

Defra consultation on a Voluntary Reporting Scheme for engineered nanoscale materials

Summary of findings and Government's response, August 2006

1.0 Introduction

1 On the 31 March 2006, the Department for Environment, Food and Rural Affairs (Defra) published a consultation seeking views on a proposal for a "Voluntary Reporting Scheme" for engineered nanoscale materials. This paper summarises and responds to the findings of the consultation.

2 There is currently very little evidence on which to determine the potential risks posed by engineered nanoscale materials. It is therefore difficult to assess the extent to which current controls and regulations cover these materials, or the type of additional measures that may be necessary to control potential risks.

3 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. The building of an evidence base in this way will allow for a more informed debate about the nature of appropriate controls.

4 The consultation document was sent to over 120 relevant stakeholders, as well as being made available on the Defra web-site. 37 replies were received during the 12 week consultation period, and the relevant consultation web-pages were accessed on 4484 occasions. The breakdown of respondents, by category, can be seen in Table 1 (see also Annex 1 for a full list). All respondents were asked if they were content for their views to be made public, and non-confidential responses are available from the contact point listed below in paragraph 7.

Category	Number
Academic	6
Industry and trade associations	15
Civil society organisations	8
Other	7
Responses to be kept confidential	1
<i>Total</i>	<i>37</i>

Table 1. Breakdown of respondents

5 During the consultation period, the Voluntary Reporting Scheme was discussed at Defra's Nanotechnologies Stakeholder Forum; a multi-stakeholder and expert group that meets regularly to discuss Government activities around nanotechnologies. An additional open workshop was organised for interested parties to discuss the consultation with Defra. While these occasions have helped to inform Defra's thinking on the Voluntary Reporting Scheme and nanotechnologies policy more generally, their outputs have not been directly considered in this summary of consultation responses, and for this reason, all participants were requested to submit their views in writing to Defra.

6 We are most grateful for all the responses received. In undertaking this consultation and drawing up this summary, we have been guided by the arguments advanced by respondents in support of their views. What follows then should be regarded as a summary of statements provided by respondents in respect of their perceived priorities on the issues covered in the consultation document. The same points were often made in response to different questions, and to avoid repetition, we have grouped issues around what we feel are the most appropriate questions. Government responses to the issues raised are included in ***bold italics*** at the end of each set of questions.

7 You can obtain copies of this report from:
<http://www.defra.gov.uk/corporate/consult/nanotech-vrs/index.htm>

or:

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2.0 Views expressed and Government's response

2.1 An evidence based approach to appropriate controls

Question 1: do you agree with the overall 'green-line' approach of moving towards evidence-based, appropriate controls? If not, what alternative would you suggest?

8 The majority of respondents expressed support for the Government's evidence based approach for determining the nature of appropriate controls for the potential risks posed by free engineered nanoscale materials.

9 Several respondents emphasised, at the same time, that the Voluntary Reporting Scheme, on its own, would not be sufficient for building the necessary evidence, and that it needed to be paralleled by a significant programme of publicly funded research on potential risks. It was suggested that the Government's commitment in this respect was still lacking.

10 Several respondents expressed specific concerns that animal tests – argued to be outdated in comparison with modern non-animal tests – should not be used to develop the evidence base. Emphasis was placed on the role of toxicogenomics – a scientific field concerned with the way a given chemical targets gene function within a living cell.

11 It was notable, however, that civil society organisations were not in agreement with the Government's overall approach, arguing that it demonstrated insufficient precaution. There was particular concern that while Government works towards an evidence base, little is being done to manage potential environmental risks. It was rather felt that the environmental release of free engineered nanoscale materials should be prevented until there are a set of risk assessment procedures in place that can determine the acceptability of any risks posed to the environment. In the current absence of such measures, it was argued by one respondent in particular that there should be a labelling scheme to enable consumer choice over the products of nanotechnologies (including food, health and beauty products).

