



SID 5 Research Project Final Report

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Project identification

1. Defra Project code	CB01075
2. Project title	A scoping study to identify gaps in environmental regulation for the products and applications of nanotechnologies
3. Contractor organisation(s)	Central Science Laboratory
4. Total Defra project costs	£ 29,529
5. Project: start date	16 September 2005
end date	17 March 2006

6. It is Defra's intention to publish this form.
Please confirm your agreement to do so. YES NO

(a) When preparing SID 5s contractors should bear in mind that Defra intends that they be made public. They should be written in a clear and concise manner and represent a full account of the research project which someone not closely associated with the project can follow.

Defra recognises that in a small minority of cases there may be information, such as intellectual property or commercially confidential data, used in or generated by the research project, which should not be disclosed. In these cases, such information should be detailed in a separate annex (not to be published) so that the SID 5 can be placed in the public domain. Where it is impossible to complete the Final Report without including references to any sensitive or confidential data, the information should be included and section (b) completed. NB: only in exceptional circumstances will Defra expect contractors to give a "No" answer.

In all cases, reasons for withholding information must be fully in line with exemptions under the Environmental Information Regulations or the Freedom of Information Act 2000.

(b) If you have answered NO, please explain why the Final report should not be released into public domain



Executive Summary

7. The executive summary must not exceed 2 sides in total of A4 and should be understandable to the intelligent non-scientist. It should cover the main objectives, methods and findings of the research, together with any other significant events and options for new work.

1. The rapid growth of nanotechnology in recent years has prompted concerns over the safety of manufactured nanomaterials (NMs) when released into the environment. A number of NMs is already being used in consumer products that are available on the UK/EU market, and a further vast number of new materials/applications is at different stages of development.
2. Defra, as the responsible authority for environmental protection (and human health through the environment), needs to understand if current regulatory frameworks are suitable for nanotechnology related processes and applications, and whether there are any regulatory gaps that can be addressed through new legislation.
3. This study has been undertaken by the Safety of nanomaterials Interdisciplinary Research Centre (SnIRC), led for this study by Central Science Laboratory (CSL), in collaboration with Risk & Policy Analysts Limited (RPA).
4. In undertaking this study, the team identified and assessed a broad range of legislation, which addresses the sectors, products or substances of relevance to nanotechnologies. The study also identified applications for nanomaterials (NMs), and relevant pieces of environmental legislation, for a wide range of industrial sectors and products; and assessed whether the existing frameworks will allow for adequate management and control of the risks posed by NMs.
5. The study identified a number of regulatory gaps, which are broadly applicable across a number of pieces of relevant legislation. Where possible, the Reviewers have also suggested a way forward to fill the regulatory gaps. In brief these gaps relate to:
6. the definition of nanotechnologies and NMs; for example;
 - 6.1. where nanotechnologies represent a *new* manufacturing process for producing materials used in *existing* products and applications;
 - 6.2. where NMs represent a *new* (or different form) of an *existing* substance used in existing products and applications; and
 - 6.3. where both nanotechnologies and NMs present *new* risks, albeit to *existing* environmental compartments.
7. the scope and objectives of relevant legislation; for example;
 - 7.1. most vertical (or sector-specific) legislation are intended primarily for market harmonisation and ensuring the safety of consumers; e.g. while the definition of cosmetics (under the Cosmetics Directive) includes NMs, the scope and objectives of the Cosmetics Directive do not address environmental risks;
 - 7.2. the definition of hazardous substances under the Restriction of Hazardous Substances (RoHS) Directive does not include NMs, however, the scope and objectives include environmental risks.
 - 7.3. in the case of Notification of New Substances Regulations (NONS), and Existing Substances Regulation (ESR) and Chemicals (Hazard Information and Packaging for Supply) Regulations) (CHIP), the definition of NMs as either new or existing substances would impact on the regulatory framework (and consequently on the environmental risks) which would be applicable to them.
8. thresholds or exemptions under relevant legislation; for example;
 - 8.1. horizontal legislation such as the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) applies to all chemicals except those supplied below 1 tonne; however, NMs are, in the short term, and for the majority of applications, likely to fall outside the scope of REACH (and various other pieces of legislation) on the basis of the low tonnage (currently used in gram to kilogram quantities).
 - 8.2. certain activities (excluding chemical production) operating under specific thresholds (production or disposal capacity) are excluded from the controls set out under the Integrated Pollution Prevention and Control (IPPC) Directive and associated legislation. Thus any emissions from small-scale sites, as well as research and development activities, are not controlled by IPPC (although other legislation may apply in some cases).

