An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials

A Report for the DTI

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1.0 EXECUTIVE SUMMARY

This report represents an analysis of the potential gaps in the regulation of the development, manufacture, supply, use and end of life of free engineered nanoparticles. Alongside the recognised benefits of nanotechnologies are prevailing uncertainties regarding health and environmental exposures and most reports have called for careful consideration of the marketing of free, engineered nanomaterials, pending further research in the face of such uncertainties. This should provide the base for regulatory evaluation in an open, inclusive and transparent manner.

In the report current and future foreseeable applications of nanomaterials are mapped against existing regulatory frameworks that might govern the lifecycle of these materials. These regulations serve a number of purposes including: controls on marketing; health and safety, consumer and environmental protection; and waste regulation. By subjecting such regulations to careful legal scrutiny of their capacity to fulfil basic risk governance functions the report draws out gaps in the regulatory provision.

Reviewing the types of legislation listed above, the Report finds potential for gaps where thresholds are set to govern whether materials or products fall within regulation. These thresholds might be set in accordance with concentrations of particular substances or via percentages or weight of such substances. Given that some nanomaterials have different properties to their non-nanomaterial counterparts, it is conceivable that these thresholds are inappropriately set for the inclusion in products of nanoparticles.

A similar problem arises where the regulation of substances coming to or placed upon the market depends upon their equivalence to substances already well regulated and understood. The ability of pre-market authorisation to identify potential risks associated with nanomaterials may depend on whether products containing nanoparticles are construed as being equivalent to authorised products already on the market. The judgement on questions of equivalence is problematic and may depend upon the producer or supplier in the first instance. This could lead to a lack of scrutiny of products that are apparently similar to existing products on the market but which contain nanomaterials with different properties.

In certain areas of regulation such as environmental protection, we may regulate processes or restrict the use or escape of prescribed substances. Here the problem is whether either the prescribed processes or substances are sufficiently exactly defined to prevent, restrict or control harm to the environmental due to the presence of nanomaterials either prior to or post entry into the environment. A number of the relevant regulations seem too narrow in scope and interpretation to ensure this.

In relation to the escape or emission of substances to the environment, the regulator needs to be able to monitor and sample the relevant media and will require technical capacity to undertake appropriate sampling of nanomaterials. Moreover, given current uncertainties in relation to the potential impacts of nanomaterials on human health and/or the environment, it may not be possible to assess the impacts of many nanomaterials. Such uncertainties relate both to the potential for adverse effects and to the level at which these effects might occur. This is a recurrent problem in our findings.

Often the regulation will govern the generation of further data as part of a system of risk governance. For example the classification of a substance as hazardous will require a supplier to provide information relating to the hazards of the substance supplied. If not classed as hazardous, no new data would be generated on the risks or hazards relating to the identified nanomaterial. Nanomaterials might then move through their lifecycle without any further assessment of their properties. Such classifications, in areas such as health and safety at work operate also as the trigger for effective risk management programmes. Limited or imprecise definitions in regulation concerning what should be subject to risk assessment may lead in turn to weak risk management.

This explanation into how the early identification of hazards may affect the substance throughout its lifecycle is a significant part of the report. A regulatory framework should ensure that any substance that may cause harm to human health and/or the environment is effectively regulated at whatever phase in the lifecycle. Yet we find that decisions made at an early stage may influence the later lifecycle of a product. Thus materials not thought harmful to humans within a particular product might have the capacity for deleterious effects bulked up in the domestic waste stream in a landfill.

An integrated approach is needed, especially since current regulation was never designed with nanotechnology in mind and is inevitably piecemeal, being contained in various statutory provisions spread over different areas of regulatory activity. Nonetheless in the interim the existing framework can be adapted generally by ensuring that where appropriate the regulation extends to nanomaterials. In this context the work of international standard setting bodies is crucial in resolving issues of definition and taxonomy, allowing effective standard setting in relation to nanoparticles and opening up the prospects of a uniform global response to the marketing and circulation of nanomaterials.

Many of the gaps identified in this report arise due to a lack of existing data on the potential effects of nanomaterials on human health and the environment. If nothing else this report demonstrates how effective regulation will depend on moving to a position of greater certainty on such questions. Even where risk assessment procedures established under existing regulatory frameworks appear robust, their ability to accurately characterise and assess potential risks associated with nanotechnologies is limited by fundamental uncertainties about the impact of exposure to free, engineered nanomaterials. Better research and better regulation ought to move hand in hand.

2.0 INTRODUCTION – A BRIEF SUMMARY OF THE CONTEXT

2.1 Nanotechnologies and Nanomaterials – Issues and Perceptions

Nanotechnologies and nanoscale materials bring new and innovative opportunities, but at the same time some of them have the potential to pose risks to human health and the environment. There is a wide range of regulation governing new materials and products coming on to the market and throughout their lifecycle in order to protect against these types of risk. However, since none of these regulations specifically address the presence of nanomaterials, this paper examines whether the existing regulatory regime is sufficiently broad to capture any potential risks arising from the use of free, engineered nanoparticles.

This analysis is centred upon existing frameworks of regulation. It attempts to conduct a comprehensive review of existing (and foreseeable future) regulations building on recent studies carried out by and for a number of UK Government departments and publicly sponsored bodies (as referenced in the literature review in Annex 1). Most of this work has flagged up the potential health and environmental risks of free, engineered nanoscale materials as an early topic for consideration. In response, this study looks to locate gaps in the framework of regulation such that nanoscale materials evade any scrutiny of risk as goods reach and remain on the market. This report is focussed primarily on an assessment of the potential risks associated with the development, manufacture, supply and use of free, engineered nanoparticles. Whilst it is acknowledged that fixed nanoparticles might also pose a threat over their lifecycle, evidence (Chaudhry, Q., Boxall, A., Aitken, R. and Hull, M., 2005)[1] suggests that free nanoparticles[2] have the potential to present a greater risk to human health and the environment. Because little is currently understood about the nature of these risks, the report presents findings from an exhaustive review of feasibly relevant regulation in order to isolate gaps in regulatory control. It is hoped that this work can lead to recommendations for regulatory development.

The term ‘nanotechnology’ is used to describe a wide range of enabling technologies (ESRC, 2003). It is widely accepted that ‘nanotechnology’ refers to the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanoscale (BSI, 2005). It has been described as ‘technologies of the tiny’ (EU, 2004), involving the manufacture of materials with one or more dimension of the order of 100nm or less.

The development of nanotechnologies redefines advances in manufacturing processes in a wide range of sectors, including consumer products,

[1] A scoping study into the manufacture and use of nanomaterials in the UK, Central Science Laboratory, Sand Hutton, York; all references included in the text refer to sources fully documented in the literature review in Annex 1.
[2] Due to their capacity to bioaccumulate and disperse.

pharmaceuticals, construction, aerospace, energy, defence and transport. A table of current applications is included in section 4 of the report (Table 1). Nanotechnology is expected to make significant contributions to a number of fields (ICON, 2006) and is described as one of the most powerful transformative technologies in human history (FoE, 2006). Yet its recognised benefits are accompanied by concerns over the potential human and environmental exposure to nanoparticles. Current scientific knowledge about the impact of nanomaterials precludes a full assessment of potential risks to human health and the environment. Given the scientific uncertainty associated with nanomaterials, nanotechnology is seen to present new challenges for regulation (Stirling, 2000).

2.2 Regulation of New Technologies

There are genuine health and safety concerns in relation to human exposure to nanomaterials. The extent to which fears over safety are well grounded is itself a matter of uncertainty since the potential risks posed by nanomaterials are not fully understood. In response to this information deficit, a number of regulatory reviews have been conducted. They attempt to ascertain the extent to which this uncertainty limits the efficacy of current regulation (Defra, 2006; FSA, 2006; HSE, 2006**;** RS/RAEng, 2004). Broadly they conclude that, given the paucity of current information about the likely impact of nanotechnology, the potential risks from free, engineered nanoscale materials need to be encompassed within regulatory structures at this stage, and that an analysis of those structures is a necessary starting point.

Lessons from biotechnology, particularly in relation to genetically modified (GM) products, show that an early evaluation of possible adverse effects alongside the balancing of potential risks and benefits is crucial to the sustainable and successful development of 'new technologies'. By the same token, it is imperative that any risk analysis is conducted in an open, inclusive and transparent manner, promoting the clear characterisation of hazards, stakeholder communication, and the implementation of measures consistent with the Government's commitment to 'Better Regulation' (BRTF, 2003). It is essential that structures of risk governance are underpinned by public trust so as to enable the successful development and application of innovative technologies.

3.0 METHODOLOGY

Initial work on this project was directed at producing an exhaustive literature review of academic, policy, and 'grey' literature relating to questions that might affect the regulation of nanomaterials. This was crucial not only to shape the main work on identifying current applications of these materials and the likely regulatory instruments to be surveyed but also to avoid replication of existing work. This literature review is appended to this report (Annex 1) and that part of the review touching upon the framework of regulation is to some degree replicated in the main body of this report.

The next stage of the work was to use existing research to identify current nanotechnology applications and materials.[3] In one sense, to isolate sectors and applications in this way may seem pointless, as over time nanomaterials may be prevalent in a huge range of products. On the other hand to review current usage does help identify potential risk by reviewing how these particular sectors or products are currently regulated thereby informing our later gap analysis.

With Table 1 in mind, a list of existing regulatory provisions applying to current and future uses of nanomaterials was produced (Table 2). The focus of Table 2 was limited to provisions at EU and UK levels. A worldwide survey of regulations within other jurisdictions that might capture nanomaterials was not feasible given the duration of this project. Where international agreements impose obligations relating to (say) hazardous materials that might impact on nanomaterials, these are generally reflected in EU legislation (ordinarily by Directives) and these are then transposed into UK law. In fact, the problem with international treaties (e.g. on transhipment of hazardous wastes) is that these do not single out nanomaterials. International standard setting may prove to be vital in due course if disputes as to the free flow of goods (such as that which arose in relation to GM products) are to be avoided. (WTO Dispute Panel Report on Complaints by the US, etc., 2006)

The Table of Current Applications of Nanomaterials (Table 1) and the three areas of potential impact (consumer protection; health and safety; environmental protection) listed in the Table of Current Regulations (Table 2) were the subject of specialist consultation using both telephone interviews with policy makers and discussions with a focus group drawn from experts within our own University setting in Cardiff.

The framework of EU/UK regulation considered in this study is found in the Regulatory Analysis (Templates) in Annex 5. This forms the core of our work. Annex 5 contains in-depth analysis of each of the relevant regulations identified in Table 2. Following this analysis, the assessed regulations were grouped under the following headings in order to produce the overview Regulatory Gaps Table in Annex 4B:

- Regulation of production and introduction to the market;
- Health and safety legislation;
- Product composition, quality and safety provisions;
- Consumer protection measures;
- Environmental controls;
- Waste regulation.

The Regulatory Gaps Table in Annex 4A draws out the main themes identified in Annex 5, and considers the scope of the controls in each regulatory instrument included. It assesses the ability of each of the legislative provisions to handle potential risks by examining how those risks are characterised, assessed and managed. The Regulatory Gaps Table in Annex 4A also

[3] The Table of Current Applications of Nanomaterials (Table 1) can be found in section 4.0 below.

includes a final 'Information Base' column, reflecting concerns as to the lack of complete information about the potential for risk posed by free, engineered nanoparticles.

This approach allows a consideration of the adequacy and practical limitations of current controls applying to nanomaterials. The Regulatory Gap Analysis Table (Annex 4A) identifies a series of potential gaps in the existing framework of regulation. These regulatory gaps are considered in detail below. Broadly speaking, gaps tend to arise as a result of legislative thresholds and definitions more designed to capture risks associated with bulk materials.

Where appropriate, the individual Regulatory Analysis (the Templates set out in Annex 5) considers future applications of nanotechnologies and likely regulatory developments in relation to all legislation studied. Because the Regulatory Analysis is complex, lengthy and consists of a detailed legal interpretation of a large number of regulations from differing fields, it has not been included in the main body of this report. Instead, key findings are highlighted below. Annex 5 can be used as a reference resource should readers wish to examine in greater detail the regulatory gaps cited in the report.

Having conducted a detailed regulatory gap analysis, an attempt has been made to map these in a manner that allows recognition of similarities and differences in the types of gaps in different policy areas. This assists in determining whether the gap is specific to nanomaterials or whether it is a more general regulatory shortfall. The regulatory gaps identified are mapped using a 'lifecycle' approach to nanotechnologies. Annex 3 and the Lifecycle Table (Table 3B) identify the following stages of a product's lifecycle which provide a framework for further analysis:

- Research and development, production and introduction to the market;
- Market use and circulation with an emphasis on human health and safety, consumer protection, and environmental protection;
- Producer responsibility for goods and issues of waste disposal.

4.0 NANOTECHNOLOGIES – CURRENT APPLICATIONS

4.1 Table 1: Current Applications of Nanomaterials

Sector	*Current applications*[4]	*Examples*
Aerospace, defence and transport	Automotive and aviation	▪ Advanced materials and coatings - Low friction and wear resistant coatings - Advanced tyres - Cooling- and ferro-fluids ▪ Energy generation - Hydrogen storage fuel cell - Catalytic converters ▪ Sensors - Exhaust emission detectors
	Aerospace and defence	▪ Electronics and IT - Advanced simulation ▪ Advanced materials and coatings - High strength lightweight laminates - Fire retardant materials - Light alloys ▪ Energy generation - Liquid jet and rocket fuel ▪ Explosives/weapons technology
Consumer products	Personal care	▪ Skincare products - Cosmetics including sunscreens ▪ Dental products - Composite filling materials
	Household	▪ Cleaning products - Detergents - Self-cleaning antiseptic/antifung-al surfaces ▪ Appliances - Air conditioning units - Refrigerators ▪ Home furnishings - Fabrics

[4] Covers early stage R&D through to products containing nanoparticles currently on the market.

	Food	▪ Food packaging and storage - Antimicrobial materials - Dirt repellent coatings ▪ Food processing - Microsieves ▪ Food engineering - Nutrient nanocapsules ▪ Food safety - Contaminant sensors - Tagging and monitoring - 'Smart' packaging
	Other commodities	▪ Clothing ▪ Sports equipment ▪ Toys
Environment and agriculture	Pollution prevention and remediation	▪ Biodegradable materials ▪ Sensors - Silicon nanowires ▪ Filtration media - Flexible membranes ▪ Catalysis - Photocatalysts
	Plant protection products	▪ Fertilisers ▪ Pesticides
Pharmaceuticals, biotechnology and medical devices	Antimicrobial materials	▪ Clinical textiles - Wound dressings ▪ Soaps
	Tissue regeneration, growth and repair	▪ Orthopaedic and dental implants - Tissue engineering - Bone growth promoters and replacement materials - Implant coatings ▪ Endovascular implants ▪ Active implantable devices - Pacemakers and hearing aids - Microchip-based drug delivery
	Medical imaging and diagnostic agents	▪ Luminescent dyes ▪ 'Lab-on-a-Chip' systems ▪ Biosensors ▪ Magnetic resonance imaging ▪ DNA arrays
	Therapeutics and drug delivery	▪ Nanotools - Surgical blades - Suture needles - Optical tweezers ▪ Targeted drug delivery ▪ Gene therapy
Energy generation and storage	Cells and batteries	▪ Solar cells ▪ Solid oxide fuel cells ▪ High performance battery materials

	Fuel additives	▪ Catalysts
Electronic and magnetic	Electronics and IT	▪ Computing - Computer hardware - Quantum computing ▪ Displays - Flat panel displays - Light Emitting Diodes (LEDs) ▪ Lasers ▪ Circuits
	Optics	▪ Lasers
	Magnetic devices	▪ Magnetic tapes ▪ Magneto-resistive devices ▪ Ferrofluids
Advanced materials	Textiles	▪ Protected fabrics - Stain resistant fabric - Water repellent fabric - Anti-odour fabric ▪ Anti-counterfeit fibres
	Coatings and pigments	▪ Paints ▪ Conductive inks ▪ Stain/water resistant coatings ▪ UV absorbers
	Printing materials	▪ Inks ▪ Absorbents ▪ Colloidal silica
	Conductors, semiconductors and insulators	▪ Conducting paste ▪ Heat dissipaters
Industrial and construction materials	Physically enhanced polymers/composites	▪ Ceramics ▪ Cement ▪ Plastics ▪ Rubber ▪ Glass ▪ Glues
	Machinery	▪ Cutting tool bits ▪ Robotics

4.2 Opinions and Views – Expert Witnesses

4.2.1 Questions Asked of Expert Witnesses

Interviews were conducted with experts and policy makers involved in nanotechnology. To assess key observations and to direct the interviews a structured questionnaire was designed (see Annex 2). Two groups of interviews were conducted, one with a select group by telephone and the other via a focus group held at Cardiff University.

The aim of the interviews was to gain expert perspectives on current and future applications of nanotechnology, thereby ensuring that the resulting analysis accurately followed from this initial identification. A secondary aim was to gain an overview of what those involved in this sector considered were

the perceived problems or gaps relating to the regulation of nanotechnology. A third area of questioning was the status of the current evidence base.

4.2.2 Summary of Responses

The specific issues identified during the telephone interviews are as follows:

(a) In general the information contained in Table 1 was satisfactory but also could include the use of nanomaterials in sport goods and nanosilver impregnated socks for first aid materials. Due to the wide applicability of nanomaterial it could almost be used in any process, application or product.

(b) Gaps in producer responsibility regulations were a particular concern as they do not extend to the formulation, manufacture, supply and use of nanomaterials. Further issues were raised over the regulation of the nanomaterials at the research and development stages with potential gaps likely.

(c) Current levels of information are problematic, whilst a lot is known about the toxicity of regulated non-nanomaterials, so little is known about nanomaterials.

(d) Due to the scale of nanomaterials, meeting defined concentration thresholds based on the risks or hazards of substances at the macro level might also be an issue. Current acceptable concentration thresholds for example in regulations dealing with prescribed substances may need to be readdressed as they fail to address the risks that may arise due to the nanoscale.

(e) Potential solutions lay with improved definitions to capture nanomateials and in setting international standards for definitions and terminology.

5.0 NANOTECHNOLOGIES AND MATERIALS – CURRENT REGULATORY PROVISIONS

Table 2: Current Regulations[5]

Legislation	Consumer Protection	Health & Safety	Environmental Protection
Notification of New Substances Regulations 1993		X	
Registration, Evaluation and Authorisation of Chemicals (proposed)		X	
Biocidal Products Regulations 2001 (as amended)	X		
Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (as amended)	X	X	
Control of Major Accident Hazard Regulations 1999 (as amended)		X	X
Control of Substances Hazardous to Health Regulations 2002 (as amended)		X	
Dangerous Substances & Explosions Atmosphere Regulations 2002		X	
Health & Safety at Work Act 1974		X	
Management of Health & Safety at Work Regulations		X	
Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003			X
Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended)	X		X
Medical Devices Regulations 2002 (as amended)	X		X
Medicines Act 1968	X		X
Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (as amended)	X		
Motor Fuel (Composition and Content) Regulations 1999 (as amended)	X		
End-of-Life Vehicles Regulations 2003			X
Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2005			X
Directive 2002/96/EC on Waste Electrical and Electronic Equipment			X
Packaging (Essential Requirements) Regulations 2003			X
Producer Responsibility Obligations (Packaging Waste) Regulations 2005			X
Veterinary Medicines Regulations 2005	X		
Building Regulations 2000 (as amended)	X		
Textile Products (Indications of Fibre Content) Regulations 1986 (as amended)	X		
Electrical Equipment (Safety) Regulations 1994	X		
Control of Pesticides Regulations 1986 (as amended)	X	X	
Fertilisers Regulations 1991 (as amended	X		
Plant Protection Products Regulations 2005 (as amended)	X		
Detergents Regulations 2005	X		

[5] Order of regulations matches the assignment of regulations to group in Annex 4B and the order of analysis in Annex 5.

Cosmetic Products (Safety) Regulations 2004 (as amended)	X		
General Product Safety Regulations 2005	X		
Additives Directive 89/107/EEC (as amended)	X		
Articles in Contact with Food Regulations 1987 (as amended	X		
Colours in Food Regulations 1995 (as amended	X		
Contaminants in Food (England) Regulations 2005	X		
Food Safety Act 1990 (as amended)	X		
Materials and Articles in Contact with Food (England) Regulations 2005	X		
Miscellaneous Food Additives Regulations 1995 (as amended	X		
Novel Foods and Novel Food Ingredients Regulations 1997 (as amended	X		
Plastic Materials and Articles in Contact with Food Regulations 1998 (as amended)	X		
Regulation (EC) No.178/2002 on General Principles of Food Law	X		
Environmental Protection Act 1990 (as amended)			X
Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended)			X
Control of Pollution (Oil Storage) (England) Regulations 2001			X
Control of Pollution (Silage, Slurry and Agricultural Fuel Oil) Regulations 1991 (as amended)			X
Environmental Protection (Prescribed Processes and Substances) Regulations 1991			X
Air Quality (England) Regulations 2000			X
Clean Air Act 1993			X
Air Quality Limit Values Regulations 2003			X
Groundwater Regulations 1998			X
Surface Waters (Dangerous Substances) (Classification) Regulations 1997			X
Surface Waters (Dangerous Substances) (Classification) Regulations 1998			X
Trade Effluents (Prescribed Processed and Substances) Regulations 1989 (as amended)			X
Urban Waste Water Treatment (England and Wales) Regulations 1994			X
Waste Management Licensing Regulations 1994			X
Water Act 2003			X
Water Environment (Water Framework Directive) (England and Wales) Regulations 2003			X
Water Industry Act 1991		X	X
Water Resources Act 1991		X	X
Hazardous Waste (England and Wales) Regulations 2005			X
Landfill (England and Wales) Regulations 2002			X
List of Wastes (England) Regulations 2005			X
Waste Incineration (England and Wales) Regulations 2002			X
Waste Management Licensing Regulations 1994			X

6.0 NANOTECHNOLOGIES AND MATERIALS – A GAP ANALYSIS OF REGULATION

6.1 Assessment of Regulations and development of the Regulatory Gap Analysis Table

Applying the methodology outlined in Section 3 a comprehensive analysis of each of the regulations identified in Table 2 above was undertaken. These analyses of the various regulatory provisions can be found at Annex 5 below. A summary of the key findings from the assessments in Annex 5 is included as a regulatory gap analysis table ('the Gap Table"). This makes an assessment of regulations by reference to a set of criteria measuring the ability of the regulation to address potential risks arising from the manufacture, formulation, supply and use of nanotechnologies.

Regulations were grouped according to their scope and purpose, however the breadth of the scope of certain regulations meant that they fell into more than one category (see for example the Chemicals (Hazard Identification and Packaging for Supply) Regulations). These particular groupings based upon potential impacts also allowed for additional lifecycle analysis. The six groups identified are:

- **Introduction/Notification** – where regulations control the entry of a substance onto the market and identify procedures demanded by the producer/supplier.
- **Health & Safety** – including both the obligations on employers to meet health and safety standards at the work place and the general health and safety standards placed upon suppliers of substances.
- **Producer Responsibility – Product Quality & Safety** – containing those regulations prohibiting or restricting the use of certain prescribed substances or demanding the application of a lifecycle approach to the design of a product thereby reducing its impact on the environment.
- **Consumer Protection** – in the form of regulations specifically designed to control the entry of products onto the market place and which lay down the procedures relating to safety and the protection of human health.
- **Environmental Protection** – regulations designed to reduce the impact of harm to the environment and the prevention and control of pollution.
- **Waste** – a wide category of regulation that covers the obligations of actors in the waste chain and sets out mwaste management options and targets.

The regulations within each of the above groups were assessed according to the certain criteria, thought to be essential for effective regulation:

- **Scope** – identifying whether particular substances are specifically identified, and where so, whether nanomaterials are captured under the scope of the prescribed substances.
- **Risk Characterisation –** whether the regulations set prescribed concentration thresholds or emission/discharge levels and whether these will capture the production or subsequent use of nanomaterials.
- **Risk Assessment –** whether the regulations demand required procedures to assess the risks posed by substances prescribed under the regulation or whether (where the regulations are general in their nature as with Health & Safety at Work,[6] and CHIP[7]), risk assessments are required to identify necessary precautions.
- **Risk Management –** whether, as a result of the risk assessment procedures, the appropriate person is made responsible for ensuring an appropriate management response (e.g. Health & Safety at Work and the need for personal protective equipment[8]) or in more general terms duty of care under environmental law[9] on the waste generator to ensure the appropriate management of waste.
- **Information Base –** whether specific information was required to be generated under a regulation, e.g. sampling or monitoring[10] for environmental protection purposes or on a more general basis, and whether the potential gap arose because of a general lack of current available scientific knowledge.

The Gap Table produced can be found at Annex 4A.

6.2 Key Findings

6.2.1 Consumer Protection

On the whole, the regulatory provisions identified in this area can be described as providing a sufficiently broad framework of consumer protection. However, there are three clear instances in which measures might fail to prevent potentially harmful nanomaterials from being placed on the market. Each of these instances described below stem from provisions whose scope is restricted to particular substances, concentrations of substances, or products.

(a) Legislation restricting the use of particular substances by percentage or weight

[6] Health and Safety at Work Act 1974
[7] Chemicals (Hazards Information and Packaging for Supply) Regulations 2002
[8] See Part 1 Health and Safety at Work Act 1974 and Regulation 4 of the Personal Protective Equipment at Work Regulations 1992.
[9] Section 34 Environmental Protection Act 1990
[10] Water Environment (Water Framework Directive) (England and Wales) Regulations 2003

Example:
Regulation 5 of the **Cosmetic Product (Safety) Regulations 2004** restricts the use of groups of cosmetic ingredients listed in Schedules 4 to 7 to the Regulations.

A potential regulatory gap arises where thresholds are set restricting the use of specific substances in cosmetic products. Thresholds restricting the percentage or weight of substance permitted in products establish safety levels based on information relating to bulk materials. Given that nanomaterials have different properties to their non-nanomaterial counterparts, it is conceivable that these thresholds are inappropriately set to capture risks arising from the inclusion in products of a nanoparticulate version of a restricted substance.

