RS Policy document: 14/06

Response by Royal Society and Royal Academy of Engineering to Defra's Consultation on a proposed Voluntary Reporting Scheme for engineered nanoscale materials

Key points

- The proposed Voluntary Reporting Scheme (VRS) could provide useful evidence to reduce uncertainty about the risks to human health and the environment from nanoparticles and nanotubes. However, directed research into the uncertainties is still urgently required to underpin regulation and should be funded immediately. This scheme could be a useful supplement to directed research, but is not a replacement.
- Government and industry have key roles to play in the responsible development of nanotechnologies. We believe that companies would benefit from participating in this scheme by demonstrating their commitment to developing nanotechnologies responsibly.
- Defra needs to be clear about how the data it collects will be analysed and how this analysis will be used to inform further development of the scheme, identify research priorities and develop specific regulations. Interpretation of the data is a key issue and it is crucial to involve independent scientists in this process.
- We have previously recommended that companies should publish the details of the testing methodologies they use to assess the safety of their products containing nanoparticles. The VRS should request this information.
- If participation in the VRS proves to be poor, Defra should be prepared to take steps to make the scheme mandatory without delay.
- If there is evidence of damage to human health or the environment from engineered nanoparticles currently being produced by industry, or if research suggests harm is likely, then action should be taken to prevent the manufacture, sale or use of the nanoparticles in question. Government should then assess whether its current approach to regulating nanoparticles is adequate.

Consultation Questions

General Questions

Q1. Do you agree with the overall 'green-line' approach of moving towards evidence-based, appropriate controls? If not, what alternatives would you suggest?

The academies believe that assessment of scientific evidence should be a central part of developing public policy.

The joint academies report, *Nanoscience and nanotechnologies: opportunities and uncertainties (*Royal Society & Royal Academy of Engineering, 2004*),* concluded that nanotechnologies have huge potential to bring a wide range of benefits to society, but their development must be guided by appropriate safety assessments and regulation to minimise any possible risks to people and the environment.

There is a lack of evidence about the impacts of free, engineered nanoparticles (including nanotubes) on health and the environment. We are pleased that, following our report, the Government has acknowledged this and is looking to increase the amount of evidence on which to base regulation. However, it is disappointing that any scheme will not be in place until over two years after the publication of the joint academies report, and as yet there is no directed research programme.

Q2 Do you agree with the proposed Voluntary Reporting Scheme? If not, what alternatives would you suggest?

Providing that industry contributes information to the Voluntary Reporting Scheme (VRS), it is a reasonable mechanism for gaining information quickly on nanomaterials currently being manufactured. However, the scheme should not detract from the need for directed research into the potential risks to human health and the environment because:

- It remains unclear what information is needed to determine the risks posed by nanoparticles. Research into the mechanisms of their interaction with humans and the environment will provide this in a way that the VRS will not.
- The voluntary nature of the scheme means that the data collected could be unrepresentative in terms of the types of nanomaterials covered under the scheme or information about them that is submitted. Such gaps may need to be addressed by directed research.

Additional directed research into hazard (toxicology) and risk (metrology and exposure assessment) is urgently required to underpin appropriate regulation. The VRS should be a useful supplement to this research and not a substitute.

Funding is required to build capacity in the emerging fields of nanotoxicology and nanoecotoxicology and to meet the research objectives outlined in the Government's own research report *Characterising the potential risk posed by engineered nanoparticles* (HM Government, 2005).

Q3. Do you have any comments on the practicality and reasonableness of this proposal?

No comment.

Q4. 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?

The joint academies report recommended that industry publish details of the methodologies used in assessing the safety of products containing nanoparticles that demonstrate how they have taken into account that properties of nanoparticles may be different from larger forms. We recommend that the VRS should request details of safety testing methodologies.

There should be a mechanism for identifying possible research needs from the information submitted to the scheme, potentially as part of the review process (see question 21). This would require including experts from Government, academia and industry in the oversight and review of the scheme. Funding should be made available to address any significant research needs emerging from this process, without delay.

Specific Questions

Q5. Do you agree with the overall aims of the voluntary scheme?

As mentioned in our answer to question 2, the academies broadly support the Voluntary Reporting Scheme, provided it does not delay addressing the health and environmental research needs outlined in the joint academies report and in the Government's first research report.

