Final Report

A scoping study to identify gaps in environmental regulation for the products and applications of nanotechnologies

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EXECUTIVE SUMMARY

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 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. A further vast number of new materials/applications are currently 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). The main aims of the study were:
   3.1. to consider the appropriateness of existing frameworks for environmental regulation in the face of the risks posed by current and projected products and applications of nanotechnologies – with a focus on the risks posed by free nanoparticles and nanotubes; and
   3.2. to identify measures that can be put in place to ensure adequate protection for human health and the environment, if any regulatory gaps are found.
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, as follows:
   4.1. *Specific Substances*: currently, two separate regimes operate under EU and UK legislation to ensure that chemical substances do not pose significant risks to human health and the environment. These distinguish between chemical substances on the market before and after September 1981. Substances on the EU market prior to September 1981 are classed as 'existing' chemicals and fall under the Existing Substances Regulation (ESR) and any chemicals placed on the market after September 1981 are classed as 'new'. These regulations will be replaced in the future by the proposed new EU chemicals Regulation (REACH). The legislation assessed in this area are the Notification of New Substance (NONS) Regulations 1993, Chemicals (Hazard Information & Packaging for Supply) (CHIP) Regulations 2002, Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances (ESR), and REACH.
   4.2. *Products and Applications*: the study considered sectors where applications and markets for nanotechnology are currently known, or anticipated in the near future. These include coatings and pigments, construction materials including coatings for drinking water pipes, cosmetics, electrical and electronic equipment, food processing, fuel cells and batteries, medical applications (including veterinary medicines), detergents, paper manufacturing, plant protection products, plastics (including food packaging), textiles, transport – lubricants and fuel additives, weapons and explosives. The legislation assessed in this area relates to the chemical content of products, manufacture and storage, and product use, and recovery and disposal.

4.3. *The Environment*: the study assessed legislation aimed at controlling emissions from manufacturing, use, recovery and disposal of substances to air, water, land or waste. The legislation assessed in this area relates to industrial emissions, water emissions, waste management**,** environmental contamination and remediation.

5. The study considered two types of potential regulatory gaps associated with legislation at different lifecycle stages for NMs, and related processes and applications:

   5.1. where a piece of legislation relating to a sector, application, product or substance fails to address an aspect of particular interest. For instance, if a piece of legislation is intended to address the human health impacts of a particular product, its failure to address possible environmental consequences resulting from the same product constitutes a regulatory gap.

   5.2. where a piece of legislation is intended to address a specific aspect of particular interest to a sector, application, product or substance, but fails to address it due to exemptions (e.g. threshold, volume or tonnage related), lack of foresight, limitations in technical or scientific knowledge, etc).

   This study was focussed more on the latter regulatory gap as it was considered that these are 'unintentional' gaps.

6. It should be noted that, as a scoping study, this Report does not provide a definitive list of 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 (Chaudhry *et al*., 2005). 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. Similarly, it is possible that other pieces of legislation (which are not identified in this study) are, or will be, relevant to sectors, products and processes involved in nanotechnologies. Nevertheless, the issues identified in this study will also be relevant to such pieces of legislation.

7. The study identified a number of regulatory gaps, which are broadly applicable across a number of relevant legislation. Where possible, the Reviewers have also suggested a way forward to fill the regulatory gaps:

   7.1. gaps relating to the definition of nanotechnologies and NMs; for example;

      7.1.1. where nanotechnologies represent a *new* manufacturing process for producing materials used in *existing* products and applications;

      7.1.2. where NMs represent a *new* (or different form) of an *existing* substance used in existing products and applications; and

      7.1.3. where both nanotechnologies and NMs present *new* risks, albeit to *existing* environmental compartments.

   7.2. gaps relating to the scope and objectives of relevant legislation; for example;

      7.2.1. 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 Cosmetic Directive) includes NMs, the scope and objectives of the Cosmetics Directive do not address environmental risks;

      7.2.2. 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.

7.2.3. in the case of NONS and ESR/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.

7.3. gaps relating to thresholds or exemptions under relevant legislation; for example;

7.3.1. horizontal legislation such as 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).

7.3.2 certain activities (excluding chemical production) operating under specific thresholds (production or disposal capacity) are excluded from the controls set out under the 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).

7.4. gaps relating to the effects (or impacts) of nanotechnologies and NMs- for example;

7.4.1. 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.

7.4.2. also, it is not clear what level of exposure is required to trigger an effect; thus whilst existing legislation such as the Integrated Pollution Prevention and Control (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.

7.5. gaps relating to specific substances, for example;

7.5.1. 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).

7.5.2. 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.

7.5.3. 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.

7.6. gaps relating to products and applications, for example;

7.6.1. 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 Regulations, 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.

7.6.2. 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.

7.7. gaps relating to the environment, for example;

7.7.1. 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 ELVs.

7.7.2. 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.

7.7.3. 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.

7.7.4. 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 (PM_{10}).

8. In conclusion, this study has identified applications for 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. The regulatory gaps identified in this study derive either from exemptions (on tonnage basis) under legislative frameworks, or from the lack of information, or uncertainties over:

- 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;
- current scientific knowledge and understanding of hazards, and risks arising from exposure to NMs;
- agreed dose units that can be used in hazard and exposure assessments;
- reliable and validated methods for measurement and characterisation that can be used in monitoring potential exposure to NMs;
- potential impacts of NMs on human and environmental health.

A substantial body of work will be required to reduce these uncertainties, factors that have also been highlighted in the Royal Society/ Royal Academy of Engineering report (2004). 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 over NM properties and associated hazards and risks becomes available in the future.

1. INTRODUCTION

1.1 Background to the Study

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 features1. Thus, nanotechnology refers to the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanoscale[1]. Whilst the term nanotechnology is new, the nanosized particles have been produced by a number of natural processes (such as volcanic eruptions), and unintentionally by industrial processes (such as metal welding, metal polishing, and vehicle combustion). A vast range of NMs is however deliberately manufactured for particular applications. Such manufactured NMs can be regularly shaped (e.g. nanoballs and nanotubes), irregularly shaped, or can be in fused, aggregated or agglomerated forms; they can also be either free or fixed. Free NMs (e.g. nanoparticles or nanotubes) 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 cannot move and are less likely to raise concerns because of this immobilisation. The large surface area, crystalline structure, reactivity and atypical properties of some NMs, coupled with their potential large-scale industrial manufacture and use in consumer products, has necessitated a review of the regulatory frameworks in relation to products and processes relevant to the nanotechnology industry.

Some manufactured 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 in the pipeline. This rapid proliferation of nanotechnology (expected to grow worldwide to 1 trillion US$ by 2015) has also prompted concerns over the safety of manufactured NMs when released into the environment.

In this context, the Government commissioned a review in June 2003 on the environmental, ethical, health and safety or social issues that might arise from the new technology. This comprehensive review was carried out by the Royal Society and the Royal Academy of Engineering and was published in July 2004. The review emphasised the need to increase understanding of the human health and environmental effects posed by nanoparticles and nanotubes, with a view to designing and implementing appropriate regulatory frameworks.

The Government published its response to the review in February 2005, accepting the recommendations made by the RS/RAEng. In doing so, it emphasised that while nanotechnology offers enormous benefits in terms of wealth creation, the new technology needs to be properly regulated to safeguard the benefits as well as people and the environment. Therefore, 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

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

applications, or whether there are certain regulatory gaps that can be addressed through amending existing legislation or new legislation.

The current 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), to review the regulatory issues with regard to the processes, products and applications of manufactured nanoparticles and nanotubes.

1.2 Project Aims and Objectives

As set out in the Project Specification, the aims of the proposed work were to:

- 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

- 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).

More specifically, the objectives set out in the Project Specification were as follows:

- using the best available information on the current and projected range of nanotechnology applications and products, to consider which environmental regulations would apply in each case;

- for these regulations, analysis should consider whether existing controls would allow adequate management and control of risks posed by nanotechnologies (particularly relating to free nanoparticles and nanotubes), or whether additional measures would be required to do so;

- this should include consideration of any practical limitations of current control methods as they relate to the control of nanotechnologies, i.e. whether the regulations 'in principle' would apply to nanotechnology, but also whether 'in practice' that would actually occur, or whether there would be barriers to doing so (such as a lack of methods for measurement or filtration); and

- the analysis should include, but not be limited to, consideration of the following types of environmental regulation:
  - regulations relating to industrial emissions;
  - regulations relating to waste management;
  - regulations relating to environmental contamination and remediation;
  - regulations relating to emissions to water from domestic/industrial use; and
  - regulations relating to transport emissions.

1.3 Approach to Identifying Regulatory Gaps

To identify a gap within the current legislation, it was first necessary to understand the existing regulatory frameworks. Figure 1.1 provides a general overview of the approach adopted by the Team to identify situations where legislation may or may not exist within the lifecycle stages of the production and application of NMs.

Figure 1.1: General Regulatory Framework for Producing, Using, Recovering and Disposing of Chemical Substances and Associated Emissions

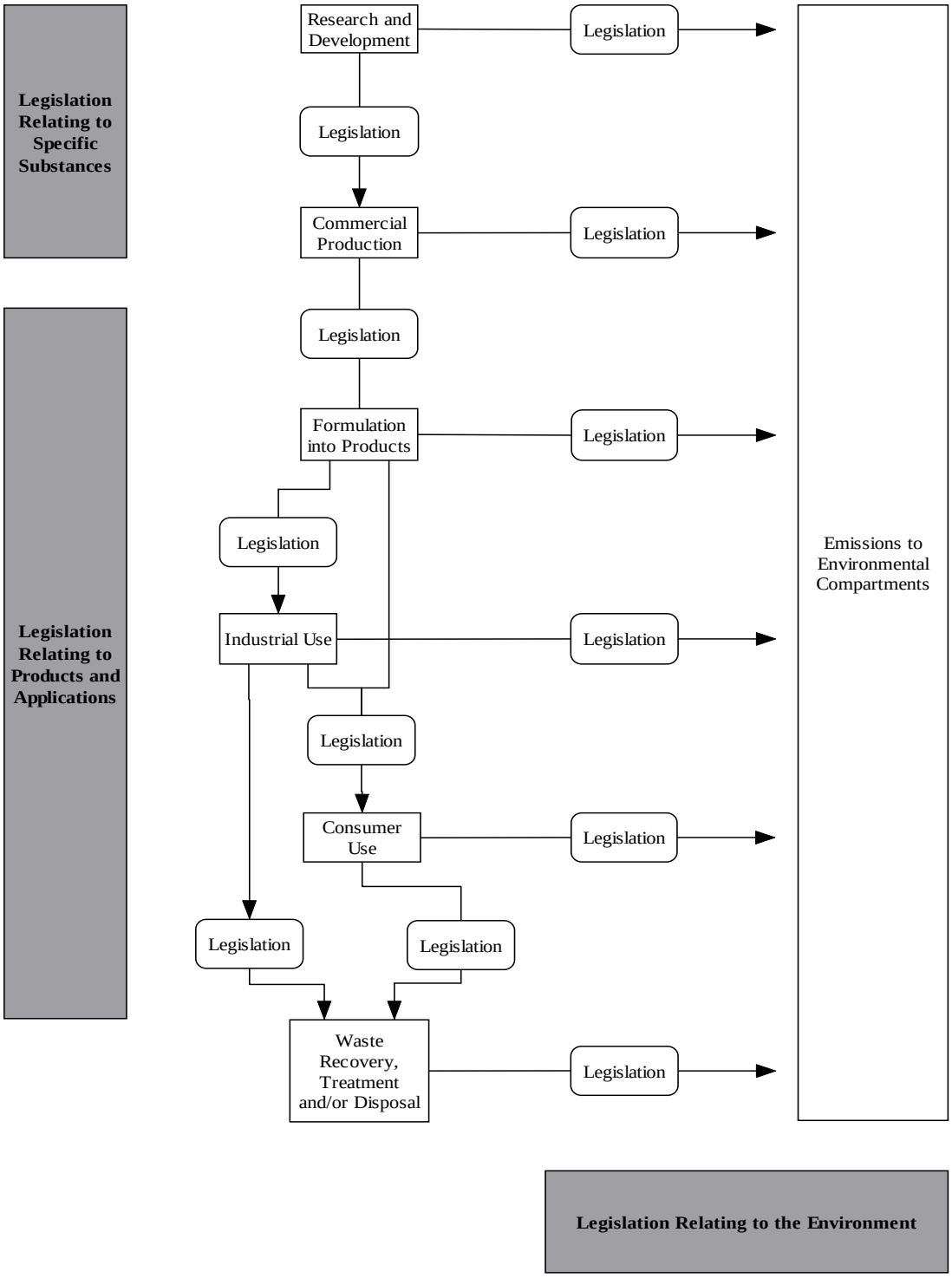

Figure 1.1 is based on the lifecycle stages used within *EUSES*[2]. It shows that NMs (or indeed any chemical substance) are developed and commercially produced, then formulated into products which may be used by industry and/or consumers, before recovery or disposal. There is the potential for legislation to exist between each lifecycle stage to control the use or management of the chemical substance from one stage to another. In addition, at each of these stages, it is possible for the chemical substance to be emitted into the environment, and these emissions may or may not be controlled by environmental legislation.

In view of these lifecycle stages and associated legislation, there is the potential for two main types of regulatory gaps:

- the first type of gap relates to where the key piece of legislation relating to a sector, application, product or substance fails to address an aspect of particular interest. For instance, if a piece of legislation is intended to address the human health impacts of a particular product, its failure to address possible environmental consequences resulting from the same product could result in a regulatory gap (depending on the scope of other related legislation) (e.g. in Figure 1.1 it could be possible to move from one lifecycle stage to another without passing through any environmental legislation); and

- the second type of gap relates to where a piece of legislation is intended to address a specific aspect of particular interest to a sector, application, product or substance, but fails to address it due to exemptions (e.g. threshold, volume or tonnage related), lack of foresight, limitations in technical or scientific knowledge, etc. For instance, if a piece of legislation is intended to address environmental impacts from a product, its failure to address emissions to water (which is clearly within its objectives and scope) constitutes a regulatory gap (i.e. in Figure 1.1, although there is environmental legislation between one lifecycle stage and another, it does not adequately address the environmental impacts).

The first type of regulatory gap is of interest as the relevant legislation may not prevent or limit the use of NMs (if it was found necessary to do so) and therefore provides a route by which NMs may enter the environment. However, where a piece of legislation is intended to harmonise the internal market or ensure the safety of human health, its scope is not intended to address environmental aspects, and it may not be appropriate to 'plug' the gap in environmental legislation by amending that particular piece of legislation.

In undertaking this study the Team identified a broad range of legislation which addresses the sectors, products or substances of relevance to nanotechnologies; however, we have focussed on the latter regulatory gap, as it is considered that these are 'unintentional' gaps.

[2] 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.

Furthermore, it should 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 (Chaudhry *et al*., 2005). Given the dynamic nature of the industry, it is likely that many more uses will be developed in the medium- to long-term future, but these have not been addressed by this study. Similarly, it is possible that other pieces of legislation (which are not identified in this study) are, or will be, relevant to sectors, products and processes involved in nanotechnologies. However, the issues identified in this study will also be relevant to such pieces of legislation.

In order to identify any regulatory gaps, it was necessary to set out the particular criteria against which the legislation should be assessed. In the context of this study, the legislation was to be assessed for its relevance for addressing the risks relating to nanotechnologies.

In a comprehensive report on risk assessment, the European Commission's Directorate General for Health and Consumer Protection (DG SANCO) (European Commission, 2000) defines a risk assessment as "a process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/events(s) occurring to man or the environment following exposure under defined conditions to a risk source(s)".

The DG SANCO report further defines risk assessment as comprising hazard identification, hazard characterisation, exposure assessment and risk characterisation. These terms are defined in Table 1.1.

Table 1.1: Stages of Risk Assessment

Stage	***Definition (from EC, 2000)***
Hazard Identification	*The identification of a risk source(s) capable of causing adverse effect(s)/event(s) to humans or the environment, together with a qualitative description of the nature of these effect(s)/event(s).*
Hazard Characterisation	*The quantitative or semi-quantitative evaluation of the nature of the adverse health effects to humans and/or the environment following exposure to a risk source(s). This must, where possible, include a dose response assessment.*
Exposure Assessment	*The quantitative or semi-quantitative evaluation of the likely exposure of man and/or the environment to risk sources from one or more media.*
Risk Characterisation	*The quantitative or semi-quantitative estimate, including attendant uncertainties, of the probability of occurrence and severity of adverse effect(s)/event(s) in a given population under defined exposure conditions based on hazard identification, hazard characterisation and exposure assessment.*

Simply stated, hazard is the potential for harm and risk is the probability (or likelihood) that the hazard is realised. The risk posed by chemical substances is generally a function of the hazard associated with the substance (effect) and the likely environmental (or human) exposure which together determine 'severity of effect' (the probability of occurrence (i.e. being exposed to the chemical) is assumed to be one).

In order for environmental legislation to be effective in addressing the risks relating to nanotechnologies, four main questions should be considered, as follows:

1. *Hazard identification and characterisation*: Does the legislation require an identification of the potential hazards from NMs (where these relate to the intrinsic physicochemical and eco-toxicological properties (i.e. effects) of the chemical)?

2. *Exposure assessment*: Does the legislation require determination, quantification and/or control of potential exposure (routes) to NMs (where these relate to both environmental concentrations (e.g. discharge limits) and pathways)?

3. *Risk calculation and characterisation*: Does the legislation require calculation and characterisation of the risk (i.e. combine the information from the hazard (or effects) and exposure to calculate risk)?

4. *Environmental action*: Finally, where NMs do get into the environment, does the legislation require and allow for effective action to ensure that exposure is controlled to acceptable levels?

Evaluation of the above questions (referred to in this study as the four-step methodology) provides the basis for identifying the regulatory gaps in environmental legislation relating to NMs.

1.4 Structure of this Report

The remainder of this Report has been organised as follows:

- Section 2 sets out the **current and future products and applications** of nanotechnologies which have been considered in this study;
- Section 3 sets out the **legislation relating to specific substances**;
- Section 4 sets out the **legislation relating to** t**he current and future products and applications** of NMs;
- Section 5 considers the appropriateness of existing frameworks for **environmental legislation** in the face of the risks posed by NMs. The key environmental legislation has been sub-divided into those relating to industrial emissions, emissions to water, waste management and environmental contamination/remediation;
- Section 6 evaluates the **regulatory gaps** in the legislative framework for nanotechnologies and discusses the possible options in determining **a way forward** for addressing the identified regulatory gaps and ensuring adequate protection for human health and the environment.

2. THE NANOTECHNOLOGY MARKET AND APPLICATIONS

2.1 The Nanotechnology Market

Nanotechnology is 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 reported to be around fifty companies in the UK which are manufacturing, processing and/or using NMs. Some of these companies may also be undertaking research and development (R&D) activities, and there are an additional 55 non-commercial R&D organisations operating in the UK.

Only a small number of companies are producing NMs in significant quantities (i.e. kilograms), however a number of R&D departments are likely to be producing small experimental quantities. Some of these departments may have the capabilities to scale-up their processes to produce large quantities.

The main NMs produced in the UK are as follows (placed in the order of production – largest first) (Chaudhry *et al*., 2005):

- nanopowders (metals, metal oxides etc, alloys) e.g. titanium dioxide, tin oxide;
- magnetic NMs;
- carbon nanotubes (single or multi-walled);
- nanoceramics;
- nano-silica (fumed, colloidal);
- quantum dots (metal and semi-conducting nanocrystals);
- polymer composites containing NMs; and
- thin films (nm scale).

Of the NM manufacturing that occurs in the UK, most is for the bulk markets in metals and metal oxides, and some is for niche markets. UK NM manufacturing does not mirror the global emphasis on fullerenes[3], nanotubes and fibres. It is therefore likely that these NMs are imported into the UK, however, this is not yet confirmed.

More companies are using NMs in their products, but only a few sectors are using them in significant quantities. The review in the remainder of this Section incorporates all (currently known) uses of NMs, i.e. not only nanoparticles and nanotubes. Whilst the concern regarding nanoparticles and nanotubes is related to their use in 'open' applications, little is known regarding the fate of NMs in 'fixed' applications. In particular, legislation relating to the chemical content and recovery/disposal of products may also be applicable. In practice, some sectors may contain the use of NMs within the manufacturing process. However, this Report considers the whole lifecycle to ensure completeness.

[3] Fullerenes are large carbon-cage molecules. The most common one is C_{60}, also called a 'buckyball' but there are many other types.

The following sectors are considered below:

- production of NMs;
- coatings and pigments;
- construction materials (including drinking water pipes[4]);
- cosmetics;
- detergents[4];
- electrical and electronic equipment;
- energy sources;
- food processing;
- medical applications (including veterinary medicines[4]);
- paper manufacturing;
- agrochemicals and plant protection products[4];
- plastics (including food packaging);
- textiles;
- transport – lubricants and fuel additives; and
- weapons and explosives.

It should be noted that an indication that legislation exists to control emissions to the environment from these sectors does not suggest that it would adequately address emissions of NMs. The adequacy of the legislation is discussed in Sections 3 to 5 and Annex 1 provides a table for each sector which identifies the key pieces of legislation that are applicable at each lifecycle stage.

2.2 Production of Nanomaterials

The main manufacturing activities, and therefore applications, of NMs in the UK have focused on metals and metal oxides, with some production and use of carbon nanotubes and quantum dots. Table 2.1 (overleaf) lists some of the substances used in producing NMs.

At present, two separate regimes operate under EU and UK legislation to ensure that chemical substances do not pose significant risks to human health and the environment. These distinguish between chemical substances on the market before and after September 1981. Substances on the EU market prior to September 1981 are classed as 'existing' chemicals under the *Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances* (Existing Substances Regulation (ESR)) and any chemicals arriving after September 1981 are classed as 'new'. *Directive 92/32/EEC amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to*

Table 2.1: Chemical Nature of Some Example NMs

NMs	Examples
Fullerenes	C_{60}, C_{70}, C_{80}, functionalised and non-functionalised

[4] These applications have been included at the request of Defra, but are not known to be currently produced or used in the UK (Chaudhry *et al.*, 2005).

Nanotubes and fibres	Carbon (organic) and inorganic, multi- and single-walled
Metals	Aluminium, Copper, Cobalt, Iron, Magnesium, Nickel, Platinum, Silver, Gold, Tin, Titanium, Tungsten
Metal oxides, carbides, nitrides, sulphides, selenides	Alumina, Ceria, Copper oxide, Manganese oxide, Nickel oxide, Titanium oxide, Tin oxide, Tungsten oxide, Yttria, Zinc oxide, Zirconia, Titanium Nitride, Tungsten Carbide, Cadmium sulphide, Gallium selenide
Quantum Dots	Metals, Alloys
Other	Clays, Ceramics, Polymers, Dendrimers, Silica

the classification, packaging and labelling of dangerous substances, provides for the risk assessment of new substances. The existing legislation will be replaced in the future by the proposed new EU chemicals Regulation (REACH). Legislation relating to specific substances is addressed in Section 3.

The manufacturing process of chemical substances may, however, result in emissions to air, water, land or waste and these are controlled under existing legislation such as *Directive 96/61/EC on Integrated Pollution Prevention and Control* (IPPC Directive) (as amended) and the *Pollution Prevention and Control (England and Wales) Regulations 2000*[5] (as amended). These are considered further in Section 5.

2.3 Coatings and Pigments

2.3.1 Applications of NMs

Coatings come in a wide variety of forms that are designed for very specific purposes; however, typical components include pigments, extenders, binders, thinners, solvents and additives. NMs may be used as an additive in paints or as a pigment or additive in printing inks.