(b) Legislation restricting the concentration of particular substances

Examples:
- Regulation 2 of the **Contaminants in Food (England) Regulations 2006** makes it an offence, for example, to place on the market certain foods if they contain contaminants of any kind specified in the Commission Regulation (No.466/2001) at levels exceeding those specified.
- Regulation 7 of the **Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2005** requires that a producer ensures that new equipment put on the market does not contain more than the permissible maximum concentration values of hazardous substances.

A potential regulatory gap arises from the setting of thresholds of permitted concentrations of substances in consumer products. Regulatory provisions establishing maximum concentration levels are often enacted for substances where there exists an extensive body of dose-response and exposure data. It is conceivable that thresholds set on the basis of known toxicity of particular substances are inappropriately set for the manufacture of those substances using nanomaterials.

(c) Legislation requiring pre-market product authorisation

Examples:
- Regulation 3 of the **Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994** provides that no 'relevant medical product' shall be placed on the market or distributed by way of wholesale dealing unless prior authorisation has been granted by the licensing authority (MHRA) or the European Commission.

- Regulation 3 of the **Novel Foods and Novel Food Ingredients Regulations 1997** requires that that the marketing of food or food ingredients falling within the scope of the Regulations be authorised.

A potential regulatory gap arises in relation to schemes requiring that products are authorised before being placed on the market. The ability of pre-market authorisation to identify potential risks associated with nanomaterials depends on whether products containing nanoparticles are construed as being equivalent to authorised products already on the market. Safety questions arise if a product authorised on the market is subsequently manufactured using nanoparticles. It is conceivable that the insertion of nanoparticles in a product *after* its authorisation as a non-nanoparticle product will lead to the marketing of nanoparticles before hazard characterisation or risk assessment processes have been conducted.

6.2.2 Environmental Protection

Current environmental legislation provides a broad framework to prevent, restrict or control the impacts of pollution on or harm to the environment. However, the scope of some regulations can be restricted to a specific sector or activity, to prescribed substances, to a prescribed product or to releases into specific media. These restrictions in scope may lead to gaps in the regulation of nanomaterials and in the ability of environmental regulation to prevent, restrict or control harm to the environmental due to the presence of nanomaterials either prior to or post entry into the environment.

(a) Legislation referring to prescribed substances and processes

(i) New manufacturing process

Such is the innovative nature of nanotechnology production that production process may not meet the pollution prevention and control activity descriptions.

Example:
Pollution Prevention and Control (England and Wales) Regulations (PPC) 2000[11] – Chapter 4, Schedule 1 - chemical industry activities must involve the production of chemicals 'in a chemical plant by chemical processing for commercial purposes' and this would exclude nanomaterials produced solely by physical production routes.

(ii) Hazardous or Dangerous Substances

Regulations refer either to identified lists of substances, which have been prescribed at the European level or to specific substances.

Example 1:
The Groundwater Regulations 1998 prohibit or restrict the release of List I or List II substances including regulation 4(1) **-** An authorisation shall not be

[11] As amended 2001 (SI 503), 2002 (SI 275 & SI 1702), 2003 (SI 1699 & SI 3296), 2006 (SI 2311), Pollution Prevention and Control (England and Wales) (Amendment) and Connected Provisions Regulations 2004 SI 3276, Pollution Prevention and Control (Unauthorised Part B Processes) (England and Wales) Regulations 2004, SI 434 and Pollution Prevention and Control (Public Participation)(England and Wales) Regulations 2005 SI 1448

granted if it would permit the direct discharge of any substance in list I – and Regulation 5(1) - An authorisation shall not be granted in relation to … any direct discharge of any substance in list II.[12]

Whether nanomaterials will be covered by the regulations will depend on whether they can be classed as a List I or List II substance. If they are classed as a List I substance their discharge into groundwater must be prohibited. A regulatory gap may arise depending upon whether nanomaterials are classed as an existing substance controlled under the regulations or not. If the nanoscale form is classed as 'existing' then any assessments may fail to identify the unique properties and potential risks associated with the nanoscale form, even though prohibitions on its discharge will apply. The problem is the availability of exemptions under the regulations after prior investigation. These will be reliant on technical knowledge, which may not be currently comprehensive, concerning the impacts of the nanoscale form.

Conversely, if nanomaterials are not classed as a list I substance, there is a danger that nanomaterials will fall outside the scope of the regulations.

Example 2:
List of Wastes (England) Regulations 2005 – A substance is classed as dangerous if it falls under regulation 2 of Chemicals (Hazard Information & Packaging for Supply) Regulations 2002.[13] Schedule 1 of the Regulations outlines specific categories of danger.

A potential gap may exist as currently no existing substance in nanosize form has been through the EU process with none being available on the UK 'Approved Supply List'. The lack of data available may mean that substances in nanosize form will not be classed as a dangerous substance within the List of Waste Regulations. This may lead to waste types containing nanomaterials being classed as non-hazardous. As a consequence waste management options may be less stringent, for example disposal to non-hazardous landfill may take place.

In summary, gaps exist in relation to the definition of prescribed processes and substances, with many of the relevant regulations being too narrow in scope and interpretation. An important question is whether the change in form is such that it might constitute a new substance, but the consequences of the answer will influence regulation in differing ways depending on whether

[12] List I and List II substances are contained in the *Dangerous Substances Directive (76/464/EEC),* however as part of the ongoing restructuring of the Community water policy, the Directive on Dangerous Substances is now integrated in the Water Framework Directive (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community.

[13] Dangerous Substance means a substance contained in the "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Seventh Edition)" (UK Approved Supply List) or if not on this list is one or more of the categories of danger contained in Schedule 1 of this regulation.

the new substance now requires first-time approval or whether its new nature takes it outside of the list regulated substances.

(b) Risk Characterisation – concentration thresholds, volumes, & tonnage

If the nanoscale form falls under the relevant definitions within the various environmental regulations, the nanomaterial may still escape the jurisdiction of the regulation if it fails to satisfy concentration thresholds
Examples:
List of Waste Regulations – concentration levels of hazardousness for those wastes with a 'Mirror' entry code;[14] **PPC Regulations** - emission levels; **Water Industry Act 1991** - discharge levels; **Producer Responsibility Obligations (Packaging Waste) Regulations 2005**; - tonnage values.

It is unlikely that, due to the possible unique properties of nanomaterials, they will meet any of the relevant concentration, emission or discharge levels. For example, the emission level values under the PPC regulations are based on the environmental risks of the macro equivalent, which may be different from the nanomaterial due to the different reactions of materials at the nanoscale. To ensure the capture of nanomaterial, the relevant competent authority needs to be able to monitor and sample the relevant media and therefore they will require technical equipment to undertake appropriate sampling to identify nanomaterials. Moreover, given current uncertainties in relation to the potential impacts of nanomaterials on human health and/or the environment, it may not be possible to assess the impacts of many nanomaterials. Such uncertainties relate both to the potential for adverse effects and to the level at which these effects might occur,

In summary, the lack of knowledge on the effects of nanomaterials is likely to lead to a gap in the setting of appropriate concentration and emission levels.

(c) Extent of legislation to regulate specific types of risk

Example:
Landfill (England & Wales) Regulations 2002; Hazardous Waste (England & Wales) Regulations 2005; & List of Wastes (England) Regulations 2005

Current waste legislation is extensive in terms of the types of waste covered dictating waste management options for certain prescribed waste types. However, one major gap in relation to reducing damage, both to human health and the environment from leaching within landfill to water sources and emissions to air, is the control of domestic waste that might contain nanomaterials. Domestic hazardous waste is exempt from the more stringent

[14] Once a waste has been identified as possessing dangerous substances it must then be assessed as to whether it is an 'Absolute' waste that is will be hazardous no matter the concentration of hazardous properties or a 'Mirror' waste which will only be hazardous if it contains dangerous substances in concentrations at or above the appropriate threshold or a test shows a hazardous property. The thresholds applied are H1 to H14 located in the Schedule 3 of Hazardous Waste Regulations.

waste management options required for commercial and industrial hazardous waste. For example, hazardous waste can only be disposed of to those landfill sites identified as hazardous. Only separately collected domestic hazardous waste is included in this provision. As such, a potential gap in the regulation of nanomaterials is the disposal of such materials to non-hazardous waste landfill, which remains the standard waste disposal route for UK domestic waste. With the existing lack of knowledge about the impacts of substances at the nanoscale, the danger that nanoparticles could move through a landfill and potentially enter any water supply is an obvious concern.

6.2.3 Health and Safety

The EU has standardised regulations relating to the control of the health and safety hazards of industrial chemicals and their risks in the workplace. In the UK this harmonised process has been adopted under the umbrella of the Health and Safety at Work Act 1974. To ensure chemicals are regulated appropriately, the regulations are aimed at suppliers, users of chemicals and the regulatory authority[15] itself. The controls upon the introduction and notification of chemicals coming onto the market will dictate how nanomaterials are regulated later in the lifecycle chain and will prove influential in determining whether nanomaterials will fall within numerous other consumer and environmental protection regulations.

(a) Legislation dealing the identification and notification of new substances

Example:
Regulation 4 of the **Notification of New Substances Regulations 1993 (NONS) – "**Subject to regulations 6 and 7, a person shall not place a new substance on the market in a total quantity of one tonne or more per year unless he has sent to the competent authority a notification including…"

Decisions made under NONS will determine the regulatory control of many nanomaterials as they move through their lifecycle. Under this system, the supplier is responsible for determining whether the nanosubstance is an existing or a new substance. A potential gap is likely to result from this process as it is unlikely that all suppliers will possess the necessary data to make an informed decision relating to whether the presence of nanoparticles suggests a new substance or an existing one. A substance will be classed as 'existing' if it is included in the European Inventory of Existing Commercial Chemical Substances.[16] As only changes in chemical structure comprise a new substance and not a change in form (size and shape), it is likely that nanomaterials may be classed as existing and that, as such, no further tests need to be conducted in relation to the potential risks of that substance. Consequently, there would be no requirement to provide additional information to subsequent users and the substance would pass through its

[15] Health and Safety Executive
[16] The Health and Safety Executive considered this issue in their report (HSE 2006), concluding that it was novel materials made from the 'bottom-up' that would require notification for example carbon fullerenes and their derivatives.

lifecycle without additional scrutiny. There would be no labelling for supply and no information to introduce, where necessary, measures to reduce potential risks during use and disposal.

It is worth noting that the Royal Society has recently produced a policy document stating that substances in the nanoform that are not on the European Inventory of Existing Commercial Chemical Substances shall be regarded as new substances[17]. This of course is not a legally binding mandate.

(b) Legislation dealing with concentration levels

Example:
Regulation 4 of the **Notification of New Substances Regulations 1993 (NONS)** (as above)
Even where a nanomaterial is identified as a new substance, notification is dependent on concentration thresholds being met. A two-tier test is applied. The first test, as laid down in Regulation 4, states that full notification is required when a new substance is placed on the market in a total quantity of one tonne or more per year. The second test, contained in Regulation 5, requires further testing of the substance where certain tonnage levels are met. The result of the second test is that the greater the quantity of a substance in production, the greater the data requirements on its properties imposed by the regulators. Much will therefore depend upon the precise quantities of new substances in circulation. As such this is taking no account of the need for and extent of testing chemicals by reference to particle size. The production of an existing substance in nanoparticulate form does not of itself trigger any additional testing. Regulation is governed at lest in part by the bulk of the material in which the nanoparticles are incorporated.

(c) Legislation dealing with marketing of dangerous substances

Example:
Regulation 4(1) of the **Chemicals (Hazards Identification for Packaging) Regulations 2002 (CHIP)**: "No person shall supply a dangerous substance or a dangerous preparation unless it has been classified in accordance with paragraphs (2) to (7)…" This requires suppliers to identify, and where appropriate, categorise the hazards of the substances supplied.

Linked closely to the identification of new substances under NONS, the CHIP Regulations rely on capturing dangerous substances because they are listed in the Approved Supply List[18] or constitute a new substance under NONS.

[17] Royal Society RS Policy Document 35/06, Nanoscience and nanotechnologies: opportunities and uncertainties; Two year review of progress on Government actions: Joint academies' response to the Council for Science and Technology's call for evidence, 2006

[18] "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Eighth Edition)" approved by the Health and Safety Commission on 26 July 2005

Currently, no 'existing' substances[19] at the nanoscale have been through this system. Consequently, the classification will be at the discretion of the supplier and this self-classification could lead to potential gaps. If classed as a new substance a safety data sheet will be required for hazardous nanomaterials. A general issue is the lack of sufficient information and knowledge available on toxicological hazards and appropriate exposure limits. It will therefore be difficult to provide the relevant data and undertake the necessary risk assessments.

Any substance classed as hazardous will require a supplier to provide information relating to the hazards of the substance supplied. If not classed as hazardous, no new data would be generated on the risks or hazards relating to the identified nanomaterial. If this were to happen, nanomaterials could move through their lifecycle without any further assessment of their properties.

(d) Legislation dealing with workplace risk management

Example:
Regulations 3, 4 and 6 of the **Control of Substances Hazardous to Health Regulations 2002** creates duties under the Regulations, prohibiting certain substances, and demands assessments of the risk to health from by work involving substances hazardous to health.

Regulations require employers to either prevent, or, in instances where this is not practical, to control potential risks from exposure to hazardous chemicals. The regulations provide a valuable system for assessing and managing any potential risks that may arise. However, there are potential gaps in relation to the management of risks arising from the use of nanomaterials. A potential gap arises as employers rely on the data sheets prepared by suppliers of chemicals under CHIP. If the substance is not classed under CHIP, no safety data sheet will be prepared and consequently employers will not, as a rule, undertake any risk assessment of the substance in the work place or, in turn, introduce any risk management procedures. Any risk assessments rely upon available information on the hazards together with knowledge of the local conditions of exposure. Risk assessments are therefore based on both sound scientific information and past experience. In terms of nanomaterials this information is likely to be incomplete and there are likely to be deficiencies in the level of available information.

6.3 Lifecycle Analysis

Nanomaterials are developed and commercially manufactured, formulated into products to be used by industry and/or consumers, before recovery or final disposal. To assess the full extent of any potential gaps in the regulatory framework, it is necessary to analyse the relevant regulations from this

[19] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) and was placed on the market before September 1981

lifecycle perspective. A Lifecycle Map (see Annex 3) provides the basis of the relevant lifecycle phases of any nanomaterial.

Later in this section there is a Lifecycle Table (Table 3B) below, which draws on the regulatory gap assessment conducted in Annex 6.[20] The Lifecycle Table represents the assessment of eight distinct lifecycle stages:

- Research & Development;
- Production of Nanomaterial;
- Supply of nanomaterials/chemicals;
- Use of nanomaterials as a raw material or within other chemicals/substances in the production of goods;
- Wholesale and retail of products;
- Commercial and industrial use of products;
- Consumer use of products; and
- End disposal

These stages are assessed against the five criteria applied in the Regulatory Gaps Table (Scope; Risk Characterisation; Risk Assessment; Risk Management and Information Base) as found in the relevant groups of regulations that are analysed in the Report. In this way it is hoped to identify the potential gaps arising at each phase of the lifecycle. In Lifecycle Table these groups are identified by an individual coloured symbol. Each group of regulations was qualified by a potential gap (see Table 3A for details).

6.3.1. The Lifecycle Table

The Lifecycle Table indicates that at each lifecycle phase potential gaps may arise in the relevant regulations, for example at the research and development phase four potential gaps are identified:

(a) Introduction/Notification Regulations

Unless the nanoscale form is considered to constitute a change in the chemical structure, a potential gap arises, as nanomaterials are likely to be classed as 'existing' substances[21] rather than as new substances. If classed as 'existing' the availability of future information for subsequent users of the nanomaterial including its physicochemical, toxicological and ecotoxicological properties may not be formulated. The nanomaterial could therefore, pass through the various stages of the lifecycle without additional scrutiny of its unique properties. As a consequence, there would be no labelling for supply and no information to introduce, where necessary, measures to reduce potential risks during use and disposal. New testing strategies may need to be identified to assess the unique qualities of nanomaterials and their potential impacts in different scenarios. If classed as a 'new' substance some potential to fall below any relevant threshold or concentration levels may

[20] Which in turn is summarised in the Gap Table (Annex 4B)

[21] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) and was placed on the market before September 1981.

remain. Potential gaps arise due to a lack of available scientific data on hazardous components and a lack of information on impacts and effects of nanomaterials on human health and the environment.

(b) Health & Safety

If identified as non-hazardous, subsequent users would be dependent on existing data as no new data would be generated on the potential risks relating to the identified nanomaterial. Consequently, nanomaterials could move through their lifecycle without any further consideration of the risk potentials to human health. Again there is a lack of available scientific data on hazardous components and a lack of information on impacts and effects of nanomaterials on human health and the environment.

(c) Environmental Protection

Relevant environmental control regulations such as the Pollution Prevention and Control Regulations do not cover emissions resulting from the R&D process. As a consequence there is no regulation of emissions at this stage in the lifecycle. In terms of discharges to water, the identified nanomaterial may not be classed as on of the prescribed substances and even if it is, it may fall below any discharge thresholds identified in the regulations. Potential gaps also may arise due to the general lack of information on impacts and effects of nanomaterials on human health and the environment.

(d) Waste

Any waste generated as a result of the activity may be difficult to classify under the appropriate regulations, although R&D waste cannot be sent to landfill. The relevant waste disposal route will be determined based on whether the waste is coded as hazardous or non-hazardous and a further gap may arise where appropriate hazardous thresholds are required to be met.

Consequently at each phase of the lifecycle different parties will be required to meet different regulatory obligations to reduce risk to human and/or the environment. For example at the R&D phase, companies must comply with appropriate waste legislation in terms of a duty of care to ensure waste is disposed by a licensed waste carrier and that R&D waste is not disposed to landfill. This duty of care applies to all following phases (Production, Supply, Manufacture, Wholesale, Consumer and Domestic use) and ensures that hazardous waste is disposed to a hazardous waste facility. Waste licensing seeks too ensure that appropriate conditions are placed upon the handling and disposal of all wastes, but as indicated above, nanomaterials in the domestic waste chain may be difficult to regulate.

A regulatory framework should ensure that any substance that may cause harm to human health and/or the environment is effectively regulated at whatever phase in the lifecycle. Whilst some regulations (such as NONS) may address both health and safety and environmental risk, others address only one specific issue for example the human health impacts of a particular consumer product. Whilst a product may be classed as safe in terms of human health, it may have a negative environmental impact particularly in terms of cumulative effects perhaps arising from disposal to non-hazardous

landfill sites and subsequent risk of leaching. In fact, the same product may be regulated differently depending on the user, for example industry will be subject to stricter controls relating to the disposal of any product containing dangerous substances than a consumer disposing the same product in the domestic waste stream Consequently, a potential gap may exist as consumer products containing nanomaterials might be disposed to landfill, with negative environmental impacts.

In summary, some of the potential gaps that may arise from a lifecycle perspective are:

1. If a nanomaterial is introduced as an 'existing substance' and not subject to notification under NONS or under any other relevant regulation, there is the possibility that it will not be subject to any additional assessment of its unique properties with possible impacts of these properties on human health and/or the environmental throughout its lifecycle.

2. Whilst many products may be deemed safe under consumer protection regulations, environmental issues may not be addressed, particularly in light of the prescriptive and often restrictive extent of environmental regulations.

3. Whilst it may appear that there are a substantial number of potential gaps in Table 3, many of the gaps arise due to a lack of existing data on the potential effects of nanomaterials on human health and the environment. The table identifies this and it reflects the impact of this paucity of information in relation to risk assessment and risk management.

Table 3A: Explanatory Note for Table 3B

Symbols

Introduction/Notification of Nanmomaterials
Health & Safety

Producer Responsibility - Product Quality & Safety
Consumer Protection
Environmental Control
Waste

Gap Identification

1 – Gap if classed as existing substance and equivalent of macro scale substance – may result in insufficient assessment of unique properties of nanomaterial

2 – Gap if classed as new substance and therefore not a prescribed substance under the regulations

3 – Gap if falls below concentration threshold levels and therefore no longer within remit of regulation

4 – Gap if classed as non-hazardous substance

5 – Gap if falls below emission/discharge levels

6 – Gap if lack of appropriate technical standards

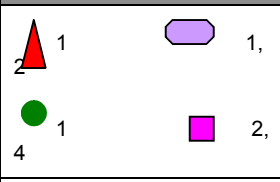
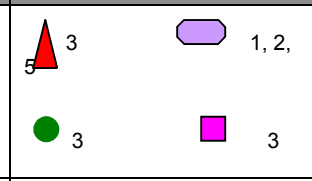
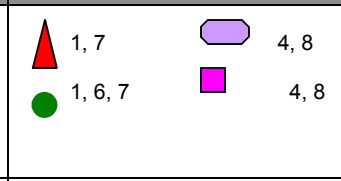
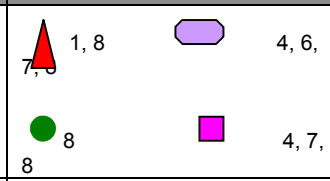
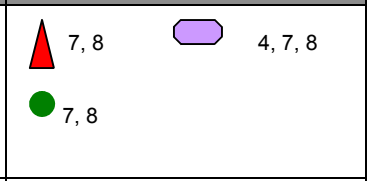
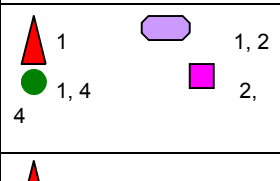
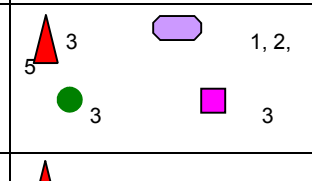
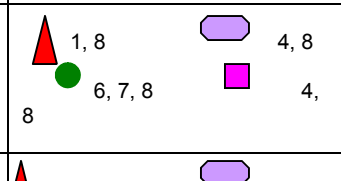
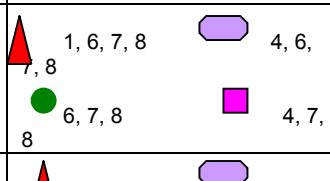
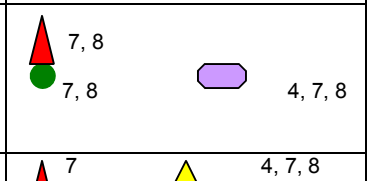
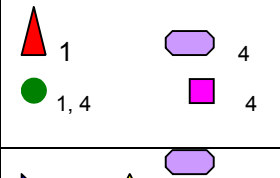
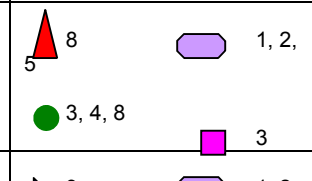
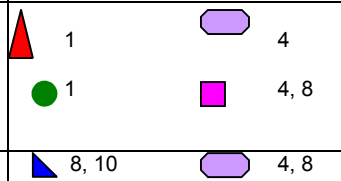
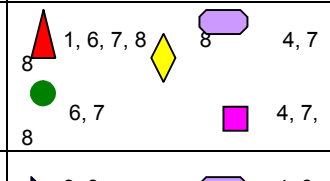
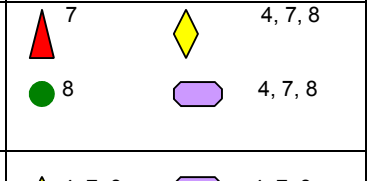
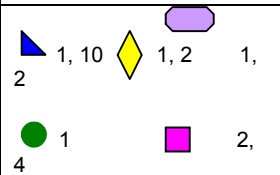
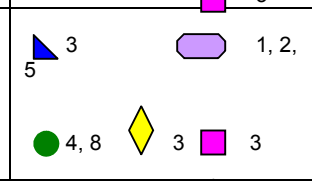
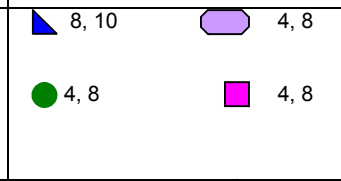
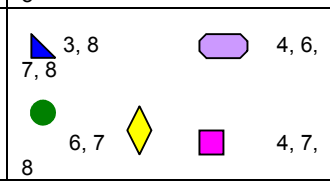
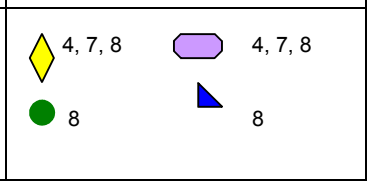
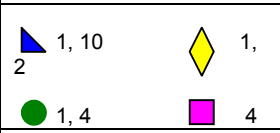
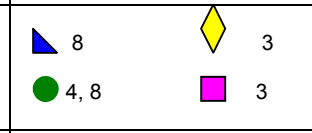
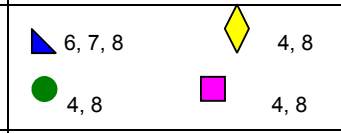
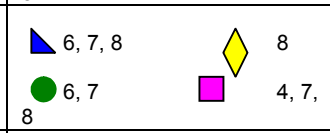
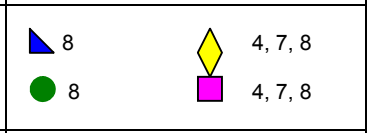
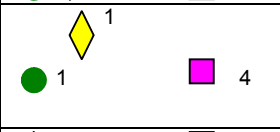
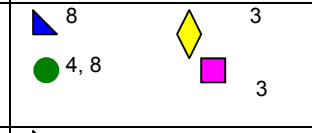
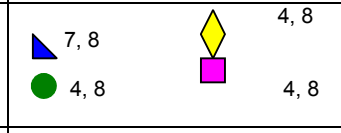
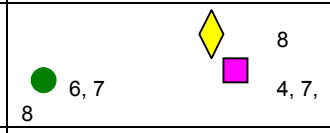
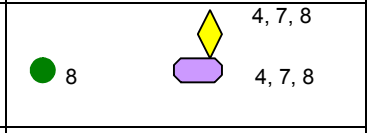
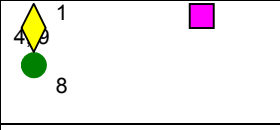
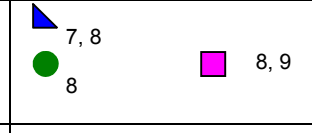
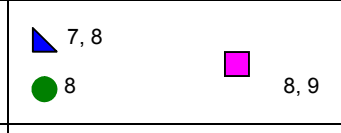
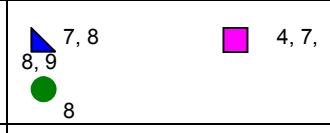
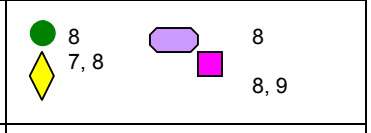
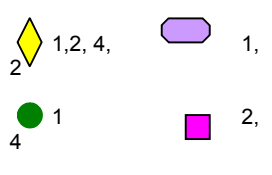
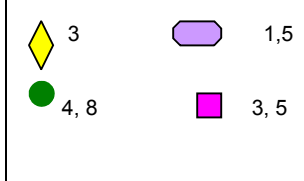
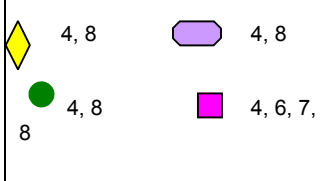
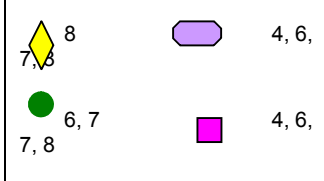
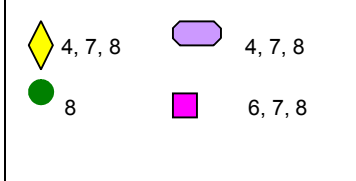
7 – Gap if lack of information on scientific data on hazardous components

8 – Gap if lack of information on impacts and effects of nanomaterials on human health and the environment

9 – Gap if hazardous waste from domestic use

10. – Gap if falls out with general scope of regulations (e.g. under Food Regulations not classed as 'novel')

Table 3B: Lifecycle Gap Table

Lifecycle	Scope	Risk Characterisation	Risk Assessment	Risk Management	Information Base
Research & Development					
Production - Nanomaterials					
Supply					
Manufacture Use in Products					
Wholesale & Retail					
Commercial & Industrial Use					
Consumer Use					
Disposal					

7.0 REGULATORY DEVELOPMENTS AND SUPPORTING MECHANISMS – HORIZON SCANNING

7.1 Standards and Definitions

The uncertain impact of nanotechnology generates questions about the extent to which new products and processes using nanoparticles fall within the scope of existing regulatory provisions. As illustrated above, the coverage under existing regulations is inevitably patchy since the measures were not designed with nanotechnology in mind. The extent to which the current regulatory framework can be adapted to include nanomaterials depends to a great extent on the setting of safety thresholds using conceptual models of risk assessment. A critical aspect of the regulation of nanotechnology is establishing the positioning of benchmarks. Standard setting organisations, such as the British Standards Institute (BSI), the International Standards Organization (ISO),[22] and the European Committee for Standardization (CEN)[23] are at the forefront of resolving issues of definition and taxonomy in relation to nanoparticles (BSI, 2005). This work is vital. It will enhance the prospects of a uniform global response to the marketing and circulation of nanomaterials. Also, at a domestic or EU level, it will form the basis of working within existing regulatory frameworks by overcoming terminological difficulties and resolving uncertainties as to appropriate standards.