9. the effects (or impacts) of nanotechnologies and NMs- for example;
 - 9.1. a general lack of knowledge relating to the effects of nanotechnologies, coupled with the distinctly different properties of NMs, result in nanotechnologies falling outside the scope of much legislation. For example, it is not clear if a waste containing NMs should be considered and treated as normal waste, hazardous waste, waste for incineration and/or landfill or even as radioactive waste.
 - 9.2. also, it is not clear what level of exposure is required to trigger an effect; thus whilst existing legislation such as the IPPC Directive may cover the relevant production and disposal processes, it relies upon knowledge of the polluting effects of emissions, which is generally lacking in relation to NMs. In addition, the River Basin Management Plans under the Water Framework Directive also implicitly require that a considerable effect (or pressure) is exerted on the water environment for definite regulatory (or remediation) action to be taken.
10. specific substances, for example;
 - 10.1. if NMs are considered as new substances (based on the definition of a new substance) under NONS, a risk assessment would be undertaken for the nano-substances which would have the advantage of generating information on the hazards and risks and also driving the risk management process (if necessary).
 - 10.2. if NMs are considered as existing substances under CHIP/ESR, there is the risk that in actual fact, little to no new information would be generated to improve the hazard or risk information relating to nanotechnologies. Thus, under the current framework it is possible for NMs to move from R&D stage to commercial production without full assessment of their properties and hazard potential.
 - 10.3. both of these regulatory frameworks will be replaced by REACH in the near future. While it may be prudent to wait for REACH to address the risks, it should be borne in mind that some nano-based products are already on the EU/UK market and any short-term risks from nanotechnologies may be realised before this time. It is also unclear how the REACH Regulation will capture all NMs (based on the tonnage exemptions and data requirements for different levels). A key issue is also whether the tests specified in the REACH Annex(es) are relevant for the risk assessment of NMs.
11. products and applications, for example;
 - 11.1. there are a small number of applications where the relevant legislation allows for testing of all or part of the product before it is placed on the market. These include biocides and plant protection products, food additives and medicines. Where such legislation exists, information will be generated regarding the hazard and risks posed by NMs. The key aim of this legislation is to protect human health (and, for the biocides and plant protection products legislation, the environment). Such measures may, therefore, protect the environment to some extent, either directly or indirectly, from NMs used in a small number of sectors.
 - 11.2. more generally, a number of sectors have legislation restricting the chemical content of products, where substances which have been identified as having hazardous properties (for example heavy metals) are limited or banned. Such legislation does not currently regulate the use of NMs in products. Whilst, in theory, it may be possible to amend such legislation to include NMs (if they were found to be hazardous), this legislation stems from European Directives and would need to be negotiated at the EU level.
12. the environment, for example;
 - 12.1. for industrial sources, it is currently unclear and/or unlikely that within the IPPC regulatory framework: existing monitoring techniques for NMs in industrial emissions are relevant, effective and available; or whether an acceptable level of emissions from NMs can be determined, thus making it very difficult to set emission limit values (ELVs).
 - 12.2. possible options in this regard relate to setting specific limits or similar technical parameters limiting the amount of NMs allowed into the environment under the IPPC permits. However, issues relating to the limitations in scientific and technical knowledge

would significantly affect effective implementation and monitoring under IPPC.

12.3. for waste recovery and disposal options, future and rising concerns in this regard relate to the definition, characteristic(s) and liability for waste containing NMs. In the short term, it would be possible for the regulatory authorities to indicate the disposal option for products containing NMs; this position can be reviewed as necessary, as better information relating to the risks becomes available in the future.