12 The Government is committed to an evidence based approach to addressing the potential risks posed by free engineered nanoscale materials. The approach is centred on a comprehensive programme of risk research, and supported by the Voluntary Reporting Scheme. It is our full expectation that through this approach, we will arrive at an evidence base that will allow us to determine the most appropriate set of controls for free engineered nanoscale materials. We understand the concerns of the civil society groups, but emphasise that we must have an evidence base when creating regulation, including new labelling schemes, and at present we do not have this.

13 We support the development of non-animal test methods for evaluating the safety of chemicals, and Defra is pursuing a programme of work in this area. We have emphasised the potential use of in-vitro tests for screening tools for nanomaterials in the guidance for participating companies. However, we do not believe that there is sufficient validation of non-animal tests to be able to rely on

them alone. We will not ask companies to generate additional data based on animal testing as part of the Voluntary Reporting Scheme.

2.2 The objectives of the Voluntary Reporting Scheme

Question 2: do you agree with the proposed Voluntary Reporting Scheme? If not, what alternatives would you suggest?

Question 3: the Government would specifically like to receive comments on the practicality and reasonableness of the proposal.

Question 4: are there any additional issues that you think are important to the development or implementation of the scheme that have not been addressed in this document?

Question 5: do you agree with the overall aims of the voluntary scheme?

14 The majority of the respondents agreed with the Voluntary Reporting Scheme as means of building further evidence on the potential risks posed by free engineered nanoscale materials. On the whole, however, civil society organisations did not feel it demonstrated a sufficient degree of precaution as part of the Government's overall approach.

15 Many respondents recognised that its success would be contingent on the willingness of industry to participate and participate fully. Some respondents therefore called for the Voluntary Reporting Scheme to be made mandatory to ensure, from the outset, representative participation and adequate monitoring of company activity.

16 Many respondents stressed the need for European and international co-ordination of reporting schemes for nanomaterials to avoid inconsistent requirements.

17 Many of the participants raised concerns in relation to how intellectual property and commercially sensitive data would be protected, stating that industry would be very unlikely to submit any data that could potentially put them at a competitive disadvantage if it was to be made public. It was stressed that this would need to be addressed before the start of the scheme, and that companies would need a clear statement about the status of their submitted data, including ownership and the uses to which it would be put. Several parties suggested that it might help if a third party, such as an industry association, collected the data.

18 There was concern, however, on the part of two respondents that commercial sensitivity would be used as a reason for companies to be selective in their submission of data.

19 We welcome the majority support for a Voluntary Reporting Scheme as a means of gathering evidence.

20 To re-iterate our earlier comment, we do not, at this time, have sufficient evidence on which to justify a mandatory reporting scheme. However, if during the

two year period while we are gathering evidence it becomes apparent that additional controls are needed, we will take action in the most rapid manner possible.

21 In taking forward the Voluntary Reporting Scheme, we understand and recognise the need to protect commercially confidential data. We will treat any information provided to us as confidential unless expressly given permission by the data owner to do otherwise. Further, should the information be the subject of a request under the provisions of the Freedom of Information Act or the Environmental Information Regulations, we will consult the provider of the data. We will also accept data submissions from third parties, such as industry associations. Conversely, we also recognise the need to release information to allow progress with the scheme to be monitored. To address this, we will publish quarterly updates setting out, in more general terms, information received.

22 Government is committed to the international co-ordination of work on the potential risks posed by engineered nanoscale materials, and this includes reporting schemes that are being progressed by other countries. The Organisation for Economic Co-operation and Development is co-ordinating work in this area.

2.3 Focus and definitions

Question 6: do you agree with the initial focus on free-engineered nanoscale materials, and the definitions of nanoscale materials for the purpose of the scheme?

Question 7: are there any other criteria or definitions for the materials that will be targeted by the scheme, which you believe, are important? The Government would welcome views on the definition of 'nanoscale material' in this consultation, and any suggested alternatives.

23 The majority of respondents agreed that the priority for the Voluntary Reporting Scheme should be 'free' engineered nanoscale materials. Several respondents felt that this should include the potential for nanomaterials to be 'free' during production, use, and disposal, and thus the potential for nanomaterials held in a fixed matrix to be released as a result of, for example, mechanical or environmental forces.