7.2 Voluntary Reporting Initiatives

Achieving a standardised approach to nanotechnology has been supplemented by the emergence of voluntary reporting initiatives. In September 2006, Defra launched a Voluntary Reporting Scheme (Defra, 2006a) designed to run for a period of two years. Its primary objective, alongside a dedicated programme of Government research, is to gather evidence relevant to understanding the potential risks posed by engineered nanoscale materials. The US Environmental Protection Agency has entered into discussion with the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) about the development of a voluntary reporting pilot program for nanotechnology companies and researchers (NNI, 2006).

7.3 Good Practice

The development of good practice standards is already beginning to gain momentum in the international sphere. Several good practice frameworks exist aiming to promote consistent approaches to the risk analysis of nanoparticles. (Shatkin and Barry, 2006:553-556; Environmental Defense and Du Pont, 2005; Jacobstein, 2006) For example, the European Commission funded 'Nanosafe I' project has developed a framework for assessing risks to workers, consumers and the environment posed by nanoparticle production (VDI, 2004). The second phase of the Nanosafe project ('Nanosafe II') is currently underway, aiming to build upon findings in the phase one project and deliver

[22] ISO Technical Committee (TC) 229. TC229 is divided into three separating Working Groups (WG), each responsible for establishing a standardised approach to the following aspects of nanotechnology: terminology and nomenclature (WG1); measurement and characterisation (WG2); and health, safety and environment (WG3).

[23] In March 2004, the CEN Technical Board established the Nanotechnology Working Group (CEN/BTWG 166) to assess the need for the standardisation of activities involving the manufacture of nanoparticles.

clear assessment and management recommendations for the safe production of nanomaterials.[24]

7.3.1 An Example: Globally Harmonised System of Classification and Labelling of Chemicals

Despite the prevalence of chemical products, there is little international harmonisation or common standards. As a result of jurisdictional variations in the definition of 'hazard', a chemical may be considered flammable in one country, but not another.

Recognising the value of the extensive global trade in chemicals, a global system of harmonising the approach to classifying and labelling chemicals has been identified as necessary. The system is anticipated to include the following elements:

(a) harmonized criteria for classifying substances and mixtures according to their health, environmental and physical hazards; and

(b) harmonized hazard communication elements, including requirements for labelling and safety data sheets[25].

GHS is currently under negotiation in the EU, and its introduction and implementation at the European level will result in it replacing CHIP. The aim of GHS is to introduce a worldwide system for hazard communication; it will therefore be a vital development for the control of nanomaterials. Central to GHS is the development of a common and coherent approach to defining and classifying hazards, and communicating information on labels and safety data sheets GHS will consequently provide the underlying infrastructure for establishing national, comprehensive chemical safety programmes. GHS is proposed to cover all types of chemicals and will be based on intrinsic properties (hazards) of chemicals and includes dilute solutions and mixtures. Pharmaceutical products, food additives, cosmetics and pesticide residues in foods will not be covered at the point of intentional intake but will be covered where workers may be exposed and this also extends to transportation.

A potential gap arises as the test of hazards looks to *known* ingredient information and due to the lack of available data on nano-ingredients the test may be incomplete. An important element of GHS is a requirement to include precautionary information in order to harmonise precautionary statements.

8.0 RESPONDING TO REGULATION – PRIORITIES

8.1 Evidence Base

Throughout this report, the Regulatory Gap Table, the Lifecycle Gap Table and the individual regulatory assessments, the lack of available information has been identified. Such is the significance of this gap that it permeates throughout the regulatory framework and to the different stages in the lifecycle of any nanomaterial. Summarised below is a list of some of the main information gaps.

[24] See Nanosafe II website: http://www.nanosafe.org/

[25] United Nations Economic Commission for Europe, Globally Harmonised System of Classification and Labelling of Chemicals, First Revised Edition, 2005 [Font]

- Effects of nanomaterials – current paucity of information on the potential effects of nanomaterials on either human health or the environment may mean that insufficient control procedures can be implemented.
- Comparison with equivalent macro scale substances - this may aggravate the existing information problems as there are currently no requirements for new tests and subsequent analysis of results to be undertaken.
- Indications of danger – the lack of sufficient information and knowledge available on toxicological hazards and appropriate exposure limits makes it difficult to provide the relevant data required in Safety Data Sheets and undertake the necessary risk assessments.
- Lifecycle approach – extended producer responsibility regulations require that a lifecycle approach be applied to the design of equipment. By so doing it is hoped to reduce the impacts of the product on human health and the environment by ensuring any hazardous components are so identified, limited, or easily separated from the product for final disposal. Gaps in the evidence base therefore may replicate throughout the substance's lifecycle.

8.2 Standards

From both the Regulatory Gap Table and the Lifecycle Gap Table it is apparent that with general standards applicable to definition and scope, nanomaterials would be captured under the regulatory framework. However at present, aided by insufficient evidence, there are difficulties in the following areas:

- Existing and new substances – appropriate guidance for those responsible for notification is required on novel applications of nanomaterials to ensure that these substances are classed accurately and consistently.

- Hazard identification – currently under various regulations suppliers are required to determine whether or not nanomaterials will be hazardous. Due to possible shortfalls in the evidence base, at present there is a risk that they may be incorrectly categorised or that parties will make contradictory determinations. On the other hand the existing regulatory framework could be utilised in the immediate future as hazard indicators are developed for free, engineered nanomaterials (accepting that not all will necessarily be hazardous). This will be aided in the future by the standardised hazard identifications being proposed under the Globally Harmonised System of Classification and Labelling.

- Listed substances: EU Directives contain prescribed substances to limit the impact on the environment, but such lists are not always uniform and this makes uniformity difficult in the UK also. While this is not a problem confined to nanomaterials, the potential prescription of such materials may exacerbate this problem.

8.3 Regulating in the face of uncertainty

The finding that knowledge of the characteristics of nanoparticles and their potential risk implications is incomplete highlights the importance of regulatory decision-making in this context. The precautionary principle is an accepted means of informing the regulation of scientifically uncertain threats. Development of nanotechnologies is continuing alongside further research as to the nature and extent of feasible new risks. The Royal Society and Royal Academy of Engineering argue that "many applications of nanotechnology pose no

new health or safety risks" while acknowledging areas where more research should be conducted.

Risk assessment processes necessarily involve elements of uncertainty, but in some cases the paucity of current scientific knowledge about the properties of nanomaterials, and their likely impact on human health and the environment, will preclude clear hazard characterisation and assessment. In the light of a lack of dose-response and exposure data, together with questions surrounding the appropriateness of safety thresholds and existing risk assessment methods there is a need for a regulatory response to ensure that potential risks are assessed in the light of available scientific information. Where a credible threat has been identified whose scope and impact are scientifically uncertain, the existing regulatory framework should be employed to ensure that scrutiny takes place, decision-making is transparent and proportionate, is undertaken on a case-by-case basis, and is subject to review as new information becomes available.

9.0 CONCLUSION AND RECOMMENDATIONS

The process of identifying relevant legislation and assessing its capacity to encompass hazards associated with nanomaterials has posed a number of challenges – not least because the list of potential uses nanotechnology is almost limitless. Nonetheless if nanotechnology is to continue to benefit a wide range of industry sectors these problems must be recognised and resolved.

The principal finding in this report is that potential regulatory gaps arise as a direct result of incomplete information about the implications of human and environmental exposure to nanoparticles, rather than any major regulatory oversight. It was unlikely from the outset of this study that each of the regulatory provisions identified would be sufficiently robust to capture all potential risks associated with use of nanoparticles. This general lack of information about the potential impacts of nanotechnologies can lead to uncertainties relating to the setting of appropriate exposure levels, and raises fundamental questions about fulfilling the manner in which obligations arising under regulations might be translated in practice.

Questions of definition and threshold levels underpin this report. Regulatory queries have been raised in respect of each of the three main areas of protection – consumer protection, environmental protection, and health and safety. As a result of incomplete information about the potential human and environmental implications of free, engineered nanomaterials, the ability of regulatory measures providing general exemptions or prescribing specific substance thresholds to capture potential risks associated with nanotechnologies is unclear. Prescriptive regulations are necessarily restrictive in nature. For example, whilst the pollution prevention regulations lay down a framework for reducing environmental harm, their remit is limited to prescribed processes and substances and, even if a process falls within the list of activities it will only be regulated under the system if it meets the production threshold levels. Consequently, the activities of many companies may fall outside the scope of these regulations whether or not they involve the use of nanotechnologies. Similarly, in relation to producer responsibility regulations, the Producer Responsibility Obligations (Packaging Waste) Regulations refer to prescribed substances, and only apply to companies with a turnover of £2,000,000 and which handle in aggregate more than 50 tonnes of packaging or packaging materials per

year. Thresholds of this nature inevitably limit the capacity to supervise the development, circulation and use of free, engineered nanoparticles.

Where regulation chooses as its primary method the prescription of certain listed substances so that their handling, use or disposal might be controlled, little attention is likely to be given to substances that have been developed through nanotechnology that are not easily categorised alongside listed substances. Such new substances potentially fall out of regulation because they are not included within the schedule of controlled substances.

Where it is possible that potential risks posed by nanotechnologies are not captured by specific definitions and thresholds set out in regulatory provisions, overarching regulations exist setting out general safety requirements (see, for example, General Product Safety Regulations 2005; Regulation (EC) No.178/2002 on General Principles of Food Law). Despite the fact that human health safeguards are established under broad regimes of safety, the potential impact of nanoparticles *after* consumer use must be borne in mind. A consideration of the implications of nanomaterials throughout their lifecycle is critical to the undertaking of thorough risk assessment processes. Even where risk assessment procedures established under existing regulatory frameworks appear robust, their ability to accurately characterise and assess potential risks associated with nanotechnologies is limited by fundamental uncertainties about the impact of exposure to free, engineered nanomaterials.

This paper was commissioned as and consequently presents a gap analysis. More thought and considerably more work needs to be given to the next logical task of devising regulatory structures that can successfully bridge such gaps. This is perhaps a more challenging task given the pressures of assuaging legitimate public concern while taking care also not to stifle innovation. In the meantime it seems apparent that some transitional solutions would assist. In the light of the paucity of information in this area, further research into the nature of free, engineered nanomaterials and the implications of human and environmental exposure must be promoted. Meanwhile, risk governance processes in characterising, assessing, managing and communicating levels of risk should be conducted within the framework of existing regulation as appropriate.

In light of the general lack of information relating to their associated risks, it is would seem prudent that an examination of the specific properties of free, engineered nanomaterials and an assessment of their associated risks be conducted prior to being placed on the market irrespective of whether those materials are deemed to be ‘new’ or ‘existing’ substances. Similarly free, engineered nanomaterials might be classed as ‘hazardous’ substances unless or until there is sufficient evidence of their safety in particular a context. Finally attention needs to be given to regulations that work by reference to thresholds to try and ensure that appropriate safety assessments are triggered outside of the threshold levels where free, engineered nanomaterials might prove problematic.

Annex 1

Literature Review on Nanotechnology Regulation

A. Introduction

The word 'nanos' is etymologically Greek, denoting 'dwarf'. (Einsiedel and Goldenberg, 2006: 213) 'Nano' is a derivative of 'nanos', and is used by scientists to denote one billionth. (Kulinowski, 2006: 14) Described as the technology of the 'vanishingly small', 'nanotechnology' has dozens of varied and contested definitions. (UNESCO, 2006: 4; Kulinowski, 2006: 14). UNESCO employs the term 'nanotechnology' to denote both basic and applied scientific research; and defines it as the "research conducted at the nanoscale…or one billionth of a metre." (UNESCO, 2006: 5)

The UK Royal Society and Royal Academy of Engineering distinguish between 'nanoscience' and 'nanotechnology', describing the former as the 'study and manipulation' of nanoscale particles, and the latter as the 'design, characterization and production' of 'structures, devices and systems' at the nanoscale. (RS/RAEng, 2004).

The US National Nanotechnology Initiative defines nanotechnology as "…research and technology development at the atomic, molecular, or macromolecular levels, in length scale of approximately 1 to 100 nm range, to provide a fundamental understanding of phenomena and materials at the nanoscale and to create and use structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size." (The US National Nanotechnology Initiative, 2006)

In essence, nanotechnology is about invisible miniscule particles that straddle the worlds of physics, biochemistry, physical chemistry, and microscopy. The particles are otherwise known as nanomaterials, and possess unique properties and behaviour not exhibited in traditional materials. (Theodore and Kunz, 2005:1-2)

Essentially, nanotechnology covers the techniques of building things from the bottom up, atom by atom, and molecule by molecule. This is generally contrasted with the traditional industry standard of building things from the top, with large chunks of traditional raw materials manoeuvred in place to construct specific products such as integrated circuits or an ocean liner. (Drexler, 1990:163-67) The distinction may not be so clear as the top down production of nanomaterials is by no means unknown. (RS/RA Eng Report, 2004:6)

Although he did not use the term 'nanotechnology', (UNESCO, 2006:7) he contemporary concept of nanotechnology is widely attributed to the Nobel Prize winning theoretical physicist, Richard Feynman, who in a famous 1959 paper: 'There is Plenty of Room at the Bottom', (Feynman, 1960: 22-35) envisioned the development of nanomachines capable of building other nanomachines and other products with atom by atom control. (Drexler, 2006:26) Feynman's hypothesis is as follows:

> The principles of physics, as far as I can see, do not speak against the possibility of manoeuvring things atom by atom …[I]t would be in principle, possible…for a physicist to synthesize any chemical substance that the chemist writes down…How? Put the atoms down where the chemist says, and so you make the substance. The problems of chemistry and biology can be greatly helped if our ability to see what we are doing, and to do things on

> an atomic level is ultimately developed – a development which I think cannot be avoided. (Feynman, 1960:33-34)

Feynman's hypothesis found an inveterate believer in Eric Drexler, a nanotechnology enthusiast, who in a 1986 book: *Engines of Creation: The Coming Era of Nanotechnology*, posits that nanotechnology has an inherent capability to manufacture anything simply by piling waste materials into a box of nanoscale assemblers that would reconfigure the materials into desired forms. UNESCO, 2006:7) In Drexler's words, "…we are moving towards assemblers, toward an era of molecular manufacturing giving thorough and inexpensive control of the structure of matter." (Drexler, 1990:240-42)

However, the prospects of molecular manufacturing and minuscule, foraging, self-replicating, out-of-control systems, (Rip, 2006:274) transforming the natural planet into "a mass of uninhabitable 'grey goo'", (UNESCO, 2006:8) have fed apocalyptic fears, (ETC Group, 2003; Joy, 2000:238) and inspired popular fiction. (Landon, 2004:131-146) This has had the unintended consequences of blurring the boundary between nano-fiction and nanotechnology reality. (Rip, 2006:274) It has also raised the fears that policy makers could overreact with a neo-Luddite proactive legislative or policy measures that could stifle or stop the technology in its tracks. (Rip, 2006:274).

B. Current and Potential Commercial Applications of Nanotechnology

The 21st Century nanotechnology, although at a nascent state, (UK Advisory Group on Nanotechnology, 2002:23) now transcends the surreal and the fictional realm as evidenced by its commercial applications in fields as diverse as environmental science, medicine, electronics, plant protection products and agrochemicals, etc. (Theodore and Kunz, 2005:1-2)

UNESCO's list of recent commercial nanotechnology products comprises: Cerax nanowax for snow skis, Franz Ziener waterproof ski jacket (Nanotex), wrinkle and stain resistant nano-care clothing, L'Oreal deep penetrating skin cream, Kodak's OLED (organic light emitting diodes) camera, performance sunglasses, nanofilm anti-reflective coating, Z-COTE sunscreen, Babolat nanotube tennis racket, InMat's nanotech tennis balls, Shockjock Aerogel footwarmers, Simmons washable bed mattress, etc… (UNESCO, 2006:1-2)

Nanotechnology is now a multi-billion dollar industry, and its value is expected to spiral to US$ 1 trillion by 2015. Currently at 49%, the United States has the largest share of the nanotechnology market, followed by the European Union's 30%, and the rest of the world's 21%. Within the European Union, the United Kingdom is said to account for close to one third of the European 30% nanotechnology market share. (Boxall, Aitken, and Hull, 2005)

In the UK, approximately 50 companies are manufacturing, processing and/or researching and using nanomaterials. Furthermore, there are 55 non-commercial entities involved in nanotechnology-related research and developments activities. (Chaudhry, Boxall, Aitken, and Hull, 2005)The main nanomaterials currently being produced in the UK include nanopowders (metals, metal oxides, alloys), magnetic nanomaterials, carbon nanotubes (single, multi-walled), nanoceramics, nano-silica (fumed, colloidal), quantum dots (metal and semi-conducting nanocrystals), polymer composites containing nanomaterials, and thin films (nm scale). (Chaudhry, Boxall, Aitken, and Hull, 2005)

(a) Nanotechnology in the Medical Field

Nanotechnology has the potential to enable precision delivery of pharmaceutical products and eliminate 'side effects' which is the bane of drug delivery. (Langer, 2003:50) According to Lorraine Sheremeta, special nanoscale materials like "…liposomes, polymers, silica and hydroxypatite are being used to encapsulate drugs and protect them from biological processes in the body." (Sheremeta, 2006:249-250)

Quite unlike their microscale counterparts, these special nanomaterials in which drugs are wrapped facilitate better drug delivery through the blood brain barrier, into the central nervous system. This efficiency in drug delivery has raised the prospects of improved drug delivery to the retina of the eye through the blood-retina barrier, as well as improved treatments for Parkinson's disease, Huntington's disease, brain tumours, etc. (Sheremeta, 2006:249-250) Other nanotechnology applications in the medical field include: improved surgical robotic tools, (Leary et al., 2006:822) medical imaging, (Winter et al., 2001:54) genetic testing, (Pilarski, et al., 2004:40-45) etc.

(b) Nanotechnology in the Environment

Nanotechnology could provide sufficient clean water for human consumption, agriculture, and industrial uses through improved method of water purification. (Bellobono, et al., 2005:87-94) The application of Nanotechnology to the environment is still in various stages of development, and deals mainly with pollution prevention and treatments. (Theodore and Kunz, 2005:3-4)

According to Louis Theodore and Robert G. Kunz, nanotechnology applications to the environment include sensing of pollutants, pH, and chemical warfare agents, ultraviolet light (UV)-activated catalysts for treatment of environmental contaminants, removal of environmental contaminants from various media, including in situ remediation of pesticides, polychlorinated biphenyls (PCBs), and chlorinated organic solvents, such as trichloroethylene (TCE), post-treatment of contaminated soils, sediments, and soil wastes, oil-water separation, destruction of bacteria, including anthrax, purification of drinking water without chlorination, etc. (Theodore and Kunz, 2005:3-4)

(c) Nanotechnology in Food Processing and Packaging

Nanoparticles could aid enzymes used in food processing to disperse more quickly through food matrices and enhance their activities. Food enzymes are used to alter food components to improve flavour, nutritional value, or other desirable characteristics. (Bai, et al, 2006:770-777)

Nanomaterials could also improve the characteristics of food packaging materials. These include the strength, barrier properties, antimicrobial properties, and stability to heat and cold. For instance, incorporation of nanoparticles of clay into an ethylene-vinyl alcohol copolymer and into a poly(lactic acid) biopolymer, considerably increased barrier properties to oxygen. The packaging could improve shelf life of food products. (Lagaron, et al., 2005:994-998)

Other nanotechnology uses in the food industry include cleansing and disinfection, and improved biosensors to detect the presence of gases in packaged food. With regards to cleansing and disinfection, it has been demonstrated that deposition of silver on nanoparticles of titanium dioxide significantly increases its bacteriocidal effects against E. coli, (Kim, et al., 2006: 143-146) while titanium dioxide combined with carbon nanotubes

significantly enhanced disinfectant properties against Bacillus cereus spores. (Krishna, et al., 2005:393-397)

C. Potential Risks and Dangers of Nanotechnology: Toxicology/Safety of Nanoparticles and Structures

Nanotechnology discourses are often characterised by potential risks of nanomaterials to humans and the environment. (Wolfson, 2003:376-396) These range from the fantastic to the genuine. For instance, Bill Joy fears that the technology could precipitate the rise of super-intelligent machines that could dominate humanity and the world. (Joy, 2000:238) There are also the fears of self-replicating nanomachines that could transform everything in their path into copies of themselves. (Reynolds, 2001:10683)

The prospect of risks is also a divisive factor, with nanotechnology protagonists and antagonists downplaying it and hyping it respectively. Gaskell et al aptly put the conflicting views on nanotechnology thus:

> With the ability to engineer and control systems at the nanometric scale, the enthusiasts predict transformative opportunities in areas as diverse as the environment, medical practice, electronics and novel materials. For the critics, the quality of life will be threatened by out-of-control self-replicating systems, miniaturized weapons of mass destruction, invisible surveillance techniques and unknown impacts of nanotubes… (Gaskell, et al., 2005:82)

It has been suggested that in the absence of hard data to the contrary, divisive, speculative and fantastic claims about nanotechnology risks will persist, especially in the realm of the science fiction. (Lewak, 2004:210)

(a) Health and Safety Risks

There are however genuine health and safety concerns from human exposure to nanomaterials. One potential point of contact with nanoparticles is the human skin. Although very little experimental data is available, smaller nanoparticles are said to have the ability to penetrate deeply enough to be absorbed by macrophages. With the available data, it is impossible to predict with certainty the extent to which nanoparticles could penetrate the skin. (Hoet, et al., 2004:12-26)

Another potential point of nanoparticles' contact with humans is through the lungs. While most dust particles are caught up in the mucus lining the airways during inhalation, nanoparticles are said to be small enough to venture deeper into the lungs and the air sacs or alveoli.

According to inhalation experiments with rodents, while low concentrations of nanoparticles could be mopped up from the lungs by macrophages, higher concentrations could potentially overwhelm the macrophages and cause inflammation of the lungs. Apart from inflammatory reactions in the lungs, inhaled nanoparticles could also adversely affect the nervous and cardiovascular systems. (Hoet, et al., 2004:12-26) Very recently, there was a nanotechnology-based product scare, when 110 European customers reported respiratory symptoms, after using "Magic Nano", a spray-on ceramic sealant designed to repel dirt. (Piller, 2006) Although this led to recall, the product apparently made no use of nanomaterials.