12.4. for the atmospheric compartment, the overall ability of existing legislation to reduce emissions to air is limited; however, it may be possible to ensure that the work following on from the Commission's Thematic Strategy on Air Pollution pays attention to emissions from nanotechnologies. This could be included in negotiations on the proposal to revise the Ambient Air Quality Directive to introduce controls on human exposure to PM_{2.5} to complement the existing limits on coarse particulate matter (PM₁₀).

13. The main regulatory gaps identified in this study thus derive from thresholds or exemptions under relevant legislation; or from the lack of information or uncertainties over clear definition(s); current scientific knowledge and understanding of hazards and risks; reliable and validated methods for monitoring exposure and potential impacts of NMs on human and environmental health.

14. A substantial body of work will be required to reduce these uncertainties. There is, however, an urgent need for setting clear, authoritative definitions for nanotechnologies and NMs, and achieving a scientific consensus to categorise different types of NMs into new or existing substances, as this will have a major bearing on the appropriateness and applicability of current and future legislation.

15. It is also recommended that findings of this study be reviewed and updated as more information with regard to NM properties, and their associated hazards and risks, becomes available in the future.

Project Report to Defra

8. As a guide this report should be no longer than 20 sides of A4. This report is to provide Defra with details of the outputs of the research project for internal purposes; to meet the terms of the contract; and to allow Defra to publish details of the outputs to meet Environmental Information Regulation or Freedom of Information obligations. This short report to Defra does not preclude contractors from also seeking to publish a full, formal scientific report/paper in an appropriate scientific or other journal/publication. Indeed, Defra actively encourages such publications as part of the contract terms. The report to Defra should include:
- the scientific objectives as set out in the contract;
 - the extent to which the objectives set out in the contract have been met;
 - details of methods used and the results obtained, including statistical analysis (if appropriate);
 - a discussion of the results and their reliability;
 - the main implications of the findings;
 - possible future work; and
 - any action resulting from the research (e.g. IP, Knowledge Transfer).

1.0 Background

The term nanomaterials (NMs) is used for materials with one or more external dimensions, or an internal structure, on the nanoscale, which could exhibit novel characteristics (such as increased strength, chemical reactivity or conductivity) compared to the same material without nanoscale feature (BSI, 2005). Thus, nanotechnology refers to the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanoscale. The manufactured NMs can be regularly shaped (e.g. nanoballs and nanotubes), irregularly shaped, or can exist in fused, aggregated or agglomerated forms; they can also be either in free or fixed forms. Free nanoparticles have the potential to penetrate cellular barriers, bioaccumulate in some target organs, or disperse in the environment. Fixed NMs, on the other hand, are embedded in a matrix and are less likely to raise concerns because of immobilisation.

A number of NMs are already being used in consumer products that are available on the UK/EU market, such as titanium dioxide in paints, and zinc oxide in sunscreens, whereas a vast range of new materials/applications is currently at different stages in the development pipeline. Such rapid proliferation of nanotechnology, estimated to grow worldwide to 1 trillion US\$ by 2015 (Roco, 2003), has also prompted concerns over the safety of manufactured NMs when released into the environment.

Defra, as the responsible authority for environmental protection (and human health through the environment), needs to understand if current regulatory frameworks are suitable for nanotechnology related processes, products and applications, or whether there are certain regulatory gaps that can be addressed through amending existing legislation or by introducing new legislation.

The main aims of this study were to:

- a. consider the appropriateness of existing frameworks for environmental regulation in the face of the risks posed by current and future products and applications of nanotechnologies – with a focus on the risks posed by free nanoparticles and nanotubes; and
- b. identify measures that can be put in place to ensure adequate protection for human health and the environment, if any regulatory gaps are found (this should include the need for supporting regulatory guidance).

This report is intended to give an essential overview of the findings of the study that have been presented in full by Chaudhry et al. (2006).

