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HEALTH AND SAFETY EXECUTIVE

Senior Management Team

Nanotechnologies – HSE’s role and current position

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Issue

1. Following Patrick McDonald’s oral presentation in February 2009, the Board asked for a paper to provide it with further information on HSE’s role with respect to nanotechnologies.

Recommendation

2. The SMT is asked to agree that the attached paper can be submitted to the HSE Board on 6 January, 2010.

Background

3. See attached draft Board paper.

Argument

4. See attached draft Board paper.

Consultation

5. HSE and HSL staff have been consulted. The Nano Team are a multi-disciplinary team from HSE and HSL made up of specialists in Process Safety, Occupational Hygiene, Human Health issues, Standards, Metrology, Research and Policy. HSE works collaboratively with OGD’s such as Defra, Department for Business Innovation and Skills (BIS) and Research Councils who are aware of HSE’s past, current and future work plans.

Presentation

6. N/A

Costs and Benefits

7. The benefits for the UK are in terms of the worker protection effort and HSE benefits as it maintains a good reputation in this area. The work done by the Nano Team allows HSE to quickly react to issues as they arise e.g. carbon nanotubes (CNT's) which have been identified as having pathogenic similarities to asbestos fibres.

For details relating to costs see below.

Financial/Resource Implications for HSE

8. The HSE staff cost is approx £75k per annum (part of 1xBand 1, 3xBand 2s, 1xBand 3 and 1xBand 4) and is affordable within the 2009/10 budget and 2010/11 indicative allocations.
9. Research - based on figures from 2003 to the end of June 2009, the spend to date has been £810k and the expected spend in the remainder of 09/10 and 10/11 is £569k. HSE has made use of funded projects at EU level and from OGD's, Industry and Universities. In addition to the £569k included in the Science plan there is an additional £235k of proposals currently within the commissioning process.
10. Communications has primarily focused on keeping the web page up to date and there is regular communication between members of the various inter-departmental groups and key stakeholders.

Environmental implications

11. N/A

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NANOTECHNOLOGIES – HSE’S CURRENT ROLE AND POSITION			

Purpose of the paper

10. To make the Board aware of current work relating to Nanotechnologies and consider it in the context of HSE’s strategy and HSE’s contribution to the Government’s nanotechnologies strategy. This follows Patrick McDonald’s oral presentation in February 2009.

Background

2. Nanotechnologies involve materials and structures that have at least one dimension of less than 100 nm (a human hair is about 80,000 nm wide). The Government’s aim is for the UK to derive maximum benefit from these new technologies and their products. There has been a long-standing interest in and support for nanotechnologies within Government. The Ministerial Group on Nanotechnologies (MGN), currently chaired by Lord Drayson, was formed last year to bring together all these interests.

3. In 2004 the Royal Society and Royal Academy of Engineering (RS/RAEng) published its report Nanoscience and nanotechnologies: opportunities and uncertainties, which was commissioned by the Government. In response to this, mechanisms were set up to deliver the RS/RAEng recommendations. HSE is represented on the Nanotechnology Issues Dialogue Group (NIDG), the Nanotechnology Research Coordination Group (NRCG) and Lord McKenzie sits on the Ministerial Group.

4. In terms of the Government response to the RS/RAEng report, and of the Government’s nanotechnologies aims, HSE has responsibility for the occupational/worker protection aspect of manufactured nanomaterials. UK Government progress in meeting the RS/RAEng recommendations was reviewed by the Council for Science and Technology (CST) in 2007. It concluded that the Government had made good progress in many areas and HSE was praised for its efforts.

5. HSE’s contribution to the Government’s nanotechnologies strategy has recently been agreed, see Annex 1. Brief descriptions of ongoing and completed research projects and how they relate to HSE’s strategy are attached in Appendix 1 of Annex 1.

Argument

Regulation

6. The occupational use of nanomaterials is regulated under the Control of Substances Hazardous to Health (COSHH). The principles of risk assessment embedded in COSHH apply to nanomaterials and even though data gaps exist, the regulatory response is to take a precautionary approach. HSE guidance on safe working with nanotechnologies is available and HSE has published specific guidance on the risk management of carbon nanotubes (CNT'S).

7. The Registration, Evaluation and Authorisation of Chemicals (REACH) Regulations are the key EU/UK legislation which cover the full life cycle of chemicals including nano-sized ones. HSE is the UK Competent Authority for these regulations. With regard to REACH, an EU Competent Authority sub-group on nanomaterials (CASG-Nano) has been established, its objective is to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. HSE provides the UK input into this group.

Research

8. Nanotechnologies research is a Government priority. The NRCG co-ordinates the UK efforts in filling data gaps. As well as contributing knowledge and experience to the NRCG, HSE leads on research on exposure control and fire and explosion which in keeping with its regulatory role is the prime focus. HSE contributes to discussions on the strategic direction of other research areas covered by the NRCG and maintains an oversight on further developments in nanotechnology of relevance to the workplace. HSE is further involved in a co-ordinated Government approach through a number of other national and international groups.

9. HSE has worked in collaboration with OGD's, industry, international organisations such as the Organisation for Economic Co-operation (OECD) and the International Standards Organisation (ISO), and regulators in other countries as a way of multiplying the benefits from our expenditure on research. The effect has been considerable and enabled HSE to influence in a way that is disproportionate to its expenditure in both national and international developments. HSE has been commended for its work in Government commissioned independent reviews.