Potential uses of NMs in coatings include:

- use of UV absorbers to help prevent degradation of coatings in the presence of UV radiation;
- use of nano-silica and nano-silver in paint for indoor and outdoor wood structures to prevent mould and fungi damage;
- dirt-repellent coatings in the form of paint and glass coatings for buildings in urban areas; and
- coatings for drinking water pipes.

The use of NMs in inks has mainly focused on anti-counterfeiting marking, by incorporating fluorescent NMs, or conductive or magnetic NMs into an ink for ink-jet printing.

2.3.2 Manufacture, Use and Disposal of Coatings and Pigments

Traditional paint and ink manufacturing consists of four major processes:

[5] Where regulations for England or England and Wales are identified, similar legislation is in place for the Scotland and Northern Ireland, unless stated otherwise.

- preassembly and premix of raw materials;
- pigment grinding, milling, and dispersing;
- product finishing and blending; and
- product filling and packaging.

These processes provide the potential for emissions from manufacturing plants to the air, water, land and waste disposal from:

- discarded raw material containers;
- pigment dust;
- filter cartridges;
- equipment cleaning wastes;
- air emissions of volatile organic compounds;
- off-specification paints and inks;
- spills and leaks; and
- waste water and surface water discharge.

Legislation exists to control emissions from the manufacturing process and also to require paint products to be labelled with hazard classification, specific components, and required safety procedures. In addition, paints containing NMs for the purpose of preventing mould and fungi are likely to fall within the scope of the *Control of Pesticides Regulations 1986* (as amended) and the *Biocidal Products Regulations 2001* (as amended), which include a requirement for approval as well as health and environmental protection measures related to the product. Coatings for use in drinking water pipes are regulated under construction products legislation and, more specifically, the *Water Supply (Water Quality) Regulations 2000* (as amended). This use is considered in the following section.

Paints containing NMs may be used by industrial or domestic users, whilst the applications for inks are most likely to be used by industry. Industrial use and disposal will be covered by similar legislation as for manufacturing emissions, however, it is possible that run-off from painted surfaces and domestic use of paints could result in discharges to sewers.

Waste paints may be considered to be hazardous waste depending on their contents, and/or may be treated before disposal as it is no longer possible to send liquid wastes to landfill under *Directive 99/31/EC on the landfill of waste* (as amended).

2.4 Construction Materials

2.4.1 Applications of NMs

The potential uses of NMs such as nanotubes, fibres and composites are being investigated to develop ultra high performance materials for construction, particularly cement. It has also been suggested that nano-silver could be incorporated into

insulation material for cavity walls to prevent mould and fungi damage, and coatings containing nanomaterials may be used in drinking water pipes.

2.4.2 Manufacture, Use and Disposal of Construction Materials

The manufacture of construction materials such as cement is covered by general legislation to control emissions to the environment. Buildings legislation also provides some guidance, and restrictions, on the use of different materials in construction. More specific legislation relates to construction products used to supply drinking water, where these include pipes and their coatings.

It is likely that much construction waste, for example, demolition rubble rather than insulation material, is likely to be considered inert waste and therefore landfilled or reused in new construction projects or road building. Depending on the components of the insulation material, it may be necessary to treat this before disposal.

2.5 Cosmetics

2.5.1 Applications

Cosmetics containing NMs are already available on the market and fall into two categories at present:

- manufactured metal oxide nanoparticles used in suncreams to provide transparent UV protection; and
- self-assembled nanostructures, for example nanosomes, which are used in anti-wrinkle cosmetics to help active molecules, such as vitamins, penetrate the skin.

The metal oxides most commonly used are titanium oxide (TiO_2), zinc oxide, and iron oxide. The Scientific Committee on cosmetic and non-food products (SCCNFP) has given the expert opinion that the use of TiO_2 in cosmetics and sunscreens is safe. Nano particulate TiO_2 is used in sunscreens due to its ability to absorb and reflect UV light whilst appearing transparent to visible light, and so is more acceptable to the consumer. In the case of microfine and ultrafine zinc oxide used in sunscreens, the Scientific Committee on Consumer Products[6] (SCCP) has stated that the safety to the consumer remains to be assessed (SCCP, 2005). (As yet the SCCP has not assessed the safety of iron oxide used in cosmetics). The Royal Society has recommended that the use of zinc oxide nanoparticles and iron oxide nanoparticles in cosmetics should "await a safety assessment".

It is also suggested that nano-silver could be used in cosmetics to treat spots and acne, although this may also be considered as a medical use. Further development of the use of nanotechnology in cosmetics is expected.

2.5.2 Manufacture, Use and Disposal of Cosmetics

[6] The Scientific Committee on cosmetic and non-food products (SCCNFP) was replaced by the Scientific Committee on Consumer Products (SCCP) in 2004.

The manufacture of cosmetics may result in emissions to air, water, land and waste, and legislation exists to control these emissions.

Sector-specific legislation also exists, concerning the safety of cosmetics for consumers. It can be assumed that the main use of cosmetics is by consumers and that this would result in emissions to sewerage systems. Waste cosmetics are most likely to be disposed of in household waste that may be landfilled or incinerated.

2.6 Detergents

2.6.1 Applications

Article 2(1) of *Regulation (EC) No. 648/2004 on detergents* (the Detergents Regulation) states that:

> *'Detergent' means any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.*

The application of nanotechnology in detergents (as broadly defined above) is potentially significant. Potential applications could include enhanced dirt removal and ensuring that material is not re-deposited on cleaned items (for example, avoiding streaks after car or window washing).

2.6.2 Manufacture, Use and Disposal of Detergents

Most detergents comprise a mixture of numerous ingredients (perhaps 30 or more) and their formulation may result in emissions to air, water, land and waste. As for other manufacturing and formulating processes considered in this section, legislation exists to control these emissions.

The environmental fate of detergents will depend, to a large extent, on the application being considered. For many applications, including household laundry detergents and industrial cleaning facilities, it would be expected that the used detergents would pass through wastewater treatment plants before being released to the environment. However, in other cases, such as the use of window cleaners, the detergents would be released directly into the environment. It would also be expected that items such as washing cloths would enter the solid waste stream for disposal to landfill or incineration.

2.7 Electrical and Electronic Equipment

2.7.1 Applications

There are a wide range of applications for NMs in electrical and electronic devices. Essentially, these applications are covered by the same legislation and are therefore grouped together. Applications include:

- the use of carbon nanotubes in electromagnetic shielding, electron field emitters (flat panel displays) and super capacitors;
- transparent conducting films for touch screen technologies, using, for example, zinc oxide, nickel oxide and chromium oxide, which may be aerosol deposited or screen printed;
- data storage devices;
- 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 other fuel cell/battery applications are also being developed and these are considered separately below, under Fuel Cells and Batteries.

2.7.2 Manufacture, Use, Recovery and Disposal of Electrical and Electronic Equipment

Substances which can be used in the manufacture of electrical and electronic equipment are regulated by *Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)* and the manufacturing processes are covered by general environmental controls.
General product safety legislation cover the use of electrical equipment by consumers, while other equipment, such as that for medical uses may be covered by more specific legislation.

Specific waste legislation in the form of *Directive 2002/96/EC on waste electrical and electronic equipment* (WEEE) governs the recovery and disposal of electrical equipment. This Directive also influences the design of the equipment to encourage recovery and recycling whilst requiring the establishment of waste collection systems and the setting of recovery and recycling targets.

2.8 Food Processing

2.8.1 Applications of NMs

There is some evidence that NMs are being incorporated into food products; at present it is likely that this only occurs outside the UK. However, many food companies are currently investing in nanotechnologies. Future uses may include changing the structure, colour and/or flavour of food products.

2.8.2 Manufacture, Use and Disposal of Food Products

The manufacture of food obviously begins with agricultural practices (see Section 2.11). There is a range of legislation relating to agriculture, and this is not considered here as NMs are likely to be incorporated into food products further down the supply chain. Legislation exists to control the use of additives in food products and novel ingredients as well as the emissions from food processing plants.

2.9 Fuel Cells and Batteries

2.9.1 Applications of NMs

A range of NMs can be applied to fuel cells and batteries to produce (Wuppertal Institute, 2005):

- solid oxide fuel cells and new fuel cell components and designs using nano-sized oxide materials;
- solar cells for consumer electronics such as laptops;
- dye-sensitised solar cells;
- nanostructured electrodes for solar cells;
- hydrogen cells for vehicles using carbon nanotubes and/or nanocrystalline material; and
- high performance battery materials and battery electrode materials, e.g. nanowire batteries.

2.9.2 Manufacture, Use, Recovery and Disposal of Fuel Cells and Batteries

Manufacturing processes are controlled by general environmental legislation; however the negative environmental impact attributed to batteries is due to their heavy metal content and specific legislation for batteries has restricted the production of batteries containing heavy metals and makes provisions for labelling requirements.

The use of batteries in consumer products is covered by general product safety and electrical legislation, however other legislation may also be applicable. Waste from batteries and electrical cells are subject to specific controls and the WEEE Directive is also likely to influence both the design and disposal of these products. *Directive 2000/53/EC on End-of-Life Vehicles* will also play a role where hydrogen fuel cells are used to power vehicles or where high performance battery materials are used in

conventional vehicles. However, consumers are also likely to dispose of batteries in household waste streams.

2.10 Medical Applications

2.10.1 Applications

A wide range of medical uses for NMs have been identified, from providing anti-microbial properties for medical devices through to improved materials and treatment methods. Examples include:

- clinical textiles e.g. theatre gowns and theatre linens, surgical masks, medical staff uniform, ward linen, bath towels, curtains;
- burn dressings containing silver nanocrystals;
- coating of catheters and endo-tubes;
- hand soap;
- surgical blades made from microstructured silicon with diamond coated cutting edges;
- powered medical implants using nanoscale electronic components;
- implantable teeth and bone prostheses using nanoparticles and bio-composites;
- cavity wounds – hydrogel and polyurethane foam;
- implants for soft tissues and tendon repairs;
- batteries for portable medical devices with nanostructured metal oxides;
- marker technology for the clinical and life sciences diagnostic markets;
- iron oxide nanoparticles for treating tumours;
- platinum wires for retinal surgery;
- monitoring of brain activity and treat neurological diseases; and
- drug delivery.

In addition, although not strictly medical items, feminine personal hygiene disposable products, incontinence pads and nappies have also been identified as possible uses of NMs.

It can also be assumed that, as for human medicines, nanotechnologies could be used to target drug delivery for veterinary medicines, as well as other possible applications in the future.

2.10.2 Manufacture, Use and Disposal of Medical Products

The manufacture and use of human and veterinary medical products are controlled by sector-specific legislation and more general environmental controls.

For human medicines, it can be assumed that many of the applications identified above would stay within a clinical environment and would be disposed of according to specific requirements. However, it could also be foreseen that products containing NMs could be used at home by the consumer, e.g. hand soap, dressings, personal hygiene products, etc., resulting in emissions to sewerage systems and disposal within household waste streams, either to landfill or incineration.

Veterinary medicines may reach the environment either directly, for example where medicines are applied to fish or directly to the body of terrestrial animals, or indirectly through excretion. Where NMs are the active ingredient it is likely that these will be metabolised and excreted in their molecular form; however where NMs are used as an excipient (i.e to deliver the drug) this may result in the NMs being excreted unchanged.

2.11 Paper Manufacturing

2.11.1 Applications of NMs

Papermaking represents a significant use of nanoparticles[7] in the form of colloidal silica and related products as absorbents during the pulping stage of paper manufacture.

2.11.2 Manufacture, Use, Recovery and Disposal of Paper

Pulp, paper and board production involves various processes and pulp manufacture can be divided into four areas:

- virgin fibre preparation and handling;
- recovered fibre (from waste paper) preparation and handling;
- pulping - this is the process by which the structure of wood or other cellulose materials is broken down to provide materials for the papermaking industry; and
- bleaching.

Paper manufacture is regulated by general environmental controls, however, its chemical content is only regulated in relation to its use for food packaging. At this stage it is not clear whether the NMs would be incorporated into the paper products; however the legislation relating to the whole lifecycle of paper products is considered here for completeness. Paper products may be recovered or disposed of by recycling, incineration or landfill, and are specifically covered by packaging waste legislation.

2.12 Agrochemicals and Plant Protection Products

2.12.1 Application of NMs

It is suggested that nanotechnologies can be applied to plant protection products (e.g. pesticides, insecticides, etc.) to increase the effectiveness of such products. For example, pesticides may be enclosed within nanocapsules or made up of nanoparticles; this means that the pesticides can be more easily dispersed, taken up by the plants, or the release of the pesticide from the capsule can be controlled in some way (e.g. time release, moisture release, heat release, etc. (ETC, 2004)). Other

[7] See http://pira.atalink.co.uk/articles/pulp/168.

possible agriculture-related uses of nanomaterials may include encapsulated fertilisers for controlled-release, and nano-scale plant nutrients (e.g. iron and titanium dioxide).

2.12.2 Manufacture, Use and Disposal of Plant Protection Products

As with biocides, the use, supply, storage and advertisement of pesticides is regulated by a number of pieces of legislation, including *Directive 91/414/EEC concerning the placing of plant protection products on the market* (as amended), the *Control of Pesticides Regulations 1986* (as amended) and the *Plant Protection Products Regulations 2005* (as amended). The legislation provides for an assessment of the active ingredients and products before placing on the market and controls on the use of such products. However, once a product is placed on the market it can be assumed that it will be released into the wider environment due to the nature of the products. Other important legislation relating to the handling, storage and use of pesticides includes the *Chemicals (Hazard Information & Packaging for Supply) Regulations 2002* and the The *Control of Substances Hazardous to Health Regulations 2002 (COSHH 2002)* (as amended). These regulations are described in Sections 3.3 and 4.4.3.

2.12.3 Manufacture, Use and Disposal of Fertilisers and Plant Nutrients

Controls applying to fertilisers are regulated by a number of EC Directives, including *76/116/EEC, 80/876/EEC, 89/284/EEC, 89/530/EEC* (all as amended by *Directive 97/63/EC*), *88/183/EEC, 93/69/EEC, 96/28/EC* and *98/3/EC*. These Directives set the conditions and criteria (e.g. minimum nutrient content, labelling and packaging) for fertilisers, which can be traded freely throughout the Community. In 2003 the European Council completed work on consolidating and simplifying these Directives into a single Regulation – *EC No. 2003/2003 relating to fertilisers* (commonly referred to as the 'Refonte' Regulation). Refonte imposes precise requirements directly on manufacturers in all Member States, however it only covers those fertilisers that have been designated as EC fertilisers. In Great Britain, *The Fertilizers Regulations 1991* (as amended) currently control the composition, labelling and packaging of fertilisers. The Regulations include prescribed names and descriptions, information to be given in the statutory statements (to be provided when fertilisers are sold), the marking and labelling of fertilisers (including specified directions for the storage, packaging, handling and use), and declarations concerning the content of certain minerals and trace elements. Separate Regulations which apply to certain types of fertiliser include *The Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003* and *The Fertilisers (Mammalian Meat and Bone Meal) Regulations 1996*. These Regulations will remain in force after the 1991 Regulations are amended or abolished.

2.13 Plastics

2.13.1 Application of NMs

NMs in plastics have a range of applications, including many in relation to food packaging, such as:

- polymer nanocomposites for food packaging and wrapping;

- anti-microbial packaging materials; and
- smart packaging (which can adjust to different conditions).

It is also understood that the use of UV absorbers such as titanium dioxide in plastics prevents degradation in the presence of UV radiation, and stabilisation benefits have been demonstrated in polystyrene, polyethylene and poly(vinyl chloride). It is not clear where these plastics may be used but it can be assumed that there are a wide variety of uses for this application, for example in vehicle interiors.

2.13.2 Manufacture, Use, Recovery and Disposal of Plastics

As for other materials, emissions from the manufacture of plastics are covered by environmental legislation. The regulation of products, if they are for general consumer use, is likely to fall under general product safety legislation. However, where the plastics are used for food packaging they will be controlled by specific legislation.

EU and UK waste policies and legislation aim to influence plastics recovery and recycling targets, and environmental policies aim to affect the design of products and the use of plastics at source. For example, the WEEE and ELV Directives aim to reduce the number of polymer types used in order to improve recycling efficiency. Packaging waste legislation is also relevant, and the plastics content of household waste streams may be recycled, incinerated or landfilled.

2.14 Textiles

2.14.1 Applications of NMs

NMs are currently being used in textiles, either integrated within the fibres or as a spray-on coating, depending on the functionality required. The following uses of NMs in textiles have been identified:

- stain resistant clothing;
- anti-odour sportswear;
- anti-microbial medical textiles;
- conducting cloth;
- water repellent fabrics; and
- textiles that can sense movement and wear.

The use of silver nanoparticles is particularly dominant, providing anti-odour and anti-microbial properties. Some applications are suggested never to wash out (where they are incorporated in the fibres) whilst others claim to last more than 50 or 100 washes. One application has been identified in the US, which uses bamboo-charcoal nanoparticles in the fibres.

2.14.2 Manufacture, Use and Disposal of Textiles

The manufacture of textiles consists of:

- fibre preparation and weaving;
- textile weaving;
- textile finishing; and
- clothing manufacture.

It appears that the NMs may be used in any of these stages, depending on the required function of the textiles. Legislation is in place to control emissions to the environment at all of these stages.

There is no specific legislation to control emissions to the environment from use of the textiles. Textiles sold to the consumer as a finished product are covered by the general product safety legislation, and the *Textile Products (Indication of Fibre Content) Regulations 1986* (as amended). However, it is also likely that chemicals used in the manufacture of textiles may enter the sewerage system as a result of washing.

Textile waste arisings originate from both consumers and industry. Textile waste may be incinerated or disposed of in landfill. Complex mixtures of fibres make separation more difficult and more costly, and this has implications for textile recycling. Textile waste in landfill contributes to the formation of leachate as it decomposes, which has the potential to contaminate both surface and groundwater sources. Although textiles are not specifically mentioned in the Landfill Directive, waste textiles can be considered biodegradable and therefore textiles are likely to be affected by the progressive targets to reduce the quantities of biodegradable municipal solid waste that may be landfilled.

2.15 Transport – Lubricants and Fuel Additives

2.15.2 Applications

NM applications in transport, specifically road transport at present, relate to the use of nanotechnology-based lubricants and fuel additives or catalysts, which reduce fuel consumption and reduce particulate emissions. One example is the use of platinum nano-composite catalysts for vehicle emission controls.

2.15.2 Manufacture, Use and Disposal of Lubricants and Fuel Additives

The manufacture of lubricants and fuel additives, and the inclusion of the latter into petrol or diesel, may result in emissions to air, water, land or waste and legislation exists to control these. The composition of fuel is also regulated for certain substances and specific controls aim to prevent environmental pollution from the storage of oil and fuels. However, it is likely that, during consumer use, some fuel and oil may reach the sewerage system from surface run-off, as well as air pollution. Disposal emissions from fuels and oil are generally controlled through vehicle and hazardous waste legislation.

2.16 Weapons and Explosives

2.16.1 Applications of NMs

Nano-sized fuels and oxidizers could be used to reduce the size of weapons while maintaining explosive power and lethality, as well as improved handling safety. An example is the use of nano-aluminium fuel coated with nanocrystalline explosive.

2.16.2 Manufacture, Use and Disposal of Weapons and Explosives

The manufacture, storage and disposal of explosives is controlled by a number of pieces of sector specific legislation, as well as more general environmental controls. However, the control of emissions to the environment from the use of explosives is less clearly regulated and it is assumed that legislation relating to contaminated land and water pollution are likely to be the most relevant.

3. LEGISLATION RELATING TO SPECIFIC SUBSTANCES

3.1 Introduction

A range of EU and UK legislation applies to the manufacture, use and disposal of chemical substances and may be relevant for the control of risks posed by NMs. The most relevant legislation in this regard is:

- the UK *Notification of New Substance Regulations 1993* (NONS Regulations), implementing *Directive 92/32/EEC amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances*;
- the UK *Chemicals (Hazard Information & Packaging for Supply) Regulations 2002* (as amended) (CHIP Regulations);
- *Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances* (Existing Substances Regulation) ; and
- the new EU Chemicals Strategy (the REACH Regulation).

This Section considers the appropriateness of this legislation in the face of the risks posed by NMs. When reading this Section, it should be borne in mind that it is currently unclear whether NMs are considered as new substances or as existing substances. The implications in terms of addressing the risks are significant.

3.2 Notification of New Substance (NONS) Regulations

The UK NONS Regulations are intended to protect humans and the environment from the possible harmful effects of new substances. The Regulations implement the 7th Amendment Directive which helps create a single market in new substances across the EU by ensuring that notification requirements are the same in all Member States. It aims to identify the possible human and environmental risks from placing new substances on the market by obtaining information about them in a systematic way so that users may be made aware of any dangers and, if necessary, recommendations for control can be made.

NONS applies to any person who places a new substance (defined as one that does not appear on the EINECS[8] inventory (except for polymers) and marketed after 18 September 1981) on the market (where this means supplying a substance or preparation, or making it available to another person within the EU and includes importation).

The Regulations introduce a system of pre-market notification for new substances which are to be placed on the market in quantities greater than 10kg. Under this system, a detailed notification file must be submitted to the UK Competent Authority (the Health and Safety Executive and the Environment Agency acting jointly) which includes a range of information on the physicochemical, toxicological and

[8] EINECS (European INventory of Existing Commercial chemical Substances) contains 100,195 substances marketed before 18 September 1981 which are considered to be existing chemicals.

ecotoxicological properties of the substance. The extent of data to be submitted varies with the quantity of the substance to be placed on the market (starting from 10kg). The review, by the Competent Authority, of the data included in a notification ensures that the substance is labelled for supply, and that there is sufficient information to take appropriate measures to reduce risks during use and disposal.

Under NONS, notification files (containing hazard information) are reviewed by a competent authority, which prepares a risk assessment based on the dossier information. There are four possible conclusions from the risk assessment; they range from 'no further information about the dangers of the substance is needed' to immediate 'recommendations for risk reduction'. The latter recommendation could require restrictions on the marketing and use of the substance in accordance with the Marketing and Use Directive (Council Directive 76/769/EEC). Once the notification file is accepted by the Competent Authority, the substance may be placed on the market throughout the EU.

3.3 Chemicals (Hazard Information & Packaging for Supply) (CHIP) Regulations

The UK *Chemicals (Hazard Information & Packaging for Supply) Regulations 2002* (usually referred to as the CHIP3 Regulations) implement *Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances* (as amended), *Directive 1999/45/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations* (as amended) and *Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC.*

The Regulations are aimed at protecting human health and the environment from the effects of chemicals by ensuring that chemicals are packaged safely. The CHIP3 Regulations have recently been revised by the *Chemicals (Hazard Information & Packaging for Supply) (Amendment) Regulations 2005* (known as the CHIP 3.1 Regulations). Suppliers of chemicals are required to identify the hazards associated with the chemicals they supply and to provide adequate information on the chemicals to their downstream users. It should be noted that the Safety Data Sheets Directive requires any person in the EU who is responsible for placing a dangerous substance or preparation on the market to supply the recipient (industrial user) of the substance or preparation with a safety data sheet. Overall, the EU Directives require that the information on the hazards and risks from chemical substances and preparations is complete, in that it takes into account available and up-to-date information.

The CHIP Regulations also implement EU Directives on the marketing and use of

dangerous substances and preparations.

3.4 Existing Substances Regulation (ESR)

Under ESR, an 'existing substance' is any substance listed on EINECS (European INventory of Existing Commercial chemical Substances), which contains over 100,000 substances. For most substances, available data on their hazardous properties and associated risks are limited. For substances produced or imported in quantities greater than 1,000 tonne/yr (referred to as HPV substances), ESR requires data sheets on properties and uses (based on available information) to be submitted.