2.0 Methods and Approaches

To achieve the aims and objectives of this study, we adopted a stepwise approach that involved:

- Identification of processes, products and applications relevant to nanotechnology;
- Identification of regulations relevant to nanotechnology processes, products and applications;
- Assessment of the appropriateness and adequacy of relevant regulations, and identification of regulatory gaps relating to specific substances; products and applications; and the environment;
- Summary of regulatory gaps identified, and conclusions.

To identify relevant legislation, we considered a recent review of the manufacture and use of NMs in the UK (Chaudhry et al., 2005), and the NM database developed by CSL, to set out the current and projected range of nanotechnology related processes, products and applications in the UK. This information was used to identify the relevant legislation to different nanotechnology products at different lifecycle stages. Thus this study considered all currently known and projected uses of NMs, i.e. not only nanoparticles and nanotubes.

It should, however, be noted that, as a scoping study, this report does not provide a definitive list of all possible uses of nanotechnologies or environmental legislation. Instead, consideration of sectors and products has been limited to those that have already been identified as existing, or have been projected for the near future. Given the dynamic nature of the industry, it is likely that many more uses will emerge in the long-term future, but these have not been addressed by this study.

To identify a gap within the current legislation, it was first necessary to understand the existing regulatory frameworks. The Reviewers adopted an approach based on the lifecycle stages used within *EUSES*¹ to identify situations where legislation may or may not exist within the lifecycle stages of the production and application of NMs. Although some sectors may contain the use of NMs within the manufacturing process, the whole product lifecycle has been considered in this study for completeness.

2.1 The Nanotechnology Market and Applications

Nanotechnology is currently a multibillion dollar industry, which is expected to grow to 1 trillion US\$ by 2015. The majority of NM manufacturing and use occurs in the United States (49%), with the European Union responsible for 30% and the rest of the world accounting for the remaining 21%. Within the European Union, the UK accounts for nearly a third of the market (Chaudhry et al., 2005).

There are around 50 companies in the UK that are manufacturing, processing and/or using NMs. Some of these companies are also undertaking research and development (R&D) activities. There are further 55 non-commercial organisations undertaking nanotechnology related R&D in the UK. Only a small number of companies in the UK are producing NMs in significant quantities (i.e. kilograms), whereas a number of R&D departments are likely to be producing small experimental quantities. The main NMs currently produced in the UK include nanopowders (metals, metal oxides, alloys), magnetic NMs, carbon nanotubes (single, multi-walled), nanoceramics, nano-silica (fumed, colloidal), quantum dots (metal and semi-conducting nanocrystals), polymer composites containing NMs, and thin films (nm scale). (Chaudhry et al, 2005). Thus NM manufacturing in the UK does not mirror the global emphasis on fullerenes², nanotubes and fibres. The review also indicated that whilst many companies are using NMs in their products, only a few sectors (e.g. paints, cosmetics) are using them in any significant quantities.

Table 1 provides a summary of various sectors that the study identified as current and projected markets and applications in relation to nanotechnology.

Sector	Potential uses of NMs considered by the study
Coatings and Pigments	<ul style="list-style-type: none"> • UV absorbers to prevent degradation • nano-silica and nano-silver to prevent mould damage • dirt-repellent coatings • conductive inks for anti-counterfeiting applications
Construction Materials	<ul style="list-style-type: none"> • Nanotubes, fibres and composites to develop ultra high performance materials for construction • Potential use of NM coatings inside drinking water pipes.
Cosmetics	<ul style="list-style-type: none"> • nano metal oxides in suncreams to provide UV protection • self-assembled nanostructures (e.g. nanosomes) to help active molecules penetrate the skin • potential use of nano-silver in cosmetics to treat spots and acne
Detergents	<ul style="list-style-type: none"> • Potential use of nanosized or nanoencapsulated ingredients for enhanced dirt removal, or to ensure that material is not re-deposited on cleaned items.
Electrical and Electronic Equipment	<ul style="list-style-type: none"> • carbon nanotubes for electromagnetic shielding • electron field emitters (flat panel displays) and super capacitors

¹ EUSES is the computer model used to undertake risk assessments for new and existing substances in accordance with the European Commission's Technical Guidance Document.