24 There was some support for a definition of a nanomaterial based on one or more dimensions at the nanoscale. This was in some cases to address the potential for materials with one-dimension at the nanoscale to generate materials with two- or three-dimensions at the nanoscale during use and disposal.

25 Other respondents, however, supported a definition based on two or more dimensions at the nanoscale, and in some of these cases, this was explicitly so that films are not included.

26 One respondent was in agreement that the size range for inclusion in the Voluntary Reporting Scheme should be up to 100nm. Another emphasised the need to continue to monitor the work of the International Standards Organisation (ISO) and the British Standards Institute (BSI) as the definition of a nanomaterial is not yet decided. Another suggested that for the purposes of the Voluntary Reporting Scheme, an upper size limit of

200 nm be used to capture all relevant materials. One respondent expressed caution, however, in adopting even a loose size range, suggesting that novel effects can occur even up to 1000nm. It was argued that there is a growing recognition that nanomaterials' novel or enhanced properties are determined by more than just size, with nanoscale structure, surface chemistry and shape being particularly important; for example, a strict size-related restriction on what materials are to be included in the Voluntary Reporting Scheme, would fail to account for cases where particle size may significantly exceed 100nm, but key physical and functional properties of the particles remain within this range. It was not therefore felt that a size range should be specified.

27 *We agree that the Voluntary Reporting Scheme should focus on 'free' engineered nanoscale materials (i.e. those not in a fixed matrix – to be clear, liquid preparations are not considered to be a fixed matrix), and that this should include the potential for materials with two- or three-dimensions at the nanoscale to be released throughout a product's life-cycle.*

28 *The issue of definition is a difficult one and we have given it considerable thought. We accept that novel effects can occur above 100nm, and that key physical and functional properties of larger particles can depend on structure at the nanoscale. We have therefore decided, for reasons of clarity and consistency, that the initial focus of the Voluntary Reporting Scheme will be all free engineered nanoscale materials with two or more dimensions up to 200nm. We nevertheless encourage the submission of data on free engineered nanoscale materials falling outside this limit if deemed relevant to providing valuable information on potential risks. This position, and thus the focus of the scheme, will be reviewed throughout the duration of the scheme, responding to the ongoing work of BSI and ISO.*

2.4 Criteria for participation

Question 8: do you agree with the initial focus on obtaining information from those who are involved in commercial production, importation or use of engineered nanoscale materials, or are there other organisations that should be encouraged to participate?

Question 9: do you think that guidance is needed on the levels of production for inclusion in the scheme, and if so, what levels of production (tonnage thresholds or other criteria) do you think would be appropriate?

Question 11: do you think that research groups should consider submitting information to the scheme? The Government would welcome discussion with any research groups who would be willing to submit information as 'case studies' to determine whether this type of information would be beneficial in terms of the aims of the scheme.

29 Many of the respondents agreed that the Voluntary Reporting Scheme should include the production, importation and use of engineered nanoscale materials. Several additionally stated that those responsible for processing nanoparticle waste streams should be encouraged to participate.

30 Many of the respondents stated that research groups should be involved, or at least not be excluded from participating in the Voluntary Reporting Scheme. It was noted

that research activities have important implications for the future commercial use of nanomaterials, and that the inclusion of this group would allow Government to take a more 'upstream' approach to building evidence on potential risks. Two respondents felt that the Voluntary Reporting Scheme should perhaps focus on those materials with clearly identified commercial or industrial relevance.

31 One respondent supported the initial focus on commercial production, but felt that there needed to be greater clarity as to what this constitutes; some materials are produced for use in R&D, and sold as such, but they do not always end up in a commercial product. It was not felt that these materials should fall within the scope of the Voluntary Reporting Scheme.

32 A production volume was generally not thought appropriate for determining participation in the Voluntary Reporting Scheme. It was noted that all data will be of value in helping Government understand potential risks; Government is unlikely to be overwhelmed by data submissions; parameters other than production volume are important in determining potential risk; and many research organisations would be excluded if there was even a relatively low production volume threshold.