In addition to the aims detailed in the consultation document, the scheme could be used to build up a network through which any key research results could be disseminated.

Q6. Do you agree with the initial focus on free engineered nanoscale materials, and the definitions of nanoscale materials for the purposes of the scheme?

We agree with the initial focus on free engineered nanoparticles. The scheme should include submissions of data on engineered nanoparticles that are free during the stages of production, use or disposal. This will include nanoparticles in fluids and some pastes (eg cosmetics).

The joint academies report noted that although it is expected that exposure from composites containing nanoparticles and nanotubes will be low – because they will typically make up a very small fraction of the final product and the functionality of the material will rely on them being retained – there is a need to test this assumption. Since the ways of fixing nanoparticles and nanotubes will often be proprietary the report recommended that, as an integral part of the innovation and design process of products and materials containing nanoparticles or nanotubes, industry should assess the risk of release of these components throughout the life cycle of the product, and make this information available to the relevant regulatory authorities. We therefore recommend that Defra encourage companies to submit data on release throughout the lifecycle of a product.

Q7. Are there other criteria or definitions for materials which will be targeted by the scheme which you believe are important?

No comment.

Q8. 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?

The main focus should be on those involved in commercial production, importation or use of engineered nanoscale materials. However, academics should be invited to submit relevant data on nanoscale materials that may not be captured through other mechanisms. We believe that academic research groups would be happy to contribute.

Q9. 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?

We suggest that any guidance given on levels of production to trigger inclusion in the scheme should be less than that set for normal chemical testing. This is because toxicity of nanoparticles is suspected to be linked to the greater surface area of a given mass of nanoparticles compared with the same mass of the same chemical in larger form.

Q10. Do you think it would be beneficial for a small number of companies to initially 'pilot' the scheme?

Given the lack of available information about nanoparticles, we believe that the scheme should be promoted widely from the start to encourage a large number of submissions, rather than being targeted at a few companies to begin with. We understand that Defra has consulted extensively with industry prior to launching the consultation. The initial consultation and the results of this one should give Defra the information needed to launch the scheme without the need for a pilot phase. The formal reviews will provide an opportunity for any alterations to be made to the scheme based on initial experience.

Q11. Do you think that research groups should consider submitting information to the scheme?

As stated in question 8, we agree that the priority focus for the scheme should be companies which manufacture, import or use free engineered nanoparticles for commercial purposes. Research groups in academia or industry should also be encouraged to submit relevant information that will not be captured through other mechanisms.

Data collected on engineered nanoparticles in the research and development stage (eg by academic researchers) could have implications for those nanoparticles being commercially developed now and in the future.

Q12. Do you have any views on the appropriate format or method for reporting to the scheme?

Reporting to the scheme should be made as simple as possible to encourage maximum participation. Defra should put in place a mechanism for ensuring that data is recorded and stored in a format that is appropriate for analysis. However, as we highlight in response to Q17, it is not clear what plans Defra has for analysing the data that is collected.

Q13. Do you have any views on the costs and benefits of participation in the scheme, including suggestions of additional costs or benefits that the scheme may provide?

The responsible development of nanotechnologies, in part through appropriate regulation, should be a key concern of government and industry and this scheme is one step towards achieving this objective. We suggest that a list of companies participating in the scheme be made publicly available. This would demonstrate to stakeholders of the companies listed (eg consumers, retailers, and asset management companies), that they are committed to this responsible development. We hope that companies would see this as a benefit of participating in the scheme.

Q14. Do you have any views on the base set of data suggested for the scheme? In particular:

- ***additional data which would be desirable for reporting under the scheme, and reasons for this;***
- ***the appropriateness of existing test methods for engineered nanoscale materials, and suggestions for alternatives that are considered to be more appropriate;***
- ***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***
- ***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.***

In terms of the data package requested, participants could be encouraged to submit any completed risk assessment forms for nanoparticles, such as Control of Substances Hazardous to Health (COSHH) forms.

Information on the range of sizes and shapes of particles being produced should be requested. For example, the aspect ratio of particles is likely to influence whether or not particles can be eliminated from the body. Information on the encapsulation of particles could also be collected under the section of the data package on rendering the substance harmless (section 6) as encapsulation is likely to affect their chemical activity and agglomeration properties.