ESR provides for the testing, risk assessment and risk management of existing substances giving rise to concern, based on priority lists of substances. These priority lists account for only a small proportion of chemical substances on the EU market. If a substance is entered onto a priority list, a Competent Authority (the Health and Safety Executive and the Environment Agency in the UK) becomes responsible for collecting additional data, preparing the risk assessment and proposing any appropriate risk management measures. It should be noted that substances are no longer being added to the priority lists due to the proposed REACH Regulation, which will replace ESR in the future (see below).

Where a substance has been entered onto one of the priority lists, manufacturers/ importers are required to submit all relevant information and corresponding study reports for risk assessment of the substance concerned to the European Chemicals Bureau (ECB). The manufacturers and importers who have submitted such information are then obliged to carry out the testing necessary to obtain any missing data and to provide the test results and test reports in order to complete the data requirements of Annex VII A to the Dangerous Substances Directive. Derogations from these requirements can be requested, for example, when a particular physicochemical property is not relevant for a substance, or where data from a higher level test already exists.

For the non-prioritised existing substances, which form the bulk of those on the EU market, only limited testing and risk assessment data are available. This may not only mean that potential risks are unrecognised, but also that the legislation to address risks to health and the environment, which often relies on the classification of substances, may not be operating as effectively as it should. Likewise, it means that downstream users do not have information on the risks that substances may pose to workers, the environment or consumers, which may affect their choices on the substances used in processes and end-products.

3.5 The New EU Chemicals Strategy (REACH)

In February 2001, the European Commission presented a White Paper with proposals for a strategy on a future chemicals policy. The formal proposal for a *Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency* etc. (COM(2003), 644 final dated October 2003) is now being considered by the European Parliament. Clearly, as

this proposal has not yet been adopted, changes to it could occur which would affect the following discussion.

This new Regulation will replace the Dangerous Substances Directive, the Dangerous Preparations Directive, the Safety Data Sheets Directive, ESR, the Marketing and Use Directive and associated Directives.

REACH is intended to address the lack of information on the majority of existing chemicals on the EU market under the current legislative framework. The aim is to ensure that equally comprehensive hazard and risk information is available on both new and existing substances by requiring manufacturers and importers to notify Competent Authorities of their intention to produce/import a substance in volumes greater than 1 tonne/yr[9] and to submit a technical dossier for registration purposes.

The technical dossier submitted should include basic physico-chemical information on the substance, test data and, where required, risk assessments (across all identified uses), as well as any classification and labelling, safety data sheets and recommendations for risk management[10]. Substances manufactured or imported in volumes of less than 1 tonne/yr do not need to be registered; there is, however, no tonnage related exemption for authorisation, restriction or classification and labelling requirements.

In the context of nanotechnologies, REACH defines a substance as "*a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process…*". A key consideration in this regard is the fact the nano-equivalent of a substance could have different physicochemical and ecotoxicological properties from the substance itself. If it is considered to be a different substance, then the registrant may submit a different registration dossier for the nano-substance (if produced in volumes greater than 1 tonne/yr). This means that the manufacturer would be required to generate hazard information on NMs prior to placing them on the market. On the other hand, if the nano-equivalent is considered to be the same as the registered substance, the hazard information would still be available, although the appropriateness of the data for the risks of NMs would be open to discussion.
Article 13 of the proposed REACH Regulation requires a Chemical Safety Assessment to be undertaken with the results presented in the Chemical Safety Report (which is submitted with the Technical Dossier) if:

- a substance is produced in quantities of greater than 10 tonne/yr. Where the substance meets the criteria for classification as dangerous or is a PBT (Persistent, Bioaccumulable and Toxic) or vPvB (very Persistent and very Bioaccumulable), the manufacturer is required to develop exposure scenarios and undertake risk characterisation(s) (in accordance with Annex I and associated guidance);

[9] This is an increase in the threshold that currently applies to new substances (from 10 kg/yr) and is a new requirement for existing substances.

[10] However, where such risk management measures are considered to be insufficient and where Community legislation is justified, appropriate restrictions should be laid down.

- a substance is selected for further evaluation by a Member State Competent Authority (or the proposed European Chemicals Agency) due to specific concerns; or a substance is a CMR (Carcinogenic, Mutagenic, or toxic for Reproduction[11]), PBT, vPvB, ED (Endocrine Disrupting), or substance of equivalent concern.

Clearly for a nano-substance, it is entirely possible that a full Chemical Safety Assessment could be required, particularly where a Member State Competent Authorities had concerns. However, it is important to note that the methodologies for chemical safety assessment are based on 'conventional' methodologies for assessing chemical risks which may not be appropriate for assessing risks associated with nano-substances.

It is not known when the REACH Regulation will come into force as the proposals are currently under examination and negotiation at the European Parliament and Council level.

3.6 Identifying the Regulatory Gaps for Substances

The process of identifying the regulatory gaps is based on the four-step methodology (hazard identification, exposure assessment, risk calculation and environmental action) set out in Section 1. This is represented in Table 3.1 below.

[11] Under the latest (29th) Amendment to the Marketing and Use Directive (Directive 2005/90/EC), it is worth noting that CMR substances (Categories 1 and 2) and preparations containing them should no longer be placed on the market.

<table>
<tr><th colspan="5">Table 3.1: Legislation Relating to NMs and their Advantages and Drawbacks</th></tr>
<tr><th></th><th>Does the legislation require an identification of the potential hazards of NMs?</th><th>Does the legislation require determination, quantification and/or control of potential exposure (routes) to NMs?</th><th>Does the legislation require calculation and characterisation of risk?</th><th>Entry into the environment</th></tr>
<tr><td rowspan="2">NONS – only applies to new substances</td><td>If NMs are considered new substances, manufacturers or importers will be required to provide the necessary hazard information.</td><td>Exposure scenarios would have to be developed for the risk assessment of the substance.</td><td>Proactive approach to risk assessment in which risks are assessed prior to substance being placed on the market.</td><td>Where a risk assessment indicates ‘recommendations for risk reduction’, restrictions on the marketing and use of the substance in accordance with Directive 76/769/EEC could be put in place.</td></tr>
<tr><td colspan="4"><u>Drawback</u>: Only applies to new substances placed on the market in quantities of over 10 kg/yr.</td></tr>
<tr><td rowspan="2">ESR - only applies to existing substances.</td><td>If NMs are considered existing substances, some data on hazards may be available (for HPVs and ‘prioritised’ substances).</td><td>Exposure scenarios would have to be developed for the risk assessment of the substance (which could include consideration of NM exposure routes).</td><td>Risk assessment undertaken for a limited number (141) of ‘prioritised’ substances.</td><td>A risk reduction strategy could be put in place after a risk assessment has been undertaken under ESR.</td></tr>
<tr><td><u>Drawback</u>: There is no requirement under ESR to undertake tests to ascertain the properties of substances (except if they are on a priority list)</td><td colspan="3"><u>Drawback</u>: Only applies to substances on priority lists</td></tr>
<tr><td rowspan="2">CHIP - only applies to dangerous substances</td><td>Some data on hazards may be available as part of the safety data sheets required.</td><td>Exposure scenarios may have to be developed for the safety data sheets.</td><td>Some risk assessment may be undertaken for the safety data sheets.</td><td>Safety data sheets could have information on disposal options.</td></tr>
<tr><td colspan="4"><u>Drawback</u> Only applies to dangerous substances and preparations.</td></tr>
</table>

Table 3.1: Legislation Relating to NMs and their Advantages and Drawbacks				
	Does the legislation require an identification of the potential hazards of NMs?	**Does the legislation require determination, quantification and/or control of potential exposure (routes) to NMs?**	**Does the legislation require calculation and characterisation of risk?**	**Entry into the environment**
REACH - applies 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).	Proactive approach to risk assessment (or evaluation) undertaken for dangerous substances over 10 tonne/yr and for substances of particular concern	Under REACH, responsibility for the management of the risks of substances should lie with the enterprises that manufacture, import, place on the market or use these substances.
	Drawback: Only applies to substances supplied in quantities over 1 tonne/yr (unless of particular concern)		*Drawback: Only applies to substances supplied in quantities over 10 tonne/yr (unless of particular concern)*	*Drawback: Only applies to substances supplied in quantities over 1 tonne/yr (unless of particular concern)*

4. LEGISLATION RELATING TO PRODUCTS AND APPLICATIONS

4.1 Introduction

This Section considers the legislation which are related to those products and applications identified in Section 2. This legislation aims to protect human health and/or the environment by addressing:

- the chemical content of products;
- the manufacture and storage of products;
- the use of products; and
- the recovery and disposal of products.

Table 4.1 (overleaf) provides a summary of the application of environmental and product legislation to a range of NM applications. As can be seen, there are core pieces of environmental legislation which relate to emissions from the manufacturing of products and waste disposal. This environmental legislation is discussed in more detail in Section 5. However, the use of many of the applications are regulated by product specific legislation. Box 4.1 below provides a list of abbreviations used in Table 4.1.

Box 4.1: Abbreviations Used in Table 4.1
CHIP – 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 – Electromagenetic Compatibility EPA – Environmental Protection Act FEPA – Food and Environment 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

Table 4.1: Summary of NM Applications and Relevant Environmental/Product Legislation

NM Applications	Production of NMs	Coatings and Pigments	Construction Materials (including drinking water pipes)	Cosmetics	Detergents	Elec. Equipment	Food Processing & Production	Fuel Cells and Batteries	Medical Applications	Paper Products	Plant Protection products	Plastics	Textiles	Transport – Lubricants and Fuel Additives	Weapons and Explosives
IPPC Directive/ PPC Regulations	X	X	X	X	X	X	X	X	X	X		X	X	X	X
Part IIA EPA 1990 (contaminated land)	X	X	X	X	X	X	X	X	X	X		X	X	X	X
Part III of FEPA 1985											X				
Dangerous Substances in Water Directive		X	X	X	X	X	X	X	X	X		X	X	X	
Water Resources Act/Trade Effluents/Control of Pollution Regs		X	X	X	X	X	X	X	X	X		X	X	X	
Water Framework Directive/Regs		X	X	X	X	X	X	X	X	X		X	X	X	X
UWWT Directive/Regs		X		X	X		X		X				X		
GPS Directive/Regs		X			X	X		X				X	X		
Biocidal Products Regulations											X				
COSHH Regulations											X				
CHIP Regs		X									X			X	X
Control of Pesticide Regs		X					X				X				
Plant Protection Products Regulations											X				
Construction Products Directive/ Building Regulations			X												
Water Supply Regs			X												
Cosmetics Directives Regs				X											
Detergent Regs					X										
RoHS Directive						X		X				X			
LVD /Regs						X		X							
EMC Directive/Regs						X		X							
Additives Directive							X								
Novel Food Regs							X								
Batteries Directive								X							
Medicinal Products Directive/Regs									X						
Medical Devices Directives/Regs									X						
Vet Meds Directive/Regs							X		X						
Materials and Articles in Contact with Food Regs										X		X			
Textile Labelling Regs													X		
Motor Fuel Regs														X	
Oil Storage Regs														X	
Manufacture and Storage of Explosives Regs															X
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			

4.2 Legislation Relating to the Chemical Content of Products

4.2.1 Overview

The most relevant legislation in this regard is:

- the *General Product Safety Regulations 2005*, implementing *Directive 2001/95/EC on General Product Safety*;
- *Control of Pesticides Regulations (COPR) 1986 (as amended), Plant Protection Products Regulations 2005* (as amended) implementing *Directive 91/414/EEC concerning the placing of plant protection products on the market*, and the *Biocidal Products Regulations 2001 (as amended)*, implementing the Biocidal Products Directive (98/8/EC);
- the Construction Products Directive (89/106/EEC), the *Building Regulations 2000* and the *Water Supply (Water Quality) Regulations 2000* (as amended);
- the *Cosmetic Products (Safety) Regulations 2004*, implementing the Cosmetics Directive (76/768/EEC) (as amended));
- *Regulation (EC) No. 648/2004 on detergents* (the Detergents Regulation), which is enforced in the UK under the *Detergents Regulations 2005*;
- *Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment* (RoHS Directive) (not yet implemented) and the *Directive 91/157/EEC on batteries and accumulators containing certain dangerous substances* implemented in the UK by the *Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994* (as amended);
- various pieces of legislation concerning food safety, most noticeably *Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption*, *Regulation (EC) No 258/97 concerning novel foods and novel food ingredients* and *Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food*;
- *Directive 2001/83/EC relating to medicinal products for human use* (as amended), and three EU Directives (*Directive 93/42/EEC concerning medical devices*, *Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices*, *Directive 98/79/EC on in vitro diagnostic medical devices*) which are implemented by the *Medical Devices Regulations 2002* (as amended); and
- the *Motor Fuel (Composition and Content) Regulations 1999* (as amended), implementing *Directive 98/70/EC relating to the quality of petrol and diesel fuels* (as amended).

4.2.2 General Product Safety Legislation

Directive 2001/95/EC on general product safety is transposed into UK law by the *General Product Safety Regulations 2005*. The purpose of the General Product Safety Directive (GPSD) is to ensure that all products intended for, or likely to be used by, consumers, under normal or reasonably foreseeable conditions, are safe.

'Products' within the meaning of the legislation can best be described as all goods that are (or could be) placed on the market, or supplied or made available (including in the

course of providing a service) to consumers for their private use. Products covered include, but are not restricted to, clothing, medicines, machinery, tools and equipment, fireworks supplied to consumers, household goods, nursery goods, gym equipment, chemicals and pesticides, and motor vehicles (DTI, 2005). Therefore, the Directive and Regulations are generally applicable to many of the uses identified in Section 2.

The GPSD provides a generic definition of a 'safe' product and obliges producers to place only safe products on the market. A 'safe product' means a product which, under normal or reasonably foreseeable conditions of use, does not present any risk or only the minimum risks considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

In broad terms, the safety of products is determined by:

- the potential for products to be the cause of adverse effects amongst consumers (i.e. the hazard); and

- the probability and severity of adverse effects occurring amongst consumers using such products (i.e. risk).

These represent respectively the hazard and the risk associated with products and the procedure by which these issues are examined is a risk assessment. Within the scope of the Directive, provisions are made to assess the risks of products.

Producers must take measures to be informed of the risks posed by their products and take appropriate measures to prevent the risks; consumers must also be informed of the risks associated with the products they supply. Under the GPSD, if a manufacturer identifies a safety risk in a product already on the market, he will need to inform its distributors and also immediately inform the relevant authority, both of the risks and the actions taken to protect consumers.

When regulatory authorities become aware of potentially hazardous products (through market surveillance, accident reports and data, or through reporting by consumers, manufacturers or others), risk assessment enables them to focus their enforcement actions on the products posing the greatest risks. This not only benefits consumer safety by addressing the high risk products, it also means that the often limited resources available to regulatory authorities can be used in the most effective way. The GPSD does not address issues of environmental risk.

4.2.3 Control of Pesticides, Plant Protection Products and Biocides Legislation

These pieces of legislation are applicable to coatings which claim to have fungicidal properties, as well as agricultural and non-agricultural pesticides containing NMs.

Part III of the Food and Environment Protection Act 1985 (FEPA) introduced the principle of statutory controls on pesticides and provides the overall legal framework for the control of pesticides. The aims of the controls are to:

- protect the health of human beings, creatures and plants;
- safeguard the environment;
- secure safe, efficient and humane methods of controlling pests; and
- make information about pesticides available to the public.

The mechanisms to achieve these aims are set out in the *Control of Pesticides Regulations (COPR) 1986 (as amended)*. These Regulations:

- define in detail those types of pesticides which are subject to control and those which are excluded;
- prescribe the approvals required before any pesticide may be sold, stored, supplied, used or advertised; and
- allow for general conditions on sale, supply, storage, advertisement, and use, including aerial application of pesticides.

The term pesticides has a very broad definition which embraces herbicides, fungicides, insecticides, rodenticides, soil-sterilants, wood preservatives and surface biocides among others.

The *Plant Protection Products Regulations 2005* (as amended) implement *Directive 91/414/EEC concerning the placing of plant protection products on the market (as amended)*. The Directive is based upon a two-tier registration system, with active ingredients assessed at Community level for inclusion on a positive list, and products subsequently registered by Member States. The Control of Pesticides Regulations will continue until all existing EC active ingredients are reviewed and placed on Annex I (positive list).

Directive 98/8/EC concerning the placing of biocidal products on the market has been implemented by the *Biocidal Products Regulations 2001 (as amended)*. The basic principles of the Directive are:

- active substances[12] have to be assessed and the decisions on their inclusion in Annex I of the Directive is taken at a Community level;
- comparative assessment will be made at the Community level when an active substance, although in principle acceptable, still causes concern. Inclusion to Annex I may be denied if there are less harmful, suitable substitutes available for the same purpose;
- Member States shall authorise the biocidal products in accordance with the Directive. They can only authorise products which contain active substances included in Annex I; and
- the producers and formulators responsible for the placing on the market of the biocidal products and their active substances must apply for authorisation and submit all necessary studies and other information needed for the assessments and decision-making.

[12] 'Active substance' means a substance or micro-organism having a general or specific action on or against harmful organisms.

The Directive harmonises trade by introducing a community wide scheme for authorising the placing of biocidal products on the market and establishes a positive list of active substances which may be used in biocidal products. Biocidal products include all products currently regulated under COPR as well as preservatives, disinfectants, water biocides, certain cleaners claiming biocidal properties and other specialist products. Over time, the Biocidal Products Regulations 2001 (as amended) will replace the current Control of Pesticides Regulations.

For both biocides and plant protection products, active ingredients are subject to a human health and environmental risk assessment before approval is granted for their use. Furthermore, toxicological and ecotoxicological data must be supplied in relation to the whole product (not just the active ingredient). Approval is normally granted only in relation to individual products and only for specified uses, and remain subject to immediate revocation, suspension or amendment at any time is safety considerations so demand.

4.2.4 Control of Fertilisers and Plant Nutrients Legislation

Fertilisers and plant nutrients are governed by a number of measures, including both EC and domestic legislation. The main controlling articles are as follows:

EC Regulation No. 2003/2003 relating to fertilisers (commonly referred to as the 'Refonte' Regulation) imposes precise requirements directly on manufacturers in all Member States, but is only applicable to those fertilisers that have been designated as 'EC fertilisers'. All EC fertilisers have minimum nutrient levels specified under Refonte and can be freely sold throughout the Community. Unlike pesticides, fertilisers designated as non-EC fertilisers do not have to be individually registered or approved for use. The regulations do, however, recognise that certain products could be hazardous in terms of explosion potential and could be used for purposes other than those for which they were intended, thus endangering both persons and property. Manufacturers must therefore take appropriate steps to avoid such use and to ensure the traceability of such fertilisers. Because Refonte is directly applicable legislation, Member States are excluded from maintaining national legislation which covers the same products.

The Fertilizers Regulations 1991 (as amended) currently control the composition, labelling and packaging of fertilisers used for agricultural, horticultural, amenity and domestic purposes in Great Britain. The Regulations include prescribed names and descriptions, information to be given in the statutory statements (to be provided when fertilisers are sold), the marking and labelling of fertilisers (including specified directions for the storage, packaging, handling and use), and declarations concerning the content of certain minerals and trace elements. A drawback of the current Regulations is that they do not contain a definition of 'fertiliser', thus products can claim to supply "plant nutrients" without a statutory declaration and no indication of their nutrient content. In addition, some 'ready-to-use products' (mainly targeted at the domestic and horticulture market) are pre-diluted to such a degree that the nutrient contents are below that required for the Regulations to apply. Currently Defra is working on domestic Regulations to implement the areas of *EC 2003/2003* where

there is national discretion; as part of this process they are proposing either the abolition, or revision, of the 1991 Regulations.

Regulations that apply to specific types of fertiliser include *The Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003* and *The Fertilisers (Mammalian Meat and Bone Meal) Regulations 1996*. These Regulations will remain in force after the 1991 Regulations are amended or abolished. In addition, there are various pieces of environmental and water-related legislation that encompass fertiliser use, including the EC *Nitrates Directive (91/676/EC)* designed to reduce and prevent water pollution by nitrate from agricultural sources (implemented in the UK by *The Protection of Water Against Agricultural Nitrate Pollution (England and Wales) Regulations 1996*).

4.2.5 Construction Products Legislation (including Water Pipes)

It has been suggested that NMs may be incorporated into building materials such as cement and insulation foam, as well as used in coatings for drinking water pipes. These products are all regulated under *Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (as amended)*.

The Construction Products Directive requires that all building materials must meet the 'essential requirements'. These requirements must, subject to normal maintenance, be satisfied for an economically reasonable working life. With regards to human health and the environment, it is required that:

"*The construction work, must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of any of the following:*

- *the giving-off of toxic gas;*
- *the presence of dangerous particles or gases in the air;*
- *the emission of dangerous radiation;*
- *pollution or poisoning of the water or soil;*
- *faulty elimination of waste water, smoke, solid or liquid wastes; and*
- *the presence of damp in parts of the works or on surfaces within the works.*"

Compliance with these requirements is ensured through compliance with European standards.

In the UK, the *Building Act 1984* is the enabling Act under which the *Building Regulations 2000* (as amended) have been made. Regulations, with respect to the design and construction of buildings and the provisions of services, fittings and equipment in or in connection with buildings, may be made for any purposes of:

- securing the health, safety, welfare and convenience of persons in or about buildings and of others who may be affected by buildings or matters connected with buildings;
- furthering the conservation of fuel and power; and
- preventing waste, undue consumption, misuse or contamination of water.

Two Regulations bear some relevance to this study:

- Part D of Schedule 1: "*if insulating material is inserted into a cavity in a cavity wall reasonable precautions shall be taken to prevent the subsequent permeation of any toxic fumes from that material into any part of the building occupied by people*" – specifically in relation to urea formaldehyde foams
- Regulation 7: "*Building work shall be carried out*
  (a) with adequate and proper materials which
    (i) are appropriate for the circumstances in which they are used;
    (ii) are adequately mixed or prepared; and
    (iii) which are applied, used or fixed so as adequately to perform the functions for which they are designed; and
  (b) in a workmanlike manner."

With respect to the first requirement, guidance (DETR, 1992) is provided on the use of urea formaldehyde foam only, indicating that formaldehyde fumes should not penetrate to the occupied parts of the building to an extent which would give rise to an irritant concentration.

The requirements of Regulation 7 will be met where materials are of a suitable nature and quality in relation to the purposes and conditions of their use. This may be established using British or European standards. The only consideration of the environmental impact of materials is given to the use of recycled materials, and it is noted that the use of such materials should not have any adverse implications for the health and safety standards of the building work.

In addition, the Construction Products Directive provides for the CE marking of products that meet the relevant harmonised standards. Many construction products, including pipes and associated fittings, are covered by BS EN standards, for example BS EN ISO 15874 to 15877 (Plastic piping systems for hot and cold water installations). However, whilst these standards address general fitness for purpose issues, they do not adequately cover the suitability of the products for use with drinking water.

Therefore, Regulations 31 to 33 of the *Water Supply (Water Quality) Regulations 2000* provide for the approval of substances, products and processes used in the provision of public water supplies. Approvals are issued by the Secretary of State for Environment, Food and Rural Affairs and the National Assembly for Wales (collectively referred to as the Authorities).

The Committee on Products and Processes for Use in Public Water Supply (CPP) provides expert advice to the Government Authorities in England and Wales on approval issues. The CPP considers whether the use of a substance or product will adversely affect the quality of water, or cause a risk to the health of consumers. Applications are required for all construction products used in contact with water in water treatment processes, water supply pipelines (including raw water pipelines) and drinking and raw water storage installations. The Water Supply (Water Quality)

Regulations require the annual publication of a list of approvals, including a list of all substances, products and processes for which approval has been granted, refused, revoked or modified, or for which their use has been prohibited.