33 *In consideration of these views, we have broadened the focus of the Voluntary Reporting Scheme to include research organisations and universities as well as commercial producers, users, and importers of deliberately produced engineered nanoscale materials. We will also welcome data from those responsible for managing engineered nanoscale materials at the end of their life-cycle.*

34 *We are grateful for the input regarding criteria for inclusion in the Voluntary Reporting Scheme, and on reflection, have decided not to use a criterion based on production volume.*

2.5 Reporting to and administering the Voluntary Reporting Scheme

Question 12: do you have any views on the appropriate format or method for reporting to the scheme?

Question 16: do you have any views about the proposed method of administration of the scheme?

35 Many of the respondents stated that the reporting format and method should be kept straightforward and flexible to encourage maximum participation. An electronic mechanism, including a web-based system, was seen as the principal means of submission, but it was felt that postal submissions should not be excluded. It was also suggested that formats already used for existing regulatory submissions should be allowed.

36 Several respondents stated that the Voluntary Reporting Scheme should have a multi-stakeholder oversight board, and that the administration process should be made transparent and accessible.

37 *We have developed a standardised data submission sheet. Participants will be able to submit this electronically (our preferred method), by post, or in person if so desired. Additionally, and in line with our earlier proposal, data prepared on other forms, including those prepared for other governments, will be acceptable as we wish to minimise additional burdens.*

38 *Government will continue to discuss the administration and findings of the Voluntary Reporting Scheme with the participants of the Nanotechnologies Stakeholder Forum and the Advisory Committee on Hazardous Substances. We will additionally publish quarterly updates setting out, in general terms, information received.*

2.6 Costs and benefits of participation

Question 13: do you have any views on the costs and benefits of participation in the scheme? Government would welcome views on the additional costs or benefits that the scheme may provide.

39 Several respondents stated that the Voluntary Reporting Scheme should be managed so that it does not impose undue burdens on small and medium sized enterprises (SMEs).

40 *We agree that burdens to SMEs should be minimised, and believe that the current proposals meet this requirement.*

2.7 Submission of data

Question 14: do you have any views on the base set of data suggested for the scheme? In particular: (a) additional data that would be desirable for reporting under the scheme, and reasons for this; (b) the appropriateness of existing test methods for engineered nanoscale materials, and suggestions for alternatives that are considered to be more appropriate; (c) whether particular pieces of information in the proposed data set are unlikely to be reported under the scheme, and what the reasons would be for this; and (d) whether you think it would be practicable for companies to indicate which items of data should be shared in a public database, and which they would prefer to remain confidential.

41 Many respondents stressed the need for those reporting to provide details of their testing methodologies, including views on their adequacy in relation to free engineered nanoscale nanomaterials. Several respondents voiced concern, however, that many appropriate measurement and characterisation techniques have not yet been developed, and many of those that are used are not standardised. This would serve to make it difficult to ensure the validity of the data and draw comparisons between different data sets.

42 Several respondents stated a need to include a system that enables those reporting to distinguish between data that is not available, data they wish to withhold for proprietary reasons, and data that can be made public. One respondent also stated that it

would be useful for companies to comment on any data categories that would unlikely be reported on, and the reasons for this.

43 Two respondents stated that all of the requested data did not seem relevant to engineered nanoscale materials, with one emphasising that the prescriptive listing of potential endpoints needs to be avoided.

44 One respondent noted that the extent of the suggested data package may deter companies from participating, and that it might be better to have core and desirable data sets.

45 One respondent felt that the data set should include product names and end uses. It was felt that this would enable product tracking and swift recall if necessary. It was also argued that the full database should be kept in the public domain. This would help to address the lack of information currently available on uses, and ensure public confidence in the Voluntary Reporting Scheme. Several respondents stated, however, that intellectual property would be a particularly sensitive issue in relation to proposed use.

