Information on experimental conditions and QA/QC procedures is also needed. Data will have been collected in a variety of ways over a period of time. Further, there are no agreed test methods for engineered nanoscale materials and some companies and organisations will have devised their own methods. We are particularly interested to know about the measurement techniques used to gather specific data.

## 2.4 Relationship of scheme to existing legislation

- 28 Information provided for this scheme does not replace the requirement for any information to be submitted under any existing legislation. Participation in the scheme will not constitute any form of accreditation or endorsement by Government of risk management practices or adequacy of data.

- 29 If an engineered nanoscale material is considered to be a new substance and a company is required to submit information to the Competent Authority for Notification of New Substances (NONS) Regulations, then this information could be submitted to the Voluntary Reporting Scheme at the same time. Data submitted under the NONS Regulations will not be transferred within Government to the Voluntary Reporting Scheme.
- 30 The new European chemicals legislation, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, entered into force on 1st June 2007. This gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on substances. As substances, nanomaterials are subject to the requirements of REACH; however, the Regulation does not currently contain provisions specific to nanomaterials, or require their specific authorisation.

## 2.5 Administration of the scheme

- 31 Defra will administer the scheme and hold the data submitted as part of the scheme.

## 2.6 Use of data collected by the scheme

- 32 The data will be held by Defra. It will be analysed by Government scientists, experts who sit on the task force groups of the Nanotechnology Research Co-ordination Group and members of the Advisory Committee on Hazardous Substances, who provide expert advice to Government, on the science behind chemicals. This Committee works to a confidentiality agreement. If this expertise is not thought to be sufficient, Government will of course consider the need to recruit additional experts for peer review.
- 33 The **identity** (i.e. name and CAS reference number) of the nanoscale materials submitted to the Voluntary Reporting Scheme will also be held on a list maintained by the Organisation for Economic Co-operation and Development (OECD). Only the identity (chemical name and CAS reference number), and no other data submitted under the scheme, will be held on this list. The OECD list will include all nanomaterials submitted to the Voluntary Reporting Scheme and similar schemes operating in other countries. This will provide an 'at a glance' record of where data is held relating to specific nanomaterials. It is hoped that this will help the international research effort by facilitating the comparison of datasets. This could help to achieve a greater shared understanding of how variations in the characteristics of nanomaterials affect their behaviour. For example, by comparing various data sets relating to a given nanoscale substance, but with differing particle dimensions, it may be possible to identify the exact dimensions which determine a given toxicological response in the substance. Such analysis would only be undertaken by competent authorities and only with the consent of the owner of the data (i.e. the company or individual who submitted the data).





34 Specifically, the data will be used to:

- build a clearer picture of the type of nanomaterials being manufactured, handled and marketed in the UK;
- draw comparisons with the findings of the Government's research programme into the potential risks posed by engineered nanoscale materials, as well as the outputs of relevant international research programmes, such as the US EPA's STAR<sup>2</sup> programme;
- review the appropriateness of the base set of data; and
- inform considerations of the nature of appropriate controls for engineered nanoscale materials.

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<sup>2</sup> Science To Achieve Results – <http://es.epa.gov/ncer/grants/>.

## 3 Communications and Review

### 3.1 Communication with participants within the scheme

35 Communication with those participating in the scheme will be ongoing. In particular, if there are changes to details of the administration of the scheme, participants will be informed in a timely manner. Reporting of any further data collected by participants in the future is encouraged.

### 3.2 Review of the scheme

36 Some elements of the scheme will be reviewed on an ongoing basis in order to allow it to evolve as appropriate. Specific issues addressed will include:

1. Take-up of the scheme. The number of companies reporting to the scheme will be monitored and quarterly updates will be published.
2. Administrative elements of the scheme. The consistency of the reporting format, methods of holding the data and data volume will be reviewed on an ongoing basis. Changes to administrative methods will be made if needed.
3. Appropriateness of the proposed data set. This will involve review by Government scientists and expert committees, such as the Advisory Committee on Hazardous Substances (ACHS). A number of factors may precipitate such a review, including developments in international fora. For example, if discussions at the ISO technical committee on nanotechnology or at the OECD Working Party on Manufactured Nanomaterials identify appropriate methods for measurement or testing of nanoscale materials, the scheme may be updated to reflect this.
4. Implications of any legislative developments within the European Union or internationally. If, during the lifetime of the scheme, there are significant developments towards putting in place an EU or international regulatory framework for nanotechnologies, then the scheme would be reviewed in light of these developments.

37 As mentioned above, some elements of review of the scheme will take place on an ongoing basis, or in response to developments at an international level. We will publish quarterly updates setting out in a general and non-attributable way, the information received and the progress that we are making with the scheme. In addition to this, there will be more formal reviews every six months, with a final review and evaluation at the end of the initial two year period of the scheme.

38 The six monthly reviews will be undertaken by Defra and discussed across Government. In addition to a more formal review of the elements highlighted above, the costs and benefits of the scheme, including administration costs, will also be reviewed at this stage.

39 It is intended that the final appraisal at the end of the scheme will include a review against the aims of the scheme. It is proposed that this review should include asking a range of stakeholders whether they believe the scheme has achieved its objectives and whether there have been other additional benefits or costs associated with the scheme. These stakeholders will include (but not be limited to) participants in the scheme, government departments and agencies, expert committees, trade associations, learned societies, and civil society organisations.

Glossary	
Acronym	Definition
<b>ACHS</b>	Advisory Committee on Hazardous Substances
<b>BSI</b>	British Standards Institute
<b>CAS</b>	Chemical Abstract Service
<b>CEN</b>	European Committee on Standardisation
<b>Defra</b>	Department for Environment, Food and Rural Affairs
<b>EU</b>	European Union
<b>HPLC</b>	High performance liquid chromatography
<b>IR</b>	Infra-red
<b>ISO</b>	International Organisation for Standards
<b>kPa</b>	Kilo – pascals
<b>nm</b>	nanometre
<b>NMR</b>	Nuclear magnetic resonance
<b>NONS</b>	Notification of New Substances
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OSI</b>	Office for Science and Innovation
<b>QSAR</b>	Quantitative Structure Activity Relationships
<b>STAR</b>	Science to Achieve Results
<b>US EPA</b>	United States Environmental Protection Agency
<b>UV</b>	Ultra violet

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