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UK Voluntary Reporting Scheme for engineered nanoscale materials

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Chapter 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 evidence¹.

2 The scheme is intended to run from September 2006 to September 2008.

3 We would like to receive data from any company or organisation involved in manufacturing, using, importing, researching, or managing wastes consisting of engineered nanoscale materials. The type of data we would welcome is set out in Chapter 2.

4 The scheme is voluntary and is not replacing existing legislation.

5 The purpose of the Voluntary Reporting Scheme, alongside a Government programme of scientific research, is to develop a better understanding of the properties and characteristics of different 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.

6 It will also lead to appropriate controls in the shortest time frame giving a predictable regulatory environment for all. Additionally, it will allow UK Government to contribute towards creating a level playing field in the global community.

7 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.

1.1 How to provide data to the scheme

8 Annex A is the data reporting form. The 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 at Annex B.

¹ 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>

9 Forms, completed as appropriate, should be sent to:

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10 We welcome both electronic and postal submissions, though electronic is preferred.

11 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

12 If you would like help with queries or require further information about this scheme please contact:

Elizabeth Surkovic 020 7082 8108
John Garrod 020 7082 8107

Chapter 2

Operation of the Scheme

13 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

14 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. 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, at this time, be interested in receiving data on engineered nanoscale materials falling outside this limit if deemed relevant to providing valuable information on potential risks.

15 We would like to receive data from any company or organisation manufacturing, using, importing, researching or managing wastes consisting of engineered nanoscale materials.

16 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

17 The suggested reporting form is provided at Annex A. It should be noted that although the attached reporting form is our recommendation, **data will be accepted in any format.**

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

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

20 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

21 The type of data that is of interest is detailed below, and 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**. Companies and organisations are not asked to generate additional data, and are **discouraged from generating any additional data that would require animal testing**. Many companies may not hold all of the information outlined below. Submission of any available information is encouraged, as any data will be helpful. The lack of a complete package of data should not deter companies from reporting under the scheme.

22 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 here 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.

23 The type of data that is sought under the scheme includes the following:

- Name and address of reporter (e.g. a company or a trade association).
- Identity of the nanoscale material:

- Chemical Abstract Service (CAS) number(s) of chemical(s) contained in the nanoscale material
- name of material (chemical and common)
- composition of the substance.
- Information on the nanoscale material including:
 - source of the material (where the material is not produced by the notifier, information would be welcomed about how the nanoscale material was obtained, i.e. details of the producer or importer of the material).
 - manufacturing process
 - intended use of the nanoscale material to include:
 - use pattern within the company, intended downstream uses and users
 - information about potential exposure pathways and likelihood of exposure via these pathways
 - statement about the benefits of the application
 - information about agglomeration or aggregation and deagglomeration and disaggregation properties
 - dimensions and shape
 - size range
 - prediction of surface area (cross referenced to approximate mass)
 - estimated production volume.
- Measurement techniques used for detection of the nanoscale material (e.g. in waste streams) or to determine the characteristics of the nanoscale material to ensure consistency and quality of product (e.g. quantity, size range etc).
- Physico-chemical properties of the nanoscale material to include the following:
 - water solubility and stability in water
 - flammability, ignition and explosion potential
 - partition coefficient n-octanol/water.
- Toxicological information about the nanoscale material:
 - for example, inhalation toxicity data, dermal toxicity data.
 - toxicity data derived from non-animal test methods, e.g. *in vitro* tests and (Quantitative) Structure Activity Relationships ((Q)SARs).
- Eco-toxicological information about the nanoscale material:
 - effects on organisms
 - degradation/biopersistence
 - bioaccumulation potential.
- Available information about environmental fate, behaviour and interactions of the nanoscale material (e.g. with other substances). Any available information about the changes that occur when the

nanoscale material enters the environment would be of interest. For example, if the nanoscale material is known to be highly reactive (e.g. is an oxidising or reducing agent) and there is information indicating that it would react to form other substances if released into specified environmental compartments.

- Information about any risk management practices currently employed in order to reduce or remove emissions of nanoscale materials to the environment or to waste streams.

24 The data reporting form is at Annex A.

25 We are particularly interested to know what measurement technique you have used to gather a specific data point. 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. To ensure that data is being compared appropriately it is important that we know how you arrived at the specific data point.

2.4 Relationship of scheme to existing legislation

26 It should be clear that the information provided in this scheme will 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.

27 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 for NONS will not be transferred within Government to the Voluntary Reporting Scheme.

2.5 Administration of the scheme

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

2.6 Use of data collected by the scheme

29 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 Government expert advisory committees who work within 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.

30 Specifically, the data will be used to:

- 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 STAR² programme;
- review the appropriateness of the base set of data; and
- inform considerations of the nature of appropriate controls for engineered nanoscale materials.

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

Chapter 3

Communications and Review

3.1 Communication with participants within the scheme

31 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

32 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 may 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.

33 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.

34 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.

35 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

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