46 *We agree that those reporting need to provide details of their testing methodologies. We also agree that reporters should indicate if they have data but do not wish to disclose it. Guidance on this point is given in the Voluntary Reporting Scheme document.*

47 *We recognise that the data reporting format is long. However, the form contains an INDICATIVE set of data, and any data field within this would be welcomed. It is not expected that all of the data fields will be completed.*

48 *Government recognises the importance of transparency and external scrutiny in taking forward the Voluntary Reporting Scheme. This will, however, always need to be balanced with the need to protect commercially confidential data and our policy objective of deriving the most appropriate form of control.*

2.8 Good practice guidance

Question 15: how should good practice guidance be developed and disseminated, and by whom? The Government would welcome views on the various elements of good practice that may be relevant in this context.

49 There was considerable support for the development and dissemination of good practice guidance. It was felt that this was the responsibility of industry and research organisations, working with Government. Some also acknowledged a role for a wider set of stakeholders (particularly academics and civil society organisations). Several respondents also saw a need for international co-ordination on good practice to ensure consistency.

50 Several respondents suggested that, as part of the Voluntary Reporting Scheme, there should be agreement to implement basic risk management practices to reduce or eliminate workplace exposures and environmental releases, and properly manage wastes.

51 *We are pleased to see the level of support for good practice guidance. We wish to further encourage this, and believe it is the responsibility of industry to develop and adopt good practice on the production, use and disposal of nanomaterials. Government, working with industry and organisations such as BSI and ISO, will do whatever it can to support any activities in this area.*

2.9 Evaluating the data

Question 17: do you have any views on the proposed uses for the data gathered by the scheme? The Government would welcome suggestions about alternative uses for data gathered by the scheme. The Government seeks views on whether any of the proposed uses may deter participation in the scheme.

52 Many respondents stated that greater clarity was needed on exactly how the data would be used, and how use would contribute to the evidence base on which to determine appropriate controls for engineered nanoparticles.

53 One respondent stated that Government's existing expert advisory committees may need additional expertise to understand fully the implications of the data, and that they may even be justification for the Government establishing a new advisory committee.

54 *Uses of the data will include comparison with data resulting from the Government's research programme on potential risks. Data 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. If this is not thought to be sufficient, Government will of course consider the need to recruit additional experts for peer review. All the uses and reviews of data will include measures to protect commercial confidentiality.*

2.10 Encouraging participation

Question 18: are there any other ways to encourage companies to participate in the Voluntary Reporting Scheme? The Government welcomes views on potential methods for publicising the scheme and encouraging participation in it.

Question 19: who should be involved with publicising and encouraging participation in the scheme?

55 Several respondents stated that regular feedback from Government, throughout the lifetime of the Voluntary Reporting Scheme would be important in demonstrating its benefits.

56 It was felt that there was a role for a wide range of stakeholders in publicising the Voluntary Reporting Scheme, including Government and its agencies, trade associations, the Confederation of British Industry, insurance companies, manufacturers and their supply chain customers, the Micro and Nanotechnology network, the Organisation for

Economic Co-operation and Development, the UK Research Councils, academics, and learned societies.

57 Government will provide quarterly feedback on the Voluntary Reporting Scheme to all participants and stakeholders. We will work with a full range of stakeholders to publicise the scheme.

2.11 Duration of the Voluntary Reporting Scheme

Question 20: do you consider the initial 2-year duration of the scheme to be appropriate/realistic?

58 Many respondents to this question agreed that two years was an appropriate timescale for the Voluntary Reporting Scheme. However, there was little consensus among other respondents. Several stated that if the Voluntary Reporting Scheme is only collecting existing data, there seemed little point in running it for more than a few months; another suggested running the Voluntary Reporting Scheme for a year, which would communicate a much greater degree of urgency to the public on the part of Government; and four respondents felt that the development of nanomaterials and our understanding of their potential risks is in its infancy, and two years is too short. Suggested timescales were up to 5 years.

59 We remain of the view that two years is an appropriate time scale for the Voluntary Reporting Scheme. We recognise that the scheme is requesting existing data, but we are also aware that companies may wish to supplement their initial data submission as more knowledge becomes available on potential risks, and that we should not preclude new producers, users, importers or researchers from providing data after the initial round of submissions. It must also be stressed that the Voluntary Reporting Scheme will be subject to regular review (6 monthly intervals), and this process will be critical in determining its future scope and role; it is important that we do not pre-empt the conclusions of these reviews.