It is expected that, in the future, the development of the European Acceptance Scheme (EAS) for drinking water construction products will replace the testing and certification responsibilities of the Water Regulations Advisory Scheme (WRAS) and the approval powers of the Government Authorities.

4.2.6 Cosmetics Legislation

Directive 76/768/EEC1 on the approximation of the laws of the Member States relating to cosmetic products (as amended) is transposed into UK law by the *Cosmetic Products (Safety) Regulations 2004* (as amended). The main objective of cosmetic products safety legislation is to safeguard public health; the Regulations do not aim to protect the environment.

A cosmetic product (as defined by the Regulations) "*means any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease*".

A cosmetic ingredient is any substance or preparation of synthetic or natural origin used in the composition of a cosmetic product. The Directive sets out a list of substances which cannot be included in the composition of cosmetic products and a list of substances which cosmetic products may not contain, outside the restrictions and conditions laid down. The Directive also contains lists of colourings, preservative and UV filters permitted in cosmetic products. It is understood that nano-titanium dioxide has been added to the list of approved UV filters.

Colouring agents (with the exception of hair dyes), antimicrobial preservatives and UV filters (unless they are intended to protect the product) can only be used if they are positively listed, that is named in Schedules 5, 6 or 7 to the Directive. If a manufacturer wishes to use a substance which is normally subject to positive listing but which is not listed in the Schedules, authorisation must be obtained.

The Secretary of State may authorise the use of a substance or ingredient in a cosmetic product for a maximum period of three years, provided that it is not otherwise prohibited. In giving an authorisation, the Secretary of State may impose conditions relating to the use of a particular substance in a cosmetic product.

It is required by the *Cosmetic Products (Safety) Regulations 2004* (as amended) that manufacturers or suppliers of cosmetic products maintain the following information:

- the qualitative and quantitative composition of the product;

- the physicochemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;
- the method of manufacture;
- an assessment of the safety for human health of the finished product;
- the name and address of the person or persons responsible for the assessment;
- existing data on undesirable effects on human health resulting from use of the cosmetic product;
- proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product; and
- data on any animal testing performed.

The safety assessment referred to above should take particular account of the following:

- the general toxicological profile of each ingredient used;
- the chemical structure of each ingredient;
- the level of exposure of each ingredient;
- the specific exposure characteristics of the areas on which the cosmetic product will be applied; and
- the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

4.2.7 Legislation relating to Detergents

Regulation (EC) No 648/2004 on detergents (the Detergents Regulation), which is enforced in the UK by the *Detergents Regulations 2005*, consolidates and revises earlier legislation on detergents. The key requirements of the Detergents Regulation are:

- restricting the use of surfactants[13] which do not meet specified biodegradation limits;
- comprehensive labelling of detergents with a full listing of ingredients; and
- making available information on the properties of ingredients.

For some ingredients (with specific reference to enzymes, disinfectants, optical brighteners, perfumes and preservation agents), information must be provided irrespective of concentration. For other ingredients, the labelling and information requirements only apply if present in concentrations above 0.2% by weight (or, in the case of allergenic fragrances, above 0.01% by weight).

In relation to the potential use of NMs, there are two key issues:

- whether or not the NMs would be used as surfactants; and

[13] Surfactants are the most important ingredients in detergents as they perform the cleaning process through surface chemical reactions.

- whether or not the NMs would be considered to be 'separate' ingredients.

If a 'conventional' surfactant was enhanced through the presence of NMs, the requirements for the 'enhanced' surfactant would be unchanged in respect of meeting the biodegradation limits. However, where a derogation from these requirements was being sought, it is possible that a risk assessment (with a focus on the aquatic environment) would be required for the 'enhanced' surfactant.

For non-surfactants, the additional presence of a nano-form of an existing ingredient would not appear to be restricted. However, since there are labelling and information requirements for some substances irrespective of concentration, it is possible that the Detergents Regulation could be amended to extend the list to include NMs as one of these specific ingredients.

4.2.8 RoHS and Batteries Directives

The European Commission Communication, in 1996, on the review of the Community strategy for waste management stresses the need to reduce the content of hazardous substances in waste, and highlights the potential benefits of Community-wide rules limiting the presence of such substances in products and in production processes.

Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) aims to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment. As from 1 July 2006, Member States shall ensure that new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, poly-brominated biphenyls PBB) or poly-brominated diphenylethers (PBDE). The RoHS Directive does not apply to batteries, which are coved by a separate Directive, as discussed below.

The *Directive on batteries and accumulators containing certain dangerous substances (91/157/EEC) (as amended)* is implemented in the UK by the *Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended).* The Directive (and implementing Regulations) places restrictions on the content, recovery and disposal of batteries and accumulators.

With regard to content, the Directive restricts the use of specific substances such as mercury, cadmium and lead. As such the inclusion of NMs would not be limited or restricted. More generally, the Directive encourages Member States to draw up programmes in order to achieve the following objectives, *inter alia*:

- reduction of the heavy metal content of batteries and accumulators; and
- promotion of marketing of batteries and accumulators containing smaller quantities of dangerous substances and/or less polluting substances.

The following definitions apply:

- 'battery' or 'accumulator' means any source of electrical energy generated by direct conversion of chemical energy and consisting of one or more primary

battery cells (non-rechargeable) or consisting of one or more secondary battery cells (rechargeable); and

- 'industrial battery or accumulator' means any battery or accumulator designed exclusively for industrial or professional uses or used in any type of electric vehicle.

Proposals for a new batteries Directive were issued in 2003, and it is expected to be adopted in 2006; the new Directive will then come into force in 2008. The primary objective of the new Directive is to minimise the negative impact of batteries and accumulators and waste batteries and accumulators on the environment, thus contributing to the protection, preservation and improvement of the quality of the environment. The new Directive widens its scope by covering all batteries and accumulators (not just those containing the specific dangerous substances); however, this has implications for the disposal of batteries, rather than the content, which is discussed below. The controls on the content of batteries and accumulators would not address the inclusion of NMs.

4.2.9 Legislation Relating to Food Safety, Food Additives, Novel Foods and Materials in Contact with Food

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law requires that food must not be placed on the market if it is unsafe, i.e. if it is harmful to health and/or unfit for consumption. In determining whether any food is unsafe, consideration is given to, *inter alia*, the likely immediate or delayed effect on health and the cumulative toxic effects. In the UK, the *Food Safety Act 1990* provides for the enforcement of this requirement.

More specifically, *Regulation (EC) No 466/2001 setting maximum levels of certain contaminants in foodstuffs* restricts the quantities of substances such as heavy metals (lead, cadmium and mercury) as well as other substances. It is unlikely that the nanomaterials used in the production and processing of foods would include those specified in the Regulation and, even if they were, it is unlikely that they would be present in quantities above the threshold limits, which are set in the order of mg/kg. This Regulation is enforced in England by the *Contaminants in Food (England) Regulations 2005*.

European legislation relating to food additives and their conditions of use aims to protect the health of consumers and guarantee the free circulation of foodstuffs in the European Union. To this end, a common list of additives for use in foodstuffs intended for human consumption has been drawn up.

Directive 89/107/EEC, on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption, provides a framework for authorizing the use of food additives. For the purposes of this Directive 'food additive' means "*any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for*

a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods".

Directive 94/36/EC on colours for use in foodstuffs (as amended) and *Directive 95/2/EC on food additives other than colouring and sweeteners* are specific Directives within the framework provided by Directive 89/107/EEC which may be relevant to the use of nanomaterials in food. The associated pieces of national legislation are the *Colours in Food Regulations 1995* (as amended) and the *Miscellaneous Food Additives Regulations 1995* (as amended). Box 4.1 provides a list of food additives as given in Directive 89/107/EEC.

Box 4.1: Categories of Food Additives (as listed in Directive 89/107/EEC)	
Colour	Modified starch
Preservative	Sweetener
Anti-oxidant	Raising agent
Emulsifier	Anti-foaming agent
Emulsifying salt	Glazing agent
Thickener	Flour treatment agent
Gelling agent	Firming agent
Stabilizer	Humectant
Flavour enhancer	Sequestrant
Acid	Enzyme
Acidity regulator	Bulking agent
Anti-caking agent	Propellent gas and packaging gas

Directive 89/107/EEC states, *inter alia*, that:

- food additives can be approved only provided that:
    - there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable;
    - they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available;
    - they do not mislead the consumer.

- the use of food additives may be considered only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as 'need'. The use of food additives should serve one or more of the purposes set out from points (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

  (a) to preserve the nutritional quality of the food: an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;

(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;

(d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

- to assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body.

Approval for food additives must take into account the likely exposure of consumers. The only substances which may be used as food additives are those included in the approved lists and then only under the conditions of use mentioned in those lists (e.g. preservatives, emulsifiers, sweeteners, raising agents). Where NMs are used as food additives, these would be covered by this legislation.

Legislation relating to novel foods may also be relevant with regards to NMs. Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the European Community before 15 May 1997. *Regulation (EC) No 258/97 concerning novel foods and novel food ingredients* lays out detailed rules for the authorisation of novel foods and novel food ingredients. The Regulation applies to:

a. foods and food ingredients which present a primary molecular structure;
b. foods and food ingredients which consist of micro-organisms, fungi or algae;
c. foods and food ingredients which consist of or are isolated from plants or isolated from animals; and
d. foods and food ingredients whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process.

In order to ensure the protection of human health, novel foods must undergo a safety assessment before being placed on the EU market. Companies that want to place a novel food on the EU market need to submit their application in accordance with Commission Recommendation 97/618/EC that concerns the scientific information and the safety assessment report required. Novel foods or novel food ingredients in categories b and c (above) may follow a simplified procedure, only requiring notifications from the company, when they are considered by a national food assessment body as “substantially equivalent” to existing foods or food ingredients (as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein).

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food aims to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

This Regulation applies, *inter alia*, to the use of:

- 'active food contact materials and articles', where this refers to materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food; and

- 'intelligent food contact materials and articles', where this refers to materials and articles which monitor the condition of packaged food or the environment surrounding the food.

It is foreseen that NMs may be used for these type of materials. The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. It is noted in the Regulation that active and intelligent food contact materials are not inert by their design and therefore the Regulation addresses the main requirements for their use to be established. It is possible that further requirements such as positive lists of authorised substances and/or materials and articles, may be adopted in the future. It will be necessary for substances to undergo a safety assessment before they are placed on a positive list.

The *Materials and Articles in Contact with Food (England) Regulations 2005* refer to Regulation EC 1935/2004, but do not provide any more specific requirements for active and intelligent materials. However, the English Regulations do set controls for the content of vinyl chloride and regenerated cellulose film.

4.2.10 Medical Legislation

Human Medicines and Medical Devices

NMs may be used within medicines or medical devices, where these are governed by different legislation.

With regard to medicines, the current relevant legislation is *Directive 2001/83/EC on the Community Code relating to medicinal products for human use* (as amended). No medicinal product may be placed on the market unless a marketing authorisation has been issued by the competent authorities of that Member State. These requirements are implemented in the UK by the *Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994* (as amended).

In granting the authorisation, the results of pharmaceutical (physicochemical, biological or microbiological) tests; pre-clinical (toxicological and pharmacological) tests, and clinical trials are taken into account. In addition, an evaluation of the potential environmental risks posed by the medical product must be assessed and, on a case-by-case basis, specific arrangements should be made to limit any risks posed to the environment. Reasons should be given for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of potential risks presented by the medicinal product for the environment.

In the UK, medicines are directly approved by the MHRA which issues a 'marketing authorisation', or licence. Manufacturers and distributors are also licensed directly by Medicines and Healthcare products Regulatory Agency (MHRA). New products which are still in development also need a licence before they can be tested on human subjects (clinical trial authorisations).

Medical devices are regulated by three Directives:

- Directive 98/79/EC on *in vitro* diagnostic medical devices - '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
  - concerning a physiological or pathological state; or
  - concerning a congenital abnormality; or
  - to determine the safety and compatibility with potential recipients; or
  - to monitor therapeutic measures.

- Directive (90/385/EEC) on the approximation of the laws of the Member States relating to active implantable medical devices – 'active implantable medical device'' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure; and

- Directive 93/42/EEC concerning medical devices - 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
  - investigation, replacement or modification of the anatomy or of a physiological process;
  - control of conception,

- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

These three Directives are transposed into UK law by the *Medical Devices Regulations 2002* (as amended).

The Directives and Regulations require that devices are designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.

Particular attention must be paid to:

- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;
- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device; and
- the devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.

The MHRA indicates that the existing legislation for medical devices requires manufacturers to carry out an analysis of the risks associated with a medical device, to eliminate or reduce these where feasible, and to assess the balance of risks and benefits. Although the legislation for medical devices does not differentiate between medical devices that use nanotechnologies and those that do not, MHRA is of the view that the existing legislation for medical devices and medicines are sufficiently broad in scope to cover risks associated with nanotechnology (www.mhra.gov.uk).

For medical devices, it is normal for particular requirements underpinning the Directives to be specified by European standards or European Commission guidance. It is understood that European standards are being developed on nomenclature for nanoparticles and, within the wider context of biological safety, on physicochemical characterisation.

Veterinary Medicines and Medical Devices

Directive 2001/82/EC on the Community code relating to veterinary medicinal products (as amended) requires an assessment of ecotoxicity for any application for a marketing authorisation for a veterinary medical product unless the applicant can demonstrate that the product is essentially similar to one already authorised or, by detailed reference to scientific literature, that the constituents have a well-established medical use and an acceptable level of safety. The Directive states that the purpose of the study of the ecotoxicity of a veterinary medicinal product is to assess the potential harmful effects which the use of the product may cause to the environment and to identify any precautionary measures that may be necessary to reduce the risks.

The Directive is implemented by the *Veterinary Medicines Regulations 2005* and veterinary medicines, manufacturers and distributors are authorised by the Veterinary Medicines Directorate. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising marketing, supply and administration.

The Directive requires the assessment to be carried out in two phases. In the first phase, the potential extent of exposure to the environment of the product, its active substances or relevant metabolites is assessed. If environmental exposure is considered to be extensive then a second phase of assessment is required where specific investigation of the effects of the product on particular ecosystems is necessary.

Guidelines have been developed to assist the environmental assessment. Phase I guidelines use a series of decision points and trigger values to assess the extent of environmental exposure. If the decision point or trigger indicates extensive exposure then the assessment enters Phase II. In Phase II, studies are carried out on the fate of the active ingredient (and/or major metabolites) in the environment and the effects on non-target organisms. The results of these studies are used to identify the environmental compartment with effects data. The comparison of exposure with effects is used to determine the risk to the environment.

The environmental assessment of veterinary medicines does not normally consider excipients, but there is a 'however' clause in the Guidelines which allows assessment/further assessment of excipients if it is considered that environmental concerns may exist. This 'however' clause could be used to require assessment of the impact of nanoparticles used as excipients. As the Directive refers to the product as the entity which is being assessed, there is scope to amend the guidelines and include assessment of nanoparticles or other excipients.

The present procedure for assessment of veterinary medicines would only address the environmental impact of NMs where they are used as an active ingredient and not where they are used as an excipient. Furthermore, some of the methods currently used to examine the fate and effects of the active ingredient may not be suitable for testing the fate and effects of NMs used in veterinary medicines (either as an active ingredient or as an excipient). It is also of note that medical devices used in the veterinary industry are not controlled by any EU or UK legislation which is a significant regulatory gap.

4.2.11 Motor Fuel Legislation

The *Motor Fuel (Composition and Content) Regulations 1999* (as amended) implement *Directive 98/70/EC relating to the quality of petrol and diesel fuels* (as amended). The Directive sets technical specifications for vehicle fuels on health and environmental grounds. These specifications provide limits for substances contained within the motor fuels in order to limit human and environmental exposure. Those parameters currently covered are shown in Box 4.2. The addition of NMs to motor fuels is unlikely to be covered by the existing legislation.

Box 4.2: Substances Controlled by the Motor Fuel Regulations	
Research octane number	Oxygen content
Motor octane number	Oxygenates—Methanol
Vapour pressure	Ethanol
Distillation:—percentage evaporated at100°C	Iso-propylalcohol
percentage evaporated at 150°C	Tert-butylalcohol
Hydrocarbon analysis:—	Ethers containing five or more carbon atoms per
Olefins	molecule Otheroxygenates
Aromatics	Sulphur content
Benzene	Lead content

4.3 Legislation Relating to Manufacture and Storage

4.3.1 Overview

Specific legislation relating to manufacturing and storage exist for oil and explosives, as discussed below, which aim to contain the products. However, other sectors are likely to be subject to more general legislation relating to manufacturing and storage, where this will include the environmental legislation discussed in Section 5.

4.3.2 Oil Storage Regulations

The *Control of Pollution (Oil Storage) (England) Regulations 2001* apply to industrial, commercial and institutional (residential and non-residential) premises storing more than 200 litres of oil. They require a person having custody or control of oil to carry out certain works and take certain precautions and other steps for preventing pollution of any waters which are controlled waters for the purposes of Part III of the Water Resources Act 1991.

These Regulations do not apply to the storage of oil:

(a) if the oil is waste oil;
(b) in any container which is situated in a building or wholly underground;
(c) in any container with a storage capacity of 200 litres or less;
(d) on any premises used -

(i) wholly or mainly as a private dwelling if the storage capacity of the container in which it is stored is 3,500 litres or less;
(ii) for refining oil; or
(iii) for the onward distribution of oil to other places; or

(e) on any farm if the oil is for use in connection with agriculture within the meaning of the Agriculture Act 1947.

Oil shall be stored in a container which is of sufficient strength and structural integrity to ensure that it is unlikely to burst or leak in its ordinary use.

Oil storage at other premises may be covered by the *Building Regulations 1991*, the *Control of Pollution (Silage, Slurry and Agricultural Fuel Oil) Regulations 1991* (as amended), groundwater legislation and/or health and safety legislation.

Therefore, whether motor fuel contains NMs or not, its storage is regulated to prevent emissions to the environment.

4.3.3 Manufacture and Storage of Explosives

The *Manufacture and Storage of Explosives Regulations 2005* aim to reduce the risks of fire and explosions. As such, they do not specifically address the risks potentially posed by NMs. However, these Regulations do require controlled manufacturing and storage, as well as licensing of facilities, potentially providing indirect controls on unintentional emissions of NMs.

4.4 Legislation Relating to Product Use

4.4.1 Overview

The *Biocidal Products Regulations 2001* (as amended) make provisions for instructions to be provided for specific instructions in order to reduce human and environmental exposure to the product. Other sectors applying NMs do not necessarily have legislation which aim to control use of the product in this way; however, there are obviously controls on the use of medicines, for example *the Prescription Only Medicines (Human Use) Order 1997* (as amended), which are not discussed here.

The *Control of Substances Hazardous to Health Regulations 2002 (COSHH 2002)* (as amended) require assessment of risks associated with the use of any substance hazardous to health before it is used, and for the adoption of appropriate measures to control the risks.

4.4.2 Biocidal Products Regulations

The *Biocidal Products Regulations 2001* (as amended) aim to control human and environmental exposure by requiring that the packaging provides information on the interval to be observed between:

- applications of the biocidal product;
- application and the next use of the article, material or substance treated by the biocidal product; or
- application and the next access by humans or animals to the area where the biocidal product has been used.

In addition, information on decontamination means and measures and duration of necessary ventilation of treated areas should also be included.

These Regulations would apply to products containing NMs, and, as such, some control on their use may be possible.

Legislation regarding the use of pest control products is enforced by the Health and Safety Executive where products are used as part of a work activity, such as by professional contractors, use in agriculture, local authorities and public utilities. Local authorities enforce controls for those areas not under HSE jurisdiction (e.g. hotels, warehouses, parks and garden centres). However, where products are used by private consumers it is possible that the products could be used without following the guidance.

4.4.3 The Control of Substances Hazardous to Health (COSHH) Regulations

The *Control of Substances Hazardous to Health (COSHH) Regulations 1988 (as amended)* came into force on 1 October 1989 and were made under the Health and

Safety at Work Act 1974. In the UK, COSHH is an important means of regulating the use of virtually all substances deemed to be hazardous to health, including those chemicals classed as Very toxic, Toxic, Harmful, Irritant or Corrosive; other chemicals used in industry or farming; and substances with occupational exposure limits. They also cover dusts and any other material, mixture, or compound used at work which can harm people's health (including micro-organisms).

The original Regulations, together with all subsequent amendments, have been consolidated into a single set of regulations, the latest of which is The *Control of Substances Hazardous to Health Regulations 2002 (COSHH 2002)* (as amended). The basic principle underlying the COSHH regulations is that the risks (immediate or delayed) associated with the use of any substance hazardous to health must be assessed before it is used, and appropriate measures must be used to control the risks. Preventing or controlling exposure to hazardous substances is achieved by a combination of measures. These measures are, in order of preference:

1. Substitution with a less hazardous chemical or product;
2. Technical or engineering controls (e.g. the use of closed handling systems);
3. Operational; controls (e.g. operators located in cabs fitted with air-filtration systems);
4. Use of personal protective equipment, including protective clothing.

Consideration must be given as to whether it is necessary to use the hazardous substance at all in a given situation, and if so whether a product posing a lesser risk to humans, animals and the environment can be substituted. Where other measures do not provide adequate control of exposure and the use of personal protective equipment is necessary it is essential that equipment is properly maintained and the correct procedures adopted. Where necessary, the exposure of workers must be monitored, health checks carried out, and employees must be instructed and trained in precautionary techniques.

In relation to the production and use of NMs, there are a number of deficiencies in our current knowledge that may limit the ability of employers to conduct adequate assessments under COSHH, and for regulators to decide whether any such assessments are adequate. For example, there is a lack of sufficient information with regard to toxicological, fire and explosion hazards of NMs; availability of reliable measurement and characterisation methods that can be used for exposure monitoring; and suitable dose units that can be used in hazard and exposure assessments. Other deficiencies in relation to COSHH may arise from the performance and effectiveness of existing control measure, such PPE, when used in the context of NMs.

4.5 Identifying the Regulatory Gaps for Products

The process of identifying the regulatory gaps is based on the four-step methodology (hazard identification, exposure assessment, risk calculation and environmental action) set out in Section 1. This is represented in Table 4.2 below.