The gastrointestinal tract is yet another point of contact of nanoparticles with humans. Nanoparticles could be absorbed via the intestine and find their way into the circulatory

system. It is not clear the extent of the damage that ingested nanoparticles could cause to the intestine. (Hoet, et al., 2004:12-26)

(b) Ecological and Environmental Risks

Early studies found that some nanoparticles caused inflammation in the lungs of rodents, and killed fish and organisms in soil and water, with significant ecological importance. (Kuzma, 2006:8) Although there is no conclusive data on the adverse effects of nanoparticles on species, the air, the soil, and water, the Royal Society and Royal Academy of Engineering in the United Kingdom recommended no use of nanoparticles and nanotubes in environmental applications until appropriate research was conducted and concluded. In the meantime factories and research laboratories were advised to treat these substances as hazardous and seek to *reduce* or remove them from waste streams. (RS/RA Eng. 2004) The UK Government, in its written response of February 2005 to the Royal Society's recommendation, states in paragraph 44 thus:

> We are supportive of the precautionary stance taken by the Royal Society and Royal Academy of Engineering in their Report. Given the uncertainty associated with risks to the environment from release of free manufactured nanoparticles and nanotubes, the Report asks industry to reduce or remove these from waste streams. We support this recommendation and will, with other stakeholders (including Local Authorities), work in partnership with industry, to help implement it. (HM, 2005:11)

While the UK Government is treading the characteristic European precautionary route with regards to the release of nanoparticles into the environment, the Office of Research Development at the US Environmental Protection Agency has no immediate plans of doing the same. (Kuzma, 2006:8)

In essence, the full ramifications of the potential risks of nanomaterials to human health and the environment are not fully understood yet, and more research would be required to do so. A preliminary framework has been drafted on what kinds of research are needed, and how the ensuing data could be incorporated into safety decisions. (Morgan, 2005:1621-1635)

D. Public Participation and Reception of Nanotechnology

In order to pre-empt and prevent the public scepticism that characterised the reception of genetically modified food, especially in Europe, scientists, stakeholders, and authorities are anxious to encourage open public participation and dialogue on the implications of nanotechnology for society. (Barnett, et al., 2006:201) The work of the Royal Society and Royal Academy of may be seen as a step at engaging the general public in a participatory dialogue. (Barnett, et al., 2006:201) In fact, the UK Government, in response to the Royal Society's Report, wrote that it was "committed to promoting constructive dialogue on nanotechnologies." (HM, 2005:20)

It has been suggested that public concerns over risk and doubts over benefits must be honestly and transparently addressed at the early stage of nanotechnology development, to obviate public scepticism. (Barnett, et al., 2006:201) It is however a contentious point, whether or not the public's lack of understanding and knowledge of new technologies is solely responsible for their scepticism. (Barnett, et al., 2006:201) Although public knowledge about risks emanates mostly from the media, (Theodore et al., 2005:292-293)

the interface between media risk amplification, and public perception of new technologies is said to be very complex and subject to debate. (Murdock, et al., 2004:37)

In the United Kingdom, little is known at present about public understandings of nanotechnology. (Barnett et al., 2006:201) There is however no evidence so far to suggest that the public mood in the UK vis-à-vis nanotechnology resonates with the sceptical mood towards genetically modified food in the 1990s. (Barnett et al., 2006:202)

A recent national survey shows that of a nationally representative sample of 1005, only 29 per cent said they had heard about nanotechnology, and only 19 per cent of the sample could offer a definition of nanotechnology. Of those who could offer a definition, 68 per cent thought nanotechnology would make life better in the future, while 4 per cent said it would make life worse. (Barnett et al., 2006:198-199) However, it is said that the Americans have much more positive views of nanotechnology than the Europeans. (Gaskell et al., 2005:84)

E. Nanotechnology Regulation

Regulating an emerging technology is said to be tricky since it necessarily involves striking a balance between precaution and venture. (Christoph, 2006:38) The precautionary principle, as championed by the European Union, requires that where an assessment of available scientific information shows reasonable grounds for concerns for possible adverse effects, in the face of scientific uncertainties, then priority must be given to human health and the environment. (Commission of the European Communities, 2000)

The UK Government, in its response to the 2004 Royal Society and the Royal Academy of Engineering Report on nanotechnology, supported the precautionary stance espoused in the Royal Society's Report. (HM, 2005:52) This however should not translate to placing a moratorium on nanotechnology R&D and applications as some groups such as the Canadian ETC have demanded. (ETC Group, 2003) The fact that there are presently 50 UK companies, and 55 non-commercial UK entities, actively involve in R&D and manufacturing of nanotechnology-based products would appear to support the fact that the Government for now has no nanotechnology moratorium plans. (Chaudhry et al., 2005)

A key issue in nanotechnology regulation is the adequacy of existing laws to grapple with issues raised by nanotechnology. In other words, are nanotechnology-specific laws imperative or would the existing laws be adequate? Scholars and groups like ETC have called for a new nanotechnology-specific regulatory regime, while others have argued that new regulations are unnecessary, since risks could be effectively managed by the effective utilisation of the existing regulatory regime. (Bennett, 2004:27)

F. Ownership and Intellectual Property Rights in Nanotechnology

Although nanotechnology is still in its infancy, Intellectual property rights already govern to the area to some extent prompting analysts to regard such rights as a threat to the technology. (Vaidhyanathan, 2006: 225) Between 1997 and 2002, US patents on nanotechnology-related products and processes grew from 3623 to 6425. (Vaidhyanathan, 2006: 227) A search of patents databases from 1976 onwards revealed over 89,000 worldwide patents on nanotechnology related inventions. (Vaidhyanathan, 2006: 227) There are fears that the rush to patent inventions relating to nanotechnology could trigger a patent 'arms race', that would lead to generally broad patent claims, encourage patent litigation, and stultify future progress and innovations in nanotechnology. (Vaidhyanathan, 2006: 232-233)

G. Liability Issues in Nanotechnology Products and Applications

It has been posited that as the commercial applications of nanotechnology increased, so would the relevance of civil liability for defective products, and the release of nanoparticles into the environment. (Hannah et al., 2006:237) With regards to nanotechnology related civil liability, the relevant area of law in the UK has been identified as tortious liability for personal injuries, liability for damage to property, and the ensuing direct economic loss, negligence, contractual liability for personal injury, liability for patent and copyright infringement, professional liability, and insurance contracts. (Hannah et al., 2006:237) The 2004 Royal Society and Royal Academy of Engineering Report advocates a strict liability regime for personal injury for the protection of the public. (RS/RA Eng. 2004)

H. The Ethics of Nanotechnology

Scholars have called for ethical governance of nanotechnology. (Sheremeta et al., 2006:74-77) One of the main ethical concerns is the use to which nanotechnology would be put? Geoffrey Hunt asks whether the technology would be used to fight world poverty, promote equality, global justice, peace, a sustainable environment and reduce over consumption. (Hunt, 2006:183) Since nanotechnology has great potentials in the medical field, Lorraine Sheremeta cautions that research involving human subjects in nanotechnology should be done in accordance with human dignity and within the limits of morally acceptable rules. (Sheremeta, 2006:249-250)

I. Risk and precaution

It has been suggested by some that the precautionary principle should not immediately apply to nanotechnologies for two reasons. First, nanotechnology is a generic term for an agglomeration of *enabling* technologies, rather than a definable set of products and processes, which can be assessed in terms of adverse effects. (Rip, 2006:270) Second, nanotechnology is mostly promise and sometimes, fantastic speculations. Consequently, it is argued that the precautionary principle is ill-suited to what amount in effect to science fiction, since 'what is "reasonable concern" becomes itself a contested issue.' (Rip, 2006:270)

There is consensus across the EU (European Commission, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) 2006) and UK, (RS/RA Eng. 2004) however; that a precautionary approach to the regulation of nanotechnologies is appropriate, given the extent of uncertainty relating to exposure to free, engineered nanoparticles (HSE, 2004; HM Government, 2005; Institute of Medicine, 2005). The extent to which existing regulatory provisions reflect the precautionary principle has been subject to debate. Whilst it is widely accepted that the use of nanotechnologies will extend to a range of industrial sectors, knowledge about potential applications and implications of nanomaterials is incomplete. In response to this information deficit, there have been calls for a detailed consideration of the manner in which hazards arising from applications of nanotechnology are managed. (RS/RA Eng. 2004) A number of regulatory

reviews have been conducted (Defra, 2005; Defra, 2006; HSE, 2006; FSA, 2006).[26] By and large, they conclude that, given the paucity of information about the likely impact of nanotechnology, a precautionary approach to risk is of paramount importance (Defra, 2005; RS/RAEng, 2004).

The precautionary principle, which has come to dominate the regulatory climate in relation to new technologies, underlies the UK government's approach to nanotechnology. This pre-emptive stance is underpinned by the government's commitment to 'Better Regulation', and more broadly by the European Community's focus on a high level of public health, safety, environmental and consumer protection. (European Commission, Communication from the Commission, COM338, 2004)

Report	**Key findings in respect of regulation**
RS/RAEng (2004) *Nanoscience and Nanotechnologies: Opportunities and Uncertainties.*	▪ Concludes that lack of evidence relating to risks posed by manufactured nanoparticles has resulted in considerable uncertainty. ▪ Recommends that relevant regulatory bodies consider whether existing regulations adequately protect human health and the environment from potential risks posed, and address any regulatory gaps arising.
HM Government (2005) *Response to the RS/ RAEng Report.*	▪ Because of their novel properties, free engineered nanoparticles should be treated as new chemicals under UK and EU legislation in order to trigger safety tests and clear labelling requirements. ▪ Safety assessment on the basis of the bulk form of a chemical cannot be used to infer safety of its nanoparticulate counterpart. Regulations must be reviewed to take into account the fact that nanoparticles might have greater toxicity than the bulk form of a chemical. ▪ The adequacy of current regulatory frameworks will be reviewed to ensure that safeguards to public health are sufficiently robust. ▪ Free, engineered nanoparticles used as ingredients in consumer products should undergo thorough safety assessment by the relevant scientific advisory body before being placed on the market. ▪ In order to ensure that products of nanotechnologies are properly regulated, sector specific regulations may be required in addition to REACH. This issue is to be addressed through regulatory review.
Defra (2006) *A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies.*	▪ Regulatory gaps identified arise from either exemptions provided for by legislative frameworks or from lack of information relation to: o The scope of definitions; o Current understanding of risks associated with exposure to nanomaterials;

[26] Defra, Characterising the Potential Risks Posed by Engineered Nanoparticles: A First UK Government Research Report (Department for Environment, Food and Rural Affairs; London; 2005); FSA, Draft Report of FSA Regulatory Review: A Review of Potential Implications of Nanotechnologies for Regulations and Risk Assessment in Relation to Food (Food Standards Agency; London; 2006); HSE, Review of the Adequacy of Current Regulatory Regimes to Secure Effective Regulation of Nanoparticles Created by Nanotechnology (Health and Safety Executive; London; 2006).

	o Agreed dose units that can be used in assessment of hazard and exposure; o Methods for risk characterisation and measurement; and o Potential impacts of nanomaterials on human health and the environment.
HSE (2006) *Review of the Adequacy of Current Regulatory Regimes to Secure Effective Regulation of Nanoparticles Created by Nanotechnology.*	▪ The principles of existing regulations are appropriate and applicable to nanomaterials. ▪ There is no need to fundamentally change existing regulations, nor to introduce new provisions. ▪ There are many gaps in knowledge about nanomaterials. These gaps will make it difficult for those involved in the regulatory process to fully discharge their responsibilities within the relevant regulations. ▪ By virtue of this lack of information, regulation in some sector areas will require the exercise of judgement. This might lead to different interpretations of the appropriate position within certain regulations. ▪ Regulatory issues must be considered on an EU-wide basis. ▪ Much of the EU legislation identified in the Report is subject to change under the envisaged REACH system.
FSA (2006) *Draft Report of FSA Regulatory Review.*	▪ Current information suggests that most potential uses of nanotechnology in relation to food will be subject to an approval process prior to being permitted for use. ▪ There are no major regulatory gaps in principle. ▪ There is uncertainty as to whether some applications of nanotechnology would be captured by certain existing regulations. ▪ The view of independent committees COT, COC, and COM is that existing procedures of risk assessment can apply to nanomaterials. ▪ There are no major gaps in information for the identification of hazards associated with nanotechnologies. ▪ Risk assessment procedures should include mechanisms to facilitate provision of information relating to nanomaterials. ▪ Onus should be placed on manufacturers of nanomaterials to supply information needed for risk assessment.

The uncertainty with which the impact of nanotechnology presents itself raises questions about the extent to which new products and processes using nanoparticles fall within the scope of existing regulatory provisions. The absence of a comprehensive understanding of the consequences of the manufacture of nanomaterials has led to demands for a robust regulatory structure that ensures that threats are anticipated and, where possible, avoided.

The regulatory emphasis in relation to new technologies is on the setting of safety thresholds using conceptual models of risk assessment. A critical aspect of the regulation of nanotechnology is establishing the positioning of benchmarks. Standard setting organisations, such as the British Standards Institute (BSI), the International Standards

Organization (ISO), European Committee for Standardization (CEN) are at the forefront of resolving issues of definition and taxonomy in relation to nanoparticles.

In spite of this drive towards the global standardisation on nanotechnology, the use of nanotechnology is not governed by a single regulatory framework. Rather, a number of different legislative provisions apply. This inevitably renders complicated the analysis of the regulation of nanotechnology. A number of scoping studies identify current legislative provisions that could conceivably address risks associated with the application of nanotechnology in various sectors of industry. (Chaudhry, et al., 2006) Risks posed to human health and those posed to the environment tend to be dealt with separately. (Aitken, 2004; Chaudhry, et al., 2006)) As a result, there is a lack of studies whose breadth is sufficient to cover risks to both human health and the environment in the context of all known current and potential uses of nanotechnology. This report provides an exhaustive examination of regulatory structures across all sectors in which nanotechnology is used, or is likely to be used.

Although regulatory gap analyses to date suggest that, on the whole, potential hazards emerging from current applications of nanotechnology fall within existing regulatory frameworks, (RS/RAEng (2004); (Chaudhry, et al., 2006) little has been said about the way in which a proper regulatory response might be modelled in the future. This provokes key questions about the optimum balance between the role of industry, producer responsibility, stakeholder involvement, and government intervention, and whether public health and environmental protection might be better served through an integrated regulatory regime (Bennett, 2004). It is inevitable that the on-going development of applications and processes using nanotechnology will place new demands on existing regulatory structures. An important and often overlooked issue is determining how regulatory approaches might respond to such a rapidly evolving industry.

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Annex 2 – Questionnaire

Assessment of Gaps in the Regulation of Nanotechnology & Nanomaterials

Questionnaire

The BRASS Centre is conducting a research project for the Office of Science and Innovation in the DTI into the actual and/or potential gaps in the regulation of nanotechnologies and nanomaterials. As a recognised expert in the sector your contribution to this research would be highly valued, and we would be very grateful if you could complete this questionnaire.

Part 1: General Details

Name:

Organisation:

Position: Sector:

Contact Details:

Part 2: Application of Nanotechnology

Current Applications

1. In the attached Table 1 (see below) of applications of nanotechnology, please comment if this is an accurate representation of known current product related applications?

Yes ☐ No ☐

Comments:

2. If No, please provide a list of product applications that are not included.

3. In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to those applications?

Future Applications

1. In your experience what areas of nanotechnology are likely to experience the greatest rate of development over the following two time periods?

a. 2 years

b. 5 years

2. In your opinion what are the main risks associated with these identified future applications (in terms of public health, environment)?

Part 3: Information Base

1. Does the current scientific knowledge on the impacts of nanotechnology and nanomaterials keep pace with the developments of nanotechnology?

Yes ☐ No ☐

2. If No, what in your opinion are the general gaps in the information/scientific knowledge base?

3. In your opinion is the practice of 'read-across' using data from an existing substance as a prediction of the toxicity of a new substance used to determine the potential risks of new applications of nanotechnology?

Yes ☐ No ☐

4(a) If Yes, what in your opinion, are the potential risks, if any, in the continuance of this practice?

4(b) In your opinion does this practice need to be controlled under a regulatory framework?

Yes ☐ No ☐

5. In your opinion, is there a need to develop an interdisciplinary centre to research the toxicity, epidemiology, persistence and bioaccumulation of nanoparticles and nanotubes and their exposure pathways?

Yes ☐ No ☐

Please provide details

Part 4: Regulation

1. What, if any, are the current practices used to monitor and collate information on any risks associated with the manufacture, supply, formulation and use of nanotechnology and nanomaterials?

2. In your opinion does the current regulatory framework adequately cover the regulation of the manufacture, supply, formulation and use of nanomaterials?

Yes ☐ No ☐

If No, Please comment:

3. In your opinion what is the most important element (e.g. regulation, guidance, information, etc) of any regulatory framework, which will ensure that nanomaterials are manufactured, supplied, formulated and used safely?

Please list any necessary appropriate measures:

4. Given the lack of scientific certainty is a regulatory approach based on the precautionary principle desirable?

Yes No

Please comment – if Yes – the role it should play/how it can be achieved and if No – the reason why?

5(a) In your opinion to what extent has it been possible to subject nanomaterials to risk assessment processes?

5 (b) To your knowledge, what have been the main findings of any risk assessments conducted under 6(a)?

5(c) Are current risk assessment processes sufficient to cover the actual or potential risks associated with nanomaterials/nanotechnology?

Yes ☐ No ☐

If No, please comment

5(d) In your opinion please outline what is the current practice in the determination of setting standards in terms of definition and taxonomy?

6. In general, current existing legislation fails to adequately govern nanomaterials due to the element of size/scale – in your opinion how can this be resolved?

7. Is there need for a moratorium on the commercialisation of nanosmaterials/nanotechnologies?

Yes ☐ No ☐

Please comment on the reasons for your response:

8. In your opinion at what point should regulation of nanomaterials commence?

9. In your opinion what are the potential risk prevention approaches?

Thank You for Your Assistance With This Research. Please return your completed questionnaire to:

Frances Hines
Research Manager
BRASS Centre
Cardiff University
55 Park Place
Cardiff
CF 10 3AT

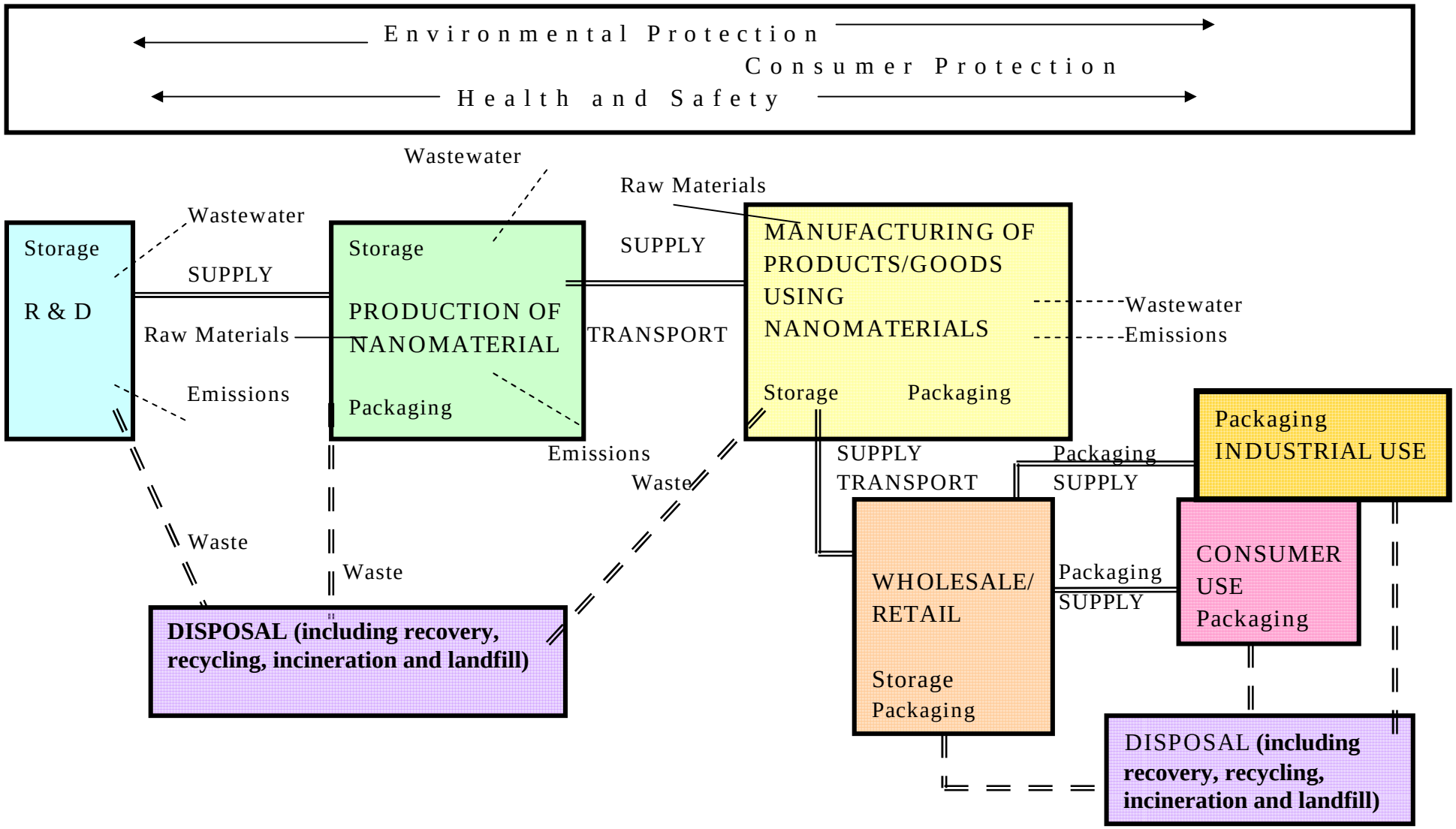
OR

FAX it to 02920 876061

OR

Email it to hinesf@cardiff.ac.uk
ANY QUERIES OR PROBLEMS PLEASE CONTACT
FRANCES HINES BRASS RESEARCH MANAGER on 02920 876562

Annex 3: NANOTECHNOLOGY LIFECYCLE MAP



Annex 4A – Regulatory Gaps Table

Regulatory Group	Scope	Risk Characterisation	Risk Assessment	Risk Management	Information Base
Summary – Group 1: The regulations considered in Group 1 are essentially linked to the issues considered in Group 2. The information derived from the classification of nanomaterials as new or existing substances may impact on the level of information available to undertake the necessary obligations under various regulations required for health and safety reasons, in particular in relation to storage, packaging, transportation, labelling and the precautions required for the management of the use of nanomaterials either as a raw material or as a substance contained within a product.					
Group 1 = Production /Introduction- nanomaterials	1. Classification of nanomaterials – if it is considered that the nanoscale form does not constitute a change in the chemical structure, a potential gap arises as nanomaterials are likely to be classed as 'existing' substances[27] rather than as new substances. If classed as 'existing' there may be a potential gap relating to the availability of future information for	1. If classed as a new substance, notification arises only where mass produced and mass triggers meet prescribed quantities - Threshold triggers used to determine the need for and extent of testing chemicals do not take account of particle size, therefore the production of a substance in nanoparticulate form does not trigger any additional testing. And may be subject to	1. Risk assessment procedures under NONS are the responsibility of the competent authority and not supplier therefore not use specific[32], which could lead to gaps in extent of information. 2. Exposure assessment qualitative due to lack of available data. 3. Hazard Identification – notification of new substances requires	1. Monitoring - COSHH When a COSHH assessment indicates the need, monitoring of exposure should be carried out using a valid and suitable method. Nanoparticles in the form of fibres, such as carbon nanotubes, may need specific exposure measurement methods to be developed. Current methods of	1. At present a dearth in the scientific data on the toxic properties of nanomaterials may require a reassessment of reference values to measure the potential risks associated with the nanoscale. 2. Suppliers of nanomaterials are responsible for providing safety data on physical and chemical properties, stability and reactivity, toxicological

[27] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) and was placed on the market before September 1981.
[28] Notification of New Substances Regulations 1992, EU Existing Substances Regulations 793/93/EEC and Biocidal Products Regulations 2002
[29] Is the document entitled "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Eighth Edition)" approved by the Health and Safety Commission on 26 July 2005
[30] Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (as amended)
[31] Registration, Evaluation and Authorisation of Chemicals

	subsequent users with the nanosubstance passing through its lifecycle without additional scrutiny of its unique properties. Consequently, no labelling for supply and no information to introduce, where necessary, measures to reduce potential risks during use and disposal. 2. Currently, no nanoscale substances have been assessed against the EU process under NONS, ESR or BPR[28] - as such self-classification under CHIPS relies on the notification of substances and their presence in the Approved Supply List[29] to determine hazardousness. With no nanoscale substances on this List, suppliers have no information on which to assess whether the	reduced level of testing due to the small quantity. Gap may arise due to potential inadequate testing of properties. 2. Due to the scale of nanomaterials a different metric for assessing exposure may be required to capture particular risks associated with the nanoscale and substances at this scale may need to be subject to a higher standard of testing.	tests to be conducted on physicochemical, toxicological and eco-toxicological properties of notified substances. Hazard information derived from this process required by suppliers under CHIP obligations. At present standardised testing in terms of timing and extent outlined in NONs relating to hazardous may not be sufficient for nanomaterials. Consequently, reference values in terms of nanoparticles may need to be reassessed due to the lack of scientific data on the toxic properties of chemicals at this scale	monitoring exposure may not be appropriate with nanoscale fibres. 2. Management of potential risks downstream - COSHH principles of good control should be capable of being adapted to the control of nanomaterials. However, the performance and effectiveness of conventional methods will need to be assessed e.g. PPE[33] will only provide the intended level of protection if correctly specified or fitted.	information, ecological information, disposal considerations and transport information. General issue is the lack of sufficient information and knowledge available on toxicological hazards, appropriate exposure limits – it will be difficult to provide the relevant data and undertake the necessary risk assessments. Current gap is the lack of available information on the potential indications of danger.