² Fullerenes are large carbon-cage molecules. The most common one is C₆₀, also called a 'buckyball' but there are other types.

	<ul style="list-style-type: none"> transparent conducting films for touch screen technologies magnetic fluids in loudspeaker system gas sensors and sensing devices optics and optical devices, photonics and photonic devices and quantum computing photovoltaics, hydrogen storage and fuel cell/battery applications
Food Processing	<ul style="list-style-type: none"> some evidence suggests NMs are incorporated into food products (at present outside the UK, but many food companies are currently investing in nanotechnologies); future uses may include changing the structure, colour and/or flavour of food products
Fuel Cells and Batteries	<ul style="list-style-type: none"> a range of NMs in fuel cell and battery applications to produce solid oxide fuel cells and new fuel cell components
Medical Applications	<ul style="list-style-type: none"> targeted drug delivery of human and veterinary medicines incorporation of NMs to provide anti-microbial properties for medical devices and clinical textiles (e.g. burn dressings containing silver nanocrystals); hand soaps coating of catheters and endo-tubes platinum wires for retinal surgery; surgical blades made from microstructured silicon with diamond coated cutting edges powered medical implants using nanoscale electronic components implants for soft tissues and tendon repairs; implantable teeth and bone prostheses using nanoparticles and bio-composites cavity wounds – hydrogel and polyurethane foam marker technology for the clinical and life sciences diagnostics iron oxide nanoparticles for treating tumours feminine personal hygiene disposable products
Paper Manufacturing	<ul style="list-style-type: none"> colloidal silica and related products as absorbents during the pulping stage of paper manufacture
Plant Protection Products and Agrochemicals	<ul style="list-style-type: none"> Nanosized or nanoencapsulated pesticides (insecticides, fungicides etc) to increase the effectiveness of products. Nanosized or nanoencapsulated fertilisers and plant nutrients for controlled-release.
Plastics (including food packaging)	<ul style="list-style-type: none"> polymer nanocomposites for food packaging and wrapping anti-microbial packaging materials and smart packaging UV absorbers in plastics to prevent degradation
Textiles	<ul style="list-style-type: none"> Incorporation of NMs to give water repellency, stain resistance, and anti-odour properties in sportswear anti-microbial properties in medical textiles; conducting cloth
Transport – Lubricants and Fuel Additives	<ul style="list-style-type: none"> NM-based lubricants fuel additives or catalysts to reduce fuel consumption and reduce particulate emissions
Weapons and Explosives	<ul style="list-style-type: none"> Nano-sized fuels and oxidizers to reduce the size of weapons while maintaining explosive power as well as improved handling safety

3.0 Overview of Regulatory Gaps

3.1 Regulatory Gaps Concerning Specific Substances

A range of existing EU and UK legislation that could be relevant to the manufacture, use and disposal of chemical substances was identified and assessed in relation to the control of risks arising from nanotechnology. The relevance of regulations and drawbacks identified in terms of controlling risks from NMs include:

NONS³

Relevance: If NMs are considered new substances, manufacturers or importers will be required to provide the necessary hazard information, exposure scenarios would have to be developed for the risk

³ Notification of New Substances Regulations 1993 (SI 1993/3050)

assessment of the substance, and a proactive approach would be adopted to risk assessment in which risks are assessed prior to substance being placed on the market. Where a risk assessment indicates 'recommendations for risk reduction', restrictions on marketing and use of the substance in accordance with Directive 76/769/EEC could be put in place.

Drawback: NONS only applies to new substances placed on the market in quantities of over 10 kg/yr.

ESR⁴

Relevance: If NMs are considered existing substances, some data on hazards may be available (for HPVs and 'prioritised' substances), risk assessments are undertaken for a limited number (141) of 'prioritised' substances and exposure scenarios would have to be developed. A risk reduction strategy could be put in place after a risk assessment has been undertaken under ESR.