10. To date, the focus of HSE's research work has been through the scientific input of HSL. EU wide research networks have been established and there is also some interchange with US counterpart NIOSH. This has been further cemented through participation in two nanoparticle working groups set up through The Partnership for European Research in Occupational Safety and Health (PEROSH) grouping of EU Occupational Health Laboratories. HSL also participates as a WHO collaborating centre in Occupational Health which deals with nanotechnology issues.

11. Our researchers and specialists, through their expertise, enable HSE to respond rapidly to matters of urgency. E.g. the development of guidance on the handling of CNT's. Research undertaken by Ken Donaldson at the University of Edinburgh identified pathogenic similarities between CNT's and asbestos fibres which attracted media attention. In response HSE produced guidance on handling and use, which was targeted on researchers through university safety officers and

others in industry. It was down to the expertise of a multi-disciplinary team that HSE was able to respond rapidly. Thomas Swann, the only UK manufacturer of CNT's was inspected.

Communications

12. A key part of the role of the HSE/HSL Nano Team is communications. There is a web page outlining HSE's approach where completed HSE/Partnership research and updates on ongoing issues are published. It also links to useful documents and further sites. We are currently updating the website and moving this to the mainstream pages of HSE's website and away from Horizon Scanning.

Current Issues

13. On 17 July 2009, the Department for Business, Innovation and Skills (BIS) launched the BIS Nanotechnology Strategy, the Government's web-based evidence gathering exercise which closed on 31 October. The evidence that stakeholders provide, when analysed later this year, will contribute to the development of a UK strategy for nanotechnologies. When the nanotechnologies strategy is complete HSE's nanotechnologies team will revisit its aims and objectives to ensure compliance with the national strategy.

14. HSE will continue to work across Government to realise the aims of the MGN by continuing to work to understand the risks presented by the new technologies and to represent HSE's views on international standards work and international nanotechnology initiatives conducted under the banner of the OECD. HSE will continue to contribute to the ongoing debate around REACH and its application to nanomaterials. Ultimately HSE seeks to generate solutions to current knowledge gaps in order to fulfil its regulatory obligations.

Next Steps

15. HSE has a good track record with regards to nanotechnologies and needs to maintain its profile in this area. The next challenges will be to:

- ▶ Maintain a proportionate level of commitment to the Government's co-ordinated response to new and emerging technologies;
- ▶ To continue to work in partnership with others, including the EU, OECD and those industry sectors investing in new technology to gain maximum benefits from any investment made;
- ▶ To support a programme of research as outlined in HSE's contribution to the Government's nanotechnologies strategy to enable HSE to understand the industry sectors and the numbers of workers who may be exposed to manufactured nanomaterials in the UK.

16. However, based on the anticipated rise in the use of nanotechnologies over the next 10 years, evidence based guidance will be needed to ensure that health and safety is a key consideration in this emerging set of technologies, along with our front line inspectors being aware of the issues and the support available from colleagues.

Financial/Resource Implications for HSE

17. The HSE staff cost is approx £75k per annum and is affordable within the 2009/10 budget and 2010/11 indicative allocations. Research spend to date has been £810k. The science plan currently includes a further £569k in the remainder of 09/10 and 10/11 plus additional proposals of £235k currently within the commissioning process.

Action

18. For the Board to agree the current approach.

Paper clearance

19. Patrick McDonald and Jane Willis.

HSE's contribution to the Government's Nanotechnologies Strategy

Final Version - October 2009

HSE's contribution to the Government's Nanotechnologies Strategy

Introduction:

Nanotechnologies offer many future benefits and have the potential to be used in a wide range of applications and products. There is an interest in nanotechnologies at the highest level in the UK Government (Prime Minister) and through the Ministerial Group on Nanotechnologies (MGN), which was established in response to a recommendation from the Council for Science and Technology that there should be a Ministerial champion for nanotechnology in Whitehall.

The Prime Minister has stressed that during this current period of economic 'down time' the UK must maintain a strong competitive edge in research and development and does not want nanotechnologies to be viewed in the same way as Genetically Modified Organisms (GMOs), but in a much more positive light such as the developments in Stem Cell research.

HSE has responsibility for the occupational/worker protection aspect of manufactured nanomaterials and is working across Government and with industry to develop a sensible risk-based approach for the regulation of these new technologies so that UK industry can fully maximise the benefits.

The aims of HSE's contribution to the Government's Nanotechnologies strategy are:

To continue to work across Government to realise the aims of the Ministerial Group on Nanotechnologies, which includes the development of a UK wide strategy for the future development and use of nanotechnologies, HSE will do this by:

- continuing to work to understand the risks presented by the various new technologies that fall within this umbrella term, so that it can advise on the adequacy of the occupational regulatory framework and the regulation of the emerging risks,
- contributing to the ongoing debate around REACH and its application to nanomaterials,
- representing HSE views on international standards work and international nanotechnology initiatives conducted under the banner of the OECD and seek to generate geared solutions to current knowledge gaps,

This work also contributes to the HSE's Strategy: The Health and Safety of Great Britain\ Be part of the solution, in particular:

"To make workplaces safer ... in emerging sectors and those sectors energised by evolving technologies, the requirement is to recognise the inherent new risks and implement appropriate methods for managing them from the beginning" and "to identify and work with those bodies best placed to bring about a reduction in the number of cases of work related ill-health."