2.12 Piloting and reviewing the Voluntary Reporting Scheme

Question 10: do you think it would be beneficial for a small number of companies to initially 'pilot' the scheme? The Government would welcome discussion with any companies who would be willing to participate in such a pilot.

Question 21: do you agree with the frequency of and process for reviewing the scheme? Government would welcome views about how the scheme should be reviewed, and on what elements/criteria should be addressed within the reviews.

60 Many respondents felt that a pilot stage would only serve to delay the Voluntary Reporting Scheme unnecessarily, and that a full range of organisations need to be involved from the outset. It was recognised that the reviews built into the Voluntary Reporting Scheme would allow for the necessary changes to be made, and that Defra has

already consulted widely on the Voluntary Reporting Scheme. Several respondents took the contrary position, arguing that a pilot stage would help to iron out any flaws.

61 The majority of respondents agreed with the timescale and iterative nature of the reviews.

62 It was suggested that progress be reviewed by a number of different stakeholders, including independent scientists, representatives of the Micro and Nanotechnology network, the Government's Advisory Committee on Hazardous, the Laboratory of the Government Chemist, and civil society organisations.

63 We are persuaded that a pilot is unnecessary and will only serve to delay the collection of important data. Further, there are reviews built into the Voluntary Reporting Scheme that will provide an opportunity for any changes to be made.

64 We are committed to wide stakeholder participation in our work in developing appropriate controls for free engineered nanoscale materials, and this is no different for the Voluntary Reporting Scheme.

2.13 The Regulatory Impact Assessment

<p>Question 22: do you have any comments on the broad content of the partial RIA, which accompanies this consultation?</p>
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65 Many of the respondents expressed agreement with the conclusions of the Regulatory Impact Assessment.

66 Two respondents, however, stated disappointment that issues of public confidence and credibility were not taken into account in rating the options; two said the notion of a moratorium had been effectively ignored and the RIA had been constructed to meet the needs of industry and a predetermined decision; and several felt that a mandatory scheme would have been the best option to ensure sufficient information is made available – the additional costs associated with a mandatory approach were viewed as minimal.

67 We recognise the critical role that public confidence plays in today's regulatory environment, and this is exactly why we believe that the voluntary option, which does not delay the collecting of important risk data from companies, is the most appropriate one.

68 The development of the RIA was informed by the views of a full range of stakeholders, including academics, industry and civil society groups.

3.0 Next steps

69 Government is committed to the Voluntary Reporting Scheme as a means of gaining valuable data on the potential risks posed by free engineered nanoscale materials. It is our intention to launch the scheme in September 2006. To support

this, we have drawn up a detailed set of guidelines for participants, and we will continue to work with key stakeholders to publicise the scheme as widely as possible. We will keep stakeholders informed of our progress¹.

Annex 1 – list of consultation respondents

American Chemistry Council
Animal Aid
Association of British Healthcare Industries
BASF
British Chemical Distributors and Traders Association
British Coatings Federation
British Standards Institute
British Union for the Abolition of Vivisection (BUAV)
Central Science Laboratory (CSL)
Chemical Industries Association
Corporate Watch
Cosmetic Toiletry & Perfumery Association
Environmental Defense
European Nanotechnology Trade Alliance
Greenpeace
Institute of Occupational Safety and Health
International Institute of Synthetic Rubber Producers
Ionbond
Laboratory of the Government Chemist
Leeds University (student)
Nanotechnology Industries Association
Nanowatch
Non-Ferrous Alliance
People for Ethical Treatment of Animals
Pilkington
Royal Society and Royal Academy of Engineering
Scottish Natural Heritage
Soil Association
Tetronics R&D
Trades Union Congress
UK Cleaning Products Industry Association
Universities Safety and Health Association
University of Newcastle
University of Oxford (Begbroke Science Park)
University of Oxford, Department of Materials
University of Sheffield

¹ See also: <http://www.defra.gov.uk/environment/nanotech/index.htm>