Table 4.2: Legislation Relating to Products and their Advantages and Drawbacks				
Product	**Does the legislation require an identification of the potential hazards of NMs?**	**Does the legislation require determination, quantification and/or control of potential exposure (routes) to NMs?**	**Does the legislation require calculation and characterisation of risk?**	**Entry into the environment**
Coatings and Pigments – General	Possibly under the GPSD.			Manufacturing emissions may be covered by IPPC but there is no legislation preventing emissions from use
	<u>Drawback</u>: The GPSD does not regulate environmental hazard 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 this product			
Coatings and Pigments – Fungicide Paint	The Biocides and COPR Regulations, require a hazard assessment of active substances (where these may be NMs)	The Biocides and COPR Regulations, require an exposure assessment of active substances (where these may be NMs)	The Biocides and COPR Regulations, require a risk assessment of active substances (where these may be NMs)	Under the Biocides and COPR Regulations, information must be given on use and remediation.
	<u>Drawback:</u> NMs included in biocidal products but not as the active substance may not be fully identified or assessed.			
Construction Materials – General	Hazard of products containing NMs may be identified through use of standards to certify quality of building materials	Construction Products Directive requires control of dangerous particles in the air – this could result in controls on NMs	Risks of products containing NMs may be identified through use of standards to certify quality of building materials	Manufacturing emissions may be covered by IPPC but there is no legislation preventing emissions from use
	<u>Drawback:</u> May only apply to NMs if other legislation has already identified them to be dangerous			
Construction Materials – Insulation		Legislation limits exposure to toxic substances – this does not currently include NMs		
	<u>Drawback:</u> Existing guidance only refers to urea formaldehyde			
Construction Materials – Drinking Water Pipes	Legislation requires that products used in the supply of drinking water must be approved by the Secretary of State.			Manufacturing emissions may be covered by IPPC and the legislation may prevent emissions from use by requiring prior testing and approval.
	<u>Drawback:</u> It is not clear to what extent to the test methods used would be able to assess the potential hazard, exposure or risk resulting from the use of NMs in coatings in drinking water pipes.			
Cosmetics	Hazard identification is required to place a substance on a positive list and companies are required to assess the safety of product for humans. This could include consideration of NMs.	Exposure assessment is required to place a substance on a positive list and companies are required to assess the safety of product for humans. This could include consideration of NMs.	Risk characterisation is required to place a substance on a positive list and companies are required to assess the safety of product for humans. This could include consideration of NMs.	Manufacturing emissions may be covered by IPPC but there is no legislation preventing emissions from use
	<u>Drawback:</u> 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 does not consider environmental risks			

<table>
<tr><th colspan="5">Table 4.2: Legislation Relating to Products and their Advantages and Drawbacks</th></tr>
<tr><th>Product</th><th>Does the legislation require an identification of the potential hazards of NMs?</th><th>Does the legislation require determination, quantification and/or control of potential exposure (routes) to NMs?</th><th>Does the legislation require calculation and characterisation of risk?</th><th>Entry into the environment</th></tr>
<tr><td rowspan="2">Detergents</td><td>For surfactants, biodegradation testing is required. This would apply to uses of NMs in surfactants.</td><td></td><td>Where surfactants fail a biodegradation test, a risk assessment may be required - which could include consideration of NMs.</td><td rowspan="2">Manufacturing emissions may be covered by IPPC but there is no legislation preventing emissions from use</td></tr>
<tr><td colspan="3"><u>Drawback:</u> Nano-forms of existing non-surfactant ingredients are unlikely to be addressed. However, for some ingredients (such as optical brighteners), a new NM-based ingredient would need to be identified and the detergents labelled (irrespective of their concentration)</td></tr>
<tr><td rowspan="2">Electrical and Electronic Equipment</td><td></td><td>Legislation limits exposure to hazardous chemicals – this does not currently include NMs</td><td></td><td>Manufacturing emissions may be covered by IPPC and legislation aims to limit emissions of hazardous substances into the environment</td></tr>
<tr><td colspan="4"><u>Drawback:</u> Legislation only addresses specific named substances that have already been identified as hazardous</td></tr>
<tr><td rowspan="2">Food</td><td>Additives and novel foods must be authorised before use, where this includes hazard identification. This would include consideration of NMs</td><td>Additives and novel foods must be authorised before use, where this includes exposure assessment. This would include consideration of NMs.</td><td>Additives and novel foods must be authorised before use, where this includes risk assessment. This would include consideration of NMs</td><td>Treatment and processing emissions may be covered by IPPC but there is no legislation preventing emissions from use</td></tr>
<tr><td colspan="4"><u>Drawback:</u> Additive and novel food legislation only considers human health and does not consider environmental impacts or emissions.</td></tr>
<tr><td rowspan="2">Fuel Cells and Batteries</td><td></td><td>Legislation limits exposure to hazardous chemicals – this does not currently include NMs</td><td></td><td>Manufacturing emissions may be covered by IPPC and legislation aims to limit emissions of hazardous substances into the environment</td></tr>
<tr><td colspan="4"><u>Drawback:</u> Legislation only addresess specific named substances that have already been identified as hazardous</td></tr>
<tr><td rowspan="2">Medical Applications</td><td>Legislation requires hazard identification for medicines and medical devices. This would include consideration of NMs</td><td>Legislation requires exposure assessment of medicines and medical devices. This would include consideration of NMs</td><td>Legislation requires risk assessment of medicines and medical devices. This would include consideration of NMs</td><td rowspan="2">Manufacturing emissions may be covered by IPPC and consideration is given to disposal of medical applications and associated impact on the environment</td></tr>
<tr><td colspan="3"><u>Drawback:</u> Only minimal consideration is given to the environmental impact of medical applications</td></tr>
<tr><td>Paper Manufacturing</td><td colspan="3">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.</td><td>Manufacturing emissions may be covered by IPPC and legislation limits the environmental impact of packaging waste</td></tr>
</table>

Table 4.2: Legislation Relating to Products and their Advantages and Drawbacks				
Product	**Does the legislation require an identification of the potential hazards of NMs?**	**Does the legislation require determination, quantification and/or control of potential exposure (routes) to NMs?**	**Does the legislation require calculation and characterisation of risk?**	**Entry into the environment**
Plant Protection Products	The Pesticides and COPR Regulations, require a hazard assessment of active substances (where these may be NMs)	The Pesticides and COPR Regulations, require an exposure assessment of active substances (where these may be NMs)	The Pesticides and COPR Regulations, require a risk assessment of active substances (where these may be NMs)	Under the Pesticides and COPR Regulations, information must be given on use and remediation.
	<u>Drawback:</u> NMs included in plant protection products but not as the active substance may not be fully identified or assessed.			
Fertilisers and Plant Nutrients	Regulation EC 2003/2003 requires that high nitrogen content fertilisers (where these include NMs) conform to certain characteristics to ensure they are harmless, mainly in terms of explosion hazard.	The Fertilizers Regulations 1991 control the composition, labelling and packaging of fertilisers, including specified directions for the storage, packaging, handling and use (where these may be NMs).	There is no legal requirement for the provision of risk calculation and characterisation, other than for the explosion hazard of high nitrogen content fertilisers (where these include NMs).	Manufacturing emissions may be covered by IPPC (under Annex III of Directive 96/61/EC particular attention must be paid to nitrates and phosphates). Various water regulations encompass fertiliser use, incl. the Protection of Water Against Agricultural Nitrate Pollution (England and Wales) Regulations 1996.
	<u>Drawback:</u> EC and domestic fertiliser/plant nutrient regulations do not regulate environmental hazards and risks associated with the use of these products. Water regulations address eutrophication, etc., but it is possible that other environmental risks of NMs would not be addressed for fertilisers and plant nutrients.			
Textiles	Possibly under the GPSD.			Manufacturing emissions may be covered by IPPC but there is no legislation preventing emissions from use
	<u>Drawback</u>: The GPSD does not regulate environmental hazard 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 this product			
Transport – Lubricants and Fuel Additives		Legislation limits exposure to hazardous chemicals – this does not currently include NMs		Manufacturing emissions may be covered by IPPC and legislation aims to limit emissions of hazardous substances into the environment
	<u>Drawback:</u> Legislation only addresses specific named substances that have already been identified as hazardous			
Weapons and Explosives	Some data on hazards may be available where substances are classified as dangerous – NMs are not currently classified as dangerous	Legislation controls storage of explosives, but not necessarily exposure. Exposure scenarios may have to be developed for dangerous substances – NMs are not currently classified as dangerous	Some risk assessment may be undertaken where substances are classified as dangerous – NMs are not currently classified as dangerous	Information on disposal may be available where substances are classified as dangerous

5. LEGISLATION RELATING TO THE ENVIRONMENT

5.1 Introduction

This Section considers the appropriateness of existing frameworks for environmental legislation in the face of the risks posed by NMs. The key environmental legislation of potential relevance to nanotechnologies have been sub-divided into:

- legislation relating to industrial emissions (Section 5.2);
- legislation relating to emissions to air (Section 5.3)
- legislation relating to emissions to water (Section 5.4)
- legislation relating to waste management (Section 5.5); and
- legislation relating to environmental contamination/remediation (Section 5.6).

5.2 Legislation Relating to Industrial Emissions

5.2.1 Directive 96/61/EC on Integrated Pollution Prevention and Control

The key piece of European legislation relating to industrial emissions is *Directive 96/61/EC on Integrated Pollution Prevention and Control* (as amended) (the IPPC Directive). It lays down measures designed to prevent or, where that is not practicable, to reduce emissions of pollutants to air, water and land from activities mentioned in Annex I of the Directive, including measures concerning waste. Pollution, and hence 'pollutant', is given a wide definition in the Directive, meaning "*the direct or indirect introduction…of substances…into the air, water or land which may be harmful to human health or the quality of the environment, result in damage to material properties or impair or interfere with amenities and other legitimate uses of the environment*".

Under IPPC, relevant activities must obtain a permit to operate. A permit application must include a description of the nature and quantities of foreseeable emissions from the installation into each medium as well as identification of significant effects of the emissions on the environment. Emission limit values (ELVs) may be set (in the permit) for all pollutants likely to be released in significant quantities. Permits issued by the authorities must also contain suitable release monitoring requirements, specifying measurement methodology and frequency, and the operator must provide monitoring data to enable compliance assessment.

The IPPC Directive is implemented in the UK by the *Pollution Prevention and Control (England and Wales) Regulations 2000* (the PPC Regulations) and similar legislation in the Scotland and Northern Ireland; it replaces the pollution control regime set up under Part I of the *Environmental Protection Act 1990* and the transitional process will be completed by 2007.

There are a number of key issues in assessing whether the IPPC Directive and the national legislation would apply to sectors producing, using and emitting NMs. These

essentially relate to the scope, the interpretation and the practical application of the Directive/legislation.

Issues Relating to Scope

It is uncertain whether existing IPPC activity descriptions will capture nanotechnology production routes. The scope of the IPPC Directive (and national legislation) is described in terms of traditional unit operations and unit processes. Such is the innovative nature of nanotechnology production that they may not meet the IPPC activity descriptions. For example, in the PPC Regulations, chemical industry activities must involve the production of chemicals 'in a chemical plant by chemical processing for commercial purposes' and this would exclude NMs produced using solely physical production routes.

Essentially, those sectors using NMs, as identified in Section 2, are generally covered by Annex I of the IPPC Directive, where this includes: energy industries; production and processing of metals; mineral industry; chemical industry; waste management; and other activities. This latter category includes pulp production, paper and board production, pre-treatment or dyeing of fibres, and various food processes. However, most of these activities (but not those in the chemical industry) are subject to a threshold capacity below which IPPC does not apply: for example, plants for the pre-treatment or dyeing of fibres or textiles are excluded where the treatment capacity is below 10 tonnes per day. These thresholds mean that small scale sites, as well as all research and development activities, are not covered by the IPPC Directive and national legislation.

Assuming that a sector producing or using NMs is covered by IPPC, consideration should then be given to the pollutants which are required to be limited. A permit must include emission limit values (the mass, concentration or level of an emission which may not be exceeded over a given period) for pollutants likely to be emitted in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another. Particular, but not exclusive, attention must be paid to certain substances and preparations listed in Annex III (reproduced in Table 5.1 below) to the Directive.

Table 5.1: Annex III of Directive 96/61/EC – Indicative List of the Main Polluting Substances

Air	**Water**
Sulphur dioxide and other sulphur compounds	Organohalogen compounds and substances which may form such compounds in the aquatic environment
Oxides of nitrogen and other nitrogen compounds	Organophosphorus compounds
Carbon monoxide	Organotin compounds
Volatile organic compounds	Substances and preparation which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction in or via the aquatic environment
Metals and their compounds	Persistent hydrocarbons and persistent and bioaccumulable organic toxic substances
Dust	Cyanides
Asbestos (suspended particulates, fibres)	Metals and their compounds
Chlorine and its compounds	Arsenic and its compounds
Fluorine and its compounds	Biocides and plant health products
Arsenic and its compounds	Materials in suspension
Cyanides	Substances which contribute to eutrophication (in
Substances and preparation which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air	
Polychlorinated dibenzodioxins and polychlorinated dibenzofurans	

Table 5.1: Annex III of Directive 96/61/EC – Indicative List of the Main Polluting Substances	
Air	**Water**
	particular, nitrates and phosphates) Substances which have an unfavourable influence on the oxygen balance (and can be measured using parameters such as BOD, COD, etc.)

Of relevance to NMs is that Annex III to the Directive includes metals and their compounds, dust, asbestos (suspended particulates, fibres) and substances and preparations which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air or aquatic environment. Potentially, NMs could fall within one or more of these categories, although inclusion within the last category of substances would depend upon the findings of scientific research.

Issues of Interpretation

However, whether or not a NM fits within the Annex III descriptions, the Directive clearly requires emission limit values to be set if it falls within the Directive's definition of 'pollution' and if it is likely to be emitted in 'significant quantities'. It is therefore necessary to determine whether a NM is a pollutant and, if so, what constitutes a significant quantity for the purposes of the Directive.

NMs are currently being produced in small quantities (usually kg) and at significant cost; it is thus unlikely that they would be released or disposed of arbitrarily. If the nano-equivalent of a substance is considered to be an existing substance (for example, metals), then ELVs relating to the existing substance would, in simple terms, cover the NM releases. However, the ELV will have been determined on the basis of the environmental risk arising from the existing substance, which may differ significantly (in either direction) from the NM. If the NM was not considered to be an existing substance, or was not covered by an existing ELV, the term 'significant quantities' may exclude consideration of NM emissions, unless it was assessed in relation to the environmental significance of the NM itself.

Application Issues

Assuming that all the above conditions were met and it was decided that an ELV was required, it would be necessary to determine an acceptable level of emissions of NMs. The PPC Regulations require that applicants or operators do not simply provide basic technical details of levels of releases but that they assess the "environmental impacts, explore options for improvement and make proposals for the consideration of the regulators". Given the current uncertainty in relation to the potential impacts of some NMs on human health and/or the environment in relation both to the potential effects and the level at which these effects might occur, it is difficult to see how these impacts could be adequately assessed for many types of NMs. Based on existing scientific knowledge, it would be near impossible to determine an acceptable level of emissions or appropriate Best Available Technology (BAT).

In addition, ELVs are set so that environmental assessment levels (EALs) are not exceeded. For example, in relation to air emissions, current EALs are derived from a hierarchy of information sources including the Expert Panel on Air Quality Standards (EPAQS), EC Air Quality Directives (see below) and World Health Organisation Air Quality Guidelines for Europe. However, the majority of EALs for air have been extrapolated from occupational exposure limits (OELs) using suitable uncertainty factors, which allow for the differences between occupational exposure to chemicals and the exposure of the general population to the pollutant in ambient air. It is not known whether such limit values will be revised although it is unlikely that this will happen in the short term. The absence of this hierarchy of information could cause difficulties in setting appropriate EAL/ELVs.

Finally, assuming that ELVs could be established, it would be necessary to monitor industrial emissions for NMs to ensure compliance. In terms of air emissions, stack monitoring (for particulates) is generally assessed in terms of mass of PM_{10}. Based on current evidence about the relative toxicity of some NMs compared with the same material at the macro scale, it is possible that ELVs relevant to nanoparticles would, on a mass basis, be much lower. It is also possible that they could be based on an alternative metric such as particle number or surface area within an appropriate size range. While methodologies to measure these parameters are available, they have not yet been applied to stack measurement. It is unlikely, that the systems as currently available would be well suited to this type of environment, particularly in terms of robustness and ability to tolerate temperature extremes. Broadly similar problems would arise in monitoring NMs in effluent discharges.

5.2.2 Directive 96/82/EC on the Control of Major Accident Hazards Involving Dangerous Substances

Directive 96/82/EC on the control of major accident hazards involving dangerous substances (known as the Seveso II Directive, and since amended by Directive 2003/105/EC) is aimed at the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for man and the environment of any which do occur. 'Major accident' means an occurrence, in particular a major emission, fire, or explosion, resulting from uncontrolled developments in the course of the operation of any establishment, and leading to serious danger to human health and/or the environment. In the UK, the Directive is implemented by the *Control of Major Accident Hazard Regulations 1999* (COMAH) (as amended). Responsibility for COMAH is held jointly by the Health and Safety Executive (HSE) and the Environment Agency (for England and Wales) or the Scottish Environment Protection Agency. COMAH applies to approximately 1,200 UK establishments (Environment Agency figures) that have the potential to cause major accidents because they use, or store, significant quantities of dangerous substances.

'Dangerous substances' include a number of named substances such as ammonium nitrate, oxygen, hydrogen, formaldehyde, halogens and petroleum products, as well as substances falling into certain categories, such as toxic, oxidising, explosive, flammable, dangerous for the environment, and some carcinogens. The Regulations apply at two thresholds, a lower-tier and top-tier, depending upon the quantity of the dangerous substances stored. The lower-tier threshold ranges from 1kg for

environmentally dangerous chemicals such as polychlorodibenzofurans, up to 2,500 tonnes for petroleum products. If the lower-tier threshold is equalled or exceeded operators must notify the joint Competent Authority and prepare a Major Accident Prevention Plan (MAPP). The top-tier threshold ranges from 1kg to 25,000 tonnes for the above-mentioned substances. If this threshold is equalled or exceeded operators must comply with additional requirements to provide a Safety Report and have an on-site emergency plan. Local authorities must also prepare an off-site emergency plan for each top-tier site. COMAH places duties on the Competent Authority to inspect activities subject to the Regulations and prohibit the operation of an establishment if there is evidence that measures taken for prevention and mitigation of major accidents are seriously deficient. It also has to examine safety reports and inform operators about the conclusions of its examinations within a reasonable time period.

COMAH does not apply to military establishments, to radioactive substances present on sites for which a nuclear site licence has been granted, to certain activities carried out by the extractive industries or to waste land-fill sites. Also, the Regulations do not apply in Northern Ireland, and neither do they apply to the transport of dangerous substances by air, road, rail, waterways, sea and pipeline.

In the context of NMs, it is currently unclear (and/or unlikely) that:

- *the existing definition of 'dangerous substances' would apply to the majority of NMs.* Most NMs are likely to fall outside the very prescriptive COMAH definition of a 'dangerous substance', and therefore will not be covered by these Regulations. For example 'nickel compounds in inhalable powder form' are included (but see second bullet point, below), but there is no reference to other metallic compounds such as aluminium, copper, iron, silver, titanium, etc. which may be used as NMs and which could be considered as dangerous to human health or the environment; and

- *in cases where the definition of 'dangerous substance' is applicable, even the lower-tier threshold would be equalled or exceeded.* Because of the threshold limits laid down in COMAH the majority of NMs are unlikely to be covered by the Regulations, even if they comply with the 'dangerous substances' definition. For example, in the case of inhalable nickel, the quantity must equal or exceed 1 tonne in order for COMAH to be applicable. In most cases such thresholds are unlikely to be met for NMs.

The wide diversity of NMs makes it highly likely that some have the potential to pose an accident hazard in terms of emission, fire, or explosion. Whether or not they comprise a 'major' accident hazard will depend primarily on the magnitude of any potential effects on human health or the environment (e.g. how toxic or how combustible the substance is) and the quantity of material involved.

As has been discussed earlier, NMs are generally only produced and used in small quantities, therefore it could be construed that they are unlikely to pose a major accident hazard. However, due to the atypical physicochemical and unknown ecotoxicological properties of NMs compared to their macro-equivalents, it is possible

that small quantities could have a significant impact on human health and the environment due to accidental release. Addressing the three main hazard concerns specified in the COMAH Regulations, namely emission, fire, and explosion, the following scenarios can be envisaged concerning NMs:

Emission hazards: emission of NMs due to accidents could result in their release to water, land or air. Accidents may be in the form of spills, inadvertent discharge to sewage or wastewater systems, accidental dumping, accidental release of dust to the atmosphere, etc. If the quantity of material emitted is large enough and/or the material has sufficient eco-toxicological properties, it could result in a serious danger to human health and/or the environment. Several substances used in the manufacture of NMs are known to be toxic in macro-form, including some metals and metal oxides, and current evidence suggests that the relative toxicity of such NMs is increased compared with the same material at the macro scale. In addition, it is possible that substances that are innocuous at the macro scale could be harmful at the nanoscale.

Fire hazards: due to the large specific surface areas of nanopowders it has been speculated that there could be an increased likelihood of them becoming electrostatically self-charged. Charges can build-up on powders during transport, handling and processing, and charging tendency has been found to drastically increase with increasing surface area. The effect of such charging may make these powders ignite more easily, either through spontaneous combustion or ignition. Aside from the obvious risks to human health and the environment from fire, there is also a high likelihood of the spread of NMs from airborne emissions of uncombusted material.

Explosion hazards: it is recognised that explosion severity tends to increase with decreasing particle size (although for some substances this effect levels off) but it is only recently that research has been conducted into the explosion characteristics of nanopowders. So far only a limited number of materials have been tested, but there is speculation that the increased surface area of nanopowders compared to other powders will increase the explosive properties. Again, in terms of risk to the environment from explosion, perhaps the most likely scenario is not through direct damage (whilst this has serious human health implications it is likely to have a only a local effect on the environment), but through the dispersal into the atmosphere of nanopowders and their subsequent toxicological effect. At present only a small number of nanopowders are produced in the type of quantities that might present a dust explosion hazard (e.g. carbon black), however there is a growing demand for nanopowders, and a recent literature review[14] by the Health and Safety Laboratory called for more research to determine the explosion characteristics of a representative range of such materials.

In conclusion, the combination of a prescriptive definition of what constitutes a ‘dangerous substance’ and the high (in terms of NMs) threshold values associated with such substances is likely to significantly restrict the scope of the COMAH Regulations in terms of the NMs. As a consequence the current potential for COMAH to prevent major accidents involving NMs, and limit the consequences for man and the environment of any accidents that do occur, is likely to be very limited. However, if in the future certain NMs are found to be more dangerous than their macro-

[14] Literature review – explosion hazards associated with nanopowders. HSL/2004/12. (http://www.hse.gov.uk/research/hsl_pdf/2004/hsl04-12.pdf)

equivalents, then it may be possible to categorise these materials in terms of hazard. For example, if the macro-substance is classified as toxic, the nano-substance may be classified as very toxic. This would result in lower threshold values for specific NMs and would increase the applicability of COMAH.

5.3 Legislation Relating to Air Quality

The key pieces of European legislation relating to air quality, and which may be relevant to NMs, are:

- the EU's Framework *Directive 96/62/EC on ambient air quality assessment and management* and daughter Directives; and
- *Directive 2001/81/EC setting national emission ceilings for certain atmospheric pollutants*.

In the UK, *The Air Quality Strategy for England, Scotland, Wales and Northern Ireland – Working Together for Clean Air* was published in January 2000. It sets objectives for key health-threatening pollutants. These objectives are given statutory backing by the *Air Quality (England) Regulations 2000* (as amended). The *Air Quality Limit Values Regulations 2003* implement the EU Framework Directive on air quality and subsequent daughter Directives.

Industrial air emissions from some 5,000 large industrial installations are regulated under the *Pollution Prevention and Control (England and Wales) Regulations 2000* (PPC Regulations), and similar legislation in Scotland and Northern Ireland which, as discussed above, implement the IPPC Directive. But the PPC Regulations also provide for a separate, national system of controls upon emissions to air from (in England and Wales) some 23,000 smaller industrial installations. There is also legislation for dealing with industrial smoke pollution in the *Clean Air Act 1993*.

The main aim of air quality legislation is to protect human health and the environment by avoiding, reducing or preventing harmful concentrations of air pollutants. The above Directives and Regulations cover a range of key air pollutants, including:

- sulphur dioxide, nitrogen dioxide, fine particulate matter (PM10), suspended particulate matter and lead;
- benzene and carbon monoxide;
- ozone;
- polycyclic aromatic hydrocarbons (PAHs) (benzo-a-pyrene as indicator), cadmium, arsenic, nickel compounds and mercury.

It is of note that other pollutants to be considered at a further stage under the Framework Directive on Air Quality are dioxins, VOCs, methane, ammonia, nitric acid and PAHs (general). Proposals for other substances to be covered by daughter Directives will be considered on the basis of new scientific evidence on environmental or health effects (NSCA, 2004). It is of note that there are also a number of international initiatives, where these generally address the pollutants

identified above (as well as greenhouse gases). These international initiatives are largely implemented by the legislation already discussed.