HSE's contribution to the Government's Nanotechnologies Strategy

Objectives:

Current research by HSE into the health risks of manufactured nanomaterials focuses almost exclusively in workplace exposure and exposure control. This focus assumes that Department of Health will lead the Government's work into the toxicology of these materials and will fund the necessary research. Progress has been slow in this area leaving HSE vulnerable to the charge that it is unable to discharge its regulatory functions because of a lack of data on the hazards posed by nanomaterials. However, exposure measurement and control in the workplace remain central to the research programme for 2009 to 2011.

The objectives of HSE's contribution are to:

- a. maintain a proportionate level of commitment to the Government's coordinated response to new and emerging technologies through NIDG and NRCG; and meet the requirements of the Ministerial Group;
- b. review HSE's role in 2010 in response to
 - i) emerging research results,
 - ii) HSE priorities,
 - iii) the overarching UK Government Strategy for Nanotechnologies (completed Jan 2010),
- c. work in partnership with others, including the EU, OECD and those industry sectors investing in new technology to gain maximum benefit from any investment made .
- d. support a programme of research to enable HSE to:
 - i) understand the **industry sectors** and the **numbers** of workers who may be exposed to manufactured nanomaterials in the UK e.g. those manufacturing nanoparticles, those involved in using nanoparticles to produce products and those dealing with materials and products at the end of their lifespan in the waste and reclamation industry,
 - ii) understand the likely **routes** of exposure to nanomaterials, and carry out targeted investigations/studies to assess the performance of risk management measures, work practices, controls and protective measures,
 - iii) understand the **levels** of exposure found in the workplace. In particular to distinguish between the **risk** of exposure, (not the harmful effects) in three key areas:
 - Development - in universities where much of the development work with these materials is being carried out,
 - Manufacturing - in spin-off companies as the technologies mature and develop,
 - Downstream usage.
 - iv) understand the **measurement** techniques that can be applied to nanomaterials, recognising the difficulties and issues inherent to

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metrology at this scale and working with international partners to agree measurement protocols that can be used by duty holders,

- v) where necessary to research interventions to tackle any specific risks identified and mitigate those risks
 - vi) understand the detail of life-cycle analysis* which is relevant to our responsibilities under REACH and also link into the NRCG Task Force 2
 - vii) understand the process safety risks arising from the manufacture and use of nanomaterials and any additional controls that may need to be used to handle these materials safely.
- e. support HSE as the REACH CA in developing and negotiating a technically sound mechanism for including nanomaterials within the REACH framework;
 - f. move the nanotechnologies topic from horizon scanning on to mainstream H&S.

* Life Cycle Analysis', or '[cradle-to-grave](#) analysis' is the consideration and valuation of the environmental impact of a given product/substance created by its existence.

Context and History of HSE's Work to Date

Summary

- There is an interest in nanotechnologies at the highest level in the UK Government (Prime Minister) and in the EU and beyond;
- HSE has responsibility for the occupational/worker protection aspect of manufactured nanomaterials;
- HSE is involved in research activities to plug some of the gaps that exist in current knowledge;
- HSE is working with other government departments and agencies to provide a 'cross-government' approach to dealing with these new technologies;
- HSE is applying the results of research to provide advice and, where required, support regulatory action;

Is there a problem and how big is it?

- 1) There is no conclusive information on the number of workers involved in either handling nanoparticles, the materials being used or manufacturing products incorporating nanoparticles. However, in 2008 in the UK there were 38 companies and 55 Universities listed by Defra as manufacturers and the MNT network identified 540 companies with an interest in future product development.
- 2) In 2007 HSL's horizon scanning team conducted a survey of trends in nanotechnology and identified that US patents were shifting to application of the technologies, indicating that worker exposure would increase. Also, the Woodrow Wilson data base¹ shows that from March 2006 to February 2009, the number of consumer products containing nanomaterials has increased from 212 to just over 800 globally (27 produced in the UK). Despite the current economic down turn it is predicted that nanotechnology industries will continue to grow albeit at a slower rate.
- 3) Based on the anticipated rise in the use of nanotechnologies over the next 10 years, evidence based guidance will be needed to ensure that health and safety is a key consideration in this emerging set of technologies.

Background

- 4) HSE's involvement in nanotechnology started from the late 1990's with its occupational hygiene interest in the manufacture and use of ultrafine particles such as carbon black and titanium dioxide, and exposure to inadvertently produced particles e.g. welding fume. Our interest increased and widened as the result of an HSE horizon scanning exercise undertaken in 2003 which identified nanotechnology as an area of interest which could impact substantially on the regulation of H&S in the future. A paper was put to the HSC in 2004². HSE has critically reviewed the available information on explosion³ and toxicological⁴

¹ <http://www.nanotechproject.org/inventories/>

² http://intranet/boards/hsc_meetings/2004/papers/c42.pdf

³ http://www.hse.gov.uk/research/hsl_pdf/2004/hsl04-12.pdf

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hazards of nanomaterials of relevance to the workplace and the occupational exposure⁵ situation. The HSE reviews were submitted to the Royal Society and Royal Academy of Engineering (RS/RAEng) for inclusion in their report "Nanoscience and nanotechnologies: opportunities and uncertainties"⁶.