We suggest that the data collected under the scheme be made as transparent as possible, however, we recognise that some of the data requested could be commercially sensitive. Industry should be encouraged to indicate what information could be made publicly available. Even if the data submitted to the scheme remains confidential, the methodologies used in safety testing should be submitted and made publicly available (as mentioned in our response to Question 4).

The motivation to participate in voluntary schemes can be reduced if participants do not receive feedback. Defra should consider providing suitably anonymised feedback on what data has been submitted and any emerging trends could be given to participants to demonstrate the value of submitting to the scheme. This could also be made publicly available.

Q15. How should good practice guidance be developed and disseminated, and by whom? Do you have any views on the various elements of good practice that may be relevant.

Those working with nanomaterials, health and safety regulators and those involved in occupational health should work together to produce good practice guidance. This guidance should be developed for academia as well as industry.

Those developing good practice in the UK should also be aware of international efforts to do the same, such as the work of the International Council on Nanotechnology http://icon.rice.edu/projects.cfm?doc_id=4388.

Q16 Do you have any views about the proposed method of administration of the scheme?

No comment.

Q17 Do you have views on the proposed uses for the data gathered by the scheme? Are there alternative uses for data gathered by the scheme? Will proposed uses may deter participation in the scheme?

The consultation document does not make it clear how the data will be analysed and how this analysis will be used to inform research priorities, further development of the scheme and development of specific regulations. Interpretation of the data is a key issue, and it is crucial to involve independent scientists in this process. We welcome the fact that the Nanotechnology Research Coordination Group (NRCG), Nanotechnology Issues Dialogue Group (NIDG) and relevant expert scientific committees will be involved in considering the data, but we note that the membership of these committees may need to be supplemented to ensure they contain the relevant expertise. Alternatively, Defra could consider establishing a separate independent scientific advisory committee reporting to Defra, Department for Trade and Industry (DTI) and the Department of Health on this issue.

To ensure that policy is not based on misinterpreted or invalid data, mechanisms will need to be put in place for evaluating the validity of the data collected and ensuring that the data submitted by different companies is comparable.

Q18. Are there any other ways to encourage companies to participate in the voluntary reporting scheme? What may be useful methods for publicising the scheme and encouraging participation in it?

No comment.

Q19. Who should be involved with publicising and encouraging participation in the scheme?

We suggested Defra, trade associations, Micro and Nanotechnolgies Network (MNT) and DTI should be involved in publicising and encouraging participation in the scheme. If academic research groups are to be encouraged to submit data, Research Councils UK and learned societies could be involved in publicising the scheme.

Q20 Do you consider the initial 2 year duration of the scheme to be appropriate and realistic?

At present, the initial two year duration seems appropriate, but the lifetime of the scheme should be assessed at the regular reviews. During the regular reviews, if participation is deemed to be poor, Defra should take steps to make the scheme mandatory without delay.

Q21 Do you agree with the frequency of and process for reviewing the scheme? How should the scheme be reviewed, and what elements and criteria should be addressed within the reviews?

In addition to reviewing the process and the costs and benefits of the scheme, there should be an opportunity to examine the data received and assess if research should be commissioned into specific areas. Independent scientists should be involved in this assessment.

If there is evidence of damage to human health or the environment from engineered nanoparticles currently being produced by industry, or if research suggests harm is likely, then action should be taken to prevent the manufacture, sale or use of the nanoparticles in question. Government should then assess whether its current approach to regulating nanoparticles is adequate.

Q22 Do you have any comments on the broad content of the partial RIA which accompanies this consultation (see Annex B)? Comments are welcome on the impacts of the options set out in the partial RIA, in particular the impact on small businesses, competition, and the costs and benefits of the options set out.

We are disappointed that the issues of public confidence and credibility appear not to have been taken into account in rating the options for reporting, outlined in Table 2 in the partial regulatory impact assessment (annex B of the consultation document).

Do you have any other comments on the scheme or consultation?

No comment.

References

Royal Society and Royal Academy of Engineering (2004) Nanoscience and nanotechnologies: opportunities and uncertainties. RS policy document 19/04. Royal Society: London. See: www.nanotech.org.uk

HM Government (2005) *Characterising the potential risks posed by engineered nanoparticles: A first UK Government research report*. Defra: London.
See: www.defra.goc.uk/environment/nanotech/nrcg/pdf/nanoparticles-riskreport.pdf