It can be seen from the above list of substances that existing legislation relating to air pollution and air quality covers a specific list of substances, for which the health and environmental effects have already been identified. As such, existing legislation in relation to air pollution, excluding that controlled by the PPC Regulations (which is discussed above) would not regulate emissions of NMs, based on the nanoscale substances currently used.

More broadly, however, the Commission's Thematic Strategy on Air Pollution, released in September 2005, focuses on reducing emissions of five primary air pollutants including particulate matter (PM); special attention is paid to fine particulates (also known as $PM_{2.5}$, which are particles with a diameter of less than 2.5 micrometers), which are strongly correlated with harmful effects on human health as they can penetrate into sensitive areas of the lungs. The Strategy notes that there is insufficient evidence to determine a safe level of human exposure to particulates and in practical terms all increases in PM levels should be regarded as harmful. Furthermore, the World Health Organisation and the Commission's Scientific Committee on Health and Environmental Risk have recommended on health grounds that air quality standards should not be relaxed, highlighting that the latest evidence strongly suggests that the smallest particulates ($PM_{2.5}$) need to be regulated.

The Strategy and the accompanying proposal to revise the Air Quality Framework Directive would for the first time introduce controls on human exposure to $PM_{2.5}$ to complement the existing limits on coarse particulate matter (PM_{10}). The proposed approach would establish a concentration cap for $PM_{2.5}$ in ambient air in the most polluted areas at a level that would prevent unduly high risks to the population. This would be coupled with an obligation on Member States to reduce average human exposure to urban background levels of $PM_{2.5}$ over 10 years starting from 2010, with the aim of achieving a 20% reduction. The proposal also envisages more comprehensive monitoring of including $PM_{2.5\ to}$ allow a better understanding of this pollutant and make possible policy improvements in future.

The implications of these proposals for nanoparticles are however unclear, as the legislative proposals are yet to be fully developed.

5.4 Legislation Relating to Water Emissions

5.4.1 Overview

The key pieces of European legislation relating to water quality, and which may be relevant to NMs, are:

- *Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community* and subsequent 'daughter' Directives;
- *Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances* (as amended);
- *Directive 91/271/EEC on urban waste water treatment* (as amended); and

- *Directive 2000/60/EC establishing a framework for community action in the field of water policy* (which will repeal Directive 76/464/EEC and Directive 80/68/EEC).

These are transposed and/or implemented through a range of national legislation, including:

- the *Water Industry Act 1991*, the *Water Resources Act 1991*, and the *Water Act 2003;*
- the *Trade Effluents (Prescribed Processes and Substances) Regulations 1989* (as amended), *the Environment Protection (Prescribed Processes and Substances) Regulations 1991*[15] (as amended), and the *Pollution Prevention and Control (England and Wales) Regulations 2000* and similar legislation in Scotland and Northern Ireland;
- the *Surface Waters (Dangerous Substances) (Classification) Regulations 1997* and *1998*;
- the *Groundwater Regulations 1998*;
- the *Urban Waste Water Treatment (England and Wales) Regulations 1994*; and
- the *Water Environment (Water Framework Directive) (England and Wales) Regulations 2003* and similar legislation in cross border river basin districts and in Scotland and Northern Ireland.

Legislation relating to water emissions is based either on lists of substances which are prohibited or limited in emissions to the aquatic environment or on requirements for specific treatment methods. It is of note that the IPPC Directive and associated national legislation are also relevant to water emissions and are discussed above.

5.4.2 Hazardous Substances

Essentially, Directive 76/464/EEC on dangerous substances introduced the concept of List I and List II substances. Directive 76/464/EEC will be repealed by Directive 2000/60/EC, the Water Framework Directive (WFD). Article 6 (List I substances) was repealed when the WFD entered into force in 2002 and the candidate List I has been replaced by a list of priority substances under the WFD. These priority substances include plant protection products, biocides, metals (cadmium, lead, mercury and nickel) and other groups of substances. Member States are required to adopt measures to eliminate the pollution of water bodies by 'priority substances', as well as "*progressively reduce pollution by other substances which would prevent Member States from achieving the objectives for the bodies of surface water*". Some nanotechnology substances would be covered in the overall definition of a pollutant under Annex VIII of the WFD, where this includes metals and their compounds. The Directive requires the Commission to review the list every four years.

However, the 'rest' of 76/464/EEC, including the emission reduction programmes for List II substances will remain in place until 2013. Substances that will remain

[15] These Regulations will be revoked following full implementation of IPPC.

regulated through national emission reduction programmes until 2013 are shown in Box 5.1. A number of the metals are produced at the nanoscale.

Box 5.1: Substances Regulated by Directive 76/464/EEC

The following metalloids and metals and their compounds: Zinc Copper Chromium Selenium Arsenic Antimony Molybdenum Titanium Tin Barium Beryllium Boron Uranium Vanadium Cobalt Thallium Tellurium Silver	Biocides and their derivatives not appearing on the priority substances list Substances which have a deleterious effect on the taste and/or smell of the products for human consumption derived from the aquatic environment, and compound liable to give rise to such substances in water Toxic or persistent organic compounds of silicon, and substances which may give rise to such compounds in water, excluding those which are biologically harmless or which are rapidly converted in water into harmless substances Inorganic compound of phosphorus and elemental phosphorus Non-persistent mineral oils and hydrocarbons of petroleum origin Cyanides, fluorides Substances which have an adverse effect on the oxygen balance, particularly: ammonia, nitrites

In the UK, *the Environment Protection (Prescribed Processes and Substances) Regulations 1991*[16] (as amended) list a number of List I substances whose releases to water are prescribed for Integrated Pollution Control. The same substances (together with carbon tetrachloride) are also prescribed substances under the *Trade Effluents (Prescribed Processes and Substances) Regulations 1989* (as amended). In relation to NMs, it is of interest that the only metals regulated in this way are mercury and cadmium and their compounds (which are not generally used as NMs).

Similarly to Directive 76/464/EEC, Directive 80/68/EEC (the Groundwater Directive) contains List I and List II substances, however, the lists are not identical across the two Directives. In the UK, the Groundwater Directive is implemented by the *Water Resources Act 1991* and the *Groundwater Regulations 1998*. There is a prohibition on List I substances into groundwater. The Commission has subsequently issued *a proposal for a Directive on the protection of groundwater against pollution* (September 2003), which aims to ensure good groundwater quality by 2015, as required by the WFD. This sets out specific measures for preventing and controlling groundwater pollution, criteria for assessing good chemical status and for identifying significant and sustained trends in increases of pollutant concentrations (NSCA, 2004). Pollutants for which limits must be set include: ammonium, arsenic, cadmium, sulphate, trichloroethylene and tetrachloroethylene. Member States must also establish threshold values for all pollutants identified as putting groundwater at risk.

5.4.3 Domestic and Industrial Sewage

The *Urban Waste Water Treatment (England and Wales) Regulations 1994*, and similar in the Scotland and Northern Ireland, implement *Directive 91/271/EEC on*

16 These Regulations will be revoked following full implementation of IPPC.

urban waste water treatment (as amended). The aim of the Directive is to protect the environment from the adverse effects of urban waste water and industrial wastewater discharges.

Receiving waters are classified according to 'sensitivity', and the minimum treatment required (primary, secondary or tertiary) is related to this sensitivity classification. Limit values for various industrial sector discharges to rivers, estuaries and coastal waters should be set in regulations.

The Directive has been implemented through the *Urban Waste Water Treatment (England and Wales) Regulations 1994* (as amended). Discharges to controlled waters are currently regulated under PPC Regulations and consents issued under regulations made the *Water Resources Act 1991*.

Under the *Water Industry Act 1991*, occupiers of trade premises may not discharge any trade effluents into a public sewerage unless authorised by the sewerage undertaker. An application to discharge should include details of the effluent, quantity to be discharged in any one day, and the highest rate at which it is proposed to discharge. The *Water Act 2003* adds to these requirements and will require applications to describe the steps to be taken for minimising the polluting effects of the discharge on any controlled waters and minimising the effects of the discharge on sewerage services.

In granting an application, the sewerage undertaker may impose conditions covering the rate, quantity and composition of effluent and the sewer into which it may be discharged, and the time or times of day. Conditions may also relate to the provision and maintenance of inspection and test equipment, as well as to steps taken for minimising the impact of the discharge.

Where a process regulated under Part I of the Environmental Protection Act 1990 proposes to discharge trade effluent into a sewer, it also requires a consent from the sewerage undertaker.

The *Trade Effluents (Prescribed Processes and Substances) Regulations 1989* (as amended) enable compliance with Directive 76/464/EEC and subsequent 'daughter' Directives. In addition, the *Urban Waste Water Treatment (England and Wales) Regulations 1994* impose requirements relating to the discharges of industrial waste water, with sewerage undertakers being empowered to modify trade effluent consents and agreements to ensure compliance.

In terms of NMs, it is possible that products such as cosmetics, medicines, paints etc. may enter the domestic and public sewage system. However, given that the Urban Waste Water Treatment Directive and associated Regulations specify treatment methods and require monitoring of specific substances, NMs in wastewater would not be identified under this legislation. The limitations of monitoring techniques for NMs would make it difficult for this legislation to control emissions of NMs to the environment, even if the substances themselves were included in the legislation.

Sewage Sludge

Materials which are not discharged from waste water treatment plants are retained in the sludge. The residual sludge from sewage treatment plants treating domestic or urban waste waters (and from other sewage treatment plants treating waste waters of a similar composition) may be disposed of to landfill, incineration or directly to agricultural land. In the UK, around half of the sludge produced is applied to the land (CEC, 2004).

Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (as amended) regulates the use of sewage sludge in agriculture so as to prevent harmful effects on soil, vegetation, animals and humans. The Directive lays down limit values for concentrations of heavy metals in the soil, in sludge and for the maximum annual quantities of heavy metals which may be introduced into the soil. The implementing legislation in the UK is the *Sludge (Use in Agriculture) Regulations 1989* (as amended) in England, Wales and Scotland and similar in Northern Ireland. Representative samples must be tested so as to determine:

- the pH value;
- the percentage content of dry matter, organic matter, nitrogen and phosphorus; and
- the concentrations per kilogram of dry matter of chromium, zinc, copper, nickel, cadmium, lead, and mercury.

5.4.4 Water Framework Directive

At the Community level, *Directive 2000/60/EC establishing a framework for community action in the field of water policy* (Water Framework Directive (WFD)) entered into force on 22 December 2000. It is the main EU Directive for controlling water quality and will repeal a number of other Directives. The purpose of the Directive is to establish a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater which, *inter alia*:

- prevents further deterioration and protects and enhances the status of aquatic ecosystems and, with regard to their water needs, terrestrial ecosystems and wetlands depending on the aquatic ecosystems;

- aims at enhanced protection and improvement of the aquatic environment, *inter alia*, through specific measures for the progressive reduction of discharges, emissions and losses of priority substances and the cessation or phasing-out of discharges, emissions and losses of the priority hazardous substances; and

- ensures the progressive reduction of pollution of groundwater and prevents its further pollution

The Directive puts in place the concept of River Basin Management Planning. In each river basin district, Member States must identify (anthropogenic) pressures on the water bodies and draw up a river basin management plan, which includes ecological and chemical quality objectives for each water body and a programme of measures for achieving those objectives.

According to the WFD, "*with regard to pollution prevention and control, Community water policy should be based on a combined approach using control of pollution at source through the setting of emission limit values and of environmental quality standards*". The WFD thus takes into account actions (where these include emission limit values) taken under IPPC to limit or reduce emissions from local point sources.

The Water Framework Directive is transposed by the *Water Environment (Water Framework Directive) (England and Wales) Regulations 2003*, and similar legislation in cross border river basin districts and in Scotland and Northern Ireland. The measures which can be used to achieve WFD objectives include the controls, permits, etc., already established under existing EU and national water legislation.

NMs which have effects on the chemical or ecological quality of waters could be considered a pressure under the WFD. However, identifying them may require changes to the thresholds, monitoring techniques and pressure determinants which are currently used, making it unlikely that NMs will be identified as a pressure on the aquatic environment (at least in the short to medium term).

5.4.5 Applicability of Water Legislation to NMs

It is possible that raw NMs and products (for example, cosmetics, medicines, paints etc.) may enter the aquatic environment via industrial discharges and/or the domestic and public sewage system.

Emissions of chemical substances to the aquatic environment are regulated according to lists of identified hazardous substances. The substances of greatest concern include heavy metals, plant protection products and biocides. Therefore, the list of priority hazardous substances which are to be controlled under the Water Framework Directive, via the Priority Substances Daughter Directive, and implementing Regulations would not address emissions of NMs.

Existing List II substances, under Directive 76/464/EEC, will remain regulated through national emission reduction programmes until 2013; these substances include some metals which are produced at the nanoscale. In addition, the Water Framework Directive and proposed Groundwater Directive allow Member States to identify pollutants which constitute a 'pressure' on particular waterbodies. In this regard it is possible that NMs could be identified as a pollutant, if scientific evidence was available to assess the impact of specific NMs on the aquatic environment. However, it would also be necessary for adequate monitoring techniques to be available.

Furthermore, given that the Urban Waste Water Treatment Directive and associated Regulations specify treatment methods and require monitoring of specific substances, NMs in wastewater would not be identified under this legislation. The limitations of monitoring techniques for NMs would make it difficult for this legislation to control emissions of NMs to the environment, even if the substances themselves were included in the legislation.

5.5 Legislation Relating to Waste Management

5.5.1 Overview

The UK waste management regime is significantly influenced by a number of EU Directives, particularly,

- the *Directive 75/442/EEC on waste* (as amended);
- the *Directive 91/689/EEC on hazardous waste* (as amended);
- the *Directive 2000/76/EC on waste incineration*; and
- *Directive 1999/31/EC on the landfill of waste* (as amended).

These Directives, and associated implementing legislation, cover the three main recovery and disposal options which may affect NMs and products containing NMs:

- incineration;
- landfilling; and
- recycling.

However, NMs, and products containing NMs, could also be classified as hazardous or radioactive waste. More specific legislation applies to waste electrical and

electronic equipment, batteries, end-of-life vehicles and packaging. The relevant legislation is discussed in detail below.

5.5.2 The Framework Directive on Waste

Directive 75/442/EEC on waste (as amended), often referred to as the Framework Directive on Waste, was the first major piece of EU legislation relating to waste management. It set up a system for the coordinated management of waste within the Community and has been amended and/or modified by subsequent directives to reflect the changing environmental concerns and knowledge.

The Framework Directive on Waste defines waste as 'any substance or object which the holder discards or intends or is required to discard'. The Directive does not cover gaseous effluents emitted into the atmosphere and wastes that are subject to specific Community legislation, particularly radioactive waste, mineral waste, some agricultural waste, wastewater, and decommissioned explosives. The Directive was transposed into UK national law by a combination of Part II of EPA 1990 and the *Waste Management Licensing Regulations 1994.*

Member States are required to take the necessary measures to ensure that waste is recovered or disposed of without endangering human health and without using processes or methods which could harm the environment, and in particular, without risk to water, air, soil and plants and animals. As such, this aims to ensure that waste, whether it includes NMs or not, is managed so that it does not endanger human health or the environment.

Under the Directive, the relevant competent authority is required to draw up as soon as possible one or more waste management plans (for instance, *the Waste Strategy 2000 for England and Wales*). Such plans shall relate in particular to:

- the type, quantity and origin of waste to be recovered or disposed of;
- any special arrangements for particular wastes;
- technical requirements for recovery or disposal; and
- suitable disposal sites or installations, etc.

Member States may take the necessary measures to prevent movements of waste which are not in accordance with their waste management plans. They shall also take the necessary measures to prohibit the abandonment, dumping or uncontrolled disposal of waste. Member States shall ensure that all holders of wastes shall hand them over to a private or public collection agency or to a disposal company, or else shall themselves conduct the disposal in compliance with the requirements of the current measures.

Section 34 of the Environmental Protection Act 1990 provides that a 'duty of care' applies to any person who produces, imports, carries, keeps, treats or disposes of controlled waste. Any person subject to the duty has to take reasonable steps to:

- prevent any other person contravening section 33 (i.e. the law relating to the unauthorised deposit, keeping, treatment or disposal of controlled waste);

- prevent the escape of waste;
- ensure that the waste is transferred only to an authorised person; and
- ensure that an adequate written description of the waste is given to anyone to whom the waste is transferred.

The *Environmental Protection (Duty of Care) Regulations 1991* (as amended) and the *Waste (Household Waste Duty of Care) (England and Wales) Regulations 2005* thus make provisions for ensuring this duty of care is fulfilled. Under the *Environmental Protection (Duty of Care) Regulations 1991* (as amended) there must be a transfer note when waste is transferred, for example from the waste producer to a carrier. This transfer note must identify the waste, along with other details. There is thus a potential that waste containing NMs could be identified in this way.

Member States shall also inform the Commission of any draft legislation which may involve the use of products which can give rise to technical difficulties and excessive disposal costs and/or which may encourage decreasing the quantities of certain wastes, the treatment of waste for the purpose of their recycling or their reuse, the use of energy deriving from certain wastes or the use of natural resources which may be replaced by reclamation materials.

Thus, whilst there is a legal requirement to ensure that waste containing NMs does not cause harm to human health or the environment, the problems arise:

- in understanding the risks posed by waste (products containing) NMs to assess the most effective form of management/disposal; and
- if specialised management/disposal is required, identifying waste (products containing) NMs amongst other waste streams (e.g. domestic, commercial, industrial, etc.)

5.5.3 Hazardous Waste

Directive 91/689/EEC on hazardous waste (as amended) aims to introduce greater harmonisation in the management of hazardous waste amongst Member States. It provides a common definition of 'hazardous waste' and lists wastes that can be classified as hazardous (including their constituents and properties). The Hazardous Waste Directive excludes domestic waste and prohibits the mixing of hazardous waste with other types of waste except where it is a necessary part of the disposal operation.

The Directive also requires that the national competent authorities publish a hazardous waste management plan. Such a plan can be published as part of the general waste management plan drawn up under the Framework Directive on Waste, or it can be published as a separate document. Member States must ensure that hazardous waste delivery sites are identified and registered, and that international standards are adhered to hazardous waste and inert waste and requires such waste to be separated in different sites. Further, the Directive states that (with only a few exceptions) waste should be treated before being landfilled to reduce the hazard to human health and the environment, and to reduce the quantity of waste. It also places a complete ban on the landfill of certain hazardous wastes, liquid wastes and tyres and provision is made for the phasing-out of co-disposal of these waste types.

The Hazardous Waste Directive is transposed in England under the *Hazardous Waste (England and Wales) Regulations 2005* and the *List of Wastes (England) Regulations 2005,* and similar legislation in Scotland and Northern Ireland.

5.5.4 Radioactive Waste

Radioactive waste is currently discharged into the UK environment due to a variety of activities, including nuclear power generation, medical applications, certain manufacturing processes (e.g. production of smoke detectors and radioluminescent watches) and research activities. Such discharges may be in the form of gases, mists, dusts and liquids. Nanotechnology applications that might be expected to be employed by the nuclear industry include self-cleaning surfaces for decontamination, 'lab on a chip' diagnostic technologies for on-line process monitoring and control, high surface area nanoparticles for catalysis or ion-exchange, nanostructured and nanocomposite materials (e.g. as advanced nuclear fuels or as novel wasteforms) and micro or nano-chemical processing as a nuclear reprocessing technology[17]. Other potential applications for radioactive NMs include their use in medical imaging (e.g. tracking radioactive molecules attached to stable nanoparticles), using nanoscale isotopes to target tumour cells in place of X-rays[18], or even as power supplies for micromachines[19].

EU activities involving radioactive substances are governed by legislation laid down under the Euratom Treaty which established the European Atomic Energy Community. The recently revised Directive 96/29/Euratom (known as the 'Basic Safety Standards (BSS) Directive') prescribes baseline safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, including the discharge or disposal of radioactive waste. In the UK, this Directive and its daughter Euratom Directives have been implemented via primary and secondary legislation including the Radioactive Substances Act 1993, the Ionising Radiations Regulations 1999 and The Radioactive Material (Road Transport) Regulations 2002.

Radioactive Substances Act 1993 (RSA93)

The purpose of RSA93 is to ensure control over the keeping and use of radioactive material and the accumulation and disposal of radioactive waste, thus ensuring minimum impact on the general public and the environment. Specifically, the regulatory regime of RSA93 prohibits:

- the keeping and use of radioactive material, including mobile radioactive apparatus, without registration, unless exempted;

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17 See, for example, the Royal Society and Royal Academy of Engineering study on Nanotechnology - response to request for initial views from the BNFL (http://www.nanotec.org.uk/evidence/82aBNFL.htm)

18 See http://www.dukeequity.com/pdf/9%20Feb%202004%20India%20Today.pdf

19 See http://www.thebulletin.org/article.php?art_ofn=so99lortie and http://www.photonics.com/readart.ASP?url=readarticle&artid=134&bhcp=1

- the disposal of radioactive waste except in accordance with an authorisation, unless excluded; and
- the accumulation of radioactive waste with a view to its subsequent disposal except in accordance with an authorisation, unless exempted, or excluded by order.

Fundamental to the application of the provisions of RSA 93 are the definitions of radioactive material and radioactive waste since these dictate which premises fall within the scope of RSA 93. Materials and wastes which fall outside the definitions are excluded from all provisions of the regulatory regime.

Any application put forward for registration must specify: the premises to which the application relates, the purpose(s) for which the premises are used, a description of any radioactive material proposed to be kept or used on the premises, the maximum quantity of radioactive material likely to be kept or used on the premises at any one time, and the manner in which radioactive material is proposed to be used on the premises. Before granting an authorisation in respect of the disposal of radioactive waste, the Chief Inspector and the appropriate Minister must consult with relevant local authorities, water bodies and other public or local authorities. The detailed arrangements for control of radioactive materials and radioactive waste, including its disposal, are contained in certificates of registration or authorisation issued in respect of particular premises. Specific conditions are placed on the following activities:

- disposal of radioactive waste - including the means of disposal and the maximum quantity disposed per unit of time;
- accumulation of radioactive waste - including the type of container, method of storage and labelling considerations;
- loss or escape of accumulated radioactive waste - including a requirement by the user to inform the appropriate authorities, to recover the waste as far is reasonably practicable and minimise the spread of any contamination; and
- record keeping and provision of information – including a requirement by the user to keep and maintain records sufficient to demonstrate whether the limitations and conditions of the Authorisation are complied with.

Exemption orders and exclusions made under RSA 93 are determined according to the definitions of radioactive material and radioactive waste. Exemptions include certain uses of geological specimens, sources for testing instruments, smoke detectors and substances of low activity (e.g. gases with a half life not exceeding 100 seconds). Currently the keeping and use of clocks and watches containing radioactive luminous material is exempt from registration and authorisation (although exemption does not apply to premises on which clocks or watches are manufactured or repaired by processes involving the use of luminous material). To comply with the revised BSS Directive it is proposed that the exclusion of clocks and watches is limited to circumstances where the total radioactivity on the premises at any one time does not exceed the relevant reporting levels in the Directive.

RSA93 is regulated in England and Wales by the Environment Agency (EA), in Scotland by the Scottish Environment Protection Agency (SEPA) and in Northern Ireland by the Industrial Pollution and Radiochemical Inspectorate (IPRI).