- 5) The Government response to the report⁷ outlined general and specific actions for Government as a whole. HSE was specifically mentioned in relation to regulatory reviews, monitoring of workplace nanotechnology issues, workplace control issues and accidental release procedures.
- 6) To manage HSE's input to this process a joint HSE/HSL nanotechnologies Team was established with representatives from those with an interest from both the technical and policy perspective.
- 7) HSE's nanotechnology work has evolved into being part of a pan governmental programme to address the regulatory issues relating to nanomaterials, driven in part by the RS/RAEng report. UK Government progress has been published⁸⁹ and reviewed by the Council for Science and Technology (CST) in 2007¹⁰. It concluded that whilst the Government had made good progress in many areas - including standards and metrology, international engagement and minimising workplace and public exposure - it had not provided sufficient support for research into the toxicology and health and environmental effects of nanomaterials.
- 8) The Government's current aim is for the UK to derive maximum benefit from these new technologies and their products; the vision of the UK Government for nanotechnologies is –

"for the UK to derive maximum economic, environmental and societal benefit from the development and commercialisation of nanotechnologies, and to be in the forefront of international activity to ensure there is appropriate control of potential risks to health, safety and the environment".

Current cross government structures

- 9) In response to the 2004 RS/RAEng report, a cross-Government group to co-ordinate research into nanotechnologies was formed - the Nanotechnology Research Co-ordination Group (NRCG); HSE was an original member and is the key contributor on worker protection.
- 10) Following the CST Review, the Government acknowledged the need for greater championship of some of the issues surrounding nanotechnologies. In its response Government agreed to provide a champion for nanotechnologies across Government and announced the establishment of a Ministerial Working Group to bring together those ministers with responsibility for the research base:

⁴ <http://www.hse.gov.uk/horizons/nanotech/healtheffects.pdf>

⁵ <http://www.hse.gov.uk/research/rrhtm/rr274.htm>

⁶ <http://www.royalsoc.ac.uk/landing.asp?id=1210>

⁷ <http://www.dti.gov.uk/files/file14873.pdf>

⁸ <http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-progressreport.pdf>

⁹ <http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdf>

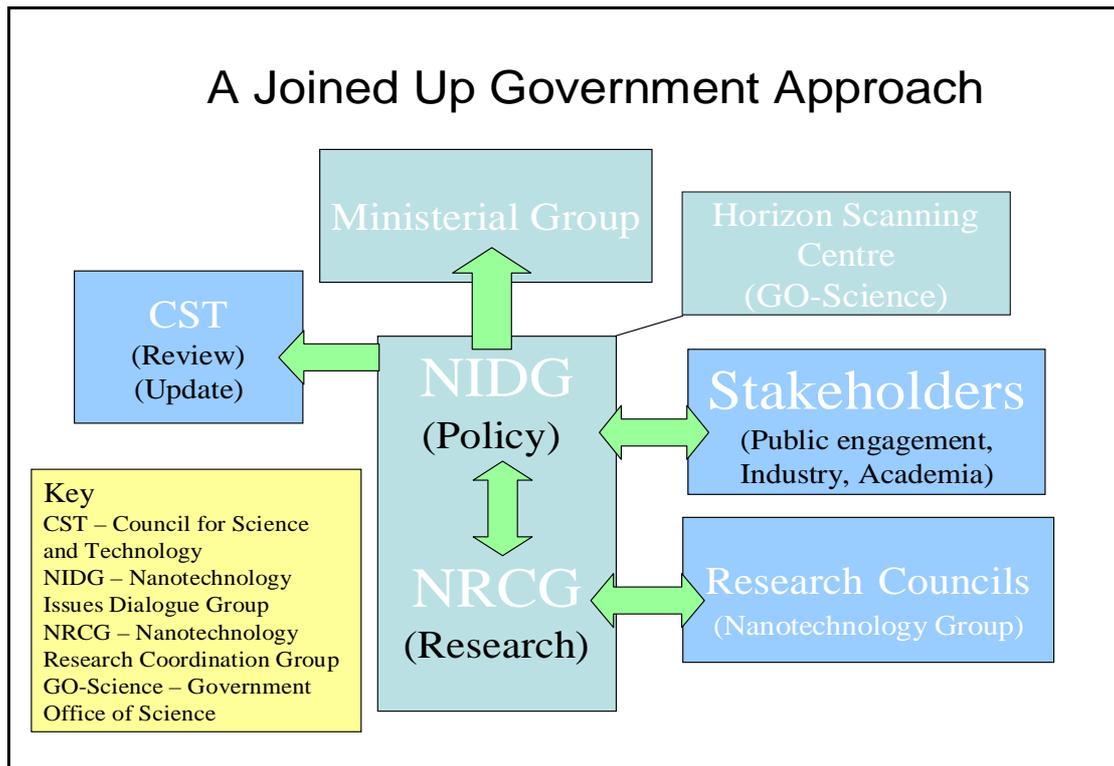
¹⁰ http://www2.cst.gov.uk/cst/business/files/nano_review.pdf

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innovation, health and safety and the environment. The bodies concerned with delivery of UK nanotechnology strategy are illustrated in figure 1.