Drawback: There is no requirement under ESR to undertake tests to ascertain the properties of substances (except if they are on a priority list).

CHIP⁵

Relevance: Some data on hazards may be available as part of the safety data sheets required, exposure scenarios may have to be developed for the safety data sheets, and some risk assessment may be undertaken for the safety data sheets. Safety data sheets could have information on disposal options.

Drawback: Only applies to dangerous substances and preparations.

REACH⁶

Relevance: REACH will apply to all substances. Manufacturers or importers will be required to provide the necessary hazard information. Exposure scenarios would have to be developed for the risk assessment of dangerous substances (taking into account tonnage considerations). A proactive approach to risk assessment (or evaluation) would be undertaken for dangerous substances over 10 tonne/yr and for substances of particular concern. Under REACH, responsibility for management of risks should lie with the enterprises that manufacture, import, place on the market or use the substances.

Drawback: Only applies to substances supplied in quantities over 1 tonne/yr (unless of particular concern).

3.2 Regulatory Gaps Concerning Nanotechnology Products and Applications

Table 2 provides a summary of the environmental (and product related) regulations to a range of NM applications. As can be seen, there are core pieces of environmental legislation, which relates to emissions from the manufacturing of products and waste disposal.

⁴ Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ, L84, 5/4/1993, p1)

⁵ Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (SI 2002/1689) *as amended by* Chemicals (Hazard Information & Packaging for Supply) (Amendment) Regulations 2005 (SI 2005/2571)

⁶ Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}, *and* Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals: COM(2003), 644 final dated 29/10/2003: 2003/0256(COD), 2003/0257(COD)

Waste Framework Directive/EPA 1990		X	X	X	X	X	X	X	X	X		X	X	X	X
Hazardous Waste Directive/Regs		X	X			X		X	X	X		X	X	X	X
Landfill Directive/Regs		X	X	X		X	X	X	X	X		X	X	X	
Waste Incineration Directive/Regs		X	X	X		X	X	X	X	X		X	X	X	
WEEE Directive/Regs						X		X				X			
ELV Directive/Regs								X				X		X	
Packaging and Packaging Waste Directive/Regs										X		X			

CHIPS – Chemical (Hazard Information and Packaging for Supply), **ELV** – End of Life Vehicles (note this abbreviation relates to emission limit values elsewhere in this Report), **EMC** – Electromagnetic Compatibility, **EPA** – Environmental Protection Act, **GPS** – General Product Safety, **IPPC** – Integrated Pollution Prevention and Control, **LVD** – Low Voltage Directive, **PPC** – Pollution Prevention and Control, **RoHS** – Restriction of Hazardous Substances, **UWWT** – Urban Waste Water Treatment, **WEEE** – Waste Electrical and Electronic Equipment

A brief overview of the regulatory deficiencies and gaps identified in relation to products and applications of NMs is given below:

- o Coatings and Pigments: biocidal legislation should apply where coatings have anti-fungal properties. NMs included in biocidal products, but not as the active substance, may not be fully identified or assessed.
- o Construction Materials: Relevant Directive may only apply to NMs if other legislation has already identified them to be dangerous. For insulating materials, existing guidance only refers to urea formaldehyde. It is also unclear to what extent the available test methods would be able to assess the potential hazard, exposure, or risk resulting from the use of NMs in coatings in drinking water pipes.
- o Cosmetics: Only ingredients requiring entry on a positive list, e.g. UV filters, are assessed by the Scientific Committee; consideration of risk is limited to human health and not environmental risks.
- o Detergents: Biodegradation testing would apply to use of NMs in surfactants; however, nano-forms of existing non-surfactant ingredients are unlikely to be addressed.
- o Electrical and Electronic Equipment: Relevant legislation limits exposure to hazardous chemicals (specific named substances that have already been identified as hazardous) – this does not currently include NMs.
- o Food Processing: Additive and novel food legislation only considers impacts on human health and does not consider environmental impacts or emissions.
- o Fuel Cells and Batteries: Legislation only addresses specific named substances that have already been identified as hazardous.
- o Medical Applications: Legislation would include consideration of NMs in hazard identification, exposure assessment and risk characterisation for medicines and medical devices; however, only minimal consideration is given to the environmental impact of medical applications.
- o Paper Manufacturing and Plastics (including food packaging): Legislation relating to food contact materials recognises the potential use of active and intelligent food contact materials. It is likely that materials will undergo a safety assessment before use, perhaps with a positive list of approved substances. This is still under development but could include NMs.
- o Plant Protection Products: NMs included in plant protection products, but not as the active substance, may not be fully identified or assessed.