Ionising Radiations Regulations 1999 (IRR99)[20]

IRR99 imposes duties on employers to protect employees and other persons against ionising radiation arising from work with radioactive substances and other sources of ionising radiation. They also impose certain duties on employees. The Regulations are enforced by the Health and Safety Executive (HSE) and aim to ensure that exposure to ionising radiation arising from work activities, whether man-made or natural, is kept as low as reasonably practicable and does not exceed specified dose limits for individuals. Specific controls include the prohibition of specified practices without the authorisation of the HSE, hazard assessment to prevent and limit the consequences of identifiable radiation accidents, the imposition of dose limits (mSv per calendar year, depending on age and sex) of ionising radiation which employees and other persons may receive and the preparation of contingency plans for 'reasonably foreseeable' radiation accidents.

The Radioactive Material (Road Transport) Regulations 2002 (as amended)

The *Radioactive Material (Road Transport) Regulations 2002* (as amended) regulates all road transport of radioactive material, including radioactive waste, and is based on the International Atomic Energy Agency's (IAEA) Regulations for the Safe Transport of Radioactive Materials 1996. The Regulations specify the requirements that must be fulfilled before the shipment of radioactive material, including the issuing of approval certificates, the types of packaging to be used, the mode of transport and the preparation of emergency arrangements. RAMRoad 2002 is regulated by the Department for Transport.

Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR)

REPPIR provides protection to members of the public from emergencies that might arise from work with ionising radiations. A radiation emergency is defined as an accident or event in which a member of the public receives an effective dose greater than 5 mSv within a period of 1 year. Companies and organisations that hold unsealed radioactive materials must carry out an assessment to decide whether these Regulations apply. REPPIR places legal duties on hospitals, universities, rail transport carriers, local authorities and employers of people who intervene in a radiation emergency. REPPIR is regulated by the Health and Safety Executive.

Hazardous Waste Regulations

As stated above, production and disposal of radioactive waste in the UK is covered by the Radioactive Substances Act 1993. However, when radioactive waste consignments are being transferred from a site, under the conditions of an EA Authorisation, other hazardous properties (e.g. chemical toxicity) may cause the

[20] In Northern Ireland Ionising Radiations Regulations (Northern Ireland) 2000 apply.

Hazardous Waste (England and Wales) Regulations 2005 (as discussed above) to apply.

The nuclear industry is one of the most heavily regulated industries. It is reasonable to expect, therefore, that the production, use and disposal of radioactive NMs will be encompassed by the existing legislation and will be similarly controlled. For example, radiation exposure limits will still be relevant whether the dose comes from a nanometre-thick layer of fissile material or from a solid object of the same substance. Where potential problems may arise is in the containment of NMs which, due to their small size, have the potential to disperse far more widely than standard radioactive substances. In addition, whilst the health risks of radioactive substances are well documented, there is little or no information on the risks posed by radioactive NMs, which may have the ability to penetrate cell membranes and cause greater damage to cells due to their proximity to the DNA.

5.5.5 Waste Incineration

Directive 2000/76/EC on waste incineration was adopted and entered into force in December 2000. The Waste Incineration Directive covers the incineration of both hazardous and non-hazardous waste, requiring strict emission limits, based on best available techniques, as well as compliance with the IPPC Directive. Limit values have been set for, *inter alia*, heavy metals, and for discharges into water and leachate from residues. Operators of incineration plants will require a permit from the competent authority and monitoring requirements are specified.

The Directive is implemented through the *Waste Incineration (England and Wales) Regulations 2002*, and similar legislation in Scotland and Northern Ireland. The Regulations largely amend the *Pollution Prevention and Control (England and Wales) Regulations 2000* to incorporate the requirements of the Directive. In this regard, emissions from incinerators are managed in the same way as for other industrial activities, as discussed in Section 5.2.1.

5.5.6 Landfill

Directive 1999/31/EC on the landfill of waste (as amended) aims to reduce the amount of waste landfilled, to promote recycling and recovery, and to establish high standards of landfill practice across the EU. Three types of landfill sites are defined by the Directive – hazardous waste, non-hazardous waste and inert waste, and all sites must be licensed. All waste will need to be pre-treated prior to landfilling, unless this would have no environmental benefit or is not feasible.

The Directive was adopted in April 1999 and is implemented through the *Landfill (England and Wales) Regulations 2002*, and similar legislation in Scotland and Northern Ireland. The *Pollution Prevention and Control (England and Wales) Regulations 2000* (and similar) also apply and, in this regard, emissions from landfill sites are managed in the same way as for other industrial activities, as discussed in Section 5.2.1.

5.5.7 Waste Electrical and Electronic Equipment (WEEE) Directive

The purpose of *Directive 2002/96/EC on waste electrical and electronic equipment* (WEEE) is, as a first priority, the prevention of WEEE, and in addition, the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all operators involved in the lifecycle of electrical and electronic equipment, e.g. producers, distributors and consumers and in particular those operators directly involved in the treatment of waste electrical and electronic equipment.

This Directive applies to electrical and electronic equipment falling under the categories shown in Table 4.3.

Box 4.3: Electrical and Electronic Equipment Covered by the WEEE Directive	
Large household appliances Small household appliances IT and telecommunications equipment Consumer equipment Lighting equipment Electrical and electronic tools (with the exception of large-scale stationary industrial tools)	Toys, leisure and sports equipment Medical devices (with the exception of all implanted and infected products) Monitoring and control instruments Automatic dispensers

As a minimum the following substances, preparations and components have to be removed from any separately collected WEEE and treated as specified in the Directive:

- polychlorinated biphenyls(PCB) containing capacitors in accordance with Council Directive 96/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT);
- mercury containing components, such as switches or back lighting lamps,
- batteries,
- printed circuit boards of mobile phones generally, and of other devices if the surface of the printed circuit board is greater than 10 square centimetres;
- toner cartridges, liquid and pasty, as well as colour toner;
- plastic containing brominated flame retardants;
- asbestos waste and components which contain asbestos;
- cathode ray tubes;
- chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC) or hydrofluorocarbons (HFC), hydrocarbons (HC);
- gas discharge lamps;
- liquid crystal displays (together with their casing where appropriate) of a surface greater than 100 square centimetres and all those back-lighted with gas discharge lamps;
- external electric cables;
- components containing refractory ceramic fibres as described in Commission Directive 97/69/EC adapting to technical progress Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances;
- components containing radioactive substances with the exception of components that are below the exemption thresholds set in Article 3 of and Annex I to Council Directive 96/29/Euratom laying down basic safety standards for the protection of

the health of workers and the general public against the dangers arising from ionising radiation; and

- electrolyte capacitors containing substances of concern (height >25mm, diameter >25mm or proportionately similar volume).

This legislation also requires that Member States should make provisions for producers to provide reuse and treatment information to reuse centres and treatment and recycling facilities for each new type of electrical and electronic equipment put on the market, including the location of dangerous substances and preparations. Therefore, there is the potential for the identification of electrical waste products containing NMs. There is also the provision for other treatment technologies, possibly in respect of components containing NMs, to be introduced by regulatory committee procedure. None of the current specified treatment methods are intended to address the risks of NMs.

5.5.8 Batteries Directive

In order to achieve its environmental aims, *Directive 91/157/EEC on batteries and accumulators containing certain dangerous substances* (as amended) prohibits the placing on the market of certain batteries and accumulators containing lead, mercury or cadmium. It also promotes a high level of collection and recycling of waste batteries and accumulators and improved environmental performance of all operators involved in the lifecycle of batteries and accumulators, e.g. producers, distributors and end-users and, in particular, those operators directly involved in the treatment and recycling of waste batteries and accumulators.

In order to prevent waste batteries and accumulators from being discarded in such a way as to pollute the environment, and to avoid end-user confusion about the different waste management requirements for different batteries and accumulators, it is proposed that this Directive is amended so as to apply to all batteries and accumulators placed on the market. Treatment should meet the minimum requirements set out in Annex III, Part A, where this includes, as a minimum, the removal of all fluids and acids. This Directive is implemented in the UK by the *Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994* (as amended). Therefore, this legislation provides the potential for identifying electrical waste products containing NMs, and could already provide for the special treatment of components containing NMs. However, it is not clear whether the specified treatment methods would address the risks of NMs.

5.5.9 Packaging Waste

Directive 94/62/EC on Packaging and Packaging Waste (as amended) seeks to reduce the impact of packaging on the environment by introducing recovery and recycling targets for packaging waste and encouraging minimisation and reuse of packaging. This Directive is implemented in the UK by the *Producer Responsibility Obligations (Packaging Waste) Regulations 2005* and through the *Packaging (Essential Requirements) Regulations 2003 (as amended)*. In brief, the Essential Requirements Regulations require that:

- packaging must be the minimum subject to safety, hygiene and acceptance for the packed product and for the consumer;
- noxious or hazardous substances in packaging must be minimised in emissions, ash or leachate from incineration or landfill; and
- packaging must be recoverable through at least one of: material recycling, incineration with energy recovery, composting or it must be biodegradable.

It is not clear whether (or to what extent) NMs are present in the paper packaging end product or whether they are simply part of the paper production process. However, where NMs remain in the packaging (as is likely to be the case for plastic packaging) there is the potential for their emissions to be minimised under the relevant legislation, if such NMs should be found to be hazardous.

5.5.10 End of Life Vehicles

Directive 2000/53/EC on End-of-Life Vehicles is implemented in England and Wales by the *End-of-Life Vehicles Regulation 2003*. The Directive (and Regulation) lay down measures which aim, firstly, to prevent waste from vehicles, and also to encourage the reuse, recycling and other forms of recovery of end-of-life vehicles and their components so as to reduce the disposal of waste. The Directive also aims to improve the environmental performance of all the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-of-life vehicles. In particular it:

- restricts the use of certain heavy metals in the manufacture of new vehicles;
- requires that certain components are marked to aid recovery and recycling, and that information is provided to facilitate dismantling;
- requires that end-of-life vehicles can only be scrapped (‘treated’) by authorised facilities, which must meet specified environmental treatment standards.

In its current form, the Directive (and associated Regulation) would not specifically address the inclusion of NMs in vehicle components, although the specified environmental treatment standards may address (some) risks from NMs.

5.5.11 Applicability of Waste Legislation to NMs

The key issues in assessing the applicability of waste legislation to NMs relate to:

- the behaviour of NMs in waste, i.e. the implications of product decomposition; and
- classification and identification of waste containing NMs.

In relation to the first issue, current scientific knowledge on the impact of NMs in the environment is limited, and therefore it is not known how the breakdown of products containing NMs will impact on the environment. Secondly, in the absence of this knowledge, it may not be possible to classify waste containing NMs and identify the best disposal route for such waste. However, it is noted that, should the waste be incinerated or landfilled, emissions from waste disposal sites are regulated by the IPPC Directive and associated national regulations. Thus, the issues discussed in Section 5.2.1 relate to the applicability of waste disposal legislation.

5.6 Legislation Relating to Environmental Contamination and Remediation

5.6.1 Contaminated Land

Nanotechnologies are indicated to yield a variety of environmental benefits; more specifically, some of the applications are expected to help in environmental remediation of contaminated land. However, there is some concern over the intentional release of NMs in this way. Therefore, taking into account such concerns, release of NMs to land could result from two sources:

- the unintentional release of NMs into the terrestrial (land) environment; and
- the intentional release of nanotechnologies to land, for instance, as part of environmental remediation.

In the UK, the main contaminated land regime can be found in *Part IIA of the Environmental Protection Act 1990* (henceforth referred to as Part IIA); it provides a definition of contaminated land and how it is to be identified and dealt with.

Under Part IIA, contaminated land is defined as: "*any land which appears to the local authority in whose area it is situated to be in such a condition, by reason of substances in, on or under the land, that (a) significant harm is being caused or there is a significant possibility of such harm being caused; or (b) pollution of controlled waters is being, or is likely to be, caused*".

DETR Circular 02/2000 provides statutory guidance regarding this definition and the *Contaminated Land (England) Regulations 2000* deal with various procedural details such as the description of special sites, public registers, remediation notices and appeals (corresponding legislation can be found in Wales, Scotland and Northern Ireland).
According to the Regulations, the local authority should determine that land is 'contaminated land' on the basis that significant harm is being caused where:

- it has carried out an appropriate scientific and technical assessment of all the relevant and available evidence; and
- on the basis of that assessment, it is satisfied on the balance of probabilities that significant harm is being caused.

Owing to current scientific and technical limitations (and unknowns), it is unclear and/or unlikely that land where NMs have been released, on purpose or not, would satisfy the above definition for significant harm being caused (or even 'a significant possibility of such harm being caused') purely because of their nanoscale properties. Of course, if they were of a particular chemical substance in a quantity to satisfy this definition, then the normal rules relating to contaminated land would apply. It should be borne in mind that the Regulations require a clear 'pollutant linkage' to be established between the contaminant or pollutant and a target. It also recognises that harm to health and the environment arises not from the mere presence of contaminating substances in land, but from their movement along a 'pathway' to where they can cause damage to a 'target' - a linkage which could be difficult to establish for any substance, including a nanomaterial, even if it was believed to be hazardous.

Also, in practice, not all land affected by contamination will pose unacceptable risks to human health or the environment, and as such, the majority of such land may be expected to remain outside the scope of the Part IIA regime. In fact, the current lack of knowledge on the health and environmental impacts of NMs means that land where NMs are released is likely to fall outside the Part IIA regime, pending future developments in scientific knowledge.

Part IIA places specific duties on local authorities (i.e. the borough or district council) to inspect their areas to identify land falling within this definition and, where they do, to require its remediation in line with the 'suitable for use' approach. The Environment Agency is responsible for dealing with defined special sites (which are sites where the risks from contamination are perceived to be higher), for providing technical guidance (in relation to priority contaminants) and reporting on progress made.

In terms of remediation, the regulator is required to contact those they think are responsible for the contaminated land to discuss the case including liability and remediation requirements. If there is no satisfactory outcome, such as voluntary action, a remediation notice may be served to ensure the land is remediated. Part IIA provides detailed rules for assigning liabilities for contaminated land, based on the 'polluter pays' principle. If a remediation notice has to be served, or if the authority carries out the remediation in an emergency, the cost of remediation will normally lie with the person(s) who caused or knowingly permitted the contamination. However, if this person(s) cannot be identified, the owner or occupier of the land will be responsible (unless the problem is one of water pollution).

In general, there are few significant regulatory initiatives at the EU level which are intended to deal with contaminated land, particularly where it relates to historic contamination and/or retrospective liability. However, *Directive 2004/35/EC on*

environmental liability with regard to the prevention and remedying of environmental damage covers new land contamination. This is discussed further below. It is also understood that the European Commission is also working on ideas for a possible Soil Thematic Strategy which may address land contamination.

5.6.2 Directive 2004/35/EC on Environmental Liability

Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage covers all professional and commercial activities (but excludes nuclear installations) which cause "significant environmental damage". This is defined as damage to biodiversity protected under EC designated habitats and protected species whether in or outside a designated habitat, and Member States may extend the definition to include wildlife sites protected under national legislation. It also includes damage to land and soil where there is serious harm to health and water pollution leading to a decline in water quality as defined by the WFD. It would apply only to damage from incidents occurring after it comes into force in April 2007 and is based on the 'polluter pays' principle.

Under the Environmental Liability Directive, strict liability would apply in respect of damage to land, water and biodiversity from activities regulated by specified EU legislation and fault-based liability would apply in respect of biodiversity damage from any other activity. However, defences would exist for damage caused by an act of armed conflict, natural phenomenon, or from compliance with a permit, and emissions which at the time they were authorised were not considered to be harmful according to the best available scientific and technical knowledge. It is therefore possible that any damage from NMs could be considered to have been non-harmful according to the best available scientific and technical knowledge at the time.

6. SUMMARY OF REGULATORY GAPS AND CONCLUSIONS

6.1 Summary of Regulatory Gaps

6.1.1 Overview

This study has identified applications for NMs for a wide range of industry sectors and products. The study has been undertaken to understand which pieces of environmental legislation would apply to the manufacture of NMs and the associated applications, and whether the existing controls would allow for adequate management and control of risks posed by NMs.

In general, a number of regulatory gaps have been identified which are broadly applicable across the relevant legislation, as follows:

- gaps relating to the definition of nanotechnologies and NMs, for example:
    - where nanotechnologies represent a *new* manufacturing process for producing materials used in *existing* products and applications;
    - where NMs represent a *new* (or different form) of an *existing* substance used in existing products and applications; and
    - where both nanotechnologies and NMs present *new* risks, albeit to *existing* environmental compartments;

- gaps relating to the scope and objectives of relevant legislation, for example;
    - 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 Cosmetic Directive) includes NMs, the scope and objectives of the Cosmetics Directive does not include environmental risks;
    - 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;
    - 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;

- gaps relating to thresholds or exemptions under relevant legislation, for example:
    - horizontal legislation such as 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 legislation) on the basis of the low tonnage (in gram to kilogram quantities currently being used);
    - certain activities (excluding chemical production) operating under specific thresholds (production or disposal capacity) are excluded from the controls set

out under the IPPC Directive and associated Regulations. Thus 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); and

- gaps relating to the effects (or impacts) of nanotechnologies and NMs, for example:
  - 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 waste NMs should be considered and treated as normal waste, hazardous waste, waste for incineration and/or landfill or even as radioactive waste.
  - also, it is not clear what level of exposure is required to trigger an effect; thus while existing legislation such as Integrated Pollution Prevention and Control (IPPC) may cover the production and disposal processes of relevance, it relies upon knowledge of the polluting effects of emissions, which is generally lacking in relation to NMs. 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.

The relevance of these gaps to the lifecycle stages (identified in Figure 1.1) is discussed below.

6.1.2 Research and Development (R&D)

There are more than 50 organisations in the UK undertaking research and development on nanotechnologies and NMs. The key issue at the R&D phase is the potential for direct environmental emissions of NMs to air, land and water. The main piece of legislation for environmental emissions is the IPPC Directive and associated national Regulations. However, the current scope of the IPPC legislation does not apply to research and development, and therefore there are no regulatory controls on the emissions at this stage of the lifecycle.

A comparison can be made in this respect to the regulation of genetically modified organisms, and in particular *Directive 90/219/EEC on the contained use of genetically modified micro-organisms for the purposes of protecting human health and the environment* where the R&D phase is regulated to reduce environmental and human health impacts.

Following R&D, and before the move to commercial development, a key issue in the management of NMs arises; the question of whether NMs are new or existing substances. The importance of this issue relates to the requirement for industry to provide information on the substance, such as physicochemical, toxicological and ecotoxicological properties. 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). In the short term, there may be some limitations on the tests used, the results and the validation methods.

If on the other hand, NMs are considered as existing substances and are covered by CHIP/ESR, there is the risk that 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 to commercial production without full assessment of their properties and hazard potential.

Furthermore, both regulatory frameworks for new and existing substances 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. Under REACH there will be no difference in the data requirements for new and existing substances. However, the data requirements will vary according to the tonnage of substance produced, with the threshold for providing information, set at 1 tonne per year per manufacturer/supplier. If NMs are considered as new substances it is unlikely that they will be produced in sufficient quantities, at least in the short term, to trigger the data requirements of REACH. If the NMs are considered to be existing substances (and are therefore counted within larger quantities of production), there is concern that the nano form of the substance will not receive adequate consideration, compared to the bulk form, in assessing the risks of the substance.

SCENIHR (2005) notes that the safety evaluation of nanoparticles and nanostructures cannot rely solely on the toxicological profile of the equivalent bulk material. In carrying out the risk assessment for products of nanotechnology, new testing strategies will be required that will address the product specification, the intended use and identification of the potential exposure scenarios, both human and environmental.

The regulation of NMs based on tonnage as a threshold, as proposed for existing chemicals under REACH, needs to be considered further because there are many more nanoparticles to the tonne than is the case for larger particles, and their behaviour in the body and in the environment may be different (SCENIHR, 2005). Other materials exempted from the REACH Regulation such as intermediates and polymers may also pose regulatory gaps under REACH (there is currently no limit to the potential applications and uses of nanoparticles).

It is therefore possible that some, or all, NMs could be taken forward to commercial production without full consideration of the hazards and risks posed by the substances.

6.1.3 Commercial Production of NMs

In the UK, NM manufacturing activity is mostly in the area of metals and metal oxides, although it is possible that other NMs could be produced in the future. In general, the manufacture of chemicals is regulated by the IPPC Directive and associated national Regulations. However, there are a number of concerns relating to the application of the IPPC Directive and Regulations, as follows:

- physical manufacturing of NMs may not be covered within the definition of the chemicals industry, therefore emissions from such activities may not be regulated;
- assuming that the process is covered, emissions of NMs will only be controlled if they fall within the Directive's definition of 'pollution' (i.e. harmful to human health or the quality of the environment). If they are considered existing substances they may be controlled by existing ELVs (for example, those for metals and their compounds) however, these ELVs will be based on the environmental risk arising from the existing substance. If NMs are considered to be new substances they would not require monitoring and limiting under IPPC until such time that evidence exists on their potential (or otherwise) to cause human harm and/or affect environmental quality;
- the term 'significant quantities' may exclude consideration of NM emissions, unless the ELV was assessed in relation to the environmental significance of the NM itself; and
- scientific understanding of the effects of NMs and the available technology to monitor emissions is limited, and thus it is not possible to set an acceptable level of emissions (ELV).

It is therefore possible that, if the process of manufacturing NMs results in emissions of nanoparticles, these could be emitted into the environment, and the potential for the existing legislation to control these emissions is currently limited.

6.1.4 Formulation of NMs into Products

Commercially produced NMs may be used in a range of applications, as discussed in Sections 2 and 4. Legislation tends to define rather specifically the products, sectors or applications which they intend to address; for vertical legislation in particular, such definitions, by nature, tend to encompass the products or sectors where nanotechnologies are applied. However, the relevance of the legislation in addressing the environmental risks from nanotechnologies is often limited (as seen in Section 4). In practice, most vertical (or sector-specific) legislation are intended primarily for market harmonisation and ensuring the safety of consumers; environmental considerations are often complementary to the human health aspects or included as a new aspect in revisions of the legislation. Legislation governing products can be divided into three categories:

- legislation requiring an approvals process for some or all ingredients;
- legislation prohibiting or limiting use of specific substances; and
- legislation with a general health or environmental safety requirement.

Products with Approval Processes

Product legislation requiring an environmental and/or human health risk assessment of the product/active ingredients exists for six current uses of NMs. These products are:

- biocides and plant protection products;
- construction materials in contact with drinking water;
- food additives;
- materials in contact with food;
- medicines and (human) medical devices; and
- cosmetics (for some ingredients).

Only the first of these directly considers environmental risk. Therefore, whilst substances used in the other products undergo a human health risk assessment, this may not adequately address the risks posed by the substances to the environment.

Products with Prohibited or Limited Substances

Regulations for electrical equipment, batteries, detergents and motor fuel prohibit or limit the use of specific substances in products to protect the environment. In their existing form, such regulations are based on current knowledge of specific hazardous substances and would not address the risks posed by NMs. Whilst, in theory, it may be possible to amend such legislation to include NMs (if they were found to be hazardous), these Regulations stem from European Directives and would need to be negotiated at the EU level.

Products with a General Safety Requirement

All goods that are (or could be) placed on the market, or supplied, or made available (including in the course of providing a service) to consumers for their private use are covered by the General Product Safety Directive (GPSD) and the General Product Safety Regulations 2005. The GPSD provides a generic definition of a 'safe' product and obliges producers to place only safe products on the market. However, in these terms, safety relates to human health rather than the environment.

Whilst construction products also have a general safety requirement in relation to human health, it is also of note that the Construction Products Directive requires that construction work should not result in the presence of dangerous particles in the air. The applicability of this requirement to NMs could be open to interpretation, based on the findings of scientific research.

6.1.5 Industrial and Consumer Use

Fungicidal paint is the only product containing NMs for which legislation exists to control the use of the product. Other products can be used either by industry or by private consumers. Industrial use of products containing NMs is largely covered by

the IPPC Directive and associated national Regulations, but, as previously discussed, a number of issues exist in relation to IPPC and NMs.