- 11) As well as contributing knowledge and experience to the NRCG, HSE leads on research on exposure, risk management and fire & explosion, issues of particular relevance to HSE's remit. HSE also maintains an oversight on developments in nanotechnology of relevance to the workplace.

Figure 1 - The UK Government approach to nanotechnology



- 12) HSE is also involved in the coordinated Government approach through a number of other national and international groups:

- Nanotechnology Issues Dialogue Group (NIDG)
- Nanotechnologies Stakeholders' Forum (NSF)
- EU Competent Authorities Subgroup on Nanomaterials (REACH-CASG Nano)
- Royal Commission on Environmental Pollution (RCEP)
- Nanotechnologies Industry Association (NIA)
- Institute of Nanotechnology
- European Nanotechnology Association (ENTA)
- OECD Working Party on Manufactured Nanomaterials (WPMN)

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- Standards: BSI NTI/1 (British Standard Institute), CEN 352 (European Committee for Standardization), ISO TC229 (International Organization for Standardization)

HSE Research Work

- 13) The prime focus of HSE research is on the exposure and the control of exposure in the workplace to manufactured nanomaterials. HSE is not undertaking any research into the toxicology of individual substances; this is for others to undertake (DH/HPA, industry). However, if partnership opportunities arise to investigate general principles, such as relevant dose metrics or effects via the inhalation route, then HSE may consider involvement. There is also a programme looking at the flammability and dust explosion risks from nanomaterials. Unlike research into toxic risks, very few groups around the world are researching fire and explosion risks.
- 14) Brief descriptions of ongoing and completed projects with how they relate to our strategy are appended as Annex 1.

Collaboration

- 15) From the start of the programme, HSE has worked in collaboration with other government departments, industry, international organisations such as OECD, International Standards Organisation and regulators in other countries as a way of multiplying the benefits received from our expenditure on research in this area. The multiplier effect has been considerable and this approach has also enabled HSE to influence, in a way that is disproportionate to our expenditure, in both national and international developments. HSE has been commended for its work in government commissioned independent reviews. It is considered important to maintain a presence in this area and work with others to plug the gaps in current knowledge; otherwise this 'political' capital will dissipate quickly.
- 16) The focus of HSE's research work has to date been through the scientific input of HSL: EU wide research networks have been established and there is also some interchange with US counterpart NIOSH. This has been further cemented through participation in two nanoparticle working groups (toxicology and characterisation) set up through the PEROSH grouping of EU Occupational Health Laboratories. HSL also participates as a WHO collaborating centre in Occupational Health which deals with nanotechnology issues.

Outputs from the Research Programme

- 17) The most significant advice to our specialists are the findings regarding filters and PPE - notably from the multicentre EU Nanosafe 2 project and the multicentre USA/UK NIOSH project based at DuPont, USA. The evidence gathered on risk reduction measures from observation by the specialists accompanying sampling teams on site visits for NANOSH (see annex 1 for more details) has enabled fuller COSHH based control advice to be given. Our current advice is summarised in an information note,¹¹ which is being considered for revision and updating.

¹¹ <http://www.hse.gov.uk/pubns/hsin1.pdf>

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- 18) In 2008 research undertaken by Professor Ken Donaldson of the University of Edinburgh, observed granuloma formation in the lining of the abdomen of mice injected with high aspect ratio CNTs. The work raised the possibility that the types of carbon nanotube which Professor Donaldson used are similar in terms of their toxic properties to asbestos fibres.
- 19) The research suggests to some that carbon nanotubes could cause mesothelioma but there is no evidence to support this at present. Granuloma formation should not be seen as an early stage of induction of mesothelioma. However, it does demonstrate an analogous health hazard which needs to be further explored.
- 20) HSE was able to respond to media concerns that Carbon Nanotubes (CNTs) will be the '**new asbestos**' of the 21st Century because our state of knowledge enabled specialists to prepare a robust response to the press interest in CNTs/asbestos for Lord McKenzie and to provide technically up-to-date sound advice to industry and academia. This has been published recently¹²
- 21) HSE specialists have been able to put the knowledge they have gained through research activities to practical use taking action taken over H&S concerns at two Universities

Regulation

- 22) HSE has reviewed the adequacy of the regulatory framework in relation to potential concerns for health and safety in the workplace arising from supply, use and production of nanomaterials¹³. The review concluded that:

"...the principles of the existing regulations and the interconnections between them are appropriate and applicable to nanomaterials. We perceive no need to fundamentally change the regulations themselves, or to introduce new regulations. However, there are important issues which require attention if, in reality, the current and foreseeable future general regulatory framework is to operate effectively in relation to nanomaterials."

- 23) The issues that need consideration encompass:
- a) knowledge gaps, particularly relating to the toxicological hazards, and the breadth of the regulations concerning nanotechnologies.
 - b) The pace of change in technological understanding which is accelerating as more researchers gain skills in this area. If HSE does not maintain its knowledge base it is unlikely to be able to catch up.
 - c) legislation is not UK based and will require changes at EU level
 - d) the impact of REACH, the new chemicals legislation.
- 24) With regard to REACH, a REACH CA sub-group on nanomaterials (CASG-Nano) has been set up to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. On this basis, the CASG-Nano will provide recommendations to the REACH CAs advising the

¹² <http://www.hse.gov.uk/pubns/web38.pdf>

¹³ <http://www.hse.gov.uk/horizons/nanotech/regulatoryreview.pdf>

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Commission. HSE, in its role as the REACH CA, is the UK representative on this body and is playing a key role in developing a common position.