- o Agrochemicals (Fertilisers and Plant Nutrients): EC and domestic fertiliser/plant nutrient legislation does not regulate environmental hazards and risks associated with the use of these products. Water legislation address eutrophication etc., but it is possible that other environmental risks of NMs would not be addressed for nanosized fertilisers and plant nutrients
- o Textiles: The GPSD⁷ does not regulate environmental hazards and risks. In addition, hazards may only be identified after a product is placed on the market. It is possible that the environmental risks of NMs would not be addressed for a product containing NMs.
- o Transport – Lubricants and Fuel Additives: Legislation only addresses specific named substances that have already been identified as hazardous.
- o Weapons and Explosives: Some risk assessment may be undertaken where substances are classified as dangerous – most NMs are not currently classified as dangerous

3.3 Regulatory Gaps Concerning Environmental Emissions, Contamination and Remediation

NMs could enter the environment either intentionally or unintentionally. For industrial sources, it is currently unclear and/or unlikely that within the IPPC⁸ regulatory framework:

- the existing monitoring techniques for NMs in industrial emissions are relevant, effective and available;
- an acceptable level of emissions from NMs can be determined; and
- appropriate emission limit values (ELVs) will be set for NMs (under the permits), as they are unlikely to be released in significant quantities (in tonnage terms) – however, this is dependent on whether they are considered as new or existing substances.

These considerably limit the effectiveness of IPPC in addressing the potential emissions of NMs into the environment. Possible options in this regard relate to setting specific limits, or similar technical parameters, limiting the amount of NMs allowed into the environment under the permits. This should be possible at the UK level, although issues relating to the limitations in scientific and technical knowledge would significantly affect effective implementation and monitoring under IPPC.

Water and air pollution legislation is based on lists of specific substances, which must be controlled, based on existing evidence of their health and/or environmental impacts. The inclusion of metals as water pollutants could cover some NMs, if these are deemed to be existing substances; however, the ability to monitor and remove nanoparticles is limited. Other NMs are unlikely to be covered by these lists of specific substances. Terms such as 'significant' may also restrict the relevance of legislation, where significant quantities (in tonnage terms) of traditional pollutants are not comparable to the likely releases of NMs.

For the atmospheric compartment, the overall ability of existing legislation to reduce emissions to air is limited; however, it may be possible to ensure that the work following on from the Commission's Thematic Strategy on Air Pollution pays attention to emissions from nanotechnologies. This could be included in negotiations on the proposal to revise the Ambient Air Quality Directive to introduce controls on human exposure to PM_{2.5} to complement the existing limits on coarse particulate matter (PM₁₀).

It is not clear if waste NMs, or products containing NMs, should be considered and treated as normal waste, hazardous waste, waste for incineration and/or landfill or even as radioactive waste. It is probable that waste streams containing different NMs with different properties, chemical identities and structures may need to be classified in different ways. This is directly linked to a lack of information on the effects of NMs. However, it is unlikely that identification and separation of consumer products containing NMs would be possible under the existing framework, which also has implications for waste

⁷ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) (OJ L011, 15/1/2002, p4)

⁸ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L257, 10/10/1996, p26) (as amended)

management. It should also be noted that, should waste NMs and products be incinerated or landfilled, the IPPC Directive and Regulations apply, with the associated issues relating to NMs.