[32] This is likely to change under REACH with responsibility for risk assessment lying with the supplier and not the Health & Safety Executive and the Environment Agency.
[33] Personal Protective Equipment

	nanomaterial is hazardous or not. An incorrect classification could lead to consequences in subsequent legislation applicable to the use of the substance and on the potential controls to reduce damage to human health or the environment. 3. Research & Development – Often regulations do not extend to R & D for example the absence of prior authorisation for the use of new substances in biocidal products for R&D or experimental purposes could potentially allow new substances incorporating nanoparticles to be uncontrolled or unregulated. In addition, the Medicines Regulation[30]s does not extend to cover medicinal products intended for research and development trials. This creates a potential gap in the regulation of risks associated with	**Horizon Scanning – REACH**: Registration dependent on tonnage triggers, which currently may exclude nanomaterials 2. Data requirements	**Horizon Scanning – REACH**: Extend the responsibility to both new and existing	**Horizon Scanning – REACH**: Whilst risk management is	

	nanomaterials, relating in particular to the subsequent disposal of products and downstream environmental exposure to potentially hazardous substances **Horizon Scanning – REACH**[31]: If the nano-equivalent is considered to be the same as the registered substance appropriateness of existing data may be insufficient. No chemical at the nanaosize scale currently considered as 'substances of very high concern'.	will vary according to tonnage of substance produced – current proposed threshold may be too high for nanomaterials.	substances but only applies to substances supplied in quantities over 10 tonne/yr (unless of particular concern In addition, there is a question over whether the tests required are relevant for the risk assessment of nanomaterials as methodologies for chemical safety assessment are based on 'conventional' methodologies for assessing chemical risks which may not be appropriate for assessing potential risks associated with nano-substances.	identified as the responsibility of those enterprises that manufacture, import, place on the market or use these substances – the responsibility only applies to substances supplied in quantities over 1 tonne/yr (unless of particular concern).	
Summary – Group 2: A number of regulations are considered under this heading from those that deal specifically aimed at suppliers, those aimed at recipients and users of chemicals and those aimed at the regulatory authority. Suppliers must ensure that they convey information to the recipients on the physicochemical (e.g. flammability) and toxicological hazards of their chemicals. NONS (see Group 1 above) requires standardised testing of hazardous properties of industrial chemicals new onto the market. The information generated by these tests can be used further downstream by users in assessing appropriate risk assessments for risk management procedures required to ensure the safe use, transportation and disposal of chemicals.					
	Scope	**Risk Characterisation**	**Risk Assessment**	**Risk Management**	**Information Base**

Group 2 = Health & Safety	1. Definition of Hazardous Substance (COSHH, CHIP, Dangerous Substances & COMAH[34]) – whether a substance is classed as hazardous and therefore requiring certain undertakings will depend on the classification used under CHIP[35]. As discussed in Group 1, suppliers use the Approved Supply List[36]. As yet, no 'existing' substances in nanosized form have been through this EU system. Suppliers will need to gather and consider all of the relevant data on that substance and determine the classification themselves using any available guidance. Due to the general lack of available data on nanomaterials and any consequential impacts and subsequent hazards	1. Hazardous to Health (COSHH) – substance is hazardous to health if it is on the Approved Supply List or meets an approved occupational exposure limit or is present as a dust at a concentration greater than 4 mg/m3 (respirable fraction) or 10mg/m3 (inhalable fraction), as 8-hour time-weighted average values. From current, limited understanding of the toxicology of nanomaterials it would be unwise to regard exposures to nanomaterials at or below 4 mg/m3 (8h TWA) respirable dust as representing adequate control	1. Material Safety Data Sheets (CHIP) - General issue is the lack of sufficient information and knowledge available on toxicological hazards, appropriate exposure limits – it will be difficult to provide the relevant data and undertake the necessary risk assessments. Poor quality of the data could lead to an incorrect interpretation of the data by users downstream. However, where nanomaterials are classed as hazardous MSD sheets will be required. 2. COSHH risk assessment is based on using available information on the hazards and knowledge of the local	1. An accurate risk assessment should lead to an employer putting into place appropriate risk management procedures. Where appropriate information exists for nanomaterials, risk management procedures are likely to be implemented, however at present the current level of information and knowledge may lead to potential gaps in the appropriate precautionary measures. 2. Monitoring – a good risk management system will also involve a monitoring of exposure – due to scale of nanomaterials a specific exposure	1. To conduct risk assessments the following information is lacking; a. sufficient toxicological hazard information for most nanoparticles; b. reliable, affordable and standardised exposure measurement and characterisation methods; and c. an agreed definition of the most appropriate dose metric(s) to use in hazard and exposure studies. This applies to COSHH & Biocidal products. 2. Potential risks to health – employers under COSHH must undertake health surveillance of employers at risk of exposure – current there is insufficient

[34] Control of Substances Hazardous to Health Regulations, Chemicals (Hazard Information and Packaging for Supply) Regulations, Dangerous Substances and Explosive Atmospheres Regulations 2002 & Control of Major Accident Hazards Regulations

[35] The regulation does not extend to chemicals such as cosmetics and medicines.

[36] Chemicals examined under NONS, ESR or BPR in the UK (or, in other EU Member States, the corresponding regulations) will have their classification and labelling (C&L) agreed at EU level and entered into 'Annex I' of the Dangerous Substances Directive. This 'Annex I' (transposed into the UK 'Approved Supply list', ASL) also lists the C&L for a considerable number of other existing substances that have been through the EU-wide procedure of agreeing C&L positions.

	– the process of classification could lead to incorrect classifications resulting in any potential hazards not being addressed down the supply chain. If classified as non-hazardous - subsequent users would be dependent on existing data as no new data would be generated on the potential risks or hazards relating to the identified nanomaterial. Consequently, nanomaterials could move through their lifecycle without any further assessment of their properties. 2. Major Accidents – Sites that store dangerous substances contained in a prescribed list of substances. Most nanomaterials are likely to fall outside the very prescriptive COMAH definition of a 'dangerous substance', and therefore will not be covered by	associated confidently with health protection[37]. 2. Major Accidents – Where sites store substances containing nanomaterials that may be covered by the prescriptive list, they must then meet threshold levels. It is unlikely that the storage of any nanomaterials will meet the high threshold levels outlined in COMAH.	conditions of exposure. Risk assessment are therefore based on both sound scientific information and past experience; in terms of nanomaterials this information is likely to be incomplete and there are likely to be deficiencies in the level of available information 3. COMAH – top tier sites are required to undertake risk assessment, which results in a safety report. To undertake an appropriate risk assessment, data must be relevant to the actual formulation used – consequently an assessment of the range of formulations with a corresponding range of effects and subsequently a range of effects data. At present it is unlikely that this range of data	measurement method may need to be developed. 3. Under the Health & Safety at Work Act, employers must ensure the safety of all employees at work. They are required to assess any potential risk arising from the use of certain products and act accordingly. The risk assessment process and management of any potential risks is often aided by the relevant information provided by producers and suppliers. Any gaps existing at the supply of information stage will be carried down the supply chain. 3. Biocidal Products - Prior to placing on the market of a product for use in experimental or R&D purposes, a dossier of information on the	knowledge available concerning the potential risks to employees. 3. Often the identification of the relevant classification is the responsibility of the producer or site e.g. (COMAH). It is the onus of the site operator to identify the appropriate hazards, with insufficient information currently available, concern must be raised over the current identification of hazard classification. Incomplete information will also have a bearing on the effectiveness of safety measures put un place according to employer obligations. 4. An HSE report has identified that increasing range of explosive materials are being manufactured as

[37] Health and Safety Executive, Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology

[38] Health and Safety Laboratory, *Literature Review: Explosion Hazards Associated with Nanopowders*, HSL/2004/12 (HSe; 2004).

	these Regulations. Many potential sources for nanomaterials (e.g. aluminium, copper, iron, silver, titanium) which could be considered dangerous are not referred to in the list.		is available to fully comply with risk assessment requirements.	possible effects on human or animal health and the environment must be compiled. The required dossier will likely reveal information on biocidal products with nanoparticles.	nanopowders.[38] Although extensive literature on explosive characteristics of micron-scale powders, no data on nanopowders.
<u>Summary – Group 3:</u> The concept behind Extended Producer Responsibility applies equally to nanomaterials, requiring producers or manufacturers to minimise human and environmental exposure to free nanoparticles at all stages of the lifecycle and should also form an integral part of the innovation and design process. A number of types of products, substances or activities have been identified by the regulator for control applying a lifecycle approach; this requires manufacture to consider at the design phase, the means of limiting the impacts of the product on the environment and human health.					
	Scope	**Risk Characterisation**	**Risk Assessment**	**Risk Management**	**Information Base**
Group 3 = Producer Responsibility – Product Quality & Safety	1. <u>Prohibition or Restriction of Certain types of substances</u> The prohibition or restriction can extend to prescribed substances (RoHS) or to more general substances (ELV). In RoHS, whether nanomaterials are covered by the regulations will depend on whether the set concentration levels are set. Restricted substances under ELV	1. <u>Thresholds Limits</u> The issue is whether the threshold limits are set at appropriate levels to prevent the materialisation of potential risks to human health or the environment posed by nanoparticles in substances/products. Often the limits set do not refer to particle size (e.g. motor fuel). It is conceivable that the present limits in	1. In some of the regulations the scope is restricted to a <u>specific safety procedure</u> for example the need to obtain a detonation resistance certificate[41] and does not regulate any potential environmental hazards and risks associated with the use of these products. There is no assessment required	1<u>. Design Requirements</u> A number of the regulations require that a lifecycle approach be applied to the design of equipment. By so doing reducing the impacts of the product on human health and the environment by ensuring any hazardous components are so identified, limited or	If nanomaterials are accurately classified and increased information on potential impacts become available many of the regulations should ensure that nanomaterials are captured and managed appropriately. 2. <u>Lifecycle Approach</u> - the lack of scientific information on the

[39] For example the presence of heavy metals in *Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended)*and *End of Life Vehicles Regulations 2003*

	are those identified in the Approved Supply List (see comments above on whether nanomaterials will be covered by this List). 2. Extent of definition – for many of the regulations there are potential gaps on whether the nano-equivalent of a substance will be classed as an 'existing' substance or as a new substance[39]. If classed as an 'existing' substance, whilst perhaps covered by the regulations, whether the unique properties of the nanoscale form will be identified in risk assessments. If classed as a 'new' substance, a potential gap may arise if the nanoscale form is excluded from the regulations. 3. Packaging – regulation aim to reduce	many of the regulations will fail to capture potential threats arising from the use of nanomaterials[40]. Further, given concerns that toxicological profile of nanomaterials creates a greater potential risk to human health or the environment, the concentration levels are set at too high a level to capture potential risks associated with nanoparticles. 2. The danger that thresholds are inappropriately set with regard to potential risks posed by nanomaterials means that nanocomponents and products containing nanomaterials can be marketed without further scrutiny. 3. RoHS - The	of the potential risks of nanomaterials and as such no management procedures to deal with any impacts arising out of the risk assessment. 2. Vigour of safety requirements - the medical devices Directives* explicitly require that in assessing the safety of medical devices, attention must be paid to the choice of materials used and their toxicity. Annex I to Directive 98/79/EC makes no reference to taking into account the toxicity of particular materials used in the design and manufacture of *in vitro* devices, although it is anticipated that in conducting safety assessments *in general*, material toxicity is a central	easily separated from the product for final disposal. These provisions will extent to the presence of nanomaterials once sufficient levels of information become available.	impacts of nanomaterials on human health and the environment is likely to prohibit a full lifecycle approach and as such to limit any potential harm from nanomaterials, it is recommended that they are classed as hazardous substances. 3. Medical Devices - It is recognised that knowledge about the implications of human exposure to nanoparticles is incomplete. Despite the fact European Directives[42] establish a general framework of safety, there remains, as with other current and future applications of nanotechnology, a paucity of information about the human health impact of

[40] The overarching safety framework established by the *General Product Safety Regulations 2005* applies, should the parameter limits fail to capture risks arising from the placing on the market of fuel containing nanoparticles under the *Motor Fuel Regulations*.
[41] *Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003*
[42] * - Directive 93/42/EEC concerning medical devices; Directive 98/79/EC on *in vitro* diagnostic medical devices; and Directive 90/385/EEC on implantable medical devices

	the amount of noxious metals and other substances as well as the potential toxicity of packaging waste and to limit their environmental impact. Nanomaterials are likely to be captured under the regulation if they are classed as a hazardous substance or material and if so any emissions will be minimised. As the regulations extend throughout the lifecycle of packaging including manufacturing; manufacturers will rely on information supplied to them by chemical suppliers who in turn will rely on data provided under NONS* notification. Potential gaps at these stages will therefore impact on other users.	concentration levels set down in RoHs have been derived from information of the impacts of these restricted substances at the macro level and therefore the availability at the nanoscale may require reassessment of the concentration value levels.	consideration.		exposure to nanomaterials.
	Scope	**Risk Characterisation**	**Risk Assessment**	**Risk Management**	**Information Base**
<u>Summary – Group 4:</u> ensure consumer product safety by requiring that products placed on the market or supplied by producers and distributors are deemed to be safe and establishing a framework for safety assessment.					
Group 4 – Consumer	1. <u>General Products Definition of Risk</u>[43] -	1. <u>Cosmetic Products – Concentration Levels</u>	1. <u>General Products Safety Standards –</u>	1. <u>Food – Migration of Active and Intelligent</u>	1. <u>Cosmetic Products – Information Gaps</u>

[43] As provided by the *General Product Safety Regulations 2005* - A 'safe product' is defined as a product which, under normal or reasonably foreseeable conditions of use *does not present any risk or only the minimum risks compatible with the product's use.*

Protection	The Regulation does not provide a clear definition of 'risk' in this context[44]and as such has potential implications for the assessment of product safety. It is anticipated that due to the broad nature of the regulations they will extend to cover current and potential applications of nanotechnology in consumer goods. 2. Cosmetic Products – a. Definition of cosmetic product - sufficiently wide to include nanomaterials.	– Prohibited and Restricted Substances - If substances containing nanomaterials are deemed to be equivalent to their non-nanomaterial counterpart whose use is *restricted*, the issue is whether the weight and concentration limits specified are appropriately set to account for potential risks associated with human & environmental exposure to nanoparticles. The toxicity profile of	Where no applicable product or national regulations exist, safety is assessed according to voluntary EU harmonised standards[51]. Compliance with voluntary standards does not guarantee that a product will be deemed to be safe if it fails to establish appropriate safety levels in respect of nanomaterials. Standards, therefore, can be seen to provide a *de minimis* threshold of safety. It is recommended that	Nanomaterials - Although the migration of nano-constituents to foodstuffs is potentially permitted by the Regulation[52], Article 4 requires pre-market authorisation of substances deliberately incorporated into active materials and articles to be released into food or the environment surrounding food shall be authorised and used in accordance with the relevant Community provisions	information necessary for the risk assessment of dermal exposure to nanoparticles is lacking. 2. Food – Food Safety[54] - Safety assessments of nanomaterials in food products are currently based on incomplete information, and might not accurately reflect the likely effect of nanotechnology. It is likely that applications of nanotechnology will be deemed to represent an 'emerging risk'

[44] Although note that 'serious risk' is defined by Regulation 2 as a serious risk, including one the effects of which are not immediate, requiring rapid intervention.
[45] Even if food products were to fall outside the scope of the regime established by the Food Safety Act 1990 is still sufficiently broad to cover potential dangers arising from the use nanotechnology in relation to foodstuffs in general. Products falling outside the definition of 'food' will be caught by overarching frameworks such as the General Principles of Food Law Regulation (EC) No.178/2002 and the General Product Safety Regulations 2005
[46] Food Additives Directive 89/107/EEC.
[47] *Sweeteners in Food Regulations 1995 (as amended), Colours in Food Regulations 1995 (as amended) and Miscellaneous Food Additives Regulations 1995 (as amended)*
[48] *Novel Foods and Novel Food Ingredients Regulations 1997*
[49] See Food and Drink Federation, *Response to FSA Draft Report of Regulatory Review of the Use of Nanotechnologies in Relation to Food* http://www.fdf.org.uk/responses/fdf_response_nano.pdf, accessed October 2006.
[50] *Contaminants in Food Regulation (EC) No. 315/93*
[51] Council Resolution, 7 May 1985, 'New Approach to Technical Harmonization and Standards'.
[52] *Materials and Articles in Contact with Food Regulation (EC) 1935/2004*
[53] *Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (as amended)*
[54] *General Principles of Food Law Regulation (EC) 178/2002*

	Products supplied to consumers that fall outside the scope of the Regulation 3(1) definition are likely to fall within the scope of the General Product Safety Regulations 2005, which establishes a framework for ensuring that intended for or likely to be used by consumers under normal or foreseeable conditions are safe. b. <u>Prohibited and Restricted Ingredients</u> Whether covered by regulations will depend on whether listed substances and those containing nanoparticles can be considered to be *equivalent* for the purposes of the Regulations. If classed as equivalent coverage under the regulations will be dependent on listed concentrations levels. If not classed as equivalent to the macro form it is conceivable that the use of the substance in cosmetic products will	nanomaterials if potentially markedly different from the non-nanoscale equivalent and therefore reduced quantities could pose a greater threat to human health and the environment. 2. <u>Food – Novelty Food</u> For those nanomaterials in food products aleady on the market will fail the novelty test[48] - it is unlikely that the novelty threshold has been tested in relation to the use of nanomaterials in food, given that nanotechnologies in this context are still in the research and development stage.[49] <u>Purity Criteria</u> – Under the regulations limited to 2 substances due to the uncertainty of their safety – their restriction is based on particle size. It is recommended that particle size is included in the purity criteria as standard practice and	harmonised standards that take into account the characteristics of nanoparticles are developed. 2. <u>Cosmetic Products – Safety Evaluation -</u> Precise chemical nature of the ingredient and its structural formula, if known, should be identified in the safety evaluation. Although there are no specific requirements relating to nanomaterials in cosmetic products, it is unlikely, given incomplete information about the implications of human & environmental exposure to nanomaterials, that a full safety evaluation could be conducted on cosmetic products containing nanoparticles. <u>Detergents</u> - The issue is whether the safety provisions set out in the Regulation are capable of identifying potential risks associated with	relating to food safety. <u>Whether migration thresholds are sufficient to manage potential dangers posed by nanomaterials</u> Given that the European Directive[53] does not differentiate between nanomaterials and materials and articles produced by 'traditional' means, it is uncertain whether the migration threshold set within the Directive would provide adequate protection against threats posed by nanoparticles.	pursuant to Regulation. Given the novelty of nanotechnology and the lack of complete knowledge about its implications, the feasibility of thorough risk assessment is thwarted by scientific uncertainty. 3. <u>Migratory Nanomaterials</u> - Under the 2001 Scientific Committee on Food Guidelines, the toxicological dataset required to determine safety depend on migration values. It is conceivable, given the novelty of applications of nanotechnology, datasets are insufficiently 'extensive' to establish the safety of food contact materials containing nanoparticles falling within the 'high migration' category. Establishing the safety of food contact materials containing nanoparticles falling

	not be covered by the regulations. 3. Food Definition: Novel Food - It is unclear whether the uses of nanomaterials in foodstuffs will bring food product referred to in the Food Safety Act within the meaning of 'novel food'. Given that reference is made to the novelty of the food product rather than to its process of manufacture or composition, it is conceivable that the production of foodstuffs using nanotechnology is insufficient to render it 'novel' for the purposes of the Act[45]. 'Substantial Equivalence' - the test applies only in relation to certain categories of food and food ingredients. It is unlikely that current and potential applications of nanotechnology identified will fall into any of the identified categories. The consequence is that novel foods containing	therefore gain coverage of nanomaterials. Contaminant Thresholds[50] - for food containing a contaminant in quantities that pose an *unacceptable* threat to public health must not be placed on the market. It is unclear whether the thresholds specified in the Annex to Regulation 466/2001 are set at appropriate levels to control potential risks arising from applications of nanotechnology in this context. Taking into account recognised properties of nanomaterials, such as increased toxicity, it is conceivable that the maximum level thresholds specified provide inadequate protection to consumer health.	exposure to nanomaterials. It is likely that the requirements are sufficiently thorough to identify possible threats arising from the use of nanomaterials. However, a complementary risk assessment is only required in relation to surfactants that fail the ultimate biodegradability test. It is conceivable that primary and ultimate biodegradability testing fails to detect potential risks associated with exposure to nanomaterials, which might be expected to be identified by a complementary risk assessment. 3. Food – If nanomaterials did satisfy the 'substantial equivalence test' - a finding of substantial (or partial) equivalence under the Novel Food Regulations would		within the 'low migration' category, however, poses less of an evidential challenge. Given that only a limited dataset is required in relation to low migration constituents, it is conceivable that materials and articles containing nanoparticles are deemed to be 'safe' and marketed before more robust datasets on human and environmental exposure are developed.

	nanomaterials cannot be treated in the same manner with respect to safety to an existing food or food component. Food Additives – due to extent of definition, it is likely that nanomaterials will be captured as a food additive under the European regulations[46], it is also likely that should nanomaterials fail to be covered as additives under the relevant UK regulations[47], the European legislation should secure their coverage.		create a potential loophole for the safety assessment of foods containing nanomaterials, as the Regulations do not explicitly set out specific criteria to assess the safety of novel foods on the basis of particle size. In addition if found substantially equivalent, no further toxicological testing is required. In the case of the partial, toxicological testing required only in relation to novel traits.		
	Scope	**Risk Characterisation**	**Risk Assessment**	**Risk Management**	**Information Base**
Summary – Group 5: A wide variety of regulations are considered in Group 5. Whilst some control emissions from pollutants to all media, others deal solely with controlling, restricting or prohibiting emissions to air or discharges to water.					
Group 5 - Environmental Control	1. Control of Emissions Prescribed Activities Such is the innovative nature of nanotechnology production that they may not meet the activity descriptions within the PPC Regulations[55]. For	1. Control of Emissions – Threshold Levels Many of the sectors identified in the PPC regulations under which nanomaterials may be produced are unlikely to meet the prescribed thresholds and therefore are likely	1. Control of Emissions – Environmental Assessment Levels - The majority of EALs for air have been extrapolated from occupational exposure limits (OELs) using suitable uncertainty	1. Control of Emissions – Best Available Technique - Based on current scientific knowledge, there may be a number of issues in determining an acceptable level of emissions, the	1. Control of Emissions – Permit Information – provide information on the nature and quantities of foreseeable emissions from the installation. Given the current uncertainty in relation to the

[55] *Pollution Prevention and Control (England and Wales) Regulations 2000, the Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended),*

	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 nanomaterials produced using solely physical production routes. 2. Control of Emissions – Prescribed Substances & Pollutants[56] – PPC Regulations provides a list of polluting substances – whether nanomaterials will be covered by the list may depend on whether nanoscale form is classed as the equivalent of the macro form. If it is then it will be covered by the regulations – although subject to threshold	to be exempted under the regulations. 2. Control of Emissions – Emission Level Values May be set in permit for all pollutants likely to be released – may depend on whether pollutant is classed as an existing or new substance. If existing - ELV estimated on the basis of the environmental risks of the macro equivalent, which may be different from the nanomaterial. If not captured under the list of prescribed substances – the levels may be too high as they are unlikely to satisfy the 'significant quantity' threshold. 3. Water Quality – Discharge of Urban Wastewater[58] - As the regulations provide concentration level for	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. 2. Water Quality – Permitting Discharges to Groundwater – Environment Agency required to assess the risk of the discharge polluting or altering the quality of the groundwater - This may be assessed by using current	appropriate preventative measures or the Best Available Technology (BAT). The general lack of scientific knowledge on the management of nanomaterials may itself mean that the definition of BAT cannot extend to nanomaterials. 2. Control of Emissions - Monitoring - Based on current evidence about the relative toxicity of nanomaterials 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. However, the current means of measuring	potential impacts of nanomaterials on human health and/or the environment in relation both to the potential effects and the level at which these effects might occur, it may not be possible to assess the impacts of many nanomaterials. 2. Water Quality – Consent to Discharge - Even if nanomaterials qualified as a pollutant and triggered conditions on discharge consents. In order to be able to impose conditions, one requires appropriate and relevant information to ensure that appropriate volumes and rates can be applied. Trade Effluent - it is

[56] *Water Resources Act 1991, Pollution Prevention and Control (England and Wales) Regulations 2000, the Environmental Protection (Prescribed Processes and Substances) Regulations 1991 (as amended), Groundwater Regulations 1998, Surface Waters (Dangerous Substances) (Classification) Regulations 1997 & 1998*

[57] *Urban Waste Water Treatment (England and Wales) Regulations 1994*

[58] *Urban Waste Water Treatment (England and Wales) Regulations 1994*

[59] *Water Environment (Water Framework Directive) (England and Wales) Regulations 2003*

	levels (which may be too high for the nanoscale). If the nanomaterial is not classed as the equivalent of the macro form it may not be covered by the regulations. In other regulations brought under the PPC regime, prescribed substances are listed for the different media (air, land, water), nanomaterials may only be covered if they are classed as existing substances but then restricted to assessment and analysis against the macro equivalent, which may impact on any risk precaution measures. 3. Water Quality – Substances present in water – Regulations[57] seek to reduce the level of nutrients in waters categorised as 'sensitive areas'. The criteria are not prescriptive but make recommendations as to which types of nutrients should be reduced by	specific substances, nanomaterials are unlikely to be captured and even if they were captured under the regulations, it is likely that the concentration levels will be too high to capture their specific properties. 4. Water Quality – Annual Mean Concentrations - mean concentration assists in the classification of the water source ensuring that the concentration of the dangerous substance does not exceed that listed. With the low levels associated with nanomaterials it is foreseeable that in a number of occasions, they will, if classed as a dangerous substance, fall below these threshold limits.	techniques and these standard tests may not capture the different level of pressures, effects and potential risks introduced by nanomaterials.	and monitoring the emissions is unlikely to be applicable to monitoring any emissions resulting from nanomaterial pollutants. 3. Water Quality – Substances present in water - Nanomaterials, which have effects on the chemical or ecological quality of water could be considered a pressure on the quality, however in order to measure the pressure, standard tests need to be applied – current test procedures may not capture the different level of pressures introduced by nanomaterials. 4. Water Quality – Testing - It is likely that the current standards for monitoring water status will not capture the effects of nanomaterials, if the presence of substances at the nanoscale is likely to	unlikely that there is sufficient available information to fulfil the requirements to provide information on the impact of the discharge on sewerage services or the necessary steps to be taken. 3. Water Quality - no deterioration of water quality - Due to the current scientific knowledge available, any water that may be contaminated with nanomaterials that are deleterious to the environment or human health may not be detected due to the current technical standards available for monitoring water quality.