- 25) Recently, the European Parliament has taken a very precautionary stance in its views on the application of current legislation to nanomaterials. We await the European Commission's response to the European Parliament to see if further work is needed in this area.

Communication

- 26) Apart from the wide network of contacts within government, academia and industry the communications strategy of the NanoTeam comprises an internal HSE and an external component.

Internal facing: the NanoTeam have a dedicated email account operated from CSD 3, an intranet page under specialist advice supports this and outlines the work of the team, and provides contacts for more detailed advice for front line inspectors and others in HSE. There is also a web community via HSL to allow HSE and HSL staff to access and share documents.

External facing: there is a web page outlining HSE's approach and providing links to useful documents and further sites. Infoline are provided with an up to date briefing to answer straightforward queries and a contact to link them to the NanoTeam.

- 27) Completed HSE/partnership research and updates on ongoing work are published on the website (<http://www.hse.gov.uk/horizons/nanotech.htm>) along with current guidance.

External influence on HSE

- 28) The Royal Commission on Environmental Pollution produced a Report, Novel Materials in the Environment: The case of nanotechnology¹⁴ to which HSE contributed. It examined issues related to innovation in the materials sector and the challenges and benefits arising from the introduction of novel materials. This was prompted in part by concerns about potential releases to the environment from the use of manufactured nanomaterials in a wide variety of products and applications. It noted:

"Our extensive enquiries produced no evidence of actual harm. However, having analysed the potential health and environmental impacts which flow from the properties of nanomaterials, we concluded that there is a plausible case for concern about some (but not all) classes of nanomaterials"

- 29) The Government Response¹⁵ to this incorporated HSE's views. Two conclusions from the Government response with relevance to HSE are:

Conclusion 6. The Government will continue to *support the research programme at both the domestic and international level*, and looks forward to

¹⁴ <http://www.rcep.org.uk/reports/27-novel%20materials/documents/Novel-materials-summary.pdf>

¹⁵ <http://www.official-documents.gov.uk/document/cm76/7620/7620.pdf>

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Appendix 1

the completion of the Nanotechnology Research Co-ordination Group's review of its priorities.

*Conclusion 7. And where this will prove effective, the Government will continue to **work collaboratively with international partners to deliver more effective management** by assessing the effectiveness of regulatory regimes such as REACH, and considering how best to adapt these to nanotechnology.*

- 30) In order to realise these commitments, the Government intends to launch an evidence gathering exercise with stakeholders in the summer to inform the development of a UK Strategy for nanotechnologies. HSE will play a supporting role in this process but will play a key role as the REACH CA in representing UK policy on how the REACH Regulation will be adapted to address current concerns over nanoparticles.
- 31) Previously, the former Science Minister Lord Sainsbury signalled the Government's resolve regarding the safe application of nanotechnology in the UK by commissioning the RS/RAEng report. All relevant Ministers supported this when they signed the UK Government response to the RS/RAEng report and the NRCG Research Report. External contributors, including the RS/RAEng, have all highlighted what they see as inadequate government funding for research, particularly in the area of human health hazard identification in their submissions to the CST review and in submissions to the RCEP.
- 28) In January 2009, The Ministerial group made seven commitments, which the various Government departments represented on the Group will take forward. They will:
- Respond in Spring 2009 to recommendations made by the Royal Commission on Environmental Pollution about the governance of novel materials.
 - Develop a better understanding of the objectives and needs of the UK industry sectors that are likely to use nanotechnologies and nanomaterials.
 - Work with industry to develop a workable reporting scheme for nanomaterials.
 - Develop a programme of dialogue involving the full spectrum of interested parties (academia, industry, NGOs and the public) in the development of the strategy.
 - Improve the targeting and prioritisation of UK research devoted to understanding and managing the health risks associated with nanotechnologies.
 - Ensure that action is taken where there is evidence that products containing nanoparticles may pose a risk to workers, consumers or the environment.
The Health and Safety Executive, BIS and Defra will coordinate this.
 - Ahead of EU legislation, work with industry to develop a workable way of providing information about products that are being developed and placed on the market..
- 29) From a European perspective, the European Commission produced an Action Plan aimed at promoting the safe growth of nanotechnology which has led to much action including, in February 2008, publication of a Code of Conduct for responsible research in nanotechnologies. Research funding from various framework initiatives has been used by HSE to help fund its projects.

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Appendix 1

- 30) The EU Parliament has become more vocal over nanotechnology issues latterly e.g. The European Parliament, in April 2009, backed a controversial report urging the European Commission to revise its stance on nanomaterials. MEPs said all nanomaterials should be considered as new substances, and that existing legislation does not take into account the risks associated with nanotechnology. The Parliamentary activity on nanotechnology will result in increased pressure on the European Commission, EU institutions and Member States.
- 31) At the moment there is no major public pressure for action on nanotechnology, as evidenced by press monitoring. Forums such as the 'Nano Jury' run by the Guardian indicate a level of knowledge and concern balanced with positive views on the benefits of the technologies. However, there are groups who argue that all nanotechnology should be put on hold until the gaps in knowledge regarding the health and environmental hazards have been filled. This view will attain greater prominence when the first health or environmental accident happens.