4.0 Summary of Regulatory Gaps and Conclusions

The main regulatory gaps identified in this study derive from the thresholds or exemptions under relevant legislation. For example, horizontal legislation such as REACH applies to all chemicals except those supplied below 1 tonne; but NMs are, in the short term, and for the majority of applications, likely to fall outside the scope of REACH (and various other regulations) on the basis of the low tonnage (i.e. in gram to kilogram quantities currently being used).

Other regulatory gaps identified derive from the lack of information, or uncertainties, over a number of areas; for example:

- o the scope and objectives of the relevant legislation; for example, while the definition of cosmetics (under the Cosmetics Directive⁹) includes NMs, the scope and objectives of the Directive does not include environmental risks;
- o clear definition(s) encompassing the novel (or distinct) properties of nanotechnologies and NMs; i.e. whether an NM should be considered a new or an existing material. For example, in the case of NONS and ESR/CHIP where the definition of NMs as either new or existing substances would impact on the regulatory framework (and consequently on the environmental risks) which would be applicable to them;
- o current scientific knowledge and understanding of hazards and risks arising from exposure to NMs. Thus, it is currently unclear (and/or unlikely) whether the existing definition of 'dangerous substances', for example under COMAH¹⁰, would apply to the majority of NMs; and in cases where the definition of 'dangerous substance' is applicable, even the lower-tier threshold would be equalled or exceeded. It is also not clear what level of exposure is required to trigger an effect; thus while existing legislation such as IPPC covers the relevant production and disposal processes, it relies upon knowledge of the polluting effects of emissions, which is generally lacking in relation to NMs. In addition, the River Basin Management Plans under the Water Framework Directive¹¹ also implicitly requires that a considerable effect (or pressure) is exerted on the water environment for a definite regulatory (or remediation) action to be taken;
- o agreed dose units that can be used in hazard and exposure assessments. The conventional units for toxicity based on mass-dose seem to be unsuitable for toxicity measurement of NMs, and a new unit(s) are needed that reflect the distinctly different properties of NMs in terms of mass, particle size and surface area;
- o reliable and validated methods for measurement and characterisation that can be used in monitoring potential exposure to NMs;
- o potential impacts of NMs on human and environmental health. A general lack of knowledge relating to the effects of nanotechnologies may result in nanotechnologies falling outside the scope of many regulations. For example, it is not clear if waste NMs should be considered and treated as normal waste, hazardous waste, waste for incineration and/or landfill, or even as radioactive waste. Furthermore, it would not be possible to set an acceptable level of emissions due to current limitations in scientific understanding of the effects of NMs, and the available technology to monitor emissions.

⁹ Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L262, 27/9/1976,p169)

¹⁰ Control of Major Accident Hazards Regulations 1999 (SI 1999/743)

¹¹ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) (OJ L327, 22/12/2000, p1)

A substantial body of work will be required to reduce the uncertainties highlighted by the study (Chaudhry, 2006). There is, however, an urgent need for setting clear, authoritative definitions for nanotechnologies and NMs, and achieving a scientific consensus to categorise different types of NMs into new (or different form), or existing substances, as this will have a major bearing on the appropriateness and applicability of current and future legislation. It is also recommended that findings of this study be reviewed and updated as more information with regard to NM properties, and their associated hazards and risks, becomes available in the future.

References to published material

9. This section should be used to record links (hypertext links where possible) or references to other published material generated by, or relating to this project.

BSI (2005) Vocabulary – nanoparticles: Publicly Available Specification: PAS 71:2005

Chaudhry, Q., Boxall, A., Aitken, R. and Hull, M. (2005) A scoping study into the manufacture and use of nanomaterials in the UK, Central Science Laboratory, Sand Hutton, York.

Chaudhry, Q., George, C., Floyd, P., Blackburn, J., Aitken, R., Nwaogu, T. and Boxall, A. (2006) A scoping study to identify regulatory gaps for the products and applications of nanotechnologies, Central Science Laboratory, Sand Hutton, York.

Roco, M.C. (2003) Broader societal issues of nanotechnology, *J. Nanoparticle Res.* 5: 181-189.