	further treatment. With its limited coverage it is unlikely that these regulations will extend to nanomaterials.			affect the quality of water. 5. Water Quality – Programme of Measures[59] - Any programme of measures is likely to be linked to the analysis identifying pressures on water quality, any lack of information or gaps at the analysis stage will impact on identifying the relevant programme of measures in particular those relating to prevention or control of the input of pollutants.	
Summary – Group 6: Waste will be generated throughout the lifecycle of nanomaterials from formulation, manufacture, supply, use as raw material and product use by both industrial and domestic users. Waste, in general, is classified as hazardous, inert or non-hazardous. Classification may dictate the particular disposal route available to the waste type e.g. hazardous waste prohibited from disposal to non-hazardous or inert landfill. It will also determine whether waste types can be mixed or require separation, whether components need to be removed prior to treatment and disposal, whether presence of waste must meet certain acceptance criteria. An incorrect classification of nanomaterial waste or waste containing nanomaterials may result in an inappropriate waste management option being chosen. Waste legislation includes waste types, waste disposal methods, waste licensing and the identification of specific substances, which have been identified					

	Scope	Risk Characterisation	Risk Assessment	Risk Management	Information Base
Group 6 = Waste	1. In current classification system no codes identify the presence of nanomaterials, merely the presence of dangerous substances. 2. The definition of hazardous waste and whether it extends to nanomaterials may result in potential gaps in the regulation of nanomaterial waste. At present no nanomaterial has been identified as a dangerous substance under the appropriate legislation outlined in Group 1 above. As a consequence waste generators, responsible for classifying waste types, have at present insufficient information to make an accurate classification. If nanomaterials not classed as hazardous they can be disposed to landfill, mixed with other waste types	1. If classed as hazardous waste (to identify disposal route), depending on the relevant chapter of the list of wastes, nanomaterials may still be subject to relevant concentration levels[63], as not all hazardous codes are 'absolute'[64] but producer can determine if the nanosubstance meets the relevant threshold levels of hazardousness. If it is believed that they do not (often relying on available data produced under NONS, ESR and BPR[65]) they therefore fall below the threshold limits and can be classed as non-hazardous. 2. Domestic Waste The existing framework cannot accommodate any specific requirements to manage domestic	Waste management facilities are subject to emission and discharge consents and limitations to reduce the level of potential pollution arising from waste management activities. 1. Emission Levels (waste incineration) are based on best available techniques. Currently, no limits exist for fine particles, which may be a concern in terms of nanomaterials and as a consequence result in another gap in the control of any emissions from the incineration of certain nanomaterials. Present levels reflect current knowledge on the polluting effects of emissions, which may be different in terms of the effects of nanomaterials. 2. Discharges to	1. Duty of Care – lays down the system of managing the transfer and disposal of waste including the requirement for a transfer note when waste is transferred. Identification of waste is via List of Waste and as this may not capture waste containing nanomaterials, which is hazardous in particular food from food processing or packaging waste. Where waste is not properly identified it may as a consequence the most appropriate means of disposal may not be identified. 2. Technical requirements & Technical Standards – many of the current technical standards based on current knowledge of potential risks –	1. Information for waste management licences - At present the information is likely to be based on standard tests and the current test procedures may not capture the different level of pressures introduced by nanomaterials. 2. Permit Conditions relating to restricted substances allowed to be discharged from waste management facilities - It is unlikely that due to the lack of available scientific data that the relevant precautions can be evaluated and this lack of information can extend to the maximum quantity of any nanoscale substance that may be permitted to be discharged. 3. Dismantling information – (ELV) – Producers to provided

[60] Restriction on the use of certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2005
[61] End-of-Life Vehicles Regulations 2003

	3. At present some applications of nanomaterial (e.g. food processing) do not have any hazardous classification; therefore waste cannot be identified as containing nanomaterials if they are considered hazardous. 4. Numerous waste regulations have been passed under extended producer responsibility regimes to restrict certain substances being disposed via specific routes. Some are prescribed substances (e.g. RoHS[60]) and others refer to hazardous substances in more general terms (ELV[61]). Potential gaps may arise due to the extent of the definition and whether nanomaterials	waste containing products with nanosized substances, consequently disposal method may not be the most appropriate and in the UK today it is most likely to be to a non-hazardous landfill site. 3. Waste Acceptance Criteria (landfill) – Questions may arise over the lack of information relating to the disposal of consumer products to non-hazardous landfill sites and the potential risk of emissions to groundwater, surface water or surrounding environment; jeopardise environmental systems.	groundwater (waste licensing) utilises List I and List II substances[66] - concern may arise over whether nanomaterial is equated to a macro form on one of the lists, if this occurs any assessment of risks will be at the macro scale and not at the unique properties of the nanomaterial. Consequently, discharge may be permitted without any further assessment. 3. Pollution control regulations are based on the current knowledge of the polluting effects of emissions from known substances; this may be different in terms of the effects of nanomaterials.	standards may need to be reassessed due to the introduction of nanomaterials where, at present, little knowledge is known about the long-term impacts. 3. Waste Acceptance Procedures at Landfill require detailed data to be held on the quantities, source and characteristics, and in terms of hazardous – its location on the site. The current system should be capable of dealing with the disposal of nanomaterials if they are correctly classified particularly if classified as hazardous – potential gap is the management of domestic waste. WEEE is likely to	information to assist in the dismantling of hazardous materials – with current lack of available data, producers may not be able to provide the relevant information on nanomaterials present in vehicle components. 4. General Information Gaps - Potential gap due to the lack of available data in terms of the effects of nanomaterials and their potential to travel through the landfill and therefore escape.

[62] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).
[63] The thresholds applied are H1 to H14 located in the Schedule 3 of Hazardous Waste (England & Wales) Regulations 2005
[64] That is will be classed as a hazardous waste no matter the concentration level of any dangerous substance present in the waste.
[65] Notification of New Substances Regulations 1992, EU Existing Substances Regulations 793/93/EEC and Biocidal Products Regulations 2002
[66] List I and List II substances contained in the *Dangerous Substances Directive (76/464/EEC),* however as part of the ongoing restructuring of the Community water policy, the Directive on Dangerous Substances is now integrated in the Water Framework Directive (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community.

	can be captured as prescribed substances or as a hazardous substance under the Approved Supply List – as stated under Group 1, no nanomaterials exist on this list. If classed as non-hazardous, components containing nanomaterials may not be segregated and may be incorrectly disposed via a means which may result in higher exposure. However, if applying the Approved Supply List, the nanomaterial is classed as an 'existing' substance[62]a potential gap may arise if the nano form is assessed on the same principles as the macro form. If the nano form is classed as a 'new' substance and therefore assessed on its own potential risks, a gap may arise if the new substance falls out of the scope of the regulations.			capture any nanomaterials in electrical and electronic equipment if this is disposed via a 'take-back' system.	

ANNEX 4B: Legislation identified within each of the groups of regulation used in Annex 4A

Group Name	Legislation
1. Production/Introduction onto Market	Notification of New Substances Regulations 1993 Directive - Registration, Evaluation and Authorisation of Chemicals (*Proposed)* The Biocidal Products Regulations 2001(as amended) Chemicals (Hazard Information & Packaging for Supply) Regulations 2002
2. Health & Safety	Control of Major Accident Hazard Regulations 1999 (as amended) Control of Substances Hazardous to Health Regulations 2002 (as amended) Dangerous Substances and Explosive Atmospheres Regulations 2002 Health & Safety at Work Act 1974 Management of Health & Safety at Work Regulations The Biocidal Products Regulations 2001(as amended) Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (as amended) Notification of New Substances Regulations 1993
3. Producer Responsibility – Product Quality & Safety	Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003 Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended) Medical Devices Regulations 2002 (as amended) Medicines Act 1968 Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (as amended) Motor Fuel (Composition and Content) Regulations 1999 (as amended) End-of-Life Vehicles Regulations 2003 Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2005 Directive 2002/96/EC on Waste Electrical and Electronic Equipment Packaging (Essential Requirements) Regulations 2003 Producer Responsibility Obligations (Packaging Waste) Regulations 2005
4. Consumer Protection	Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended) Motor Fuel (Composition and Content) Regulations 1999 (as amended) Biocidal Products Regulations 2001 (as amended)

	Dangerous Substances & Explosions Atmosphere Regulations 2002 Medical Devices Regulations 2002 (as amended) Medicines Act 1968 Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (as amended) Veterinary Medicines Regulations 2005 Building Regulations 2000 (as amended) Textile Products (Indications of Fibre Content) Regulations 1986 (as amended) Electrical Equipment (Safety) Regulations 1994 Control of Pesticides Regulations 1986 (as amended) Fertilisers Regulations 1991 (as amended Plant Protection Products Regulations 2005 (as amended) Detergents Regulations Cosmetic Products (Safety) Regulations 2004 (as amended) General Product Safety Regulations 2005 Additives Directive 89/107/EEC (as amended) Articles in Contact with Food Regulations 1987 (as amended Colours in Food Regulations 1995 (as amended Contaminants in Food (England) Regulations 2005 Food Safety 2005 Act 1990 (as amended) Materials and Articles in Contact with Food (England) Regulations 2005 Miscellaneous Food Additives Regulations 1995 (as amended Novel Foods and Novel Food Ingredients Regulations 1997 (as amended Plastic Materials and Articles in Contact with Food Regulations 1998 (as amended) Regulation (EC) No.178/2002 on General Principles of Food Law
5. Environmental Control	Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003 Environmental Protection Act 1990 (as amended) Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended) Control of Pollution (Oil Storage) (England) Regulations 2001 Control of Pollution (Silage, Slurry and Agricultural Fuel Oil) Regulations 1991 (as amended) Environmental Protection (Prescribed Processes and Substances) Regulations 1991 Air Quality (England) Regulations 2000 Clean Air Act 1993 Air Quality Limit Values Regulations 2003 Groundwater Regulations 1998

	Surface Waters (Dangerous Substances) (Classification) Regulations 1997 Surface Waters (Dangerous Substances) (Classification) Regulations 1998 Trade Effluents (Prescribed Processed and Substances) Regulations 1989 (as amended) Urban Waste Water Treatment (England and Wales) Regulations 1994 Water Industry Act 1991 Water Act 2003 Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 Water Resources Act 1991
6. Waste Disposal	Directive 2002/96/EC on Waste Electrical and Electronic Equipment End-of-Life Vehicles Regulations 2003 Environmental Protection Act 1990 Packaging (Essential Requirements) Regulations 2003 Producer Responsibility Obligations (Packaging Waste) Regulations 2005 Hazardous Waste (England and Wales) Regulations 2005 Landfill (England and Wales) Regulations 2002 List of Wastes (England) Regulations 2005 Waste Incineration (England and Wales) Regulations 2002 Waste Management Licensing Regulations 1994

Annex 5 – Regulatory Analysis (Templates)

Annex 5 contains a comprehensive analysis of the regulations identified in the Table of Current Regulations (Table 2). Key findings are analysed in Annex 4A above.

Legislation: *Notification of New Substances Regulations 1993*[67] *(NONS)*			
Summary of Purpose: NONS aims to identify the possible risks posed to people and the environment from placing new substances[68] on the market[69]. It does this by obtaining information about new substances so that users can be made aware of the dangers and if necessary, recommendations for controls to be made. The supplier of the new substance is obliged to ensure that this information is available. The review 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			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. New Substance Part I - Interpretation	NONS deals with substances that are placed on the market after September 1981. Substances already included in the European Inventory of Existing Commercial Chemical Substances (EINECS), a list of commercial substances which were marketed in the EC at some time between 1 Jan 1971 and 18 Sept 1981, are exempt from the NONs regulations. Under the regulations, it is the responsibility of the supplier to determine whether or not their substance is on EINECS and therefore 'existing'.	1. Supplier decision – whilst accepted that the general knowledge relating to nanomaterials is increasing – it is unlikely that all suppliers will possess the necessary data to make an informed decision relating to whether a nanoparticle is a new substance or existing. A potential gap in notification may occur. 2(a) <u>If not classed as a new substance:</u> Only changes in chemical structure constitute a new substance, whereas changes in form (e.g. size or shape) do not – exception is polymers. If nanomaterials are not classed as new substances and consequently are not subject to the notification system under NONS, no further assessment of the potential risks of these substances need be conducted.	1. At present no entries exist in the Manual of Decisions[70] relating to the issue of nanoparticle notification. New guidance and policies are required to ensure that the Competent Authorities and the supplier have sufficient information available to make the necessary assessment. For certain types of nanomaterials (carbon structures) there may need to be a precautionary principle approach requiring these to be automatically classed as new substances. 2(a) There would be no additional information passed onto any subsequent users and the substance would pass through its lifecycle without additional scrutiny, therefore no labelling for supply and no information to introduce, where necessary, measures to reduce potential risks during use and disposal.

[67] Implementing part of EC Directive 92/32/EEC

[68] A substance is a chemical element or compound in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

[69] Supplying a new substance includes selling it, lending it to someone else, passing it on, giving it away or importing it into the EC.

[70] A manual, which records precedents and procedures for the interpretation on NONS, this is a guidance document and not legally binding.

		2(b)<u>If classed as new substance</u>	2(b) Substance is subject to the notification procedures outlined in Part II of the regulation.
2. Notification (*) Part II	Notification is required when a new substance is placed on the market. The notification scheme operates on a system whereby the content of any test package is in proportion to the level of the supply. The more of a substance supplied the more in depth are the required tests. **<u>2 part test</u>**: a. New Chemicals – Level of testing required is determined by the mass produced, with the lowest mass trigger currently set at 10kg per annum. b. Mass Triggers – the more of an existing substance that is produced, the more data on its properties are required by regulators.	1. Neither of the triggers used to determine the need for and extent of testing chemicals take account of particle size, therefore the production of an existing substance in nanoparticulate form does not trigger any additional testing. As such reduced notification requirements exist for small quantities. 2. Regulations as a whole do not extend to 'downstream' users (unless it has to be classified and a safety data sheet supplied with substance further down the stream) in terms of nanomaterials this may be more problematic due to the lack of scientific information currently available on the impacts of use.	1. As the properties of materials are known to change at the nanoscale, a precautionary approach is advised and under NONS nanomaterials should be subject to higher scales of testing and not subject to reduced notification procedures due to lack of quantity. 2. This is a general NONS issue that is proposed to be addressed in REACH^, which will extend the responsibility to 'downstream' users. 3. As raised in the Royal Society/Royal Academy report - consider "trigger levels" based on some property which reflects particle size.
3. Hazard Identification Schedule 1 - identification Schedule 3 - testing	1. Data from standard test methods is required on the physicochemical, toxicological and eco-toxicological properties of notified substances.	1(a) Toxicity of chemicals in the form of free nanomaterials cannot be predicted from their toxicity in a larger form and consequently in some cases they may/will be more toxic than the same mass of the same chemical in its larger form. 1(b) The standardised testing in terms of timing and extent outlined in NONs relating to hazardous may not be sufficient for nanomaterials. In terms of toxicology testing via the most relevant route of exposure – there appears to be a gap as there is concern that in terms of nanos the inhalation route could arise earlier and more often because of the identified concerns for toxicity towards the respiratory tract via the route of exposure.	1(a&b) There may need to be a reassessment of the time and extent of the tests required for nanomaterials. This would not be an overcomplicated alteration to the existing regulations.

	2. Schedule 1 outlines dangerous substance and the categories of danger and their characteristic properties.	1 (c) Concern has been raised by the HSE in terms of the possibility of the use of 'read-across' – using data from an existing substance as a prediction of the toxicity of the new substance. 2. Reference values in terms of nanomaterials may need to be reassessed due to the lack of scientific data on the toxic properties of chemicals at this scale.	1 (c) Appropriate guidance for suppliers is required to ensure that substances classed as new nanomaterials are not automatically assessed against existing data for the microsized form. 2. While the Schedule in paragraph (c) allows an exemption from the classifications it is premised on the availability of facts, which currently may not be available and as such the exemption may need to be expanded to ensure that nanomaterials do not escape the reference values.
4. Exposure Assessment Schedule 2	Need to assess the potential for exposure.	Given that the notification process will pre-empt complete production there is not usually any measured data available. Assessment therefore qualitative.	Further guidance likely to be required and a different metric for testing exposure may be required.
5. Risk Assessment & Risk Management (**) Part III	Competent Authority[71] responsible for carrying out any necessary risk assessments of the real and potential risks created by the substance to human health and the environment.	As identified by the EC, this is not an appropriate allocation of responsibility – as the suppliers of substances are a more direct source of information – therefore the risk assessment is not use specific, which could be significant in terms of nanomaterials.	General risk assessment responsibilities likely to be altered in REACH^ to place responsibility on manufacturer, importer or user. Applying a precautionary approach, nanomaterials could be treated as if they were hazardous and appropriate risk management procedures adopted.
Linked Legislation	*** - *CHIP* –** Substances to be packaged and labelled in accordance with the requirements of the Chemicals (Hazard Information & Packaging) Regulations 1993 – nanomaterials not yet fully tested should fall under the requirement to carry the label "Caution – substance not yet fully tested". ****** - ***COSHH***[72] – The information provided for a NONS notification should enable recipients of new substances who use them in their workplace to apply the requirements of COSHH. Further users of new substances need to be able to put in place the necessary containment, personal protective equipment and disposal measures, any gaps in NONS will subsequently impact on the ability of further uses to comply under the terms of related regulations.		
Horizon Scanning	**^ *Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)* –** due to replace NONS and other chemical regulations throughout the EC. Key feature of draft REACH is that the tonnage triggers for required information are higher than in NONS, consequently, the regulation of nanomaterials could be more relaxed under the regime. However, REACH should introduce testing requirements not only for 'new'		

[71] In England & Wales the Competent Authority is Health & Safety Executive working in partnership with the Environment Agency.
[72] Control of Substances Hazardous to Health Regulations 2002.

	chemicals but also for those previously classed as 'existing'. REACH is expected to place greater responsibility on the manufacturer and introduce more standardised testing procedures, therefore if REACH can be extended to include substances at the nanoscale – better regulation through the lifecycle of the substance will be introduced.

Legislation: *Registration, Evaluation and Authorisation of Chemicals (REACH)*[73]			
Summary of Purpose: The proposed new EU chemicals policy will require producers and importers of intentionally produced chemicals to register them along with the information needed to use them safely including basic health and environmental safety information on all chemicals they started producing and importing before 1981. The aim of this new legislation is to increase the necessary level of protection required for the safe use of chemicals by placing responsibility for the safety of chemicals on manufacturers. At present no date has been set for the introduction of REACH within the EU. As this proposal is still under negotiation it is premature to analysis in detail the impact of REACH on nanotechnology. REACH will replace major pieces of legislation including NONS and ESR and it is expected to place greater responsibility on the manufacturer and introduce more standardised testing procedures, therefore if REACH can be extended to include substances at the nanoscale – better regulation through the lifecycle of the substance will be introduced.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Definition	1. Definition - "*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. 1(a) <u>If nano-equivalent is considered to be a</u>	1(a) The registrant may submit a different

[73] This proposed new directive will replace the Dangerous Substances Directive, the Dangerous Preparations Directive, the Safety Data Sheets Directive, ESR, the Marketing and Use Directive and associated Directives.

		different substances?	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 nanomaterials prior to placing them on the market.
		1(b) If the nano-equivalent is considered to be the same as the registered substance?	1(b) The hazard information would still be available, although the appropriateness of the data for the potential risks of nanomaterials would be open to discussion.
	2. All substances are covered under the regulation unless they are explicitly exempted under its scope.	2. Other materials exempt from the REACH Regulation such as intermediates and polymers may also pose regulatory gaps under REACH.	It is recommended that chemicals in the nanosize scale be treated as new substances under REACH. As recognised by the HSE Report[74] the trigger thresholds limits could be reassessed once relevant data becomes available.
2. Registration	Requires manufacturers and importers of chemicals to register them and provide relevant information on their substances and to use that data to manage them safely.	1. Registration is reliant on tonnage triggers. These triggers for required information are at present higher than those required in NONS. As a consequence, nanomaterials could escape the requirements for the collection and submission into the regulatory system of information on nanomaterials. It is, therefore, unclear how REACH will capture nanomaterials based on tonnage exceptions and the different levels of data requirements.	1. The regulation of nanomaterials 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).
		2. Data requirements will vary according to the tonnage of substances produced with the threshold being set at 1 tonne per year – this may be too high a threshold for nanomaterials.	2. There is currently no limit to the potential applications and uses of nanoparticles – as such regulations need to be able to address relevant factors in particular thresholds.
3. Authorisation	REACH process will identify extremely	No tonnage trigger required. Current estimate	In France commentators have urged that

[74] Health & Safety Executive, *Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology*

	hazardous chemicals and classify them as 'substances of very high concern'. Those so identified will be made subject to a process known as authorisation. Goal is that chemicals so identified are phased out and replaced with suitable, safer replacements.	is that this is likely to be a small percentage (below 5%)[75]. A gap exists as again chemicals at the nanosize scale have not been included.	nanomaterials should be considered a special class of very high concern under REACH[76]. Once evidence is obtained on the impact they can, where appropriate, be moved from this classification.
4. Risk Assessment & Management of Risk	1. Proactive approach to risk assessment (or evaluation) undertaken for dangerous substances over 10 tonne/yr and for substances of particular concern 2. 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.	1. Only applies to substances supplied in quantities over 10 tonne/yr (unless of particular concern) 2. Only applies to substances supplied in quantities over 1 tonne/yr (unless of particular concern)	REACH will introduce testing requirements not only for 'new' chemicals but also for those previously classed as 'existing'. However, there is a question over whether the tests required is relevant for the risk assessment of nanomaterials as 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.
5. Timescales	The full implementation period for REACH is expected to be 2016 – with the highest volume chemicals and those known to have dangerous properties to be dealt with first. By 2016 it is expected that there will be safety data sheets on approximately 30,000 chemicals.	This list excludes substances at the nanosize scale, consequently any inclusion is likely to increase the estimated number of chemical substances covered.	
Linked Legislation			
Horizon Scanning			

[75] European Environmental Bureau, Countdown to REACH, media briefing on the new EU chemicals policy,
[76] AFFSET Report, 2006

Legislation: *Biocidal Products Regulations 2001 (as amended)*[77]			
Summary of Purpose: Broadly speaking, the Regulations cover non-agricultural pest control products. The Regulations aim to control human and environmental exposure to biocidal products by establishing a framework for applications to be made for agreement at Community level that an active substance can be used in a biocidal product, and by requiring that authorisation is sought and granted before biocidal products to which these Regulations apply are placed on the market. The Regulations stipulate that no person shall place on the market a new active substance for use in a biocidal product unless an application to a competent authority has been made for inclusion of that new active substance in Annex I, IA or IB of Directive 98/8/EC. Furthermore, no person shall place on the market or use a biocidal product unless that biocidal product has been authorised in accordance with the provisions of the Regulations.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Definition of 'biocidal product'	Regulation 2 defines 'biocidal product' as: 'an active substance or a preparation containing one or more active substances, in the form in which it is supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by chemical or biological means'.	No gap identified.	It is foreseen that nanomaterials will be used in the manufacture of biocidal products.
2. Active Substances	Regulation 4 prohibits the placing on the market of an active substance in a biocidal product unless an application has been made to Ministers or the competent authority for the inclusion of a new active substance listed in Annex I, IA, or IB to the Directive. Regulation 5 requires that an application is accompanied by a dossier setting out specific information about the safety of the substance. The Directive requires that a dossier includes the following information: ▪ Applicant ▪ Identity of the active substance	1. Incomplete information base Lack of complete information about nanomaterials might preclude a full safety assessment based on the data requirements set out in the Directive. In the absence of full information, the exercise of judgement might result in inconsistencies in the application of regulatory requirements.	

[77] Implementing the EC Directive 98/8/EC

	▪ Physical and chemical properties of the active substance ▪ Methods of detection and identification ▪ Effectiveness against target organisms and intended uses ▪ Toxicological profile for man and animals including metabolism ▪ Ecotoxicological profile including environmental fate and behaviour ▪ Measures necessary to protect man, animals and the environment ▪ Classification and labelling		
3. Biocidal products	Regulation 8 prohibits the marketing of biocidal products without prior authorisation or registration in accordance with the Regulations. Ministers shall not authorise a biocidal product unless: (a) the following conditions are satisfied, namely: (i) at least one active substance in the biocidal product is included in Annex I at the time the authorisation is granted; (ii) any other active substances in the biocidal product are included in Annex I or Annex IA at the time the authorisation is granted; and (iii) any requirements set out in Annex I or Annex IA relating to the active substances in the biocidal product have been fulfilled; **and** (b) the Ministers have made the determinations referred to in Schedule 3.	1. Whether safety requirements are sufficiently broad to encompass potential risks posed by nanomaterials. The principal problem arises from the lack of information relating to potential risks which in turn precludes a full safety assessment.	See Chemicals (Hazard Information and Packaging for Supply) Regulations 1994 regulatory analysis template.