Conclusion

- 32) As regulators we need to understand the cross-cutting risks associated with nanotechnologies. It is acknowledged that current knowledge is inadequate for risk assessment purposes and HSE's current advice is that a precautionary approach to dealing with uncertainty should be adopted, integrating:
- traditional risk-based decision making based around 'better regulation';
 - the engagement of stakeholders to consider both matters of risk and justification;
 - experience gained e.g. regulatory regimes for GMOs and human fertilisation & embryology.
- 33) This will ensure that we can apply a sensible, proportionate and precautionary risk management approach that errs on side of safety and where the degree of caution is proportionate to the degree of uncertainty and good health and safety practice is followed.
- 34) We are already receiving requests from researchers, industry and OGDs to provide advice on the appropriate use of nanoparticles. At this stage we can refer them to the very general advice we have already published but this does not provide practical advice.
- 35) To be able to do this we need to generate answers to the knowledge gaps and we are doing this through our research programme and, by cooperation with and the monitoring of research across the globe.
- 36) Through a modest commitment of resource over a number of years HSE has gained understanding, traction and influence in an area of technological advance of considerable benefit to the UK economy. Further work is needed, again of modest proportions, to maintain our position and ensure that we can properly regulate the various technologies, advise dutyholders and support the delivery of the Government Strategy on Nanotechnology.

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Projects

Project	Progress	Outcomes
<p>NanoAlert The work provides an information bulletin service reviewing studies on exposure and potential health effects of nanomaterials</p>	<ul style="list-style-type: none"> • Five bulletins have been published. Carbon Nanotube special edition due soon. 	<p><i>The project enables HSE to understand current hazards and risks and anticipate concerns</i></p>
<p>NANOSH This European multi-centre research project focuses on occupational exposure to nanoparticles and their health effects.</p>	<ul style="list-style-type: none"> • HSL has carried out sampling in 5 Universities. Other partners looking at other occupational sites. • Difficulties of determining exposure to <i>engineered</i> nanoparticles very clear. • Information on control measures and dermal exposure noted via observation. • Evaluation of the performance of RPE. • EU-wide database on anonymised measurements and contextual data will be set up. 	<p><i>The Project meets HSE's obligations following Government response to Royal Society Nano review. Addresses strategic objective of preventing workplace ill health.</i></p>
<p>Nanosafe2 A consortium of European companies and research laboratories has developed a research programme for the safe production and use of nanomaterials.</p>	<ul style="list-style-type: none"> • HSL has visited one industrial workplace using the kit developed in NANOSH • Review of existing Life Cycle Analysis programmes carried out • Dissemination reports on filters and PPE published providing data on risk reduction measures our inspectors can use. 	<p><i>The Project meets HSE's obligations following Government response to Royal Society Nano review. Addresses strategic objective of preventing workplace ill health.</i></p>
<p>NanoImpactNet (EU FP7) Coordination in studying the EHS impact of engineered nanoparticles and nanotechnology-based materials/products</p>	<ul style="list-style-type: none"> • Apart from NanoAlert HSL, has organised a workshop in March 2009 to develop an Occupational Health reporting system NanoImpactNet web site 	<p><i>This project is aimed at identifying and working with those bodies best placed to prevent or reduce work related ill health</i></p>
<p>Assessment of emissions of particles from printers and photocopiers</p>	<ul style="list-style-type: none"> • A reactive project in response to a paper on nanoparticle emissions from office printers. • The potential for high profile press and ministerial interest prompted this work 	<p><i>This project meets primary objective of understanding work place exposures</i></p>

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<p>Investigation of the use of enclosures to estimate exposure to engineered nanoparticles in universities and industrial workplaces</p>	<ul style="list-style-type: none"> • There is significant difficulty in differentiating engineered nanoparticles from background levels; the tent approach allows some specific exposure data to be gathered. 	<p><i>This project addresses our measurement techniques objective.</i></p>
<p>Investigation of the fire and explosion properties of nanopowders (R03.038/9926) Aims to understand the fire and explosion hazards of selected nano powders.</p>	<ul style="list-style-type: none"> • Literature search is complete and a report is issued. New specialised small scale test apparatus and associated equipment has been completed. Commissioning work has been carried out and a range of nanopowders have been tested in the apparatus including CNTs, aluminium, iron and copper. The maximum rates of pressure rise have been measured and from these the equivalent Kst values have been obtained. The maximum explosion pressures have also been measured. Minimum ignition energies have been obtained using a modified Kuhner MIKE3 apparatus. In terms of electrostatic properties of nanopowders, the surface resistivity of a range of powders have been measured and compared with micron-scale powders. . 	<p><i>The handling of nanoparticles in this project has prompted the drafting of a high quality risk assessment for nanoparticle use at HSL.</i></p>
<p>NANODEVICE project A European multi-centre research project is looking at further researching the most appropriate measurement indices and developing improved methods / devices to measure personal exposure to airborne engineered nanoparticles.</p>	<ul style="list-style-type: none"> • HSL's main involvement is in characterisation and testing programme • Start date May 2009 	<p><i>Which measurement index is appropriate is a key data gap. Data to answer this question is directly relevant to HSE's measurement objectives.</i></p>
<p>Investment Research Programme – Nanochallenge (NB. HSL funded) Objectives of this programme include 1. Exposure assessment</p>	<ul style="list-style-type: none"> • Efficiency of different sampling methods assessed. Presented at Inhaled Particle X conference in Sheffield in September 2008^[3]. • Developing methods for the characterisation of airborne nanoparticles & agglomerates / 	