However, where sectors are not covered by IPPC, it is necessary for commercial premises to obtain a consent to discharge water to the public sewerage system. This consent relates to the nature of the effluent, and a number of substances are prohibited or limited in discharges. However, the lists of controlled substances are based on existing knowledge of environmental and health effects and, as such, are unlikely to include NMs. The exception to this is the inclusion of some metals, if NMs are considered to be existing substances. However, the ability to monitor and control emissions of NMs is limited.

Similarly, consumer use of medicinal and cosmetic products is likely to result in discharges to the public sewerage system. The ability to detect and remove nanoparticles at this stage is also limited. The existing legislation specifies treatment requirements and quality objectives which are unlikely to capture NMs.

6.1.6 Waste Treatment

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 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.

6.1.7 Environmental Emissions, Contamination and Remediation

As discussed in Section 5, nanotechnologies could enter the environment either intentionally or unintentionally. The relevant legislation would thus be assessed on its ability to either control exposure (or risk) prior to or after entry into the environment.

For industrial sources, it is currently unclear and/or unlikely that within the IPPC regulatory framework:

- capacity thresholds for many IPPC activities may be set at levels which would exclude processes manufacturing, using or disposing NMs from control;
- existing monitoring techniques for NMs in industrial emissions are relevant, effective and available; and
- an acceptable level of emissions from NMs can be determined, thus making it very difficult to set ELVs.

These considerably limit the effectiveness of IPPC in addressing 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. However, 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 (PM_{10}).

6.2 Conclusions

In summary, in order for any legislation to be deemed effective in addressing the risks from nanotechnologies, the following should apply:

- the legislation should provide a definition which encompasses the unique properties of nanotechnologies and NMs;
- the scope and objectives of the legislation have to be directly relevant for the properties, uses and effects of nanotechnologies and NMs;
- the legislation should have clearly defined thresholds relating to the (potential) effects of nanotechnologies and NMs and the acceptable levels or impacts on the environment; and
- the legislation should allow for hazard identification, exposure assessment and risk calculation and characterisation of the risks of NMs and/or appropriate risk management prior to or after entry to the environment.

It is likely that the lack of understanding about the potential impacts of NMs on human and environmental health, coupled with limited validated methods for monitoring their levels in the environment, will significantly affect the ability of operators and regulators to act in this area. A substantial body of work will be required to reduce the uncertainties already clearly expressed in the Royal Society/Royal Academy of Engineering report published in 2004. There is a need for setting clear definitions for nanotechnologies and NMs, and categorising 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 a number of current and future legislation.

7. REFERENCES

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ANNEX 1:
RELEVANT LEGISLATION BY PRODUCT SECTOR

Table A1.1: Relevant Legislation for the Manufacture, Use and Disposal of Coatings and Pigments		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended)
	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (as amended)	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended)
	Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 98/8/EC concerning the placing of biocidal products on the market	Biocidal Products Regulations 2001 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use		Chemicals (Hazard Information And Packaging For Supply) Regulations 2002 (as amended)
	Directive 91/271/EEC concerning urban waste water treatment	Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended) Control of Pesticides Regulations 1986 (as amended)
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 98/8/EC concerning the placing of biocidal products on the market	Biocidal Products Regulations 2001(as amended)
	Directive 2001/95/EC on general product safety	General Product Safety Regulations 2005
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	
Disposal	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended)
	Directive 91/689/EEC on hazardous waste (as amended)	Hazardous Waste (England and Wales) Regulations 2005
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 1999/31/EC on the landfill of waste (as	Landfill (England And Wales) Regulations 2002

Table A1.1: Relevant Legislation for the Manufacture, Use and Disposal of Coatings and Pigments		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	amended) Directive 2000/76/EC on waste incineration Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	(as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.2: Relevant Legislation for the Manufacture, Use and Disposal of Construction Materials		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (as amended) Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Groundwater Regulations 1998 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (as amended) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Building Regulations 2000 (as amended) The Water Supply (Water Quality) Regulations 2000 (as amended)
Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)

Table A1.2: Relevant Legislation for the Manufacture, Use and Disposal of Construction Materials		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on the incineration of waste Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	The Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.3: Relevant Legislation for the Manufacture, Use and Disposal of Cosmetics		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Cosmetic Products (Safety) Regulations 2004 (as amended) Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Groundwater Regulations 1998 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use	Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products Directive 91/271/EEC concerning urban waste water treatment	Cosmetic Products (Safety) Regulations 2004 (as amended) Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended)
Disposal	Directive 75/442/EEC on waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.4: Relevant Legislation for the Manufacture, Use and Disposal of Detergents

Lifecycle Stage	EU Legislation	UK Legislation
Manufacture	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended)
	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (as amended)	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended)
	Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 98/8/EC concerning the placing of biocidal products on the market	Biocidal Products Regulations 2001 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD))	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	
	Regulation (EC) No 648/2004 on detergents	Detergents Regulations 2005
Use	Directive 91/271/EEC concerning urban waste water treatment	Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended)
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 98/8/EC concerning the placing of biocidal products on the market	Biocidal Products Regulations 2001(as amended)
	Directive 2001/95/EC on general product safety	General Product Safety Regulations 2005
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	
Disposal	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended)
	Directive 91/271/EEC concerning urban waste water treatment	Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended)
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003

Table A1.4: Relevant Legislation for the Manufacture, Use and Disposal of Detergents		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	(Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	

Table A1.5: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Electrical and Electronic Equipment		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (as amended) Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use	Directive 73/23/EEC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (as amended) Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility (as amended) General Product Safety Directive 2001/95/EC	Electrical Equipment (Safety) Regulations 1994 General Product Safety Regulations 2005
Recovery and Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 96/61/EC on Integrated Pollution	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Pollution Prevention and Control (England and

Table A1.5: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Electrical and Electronic Equipment		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Wales) Regulations 2000 (as amended) Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.6: Relevant Legislation for the Manufacture, Use and Disposal of Food Products (Omitting the Initial Production Stage)		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use	Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (as amended) Directive 94/36/EC on colours for use in foodstuffs (as amended)	The Food Safety Act 1990 Colours in Food Regulation 1995 (as amended)

Table A1.6: Relevant Legislation for the Manufacture, Use and Disposal of Food Products (Omitting the Initial Production Stage)		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	Directive 95/2/EC on food additives other than colours and sweeteners (as amended) Regulation EC 258/97 concerning novel foods and novel food ingredients Commission Regulation 466/2001 on setting maximum levels for certain contaminants in food Council Regulation 178/2002 on general principles of food law, including the requirement not to place unsafe food on the market	Miscellaneous Food Additives Regulations 1995 (as amended) Novel Foods and Novel Food Ingredients Regulations 1997 (as amended) The Contaminants in Food Regulations (England) 2005
Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/271/EEC concerning urban waste water treatment Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended) Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.7: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Fuel Cells and Batteries		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 91/157/EEC on Batteries and Accumulators Containing Certain Dangerous Substances Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998 Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended) Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003

Table A1.7: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Fuel Cells and Batteries		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	Framework Directive (WFD)) Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Water Act 2003
Use	Directive 73/23/EEC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (as amended) Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility (as amended) Directive 2001/95/EC on general product safety	Electrical Equipment (Safety) Regulations 1994 General Product Safety Regulations 2005
Recovery and Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002 End-of-Life Vehicles Regulations 2003

Table A1.8: Relevant Legislation for the Manufacture, Use and Disposal of Medical Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended)

Table A1.8: Relevant Legislation for the Manufacture, Use and Disposal of Medical Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
		Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2001/83/EC relating to medicinal products for human use (as amended) Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices Directive 93/42/EEC concerning Medical Devices Directive 98/79/EC on In Vitro Diagnostic Medical Devices Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003 Medicines Act 1968 The Medical Devices Regulations 2002 (as amended)
Use	Directive 2001/83/EC relating to medicinal products for human use (as amended) Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices Directive 93/42/EEC concerning Medical Devices Directive 98/79/EC on In Vitro Diagnostic Medical Devices	Medicines Act 1968 The Medical Devices Regulations 2002 (as amended)
Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.9: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Paper Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**

Table A1.9: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Paper Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use	Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food	Materials and Articles in Contact with Food Regulations (England) 2005
Recovery and Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 94/62/EC on Packaging and Packaging Waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Producer Responsibility Obligations (Packaging Waste) Regulations 2005 Packaging (Essential Requirements) Regulations 2003 (as amended) Pollution Prevention and Control (England and Wales) Regulations 2000 Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.10: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Paper Products

Lifecycle Stage	EU Legislation	UK Legislation
Manufacture	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended)
	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (as amended) Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulation 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 91/414/EC concerning the placing of plant protection products on the market (as amended)	Plant Protection Products Regulations 2005 (as amended) Control of Pesticides Regulations 1986 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Use		Chemicals (Hazard Information And Packaging For Supply) Regulations 2002 (as amended)
	Directive 91/271/EEC concerning urban waste water treatment	Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended)
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 91/414/EC concerning the placing of plant protection products on the market (as amended)	Part III of the Food and Environment Protection Act 1985 (FEPA) Plant Protection Products Regulations 2005 (as amended) Control of Pesticides Regulations 1986 (as amended)
	Directive 2001/95/EC on general product safety	General Product Safety Regulations 2005
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	

Table A1.10: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Paper Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Recovery and Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 1999/31/EC on the landfill of waste (as amended) Directive 2000/76/EC on waste incineration Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) Landfill (England And Wales) Regulations 2002 (as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.11: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Plastic Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended)
	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended)
	Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD))	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
	Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)	
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	
Use	Directive 2001/95/EC on general product safety	General Product Safety Regulations 2005
	Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food	Plastic Materials and Articles in Contact with Food Regulations 1998 (as amended)
	Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (as amended)	Materials and Articles in Contact with Food Regulations (England) 2005 (as amended)
Recovery and Disposal	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended)
	Directive 91/689/EEC on hazardous waste (as amended)	Hazardous Waste (England and Wales) Regulations 2005
	Directive 94/62/EC on Packaging and Packaging Waste (as amended)	Producer Responsibility Obligations (Packaging Waste) Regulations 2005 Packaging (Essential Requirements) Regulations 2003 (as amended)
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 1999/31/EC on the landfill of waste (as amended)	Landfill (England And Wales) Regulations 2002 (as amended)

Table A1.11: Relevant Legislation for the Manufacture, Use, Recovery and Disposal of Plastic Products		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
	Directive 2000/76/EC on waste incineration	Waste Incineration (England and Wales) Regulations 2002
	Directive 2000/53/EC on End-of-Life Vehicles	End-of-Life Vehicles Regulations 2003
	Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)	
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	

Table A1.12: Relevant Legislation for the Manufacture, Use and Disposal of Textiles		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended)
		Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended)
	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended)
		Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended)
		Water Industry Act 1991 (as amended)
		Water Resources Act 1991 (as amended)
	Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Control of Pollution (Applications, Appeals and Registers) Regulation 1996
		Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998
		Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD))	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003
		Water Act 2003
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	
Use		The Textile Products (Indications of Fibre Content) Regulations 1986 (as amended)
	Directive 2001/95/EC on general product safety	General Product Safety Regulations 2005
Disposal	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990
	Directive 91/689/EEC on hazardous waste (as amended)	Hazardous Waste (England and Wales) Regulations 2005
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 1999/31/EC on the landfill of waste (as	Landfill (England And Wales) Regulations 2002

	amended) Directive 2000/76/EC on waste incineration	(as amended) Waste Incineration (England and Wales) Regulations 2002

Table A1.13: Relevant Legislation for the Manufacture, Use and Disposal of Lubricants and Fuel Additives		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture	Directive 75/442/EEC on waste (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD)) Directive 96/82/EC on the control of major accident hazards involving dangerous substances Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended) Water Industry Act 1991 (as amended) Water Resources Act 1991 (as amended) Control of Pollution (Applications, Appeals and Registers) Regulations 1996 Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998 Groundwater Regulations 1998 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003 The Control of Major Accident Hazard Regulations 1999 (COMAH)
Use	Directive 98/70/EC relating to the quality of petrol and diesel fuels (as amended) Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 91/271/EEC concerning urban waste water treatment Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	The Motor Fuel (Composition and Content) Regulations 1999 (as amended) The Control of Pollution (Oil Storage) (England) Regulations 2001 Urban Waste Water Treatment (England and Wales) Regulations 1994 (as amended)

Table A1.13: Relevant Legislation for the Manufacture, Use and Disposal of Lubricants and Fuel Additives		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Disposal	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended)
	Directive 91/689/EEC on hazardous waste (as amended)	Hazardous Waste (England and Wales) Regulations 2005
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 1999/31/EC on the landfill of waste (as amended)	Landfill (England And Wales) Regulations 2002 (as amended)
	Directive 2000/76/EC on waste incineration	Waste Incineration (England and Wales) Regulations 2002
	Directive 2000/53/EC on End-of-Life Vehicles	End-of-Life Vehicles Regulations 2003
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	

Table A1.14: Relevant Legislation for the Manufacture, Use and Disposal of Weapons and Explosives		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Manufacture		Explosives Act 1875
	Directive 75/442/EEC on waste (as amended)	Environmental Protection Act 1990 (as amended)
	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community	Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended)
	Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances (as amended)	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (as amended)
		Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended)
		Water Industry Act 1991 (as amended)
		Water Resources Act 1991 (as amended)
		Control of Pollution (Applications, Appeals and Registers) Regulations 1996
		Surface Waters (Dangerous Substances) (Classification) Regulations 1997 and 1998
		Groundwater Regulations 1998
	Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended)	Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)
	Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD))	The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003
		Water Act 2003
	Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	
		Manufacture and Storage of Explosives Regulations 2005

Table A1.14: Relevant Legislation for the Manufacture, Use and Disposal of Weapons and Explosives		
Lifecycle Stage	**EU Legislation**	**UK Legislation**
Use	Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage Directive 2000/60/EC establishing a framework for community action in the field of water policy (Water Framework Directive (WFD))	Part IIA of the Environmental Protection Act 1990 (contaminated land) (as amended) Water Resources Act 1991 Groundwater Regulations 1998 The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Act 2003
Disposal	Directive 75/442/EEC on waste (as amended) Directive 91/689/EEC on hazardous waste (as amended) Directive 96/61/EC on Integrated Pollution Prevention and Control (as amended) Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	Environmental Protection Act 1990 (as amended) Hazardous Waste (England and Wales) Regulations 2005 Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)

ANNEX 2:
LEGISLATION REFERENCES

Short Form	Full Reference
UK Legislation – Acts	
Building Act	Building Act 1984 (1984 c55)
Clean Air Act	Clean Air Act 1993 (1993 c11)
Environmental Protection Act	Environmental Protection Act 1990 (1990 c43) (as amended)
Explosives Act	Explosives Act 1875 (1875 c17)
FEPA	Food and Environment Protection Act 1985 (1985 c48)
Food Safety Act	Food Safety Act 1990 (1990 c16)
Medicines Act	Medicines Act 1968 (1968 c67)
PPC Act	Pollution Prevention Control Act 1999 (1999 c24)
RSA 93	Radioactive Substances Act 1993 (1993 c12)
Water Act	Water Act 2003 (2003 c37)
Water Industry Act	Water Industry Act 1991 (1991 c56) (as amended)
Water Resources Act	Water Resources Act 1991 (1991 c57) (as amended)
UK Legislation - Statutory Instruments (Regulations) *Note that where regulations for England or England and Wales are identified, similar legislation is in place for the Devolved Administrations in Scotland and Northern Ireland, unless stated otherwise.*	
Air Quality Regulations	Air Quality (England) Regulations 2000 (SI 2000/928)
	Air Quality Limit Values Regulations 2003 (SI 2003/2121)
Batteries Regulations	Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (SI 1994/232) (as amended)
Biocide Regulations	Biocidal Products Regulations 2001 (SI 2001/880) (as amended)
Building Regulations	Building Regulations 2000 (SI 2000/2531) (as amended)
CHIP Regulations	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)
	Colours in Food Regulations 1995 (SI 1995/3124) (as amended)
	Contaminants in Food (England) Regulations 2005 (SI 2005/3251) (as amended)
COMAH Regulations	Control of Major Accident Hazards Regulations 1999 (SI 1999/743)
COPR	Control of Pesticides Regulations 1986 (SI 1986/1510) (as amended)
	Control of Pollution (Applications, Appeals and Registers) Regulation 1996 (SI 1996/2971)
	Control of Pollution (Oil Storage) (England) Regulations 2001 (SI 2001/2954)
Cosmetics Regulations	Cosmetic Products (Safety) Regulations 2004 (SI 2004/2152) (as amended)
Detergents Regulations	Detergents Regulations 2005 (SI 2005/2469)
	Electrical Equipment (Safety) Regulations 1994 (SI 1994/3260)
	End-of-Life Vehicles Regulations 2003 (SI 2003/2635)
	Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (SI 1991/472) (as amended)
General Product Safety Regulations	General Product Safety Regulations 2005 (SI 2005/1803)

Short Form	Full Reference
Groundwater Regulations	Groundwater Regulations 1998 (SI 1998/2746)
Hazardous Waste Regulations	Hazardous Waste (England and Wales) Regulations 2005 (SI 2005/894)
	Ionising Radiations Regulations 1999 (SI 1999/3232)
Landfill Regulations	Landfill (England And Wales) Regulations 2002 (SI 2002/1559) (as amended)
	List of Wastes (England) Regulations 2005 (SI 2005/895)
	Manufacture and Storage of Explosives Regulations 2005 (SI 2005/1082)
	Materials and Articles in Contact with Food Regulations (England) 2005 (SI 2005/898)
	Medical Devices Regulations 2002 (SI 2002/618) (as amended)
	Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (SI 1994/3144) (as amended)
	Miscellaneous Food Additives Regulations 1995 (SI 1995/3187) (as amended)
	Motor Fuel (Composition and Content) Regulations 1999 (SI 1999/3107) (as amended)
NONS Regulations	Notification of New Substances Regulations 1993 (SI 1993/3050)
	Novel Foods and Novel Food Ingredients Regulations 1997 (SI 1997/1335) (as amended)
	Packaging (Essential Requirements) Regulations 1998 (SI 1998/1165)
	Plastic Materials and Articles in Contact with Food Regulations 1998 (SI 1998/1376) (as amended)
PPC Regulations	Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000/1973) (as amended)
	Producer Responsibility Obligations (Packaging Waste) Regulations 1997 (SI 1997/648)
	Radioactive Material (Road Transport) Regulations 2002 (SI 2002/1093)
Special Waste Regulations	Special Waste Regulations 1996 (SI 1996/972)
Surface Waters Dangerous Substances Regulations	Surface Waters (Dangerous Substances) (Classification) Regulations 1989, 1992, 1997 and 1998 (SI 1989/226, SI 1992/337, SI 1997/2560 and SI 1998/389 respectively)
	Textile Products (Indications of Fibre Content) Regulations 1986 (SI 1986/26) (as amended)
	Trade Effluents (Prescribed Processes and Substances) Regulations 1989 (SI 1989/1156) (as amended)
Urban Waste Water Regulations	Urban Waste Water Treatment (England and Wales) Regulations 1994 (SI 1994/2841) (as amended)
Waste Incineration Regulations	Waste Incineration (England and Wales) Regulations 2002 (SI 2002/2980)
	Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 (SI 2003/3242)
	Water Supply (Water Quality) Regulations (SI 2000/3184) (as amended)
Community Legislation – Regulations	

Short Form	Full Reference
Contaminants in Food Regulation	Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs (OJ L077, 16/03/2001, p1) (as amended)
Detergents Regulation	Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L104, 8/4/2004, p1)
Existing Substances Regulation (ESR)	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)
Food Contact Regulation	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L338, 13/11/2004, p4)
Food Safety Regulation	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L031, 01/02/2002, p1) (as amended)
Novel Foods Regulation	Regulation EC 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L43, 14/2/1997, p1)
Community Legislation – Directives	
Air Quality Directive	Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management (OJ L296, 21/11/1996, p55)
Batteries Directive	Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances (OJ L78, 26/3/1991, p38)
Biocides Directive	Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L123, 24/4/1998, p1)
BSS Directive	Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L159, 29/6/1996, p1)
Construction Products Directive	Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (OJ L40, 11/2/1989, p12) (as amended)
Contained Use Directive	Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L117, 8/5/1990,p1)
Cosmetics Directive	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)
Dangerous Preparations Directive	Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L200, 30/7/1999, p1) (as amended)
Dangerous Substances Directive	Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196 16/8/1967, p1) (as amended)

Short Form	Full Reference
	Notable amendments include: Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC (OJ L154, 5/6/1992, p1) Commission Directive 97/69/EC of 5 December 1997 adapting to technical progress for the 23rd time Council Directive 67/548/EEC (OJ L343, 13/12/1997, p19)
Dangerous Substances Directive	Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (OJ L129, 18/5/1976, p23) (as amended)
Disposal of PCBs and PCTs Directive	Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L243, 24/9/1996, p31)
EMC Directive	Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L139, 23/5/1989, p19) (as amended)
ELV Directive	Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on End-of-Life Vehicles - Commission Statements (OJ L269, 21/10/2000, p34)
Environmental Liability Directive	Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L143, 30/4/2004, p56)
Food Additives Framework Directive	Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (OJ L040, 11/2/1989, p27) (as amended)
	European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs (OJ L237, 10/09/1994, p13) (as amended)
	European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ L061, 18/3/1995, p1) (as amended)
	Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance) (OJ L220, 15/8/2002, p18) (as amended)
Fuels Directive	Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ L350, 28/12/1998, p58) (as amended)
GPSD	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)
Hazardous Waste Directive	Council Directive 91/689/EEC of 12 December 1991 on hazardous waste (OJ L377, 31/12/1991, p20) (as amended)
IPPC Directive	Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L257, 10/10/1996, p26) (as amended)
Groundwater Directive	Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances (OJ L020, 26/1/1980, p43) (as amended)

Short Form	Full Reference
Landfill Directive	Council Directive 1999/31/EC on the landfill of waste (OJ L182, 16/7/1999, p1) (as amended)
Low Voltage Directive	Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ L077, 26/3/1973, p29) (as amended)
Marketing & Use Directive	Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ L262, 27/9/1976, p201) (as amended) *Notable amendments include:* Directive 2005/90/EC of the European Parliament and of the Council of 18 January 2006 amending, for the 29th time, Council Directive 76/769/EEC (substances classified as carcinogenic, mutagenic or toxic to reproduction - c/m/r) (OJ L33, 4/2/2006. p38)
Medicinal Products Directive	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use (OJ L311, 28/11/2001, p67) (as amended)
Medical Devices Directive	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L169, 12/7/1993, p1)
	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L189, 20/7/1990, p17)
	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L331, 7/12/1998, p1)
National Emission Ceilings Directive	Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants (OJ L309, 27/11/2001, p22)
Packaging Directive	European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L365, 31/12/1994, p10) (as amended)
RoHS Directive	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L037, 13/2/2003, p19)
Safety Data Sheets Directive.	Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (OJ L076, 22/3/1991, p35)
Seveso II Directive	Council Directive 96/82/EC of 9 December 1996 on the control of major accident hazards involving dangerous substances (OJ L010, 14/1/1997, p13) (as amended)
Urban Waste Water Directive	Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L135, 30/5/1991, p40)
Waste Directive	Council Directive 75/442/EEC of 15 July 1975 on waste (OJ L194, 25/7/1975, p39) (as amended)
Waste Incineration Directive	Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste (OJ L332, 28/12/2000, p91)
Water Framework	Directive 2000/60/EC of the European Parliament and of the Council of

Short Form	Full Reference
Directive	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)
WEEE Directive	Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) (OJ L037, 13/2/2003, p24)
Community Legislation – Other	
REACH	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)
	Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) 258/97 of the European Parliament and of the Council (OJ L253, 16/9/1997, p1)