	Schedule 3 sets requires that the biocidal product in question has no unacceptable effects on the target organisms, human or animal health, surface water or groundwater, or on the environment. Regulation 9 goes on to stipulate that Ministers shall not authorise a biocidal product for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as: (a) toxic; (b) very toxic; (c) carcinogenic category 1; (d) carcinogenic category 2; (e) mutagenic category 1; (f) mutagenic category 2; (g) toxic for reproduction category 1; or (h) toxic for reproduction category 2. Note that this classification is conducted in accordance with the Chemicals (Hazard Information and Packaging for Supply) Regulations 1994. A dossier supporting the application is also required. The dossier contain information such as the physical and chemical properties of the biocidal product relating to use, storage and transport; the product-type and field of use of the biocidal product; the intended category of users; the intended method of use; and efficacy data.		
4. Frame-formulations	Regulation 18 establishes a mechanism for frame-formulations. Accordingly, Ministers may, at the same time	1. Whether the inclusion of nanoparticles in substances already authorised or registered would fall under Regulation 18.	It is recommended that biocidal products containing nanomaterials are deemed to have sufficiently different properties to

	as granting an authorisation in respect of a biocidal product under regulation 9 or 13, or granting a registration in respect of a biocidal product under regulation 10 or 14, issue a frame-formulation which includes that biocidal product and they shall communicate that frame-formulation to that applicant. A frame-formulation is a reference to specifications for a group of biocidal products which have the same use; are used by the same type of user; and contain the same active substances of the same specification, and whose composition, when compared with the composition of a biocidal product which has been authorised or registered in accordance with these Regulations, is the same as the composition of that biocidal product. In conducting this comparison, variations which do not reduce the efficacy of, nor affect the level of risk associated with, the biocidal products in question shall be disregarded.	A potential gap arises if a biocidal product manufactured containing nanomaterials is deemed to be sufficiently similar to a biocidal product already authorised or registered, thus triggering a Regulation 18 frame-formulation.	their bulk material counterparts, thus falling outside the scope of Regulation 18.
Linked Legislation	***Chemicals (Hazard Information and Packaging for Supply) Regulations 1994*** ***Plant Protection Products Regulations 2005*** – covers agricultural pesticides and prohibits the use of pesticides without prior approval. ***Fertiliser Regulations 1991***		
Horizon Scanning			

Legislation: *Chemicals (Hazard Information and Packaging for Supply) Regulations 2002*[78]			
Summary of Purpose: CHIP applies to suppliers of dangerous chemicals and deals with the marketing of dangerous substances and preparations. Its purpose is to protect people and the environment from the effects of those chemicals by requiring suppliers to provide information about the dangers and to package chemicals safely. CHIP requires suppliers of chemicals to decide whether they are 'dangerous' and in what way, and then provide information to their customers in the form of warning labels and safety data sheets. The chemicals must also be packaged properly.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Classification	Requires suppliers to identify, and where appropriate, categorise the hazards of the substances supplied. Suppliers determine what kind of hazards associated with the chemical and explain the hazard – known as the Risk Phrase. Regulations exclude a number of substances e.g. cosmetics and medicines. CHIP applies if the substance or preparation is hazardous.	To classify substances, suppliers are obliged to use the UK 'Approved Supply List[79]', which contains substances that have been examined under various systems e.g. NONS, ESR, BPR and substances considered through an EU-wide procedure. Currently, no 'existing[80]' substances at the nanoscale have been through this system. Consequently, it will be at the discretion of the supplier to determine the classification – this self-classification could lead to potential gaps. 1. <u>If classed as hazardous?</u> Supplier would be required to provide information relating to the hazards of the substance supplied. 2. <u>If classed as non-hazardous</u>? Subsequent users would be dependent on existing data as no new data would be generated on the potential risks or hazards relating to the identified nanomaterial, consequently, nanomaterials could move through their lifecycle without any further	Due to the general lack of available data on nanomaterials and any consequential impacts and subsequent hazards – the process of classification could lead to incorrect classifications resulting in any potential hazards not being addressed down the supply chain. If the classification is wrong then all subsequent elements under CHIP may be wrong. This determination could have consequences on subsequent legislation applicable to the use of the substance and on the potential controls to reduce damage to human health or the environment.

[78] As amended 2005 (SI 2571) and enacts the EC Dangerous Substances Directive, the Dangerous Preparations Directive and the Safety Data Sheets Directive

[79] Is the document entitled "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Eighth Edition)" approved by the Health and Safety Commission on 26 July 2005

[80] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) and was placed on the market before September 1981

		assessment of their properties.	
2. Supply	CHIP deals specifically with the supply of chemical substances. Supply includes: sell, offer for sale, provide commercial samples, import or transfer chemicals from one person to another. Supply must include package to avoid spillage or inadvertent exposure along the supply line, and to label them so that all those transporting them or receiving them know something about the substances.	This requires the supplier to possess knowledge on the indications of danger, with the lack of available data – it is likely that this procedure may not be complied with fully.	The main potential gap problem will be the reliance on suppliers to classify and provide data on nanomaterials, which at present is not available. Once data becomes available specified guidance is advised.
3. Information	Regulations require suppliers to give a "materials safety data sheet" or msds, for every substance supplied. The types of information required include: Physical and Chemical properties, Stability and reactivity, Toxicological Information, Ecological Information, Disposal considerations and Transport information	If considered a new substance – a safety data sheet will be required for hazardous nanomaterials. 1. General issue is the lack of sufficient information and knowledge available on toxicological hazards, appropriate exposure limits – it will be difficult to provide the relevant data and undertake the necessary risk assessments. As highlighted in the HSE review, concern exists over the quality of the data and the interpretation of this data by others. 2. HSE has also raised concern in terms of the possibility of the use of 'read-across' – using data from an existing substance as a prediction of the toxicity of the new substance[81]. 3. New exposure scenarios may have to be developed for the safety data sheets for nanomaterials.	1. This issue should lessen once data becomes available. 2. Appropriate guidance for suppliers is required to ensure that substances classed as new nanoparticles are not automatically assessed against existing data for the microsized form
Linked Legislation	***Control of Major Accident Hazards Regulations*** - COMAH legislation requires notification (in the UK, to HSE) of sites where substances with hazardous properties that correspond to certain CHIP classification criteria are stored in quantities above specified tonnage triggers. Information provided under CHIP will be used by employers to assess and manage the risks within the work place.		

[81] Health and Safety Executive, Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology

	Control of Substances Hazardous to Health Regulations 2002 – Information provided on safety data sheets will be used by employers to assist with their risk assessment obligation under this regulation. ***Notification of New Substances Regulations 1993 –*** requires standardised testing of hazardous properties of new chemical substances, those substances identified as new feed into EU level and Annex I of the Dangerous Substances Directive. ***Dangerous Substances Directive*** – As part of the ongoing restructuring of the Community water policy, the **Directive 76/464/EEC on Dangerous Substances** is now integrated in the **Water Framework Directive** (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as **Directive 2006/11/EC** on pollution caused by certain dangerous substances discharged into the aquatic environment of the community. ***Dangerous Substances and Explosives Atmospheres Regulations*** - Employers' use of the information in the safety data sheets to assess and manage the risks covered by this type of workplace control law. ***Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996*** ***Plant Protection Products Regulations 1995***
Horizon Scanning	***Globally Harmonised System*** – currently under negotiation in the EU, this will introduce a new system for classification and labelling of substances and preparations, which will replace the current EU system and therefore CHIP. The aim of GHS is to introduce a worldwide system for hazard communication; it will therefore be a vital development for the control of nanomaterials. It aims to develop a common and coherent approach to defining and classifying hazards, and communicating information on labels and safety data sheets and as consequence will provide the underlying infrastructure for establishing national, comprehensive chemical safety programs. GHS is proposed to cover all types of chemicals and will be based on intrinsic properties (hazards) of chemicals and includes dilute solutions and mixtures. Pharmaceutical, food additives, cosmetics and pesticide residues in foods will not be covered at the point of intentional intake but will be covered where workers may be exposed and also extends to transportation. Classification includes health and environment hazards, physical hazards and mixtures. Communication of the hazards is via labels and safety data sheets. Possible gap may arise as the test of hazards looks to known ingredient information and due to the lack of available data on nano-ingredients the test may be incomplete. An important element of GHS is a requirement to include precautionary information in order to harmonise precautionary statements.

Legislation: *Control of Major Accident Hazard Regulations 1999*[82]
Summary of Purpose: COMAH applies mainly to the chemical industry, but also to some storage activities, explosives and nuclear sites, and other industries where threshold quantities of dangerous substances identified in the Regulations are kept or used. It applies to companies that manufacture, store or transport dangerous chemicals and explosives and deals with the assessing the risks and consequences of fire, explosion and substantial release of toxic chemicals in an industrial incident. A key element of COMAH is the increased emphasis on major accidents that may affect the environment.

[82] As amended by Control of Major Accident Hazards (Amendment) Regulations 2005. They implement Council Directive 96/82/EC known as the Seveso II Directive, as amended by Directive 2003/105/EC

Content for Analysis	Summary of regulation	Gap or Potential Gap	Comment/Impact
1. Notification	Requires notification of sites where substances with hazardous components and which correspond to certain CHIP* classifications are stored in quantities above specified tonnage triggers.	This is a self classification process with the onus being on a site operator to identify the appropriate hazardous classification in order to determine whether or not COMAH applies. However, part of the notification procedure involves an agreement between operator and regulator on a risk assessment and identification of the relevant measures to mitigate the risk. Access to available data on the potential effects is fundamental to the effective applicability of this regulation.	The effective operation of this regulation depends on the availability of reliable information. Historically, many substances have been marketed and used without their hazardous properties having been fully explored.[83] Without appropriate guidance, there is a danger that this may also occur in the assessment of nanomaterials.
2. Dangerous Substances Schedule 1	Schedule 1 provides a list of identified substances (Part 2) which will be classed as dangerous under the regulation and a further list of categories (Part 3) to be applied to substances not specifically identified under Part 2.	Most nanomaterials are likely to fall outside the very prescriptive COMAH definition of a 'dangerous substance', and therefore will not be covered by these Regulations. Many potential sources for nanomaterials (e.g. aluminium, copper, iron, silver, titanium) which could be considered dangerous are not referred to in the list. 1. <u>If definition not applicable to nanomaterials?</u> If chemicals at the nanosize scale do not comply with the definition, no further assessment of the potential risks need be undertaken and no safety precautions required. 2. <u>If definition applicable to nanomaterials?</u> Nanomaterial is then subject to threshold triggers - may still escape coverage under the regulations due to the relatively high threshold requirements (see box 3 below).	The actual level of danger in terms of a major accident hazard will depend on their potential impacts on human health and the environment – this will be dependent on future information on the impacts of nanomaterials. Whilst accepted that quantities are likely to be small, it cannot be assumed that the reactions and impacts of ecotoxicological properties of nanomaterials will be the same as their macro-equivalents. For example, recent research has shown that the explosive properties of nanopowders are greater due to the increased surface area.
3. Threshold Triggers	Two-tier system. Sets down a variety of thresholds	Even where the 'dangerous substance' definition is met, unlikely that the quantities of	Gap in regulation could be addressed by recognising the nanoscale properties of

[83] Health and Safety Executive, Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology

	against each of the identified substances and categories. If thresholds met or exceeded Tier 1 thresholds a Major Accident Prevention Plan must be prepared. If Tier 2 thresholds are met or exceeded additional requirement of a Safety Report and an off-site emergency plan.	materials produced and stored will meet the requirements of COMAH regulations. The threshold levels provided refer to the maximum quantities, which are present at any time and as such unlikely to extend the coverage of the regulations to nanomaterials.	chemicals can be classed as toxic or very toxic thereby ensuring they are captured under dangerous substances definition and subsequently the availability of a lower threshold. However the lower tier requires no assessment of the potential risk on the surrounding environment.
4. Risk Assessment**	Sites classed under the top tier are required to provide a safety report, which will require a risk assessment. Risk assessment involves understanding the nature of hazardous situations, what their outcome may be and how likely it is that adverse effects will occur. Risk assessments can be undertaken to different levels of detail: qualitative, semi-quantitative and quantitative.	To undertake an appropriate risk assessment, data must be relevant to the actual formulation used – consequently an assessment of the range of formulations with a corresponding range of effects and subsequently a range of effects data. At present it is unlikely that this range of data is available to fully comply with risk assessment requirements. If effective risk assessments are not possible, the relevant management systems may not be put in place by the operator.	Additional guidance will be required to ensure that any potential effects are captured.
Linked Legislation	**** - Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 -*** CHIP requires suppliers of chemicals to decide whether they are 'dangerous' and in what way, and provide information to their customers in the form of warning labels and safety data sheets. The chemicals must also be packaged properly. ** - ***Pollution Prevention and Control (England & Wales) Regulations 2000*** – risk assessment procedures required under this regulation are potentially available to operators with a duty under COMAH.		
Horizon Scanning			

Legislation: *Control of Substances Hazardous to Health Regulations 2002*[84]			
Summary of Purpose: The main piece of legislation covering control of the risks to employees and other people arising from exposure to harmful substances generated out of or in connection with any work activity under the employer's control. The main objective of the Regulations is to reduce occupational ill health by setting out a simple framework for controlling hazardous substances in the workplace.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**

[84] Implementing all or parts of the following Community provisions: Directive 78/610/EEC; Directive 89/677/EEC; Directive 90/394/EEC; Directive 96/55/EC; Directive 98/24/EC; Directive 2000/54/EC.

1. Scope	Extends to hazardous materials which are supplied substances, substances generated during work activity, naturally occurring substances and biological agents.	No gap identified.	The general framework of COSHH should provide the relevant protections to nanomaterials in the work place when information on the effects and impacts of these substances become more available. Alterations may need to be made to guidance documents as this information becomes available.
2. Hazardous to Health	Is in the Approved Supply List* with Harmful, Toxic, Very Toxic, Irritant or Corrosive, is present as a dust at a concentration greater than 4 mg/m3 (respirable fraction) or 10mg/m3 (inhalable fraction), as 8-hour time-weighted average values; has an approved occupational exposure limit and/or represents a risk to human health from its presence or the way it is used in the workplace.	Linked to CHIP** due to the reference to the Approved Supply List[85] as a means of identifying hazardous substance. Currently, no 'existing' substances at the nanoscale appear on this list. Consequently, it will be at the discretion of the supplier to determine the classification – this self-classification could lead to potential gaps. As such the gap in CHIP impacts on the effectiveness of this regulation. If the substance is not classed under CHIP, no safety data sheet will be prepared and as a consequence employers will not, as a rule, undertake any risk assessment of the substance in the work place and therefore not prepare any risk management procedures.	From current, limited understanding of the toxicology of nanomaterials it would be unwise to regard exposures to nanomaterials at or below 4 mg/m3 (8h TWA) respirable dust as representing adequate control associated, confidently, with health protection[86].
3. Risk Assessment (Reg. 6)	To be conducted by using available information on the hazards and knowledge of the local conditions of exposure. A list of elements for consideration is contained in the regulation.	Risk assessment are therefore based on both sound scientific information and past experience; in terms of nanomaterials this information is likely to be incomplete and there are likely to be deficiencies in the level of available information It has been stated that in terms of nanotechnology there is a lack of the following: a. sufficient toxicological hazard information for most nanoparticles; b. reliable, affordable and standardised	Conventional methods of measuring dust concentration may give incorrect results[88]. Consequently, users may need to consider whether current protective methods are appropriate in relation to chemicals at the nanoscale. Safety Data Sheets supplied by suppliers under CHIP is often used as a source of information for employers, however as outlined in the assessment of CHIP, the

[85] Is the document entitled "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Eighth Edition)" approved by the Health and Safety Commission on 26 July 2005

[86] Health and Safety Executive, Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology

		exposure measurement and characterisation methods; and c. an agreed definition of the most appropriate dose metric(s) to use in hazard and exposure studies[87]. Without this basic information, conducting an appropriate risk assessment will be very difficult and therefore developing or applying the appropriate risk management procedures.	general lack of available information impacts on this regulation as well.
4. Risk Management	Employers must prevent exposure, where this is not reasonably practical they must adequately control it. They are required to ensure that control measures are used.	COSHH principles of good control should be capable of being adapted to the control of nanomaterials. However, the performance and effectiveness of conventional methods will need to be assessed e.g. PPE[89] will only provide the intended level of protection if correctly specified or fitted.	One of the recommendations in the Royal Society/Royal Academy of Engineering report (Appendix I) is to suggest the introduction of occupational exposure limits for manufactured nanoparticles that are lower than might be the case for somewhat similar materials in larger particle form.
Linked Legislation	**** - Notification of New Substances Regulations 1993*** – requires standardised testing of hazardous properties of new chemical substances, those substances identified as new feed into EU level and Annex I of the Dangerous Substances Directive, transposed into the UK at the Approved Supply List. ***** - Chemical (Hazardous Information and Packaging for Supply) Regulations 2002*** - Identification and classification of nanomaterials will be the responsibility of suppliers under CHIP, this initial classification can be used by subsequent users who will also rely on the information provided in 'Safety Data Sheets'.		
Horizon Scanning	***Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)* –** due to replace NONS and other chemical regulations throughout the EC. Key feature of draft REACH is that the tonnage triggers for required information are higher than in NONS, consequently, the regulation of nanoparticles could be more relaxed under the regime. However, REACH should introduce testing requirements not only for 'new' chemicals but also for those previously classed as 'existing'. REACH is expected to place greater responsibility on the manufacturer and introduce more standardised testing procedures, therefore if REACH can be extended to include substances at the nanoscale – better regulation through the lifecycle of the substance will be introduced.		

Legislation: *Dangerous Substances and Explosive Atmospheres Regulations 2002*[90]

[87] Health & Safety Executive, Nanotechnology, Horizon Scanning Information Note No HSIN1
[88] Health & Safety Executive, Nanotechnology, Horizon Scanning Information Note No HSIN1
[89] Personal Protective Equipment
[90] Implementing Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, and Directive 99/92/EC on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres.

Summary of Purpose: The Dangerous Substances and Explosive Atmosphere Regulations 2002 implement Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, and Directive 99/92/EC on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres. The Regulations impose certain obligations employers to eliminate or reduce risks from fire, explosion, or other events arising from the hazardous properties of a 'dangerous substance'.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definitions Regulation 2(1)	Regulation 2(1) defines a 'dangerous substance' as: • A substance or preparation which meets the criteria in the Approved Guide to the Classification and Labelling of Dangerous Substances and Dangerous Preparations for classification as a substance or preparation which is explosive, oxidising, extremely flammable, highly flammable or flammable, whether or not that substance or preparation is classified under the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002; • A substance or preparation which because of its physico-chemical or chemical properties and the way it is used or is present at the workplace creates a risk, not being a substance or preparation falling within the subparagraph above; or • Any dust, whether in the form of solid particles or fibrous materials or otherwise, which can form an explosive mixture with air or an explosive atmosphere, not being a	<u>Breadth of definition</u> The question is whether the Regulation 2(1) definition is sufficiently broad to encompass substances containing nanoparticles. To date, no substances containing nanoparticles have been through the Approved Guide system.[91] It falls to the discretion of the supplier, therefore, to determine whether a substance is to be classified as 'dangerous'. Given the lack of information about the implications of exposure to nanoparticles, it is conceivable that no evidence of risk is construed as 'no risk' of harm. Comparison of substances containing nanoparticles with non-nanoparticle counterparts might result in inaccurate risk predictions. Lacking data about exposure in the workplace to nanoparticles also poses a potential problem in respect of the second and third subparagraphs. An HSE report has identified that increasing range of explosive materials are being manufactured as nanopowders.[92] Although extensive literature on explosive characteristics of micron-scale powders, no data on nanopowders.	It is recommended that the implications of exposure to nanoparticles in the workplace are examined, and criteria developed to ensure robust safety assessment.

[91] HSE, *Review of the Adequacy of Current Regulatory Regimes to Secure Effective Regulation of Nanoparticles Created by Nanotechnology* (HSE; 2006).
[92] Health and Safety Laboratory, *Literature Review: Explosion Hazards Associated with Nanopowders*, HSL/2004/12 (HSe; 2004).

	substance or preparation falling within either subparagraph above. 'Risk' is defined as 'the likelihood of a person's safety being affected by harmful physical effects being caused to him from fire, explosion or other events arising from the hazardous properties of a dangerous substance in connection with work and also the extent of that harm'.		
II. Employer responsibility and risk assessment	Regulation 3 of the Management of Health and Safety at Work Regulations 1999 require an employer to conduct a risk assessment. Regulation 5 of the Dangerous Substances and Explosive Atmospheres Regulations 2002 require employers to conduct an additional risk assessment where a dangerous substance is or may be present at the workplace. Employers are required to eliminate or reduce risk so far as is reasonably practicable (Regulation 6(3)); to make arrangements for dealing with accidents, incidents and emergencies (Regulation 8); and to provide employees with precautionary information, instruction and training where a dangerous substance is present at the workplace (Regulation 9).	<u>Incomplete knowledge base</u> See above.	Lacking data about workplace exposure to nanoparticles will have an impact on the accuracy of safety assessments. See above. Incomplete information will also have a bearing on the effectiveness of safety measures put un place according to employer obligations set out in Regulations 6, 8 and 9.
Linked Legislation	Chemical (Hazard Information and Packaging for Supply) Regulations 2002 Management of Health and Safety at Work Regulations 1999		
Horizon Scanning			

Legislation: Health and Safety at Work etc. Act 1974 (as amended)[93]			
Summary of Purpose: securing the health, safety and welfare of persons at work; protecting persons other than persons at work against risks to health or safety arising out of or in connection with the activities of persons at work; controlling the keeping and use of explosive or highly flammable or otherwise dangerous substances, and generally preventing the unlawful acquisition, possession and use of such substances; and controlling the emission into the atmosphere of noxious or offensive substances from premises of any class prescribed			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
Health, Safety and Welfare in connection with Work, and Control of Dangerous Substances and Certain Emissions into the Atmosphere. Part I– Interpretation.	The Act requires employers to ensure the health, safety and welfare of every employee at work as far as is reasonably practicable. The scope of employers' duties range from maintaining plant and work systems, providing necessary information, instruction, training, and supervision to ensure safety at work, to the maintenance of employees' working environment to make it safe and without risks to health. Employers also have health, welfare and safety obligations to non-employees. Manufacturers, importers, or suppliers of articles and substances used at work are obliged to ensure that such articles or substances pose no risks to the health, welfare and safety of persons at work; and that necessary information be furnished on the use of and design of articles and substances.	Although the Act makes no direct allusion to nanoparticles, they are ostensibly covered by the definition of 'substance' as "…any natural or artificial substance (including micro-organisms), whether in solid or liquid form or in the form of a gas or vapour".[94] It is desirable to have nanoparticles expressly mentioned in the definition of substance used in article or plant at work place due to their increasing industrial use.	The term: "so far as is reasonably practicable" is used to qualify employers and manufacturers' duty to ensure safety of employees and non-employees at work place. A higher level of responsibility might be desirable with regards to nanoparticles used in industrial settings due to the uniqueness of their properties and the potential dangers they pose to persons at work.
Risk Management	The Act requires employers to provide and maintain safety equipment and safe systems of work, ensure materials used	With current deficit of information, employers may not be able to comply with the necessary arrangements where information on how to	

[93] Chapter 37
[94] Section 53(1)

	are properly stored, handled, used and transported, provide information, training, instruction and supervision and ensure staff are aware of instructions provided by manufacturers and suppliers of equipment.	manage potential risks from the manufacture, supply and use of nanmaterials is not available. However, as the Act includes the terms 'so far as is reasonably practicable' employees will not be held liable if their existing systems do not extend to the potentials risks from nanomaterials.	
Schedule 3 – Subject Matter of Health and Safety Regulations	Schedule 3 details the scope of prohibited acts as well as certain obligatory requirements with regards to handling of articles or substances at work place. These range from the manufacture, supply, importation, transportation, labelling, etc., of any article or substance.	Again there is no specific mention of nanoparticles. The definition of 'substance' as "any natural or artificial substance (including micro-organisms), whether in solid or liquid form or in the form of a gas or vapour", would appear to cover nanoparticles.	Although the Executive or local authorities may appoint inspectors to enforce the provisions of the Act, there are no specific requirements on inspectors' qualifications. It is even doubtful at this stage whether inspectors have enough qualifications or expertise for thorough assessments of dangers posed to health and safety by nanoparticles.
Linked Legislation	**The Agriculture (Safety, Health and Welfare Provisions) Act 1956;** **The Employment Medical Advisory Service Act, 1972;** **The Public Health Act 1961;** **The Factories Act, 1961; Management of Health and Safety at Work Regulations, 1999;** **Control of Substances Hazardous to Health Regulations 2002 (COSHH)**		
Horizon Scanning			

Legislation: Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003			
Summary of Purpose: This prescribes activities for dealing with ammonium nitrate in solid form, where its nitrogen content is more that 28% of its weight. Includes action to be taken by manufacturers, importers, suppliers and enforcement authorities and the need to pass a detonation resistance test.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	Extends to the requirement of the need to satisfy a detonation resistance test for the manufacture of ammonium nitrate based fertiliser manufactured chemically and for safety controls for other ammonium nitrate material.	The manufacture of fertiliser is a current application for nanomaterials. The main focus of the Regulations is on the need to obtain a detonation resistance certificate and does not regulate any potential environmental hazards and risks associated with the use of these products. It is possible that other environmental risks of nanomaterials would	The scope of the regulations is very limited and it will not deal with any of the potential risks or effects that may arise from the use of nanomaterials in fertiliser.

		not be addressed for fertilisers and plant nutrients.	
2. Risk Assessment	Risks identified and applicable management procedures deal with the potential for detonation.	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 nanomaterials). Therefore there is no assessment required of the potential risks of nanomaterials and as such no management procedures to deal with any impacts arising out of the risk assessment.	
Linked Legislation	***The Fertiliser Regulations 1991*** - control the composition, labelling and packaging of fertilisers. The Regulations 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. ***The Protection of Water Against Agricultural Nitrate Pollution (England and Wales) Regulations 1996*** (as amended 2002) ***Action Programme for Nitrate Vulnerable Zones (England & Wales) Regulations 1999*** (as amended 2003)		
Horizon Scanning	***EC Regulation 2003/2003 for fertilisers***- specifies the composition, labelling, traceability, safeguards and packaging of EC fertilisers. The Regulation was made on 13 October 2003, and repealed four earlier Council Directives covering EC fertilisers into a single legal instrument.		