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<p>and control project 2. Fire and Explosion 3. In vitro Toxicology Assays and modelling</p>	<p>primary nanoparticles from bulk nanopowders / nanoparticles and agglomerates in liquid</p> <ul style="list-style-type: none"> • Work has explored using exhaled breath as a sampling medium for nanoparticle exposure. A poster on initial work has been presented at BNASS in July 2008 and a review of the application of biological monitoring to nanomaterials is being written. • Experiments on dustiness testing of nanopowders (including carbon nanofibres) have been carried out with NIOSH (USA). Progress was presented at 3rd International Symposium on OH implications of nanomaterials in Taiwan. • Fire and Explosion test apparatus has been designed, built and commissioned. A range of nanopowders have been purchased from industry and aluminium nanopowders from early production runs have been provided by Intrinsic (no cost). • A two-stage assay for testing the toxicity of manufactured nanoparticles has been developed and optimised, and TiO₂ nanoparticles are now being tested. 	
<p>Literature Review into the explosion hazards associated with nanoparticles</p>	<p>HSL project completed May 2004.</p> <ul style="list-style-type: none"> • Literature review^[4] 	<p><i>These three projects are published on our website. They comprised a package of evidence that was submitted for the Royal Society Review. They form the evidence base for our research objectives and projects.</i></p>
<p>Review of the occupational hygiene implications of the manufacture and use of nanoparticles.</p>	<p>IoM project completed September 2004.</p> <ul style="list-style-type: none"> • RR274 - Nanoparticles: An occupational hygiene review^[6] 	
<p>Health effects of particles produced for nanotechnologies</p>	<p>HSE toxicology review completed 2004.</p> <ul style="list-style-type: none"> • Health effects of particles produced for nanotechnologies [194KB] ^[7] 	
<p>Assessment of different metrics of the</p>	<p>Project completed. Report (RR113)</p>	<p><i>Results used to inform further investigation</i></p>

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<p>concentration of nano (ultrafine) particles in existing and new industries (2006)</p>	<ul style="list-style-type: none"> • Aerosols generated in a range of concentrations. Aerosols contained nanoparticles of different chemical composition and particle shape. • Relationships between mass, number and active surface area investigated using real-time instruments. 	
<p>Explosion properties of nanometric aluminium and nickel powder</p>	<p>Project completed. .</p> <ul style="list-style-type: none"> • (R03.037) Explosion Properties of Nanometric Aluminium and Nickel Powder ^[5] 	<p><i>Results used to inform further investigation</i></p>
<p>Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology</p>	<ul style="list-style-type: none"> • Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology [172KB]  ^[8] <p>Outcome:</p>	<p><i>Produced as part of HSE's obligation following Royal Society review. It has been incorporated in to an overall regulatory status project by Defra and has informed the UK position in EU debates on nano regulation.</i></p>
<p>Report on possible <i>in vitro</i> approaches to nanotoxicology</p>	<p>HSL project. Published as part of the NRCG Research Report:</p> <ul style="list-style-type: none"> • Characterising the potential risks posed by engineered nanoparticles  ^[9] <p>Outcome:</p>	<p><i>Results forms the evidence base for future in-vitro research proposals</i></p>
<p>Nanoparticle Occupational Safety & Health (NOSH) Consortium</p>	<p>A multi-partner international project. Completed 2007.</p> <ul style="list-style-type: none"> • Outline summary, including details of papers [45KB]  ^[10] <p>Outcome:</p>	<p><i>A large ~30 partner multinational/ multipartner project, led by DuPont in the USA. The Characterisation and filter results has informed HSE risk reduction positions and have provided base line information for work in subsequent project work – such as NANOSH.</i></p>

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Publications:

Two book chapters published:

- A chapter entitled "Measurement and characterisation of nanoparticles in the workplace" has been written by **Dave Mark** for publication in Environmental Science and Technology Issue No. 24 - "Nanotechnology: Consequences for Human Health & the Environment".
- **Gibson, R.M.** (2007) Understanding the potential Neurotoxicology of nanoparticles. In Nanotoxicology: Characterization, Dosing and Health Effects. N. Monteiro-Riviere and L. Tran, eds. Informa Healthcare, New York, Chapter 18, p. 293-310

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Two papers submitted:

- **D Bard, D Mark** and C Mohlmann. Current standardization for nanotechnology. Submitted for publication in the proceedings of the Nanosafe conference.
- K. Savolainen, L. Pykkänen, H. Norppa, G. Falck, H. Lindberg, T. Tuomi, M. Vippola, H. Alenius, K. Hämeri, J. Koivisto, D. Brouwer, **D. Mark, D. Bard**, M. Berges, E. Jankowska, M. Posniak, P. Farmer, R. Singh, F. Krombach, P. Bihari, G. Kasper and M. Seipenbusch. Nanotechnology, engineered nanoparticles and occupational safety. Submitted for publication in Safety Science.

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