Legislation: *Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended)*[95]			
Summary of Purpose: The Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 prohibit the marketing of certain types of alkaline batteries and accumulators containing more than the specified levels of 'heavy metals' (mercury, cadmium, and lead); establish design requirements for certain battery-powered equipment; and require that batteries covered by Directive 91/157/EEC carry the appropriate chemical symbol. The Regulations cover the marketing, recovery and disposal of batteries and accumulators.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition	Regulation 2(1) defines a 'battery or	Appropriateness of set thresholds	It might be argued that the mercury limits

[95] Implementing Directive 91/157/EEC on batteries and accumulators containing certain dangerous substances; and the Directive 93/86/EEC on symbols to indicate the separate collection of batteries and accumulators containing more than specified levels of dangerous substances ('the Marking Directive').

	accumulator' as: 'a source of electrical energy generated by direct conversion of chemical energy and consisting of one or more primary (non-rechargeable) batteries or secondary (rechargeable) cells containing: (a) either (i) more than 25mg mercury per cell; or (ii) in the case of alkaline manganese batteries, more than 0.025% mercury by weight; (b) more than 0.025% cadmium by weight; or (c) more than 0.4% lead by weight. Regulation 3 stipulates that no person shall market a prohibited battery. It goes on to define a 'prohibited battery' as: (a) an alkaline manganese battery which contains more then 0.025% mercury by weight; or (b) in the case of an alkaline manganese battery for prolonged use in extreme conditions, which contains more than 0.05% of mercury by weight.[96] Commission Decision 98/101/EC subsequently reduced permissible levels of mercury in primary and secondary cells to 0.0005%, prohibiting	It is expected that nanomaterials will be used in the manufacture of batteries or accumulators. The Regulations do not make reference to the method of production, so batteries and accumulators produced using nanotechnology can be expected to fall within the Regulations' ambit. The issue is whether the thresholds of heavy metals are appropriately set to cover potential risks arising from batteries and accumulators *containing* nanomaterials, and furthermore, whether new products containing nano-engineered heavy metals will fall within the definition of 'prohibited battery' in Regulation 3.	set at an inappropriately high level, given the possible implications of human and environmental exposure to nanomaterials. If this is the case, nanomaterials in batteries and accumulators can enter the lifecycle creating hazard implications downstream of manufacture. The second possibility is that new batteries and accumulators are deemed to be 'new products' that fall outside the scope of the Regulation 3 definition of 'prohibited battery'. In this case, it is advisable that a separate provision is drafted to prohibit batteries and accumulators containing levels of nanomaterials that are considered to pose a threat to human health or the environment.

[96] Note that definition of 'prohibited battery' excludes alkaline manganese button cells or batteries composed of button cells.

	the marketing of batteries and accumulators that breach this threshold.		
II. Design and packaging requirements	Regulation 4 sets out specific labelling and packaging requirements. Batteries and accumulators containing more than specified levels of dangerous substances must be given a separate collection mark and the relevant heavy metal content mark. In relation to batteries or accumulators placed on the market in Great Britain for sale within the Community, the obligation to ensure correct marking rests with the manufacturer. If this is not the case, the obligation rests with the manufacturer's authorised representative in Great Britain. The Regulations, which implement the Marking Directive 93/86/EEC, require that batteries and accumulators covered by Directive 91/157/EEC are collected separately from other household waste.	<u>Appropriateness of set thresholds</u> If the heavy metal content thresholds established in Regulation 2 are inappropriately set with regard to potential risks posed by nanomaterials, batteries and accumulators containing nanomaterials *and* comprising of levels of heavy metals below those specified in Regulation 2 can be marketed without separate collection or content marks. This will result in the entry of nanomaterials into municipal waste stream.	It is recommended that the definition of 'batteries and accumulators' contained in Regulation 2 is considered in relation to potential implications of human and environmental exposure to products that fail to satisfy the heavy metal thresholds and are this beyond the scope of the 1994 Regulations.
III. Use of batteries or accumulators in appliances	Regulation 5(1) requires that manufacturers of batteries and accumulators ensure that those batteries or accumulators can be easily removed from consumer appliances in which they are used. Regulation 5(2) imposes additional labelling requirements, stipulating that appliances excluded from Regulation 5(1) must be accompanied by instructions which inform users of the appliance content of environmentally hazardous batteries or accumulators contained therein; and which show how the batteries or accumulators can be safely removed. Excluded appliances include reference cells in scientific and professional equipment; batteries and	<u>Narrow scope of 'excluded appliances'</u> Although the list of excluded appliances contained in Schedule 1 to the Regulations potentially covers existing and future applications of nanotechnology, its scope is at present restricted.	In order to reduce entry of nanomaterials into municipal waste stream and minimise environmental exposure, appliances containing batteries and accumulators comprising of nanomaterials should also be subject to the Regulation 5(2) requirement that appliances are labelled so as to inform users of environmentally hazardous content.

	accumulators placed in medical devices designed to maintain vital functions and in pacemakers, where uninterrupted functioning is essential; and portable appliances, where replacement of the batteries by unqualified persons could create a safety hazard to the user or could affect the operation of the appliance.		
Linked Legislation	Hazardous Waste (England and Wales) Regulations 2005 List of Wastes (England) Regulations 2005		
Horizon Scanning	In November 2003 the Commission adopted proposal to revise the Batteries Directive 91/157/EEC following consultation with Member States. The proposed legislation applies to all batteries and accumulators,[97] regardless of chemical composition, use, or size. In July 2005 the European Council formerly adopted Common Position on proposed Batteries Directive. Its key objectives include: improving separate collection and recycling of spent batteries; reducing disposal of spent batteries in municipal waste stream. The new Directive was agreed on in May 2006. It is expected to come into force in the UK in 2008.		

Legislation: *Medical Devices Regulations 2002 (as amended)*[98]			
Summary of Purpose: The Medical Devices Regulations 2002 consolidates UK law on medical devices and implements three Directives: Directive 93/42/EEC concerning medical devices; Directive 98/79/EC on *in vitro* diagnostic medical devices; and Directive 90/385/EEC on implantable medical devices. The Regulations stipulate that, subject to certain specified exceptions, no person shall place on the market or put into service a medical device unless that device meets essential requirements.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Scope of	Part II of the Regulations cover 'general medical devices'.[99] Section 8 of the	No gap identified.	The placing on the market of medical devices falling outside the scope of the

[97] With the exception of those used in military applications.
[98] Implementing Directive 90/385/EEC on the approximation of the laws of 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.
[99] A 'medical device' is defined in the Regulations as: 'an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:
(a) is intended by the manufacturer to be used for human beings for the purpose of:

Regulations	Regulations stipulates that no person shall place on the market or put into service a medical device unless that device meets essential requirements set out in Annex I of Directive 93/42/EEC. Part III covers 'active implantable medical devices'.[100] Section 22 of the Regulations stipulates that no person shall place on the market or put into service a medical device unless that device meets essential requirements set out in Annex I of Directive		definitions provided is likely to be covered by the General Product Safety Regulations 2005.

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
(iii) investigation, replacement or modification of the anatomy or of a physiological process; or
(iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.'

[100] 'Active implantable device' is defined in the Regulations as 'a medical device which:

(a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and

(b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced,

even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product'.

[101] '*In vitro* diagnostic medical device' is defined in the Regulations as 'a medical device which:

(a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and

(b) is 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 –

(i) concerning a physiological or pathological state,
(ii) concerning a congenital abnormality,
(iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or
(iv) to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination'.

	90/385/EEC. Part IV applies to '*in vitro* diagnostic medical devices'.[101] Section 34 stipulates that no person shall place on the market or put into service a medical device unless that device meets essential requirements set out in Annex I of Directive 98/79/EC.		
II. Safety requirements	Annex I to Directive 93/42/EEC requires that medical devices are designed and manufactured in such as way as to guarantee the characteristics and performances referred to as 'general requirements' (Section I, Annex I). As part of the 'general requirements', devices are designed and manufactured in such a way that: 'when used under the conditions and for the purposes intended, they will not compromise the clinical condition or safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitutes acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.' Annex I requires that particular attention is paid to the choice of materials used, particularly as regard toxicity. Annex I to Directive 90/385/EEC also sets out general safety requirements, stipulating that active implantable medical devices must not present any risk to persons implanting them or,	<u>Incomplete knowledge base</u> It is recognised that knowledge about the implications of human exposure to nanoparticles is incomplete. Despite the fact the each of the three Directives establish a general framework of safety, there remains, as with other current and future applications of nanotechnology, a paucity of information about the human health impact of exposure to nanomaterials. Although the specific requirement that the toxicity of materials used is taken into consideration on assessing safety might be expected to identify potential risks associated with nanoparticles, it is conceivable, given an incomplete knowledge base, that a thorough assessment of toxicity can be conducted. <u>Vigour of safety requirements</u> Annexes to Directives 93/42/EEC and 90/385/EEC explicitly require that in assessing the safety of medical devices, attention must be paid to the choice of materials used and their toxicity. Annex I to Directive 98/79/EC makes no reference to taking into account the toxicity of particular materials used in the design and manufacture of *in vitro* devices, although it is anticipated that in conducting safety assessments *in general*, material toxicity is a central	It is recommended that the chemical properties and potential implications of uses of nanomaterials in the manufacture of medical devices are considered in further detail, and guidance issued.

	where applicable, to other persons. Annex I goes on to note that in making a safety assessment, particular attention is to be paid to the materials used and their toxicity. Annex I to Directive 98/79/EC stipulates, in its design and manufacturing requirements, that devices must be designed, manufactured and packed in such a way as to 'reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices'.	consideration.	
Linked Legislation	General Product Safety Regulations 2005 Medicines Act 1968		
Horizon Scanning			

Legislation: ***Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (as amended)*** [102]			
Summary of Purpose: The Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 implement a series of Community provisions relating to the marketing of medicinal products. A manufacturer is prohibited from placing on the market any medicinal product unless marketing has been authorised by the competent authority in each Member State. In the UK, the competent authority is the Medicines and Healthcare products Regulatory Agency (MHRA).			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition	Regulation 3 provides that no 'relevant medical product' shall be placed on the market or distributed by way of wholesale dealing unless prior authorisation has been granted by the licensing authority (MHRA) or the European Commission. 'Relevant medical product' is defined as: 'a medicinal product for human use to which Chapters II to V of Council Directive 65/65/EEC apply, and accordingly includes the industrially produced medicinal products mentioned in Article 2.2 of that Directive'.	<u>Whether incorporation of nanomaterials into existing product would require additional authorisation</u> Although it is foreseen that nanomaterials will be used in the production of medicinal products (brining new products containing nanomaterials within the scope of the Regulations), determining whether the marketing of existing products containing nanomaterials is covered by previously granted authorisation attached to the production question might be open to dispute. The addition of nanomaterials to products in relation to which authorisation has been granted raises questions about the extent to which a product must be modified before requiring separate authorisation. This is further dealt with in relation to application procedure, below. <u>Medicinal products for research and development</u> The Regulations do not extend to cover medicinal products intended for research and development trials. This creates a potential gap in the regulation of potential risks	See below. Note that the List of Wastes (England) Regulations 2005 includes 'waste from human or animal health care and/or related research' as hazardous waste for the purposes of the Hazardous Waste (England and Wales) Regulations 2005.

[102] Implementing Directive 2001/83/EC on the Community Code relating to medicinal products for human use (as amended); Directive 65/65/EEC; Directive 75/318/EEC; Chapters I to II and V to VI of Council Directive 75/319/EEC and any Regulation adopted by the Commission under Article 15 of that Directive; Directive 89/342/EEC; Directive 89/343/EEC; Directive 89/381/EEC; Directive 92/26/EEC; Directive 92/27/EEC; Directive 92/73/EEC; Regulation (EEC) No. 2309/93 and any Regulations adopted by the Commission under Article 15.4 or 22.1 of that Regulation.

		associated with nanomaterials, relating in particular to the subsequent disposal of products and downstream environmental exposure to potentially hazardous substances.	
II. Application procedure	Applications for the grant, renewal, or variation of a marketing authorisation must be made in accordance with Community provisions. Article 8 of Directive 2001/83 requires that an application includes information such as: the name of the medicinal product; description of manufacturing method; method and route of administration; description of control measures employed by the manufacturer; and results of physico-chemical, biological or microbiological tests, toxicological and pharmacological tests, and clinical trials. Article 10 provides that an applicant is not required to provide results of toxicological, pharmacological tests or clinical trials if he can demonstrate that: i. That the medicinal product is essentially similar to a medicinal product authorised in the Member State concerned and that the holder of the marketing authorisation for the original product has consented to the toxicological, pharmacological and/or clinical references contained in the file	<u>Interpretation of 'essentially similar'</u> The interpretation of 'essentially similar' will determine whether a new medicinal product falling within the broad scope of the definition of 'relevant medicinal product' provided in Regulation 3 requires separate authorisation prior to marketing. One of the principal concerns with nanomaterials is their higher toxicity, relative to that found in their non-nanomaterial equivalents. In the event that a medicinal product is deemed to be 'essentially similar' to a marketed medicinal product (the implication being that there is no requirement that the applicant provides toxicological, pharmacological, or clinical trial test results), it is conceivable that medicinal products containing nanomaterials will enter onto the market without a sufficiently robust safety assessment. <u>Adequacy of information base of safety assessment</u> In the event that medicinal products containing nanomaterials are not deemed to be 'essentially similar' to marketed products, and thus subject to separate safety assessment testing, the appropriateness of existing testing procedures under Directive 2001/83/EC for testing the safety of nanomaterials in medicinal products might be questioned. The application procedure set out in Article 8 of Directive 2001/83 requires	In the interests of the protection of human health, it is recommended that medicinal products containing nanomaterials are distinguished from products already placed on the market pursuant to Directive 2001/83.

[103] Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology.

	on the original medicinal product being used for the purpose of examining the application in question; or ii. That the constituent or constituents of the medicinal product have a well established medicinal use, with recognised efficacy and an acceptable level of safety; or iii. That the medicinal product is essentially similar to a medicinal product which has been authorised in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made. This period is extended to 10 years in the case of high-technology medicinal products having been authorised under Article 2(5) of Directive 87/22/EEC.[103]	that an applicant provides the competent authority with information including a qualitative and quantitative analysis of the constituents and of the finished product, the presence of heavy metals, biological and toxicological test results. Given the novelty of applications of nanotechnology, it is likely that the data required in order to conduct thorough safety assessments is lacking.	
Linked Legislation	▪ Veterinary Medicines Regulations 2005 ▪ Medicines Act 1968: A number of independent advisory committees are established under the Medicines Act 1968, including the Medicines Commission (MC), and the Committee on the Safety of Medicines (CSM). The MC is established under section 2 of the 1968 Act. In addition to providing advice to the UK Licensing Authority on policy issues relating to drug regulation, the MC acts as an appellate body for proposals to revoke or suspend a national marketing authorisation or to refuse applications to vary a marketing authorisation, and for appeals for human and veterinary use marketing authorisation applications that have been refused by the licensing authority on the basis of advice from the CSM or the Veterinary Products Committee. The CSM is established pursuant to section 4 of the 1968 Act. Its principal functions include considering applications for marketing authorisations, and advising Ministers and the UK Licensing Authority on the quality, efficacy and safety of medicines to ensure the maintenance of public health safety standards.		
Horizon Scanning			

Legislation: ***Motor Fuel (Composition and Content) Regulations 1999 (as amended)***[104]			
Summary of Purpose: The 1999 Regulations implement Directive 98/70/EC relating to the quality of petrol and diesel fuels. The Directive sets technical specifications on health and environmental grounds for fuels to be used for vehicles equipped with positive ignition and compression ignition engines.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Environmental specifications	Annexes I to IV set out environmental specifications for market fuels to be used for vehicles equipped with positive ignition and compression ignition engines. Specifications are set out in relation to a number of listed parameters, including: ▪ Oxygen content ▪ Lead content ▪ Sulphur content ▪ Hydrocarbon analysis ▪ Polycyclic aromatic hydrocarbons ▪ Cetane number ▪ Research octane number ▪ Motor octane number Parameter limits (minimum and maximum) are set according to weight, temperature, percentage concentration, pressure, or volume, depending on the parameter in question.	<u>Appropriateness of parameter limits</u> The issue is whether the parameter limits are set at appropriate levels to prevent the materialisation of potential risks to human health or the environment posed by nanoparticles in motor fuel. The limits set in Annexes I to IV do not refer to particle size. It is conceivable that the present limits would fail to capture potential threats arising from the use of nanomaterials in this context.	The overarching safety framework established by the General Product Safety Regulations 2005 applies, should the parameter limits fail to capture potential risks arising from the placing on the market of fuel containing nanoparticles.
Linked Legislation	General Product Safety Regulations 2005		
Horizon Scanning			

Legislation: ***End of Life Vehicles Regulations 2003 (ELV)***[105]

[104] Implementing Directive 98/70/EC relating to the quality of petrol and diesel fuels.

Summary of Purpose: The regulation is an example of extended producer responsibility (EPR), which requires that vehicles put on the market after July 2003 may not contain lead, cadmium or hexavalent chromium. Integral to the concept of EPR is that waste management is seen as part of the product lifecycle. The regulation also requires that all ELVs are only treated by authorised dismantlers, a concentration on reuse, recovery and recycling as the preferred disposal means and that vehicles are de-polluted before recycling.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	The Regulations apply to new and end of life vehicles[106] and their materials and components, irrespective of how the vehicle is serviced or repaired. A central aim is to reduce the amount of waste from vehicles and to encourage reuse, recovery and recycling.	The process involved in disposal, destruction or recycling of components containing nanomaterials may pose an increased potential risk of exposure to workers in recycling and disposal industry and to the environment. Further information on the impacts will be required.	The concept behind EPR applies equally to nanomaterials, requiring producers or manufacturers to minimise human and environmental exposure to free nanoparticles at all stages of the lifecycle and should also form an integral part of the innovation and design process. If nanomaterials are accurately classified and increased information on potential impacts become available these regulations should ensure that nanomaterials are captured and managed appropriately.
2.Hazardous Substance*	The regulations require that hazardous materials are removed before a vehicle is dismantled. It is defined as any substance which is considered to be dangerous under Directive on Dangerous Substances[107] and as such on the Approved Supply List[108]^. Where a hazardous material is permitted it must be labelled.	Currently, no 'existing' nanomaterial substances appear on this list. Operators potentially dependent on classification of ELV waste by waste generator or disposer - the lack of data available may mean that substances in nanosized form will not be classed as a dangerous substance. (See also potential gaps in List of Waste/CHIPs regulations). <u>If classed as 'hazardous'?</u>	It is recommended that due to the lack of available scientific information on the impacts of nanomaterials, wastes resulting from the development, manufacture, supply and use of nanoparticles are classed as hazardous. This will require producer guidance.

[105] End-of-Life Vehicles (Producer Responsibility) Regulations 2005 SI 263 - The Regulations require a producer to register with the Secretary of State and declare responsibility for those vehicles which he has placed on the market. A producer is required to submit to the Secretary of State an application for approval of the system he has established to collect vehicles for which he is responsible and the system for collection must contain sufficient capacity to treat those end-of-life vehicles for which he is responsible. The regulations introduce reuse, recovery and recycling targets for end-of-life vehicles treated at authorised treatment facilities.

[106] End-of-Life vehicle means a vehicle which is waste within the meaning of Article 1(a) of the Waste Directive.

[107] Directive 67/548/EEC – Annex I lists about 5,000 substances with their classification and labelling.

[108] Is the document entitled "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Eighth Edition)" approved by the Health and Safety Commission on 26 July 2005

		Hazardous components are removed from waste vehicle and segregated, thereby reducing the potential for contamination. Nanomaterials identified as hazardous and permitted will therefore be labelled. However, if applying List of Wastes – there is no hazardous code for e.g. plastics and therefore plastics containing nanomaterials would either have to be coded without identification to plastic or not be identified as hazardous, however plastic components must be identified by the use of standard component codes. <u>If not classed as 'hazardous'?</u> Component containing nanomaterials may not be segregated and may be incorrectly disposed via a means which may result in higher exposure.	
3. Heavy Metals	Producers must ensure that materials and components of vehicles put on the market do not contain lead, mercury, cadmium or hexavalent chromium except in the cases listed in Schedule 1.	The issue will be whether the prohibited materials will have a nano equivalent. If they do whether the nano equivalent is classed as an 'existing' substance – if it is a potential gap may arise if the nano form is assessed on the same principles as the macro form. If the nano form is classed as a 'new' substance and therefore assessed on its own potential risks, a gap may arise if the new substance falls out of the scope of the regulations.	
4. Information	1. Coding Standards: Producers must use standard component codes to identify any parts, which contain plastics or rubbers to facilitate recycling 2. Dismantling Information: The dismantling information shall identify, in so far as it is needed by treatment facilities, the different materials and components of the vehicle, and the location of all hazardous substances in	1. Plastics & rubbers are a leading potential area for nanotechnology applications – codes may need to be reassessed to differentiate between plastics and rubber with and without nanomaterials – particularly if the presence of nanomaterials causes the components to react differently to treatment. 2. Main potential issue is the lack of available data on nanomaterials to allow a producer to	As more information becomes available about the potential risk presented by releases at end of life, it may be necessary to consider whether this regulation needs to be modified to set out how such materials should be managed.

	the vehicle 3. Reporting: including information on the environmentally sound treatment of ELV	provide the necessary information to comply with this regulation. This will include the necessary information on how nanomaterials should be managed e.g. whether ELV waste containing nanomaterials is suitable for reuse, recovery or recycling. 3. As per (2) above, the issue is the lack of available data required to comply with this particular regulation.	
5. Technical Requirements for keeping and treating	Sets down a number of minimal technical requirements at treatment site including the need for impermeable surfaces and provided with spillage collection facilities, decanters and cleanser-degreasers.	These minimal technical requirements may need to be reconsidered in light of information on the management requirements for nanomaterials.	
Linked Legislation	**^ - *Dangerous Substances Directive*** –Annex I of this Directive, chemicals examined under NONS, ESR or BPR will have the classification and labelling agreed at the EU level and entered into Annex I – this is implemented in the UK as the Approved Supply List - Currently no substances at nanosized form listed under the Approved Supply List. **** - Chemical (Hazard Information & Packing for Supply) Regulations 2002*** – Identification and classification of nanomaterials will be the responsibility of suppliers under CHIP, this initial classification can be used by subsequent users who will also rely on the information provided in 'Safety Data Sheets'. **** - List of Waste Regulations 2005*** – Will assist in the identification of hazardous waste components		
Horizon Scanning	EC Communication **"Towards a European Strategy for Nanotechnology"** - In that communication, the EC stressed that nanotechnology must be developed in a safe and responsible manner. As such, the EC urged that any potential public health, safety, environmental and consumer risks be addressed up front by generating the data needed for risk assessment, integrating risk assessment into every step of the lifecycle of nanotechnology-based products, and adapting existing methodologies (and, as necessary, developing new ones) for the regulation of nanomaterials. The explicit mention of 'lifecycle' approach leads to the important conclusion that products containing nanomaterials must be managed after use to ensure that none of these materials can escape into the environment.		

Legislation: ***Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2005 (RoHS)***			
Summary of Purpose: The RoHS Regulations ban the putting on the EU market of new Electrical and Electronic Equipment (EEE) containing more than the permitted levels of lead, cadmium, mercury, hexavalent chromium and both polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants from 1 July 2006. There are a number of exempted applications for these substances. The regulations extend to the product, components and subassemblies of such products. RoHs falls under the extended producer responsibility (EPR) regime.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Hazardous Substances	"Hazardous substance" means lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers in quantities exceeding the maximum concentration value levels (0.1% by weight). It extends to 8 classes of EEE*. The regulations also include a list of exempt applications – Schedule 2.	1. The definition of hazardous substances under the Restriction of Hazardous Substances (RoHS) Directive does not include nanomaterials; there is the potential for some of these hazardous substances to also be available at the nanoscale e.g. cadmium-based quantum dots. This is not a complete ban on these substances only on products not containing more than the permitted level of restricted substance. The concentration level has been derived from information of the impacts of these restricted substances at the macro level and therefore the availability at the nanoscale may require reassessment of appropriate concentration value levels. 2. If nanomaterials are classed as new substances under NONS** and eventually under REACH, the definition in these regulations may need to be altered to ensure capture of any new nanosized form of the macro substance. 3. If nanoscale form classed as 'existing' substance danger that risk assessment based on macro substance and not the unique properties of the nano form.	Any potential gaps again will be dependent on the availability of data on the potential impacts of the nanoscale component in contrast to the macro scale component – as a consequence regulations may need to be adapted particularly in terms of concentration values for any identified nanoscale substances falling under the regulations' definition of hazardous substance.

Linked Legislation	**** - Directive on Waste Electrical and Electronic Equipment (WEEE)*** – categories of EEE identified in RoHS comply with the same 8 categories identified in Annex I of WEEE. ***** - Notification of New Substances*** – new nanosized form substances derived from the macro scale substance may be classed as new substance under NONS.
Horizon Scanning	

Legislation: *Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)*			
Summary of Purpose: The Directive aims to reduce the amount of WEEE being disposed to landfill by reducing the amount of WEEE produced, encouraging re-use and recycling by encouraging its separate collection and subsequent treatment. It also aims to improve the environmental performance of producers by encouraging a lifecycle approach to the production of electrical and electronic equipment, including placing the responsibility of reuse and recycling on the producer. It does not cover all electrical and electronic goods and a list is supplied. The Directive is under consultation and is not expected to be implemented into UK legislation until 2007. The Directive is an example of extended producer responsibility (EPR).			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope within the UK	The UK will introduce the requirements via the WEEE Regulations, currently not in force. In the UK it is likely that the Secretary of State will have powers to prepare and issue a code of practice for the purpose of providing practical guidance on the standards that must be met by the operator of a designated collection facility.		When information on the impacts and effects of nanomaterials becomes available, it may become necessary to readdress the methods of treating such components; this power could fill any potential gap if nanomaterials are captured by the intended UK regulations.
2. Removal of substances, preparations and components Annex II	The purpose of the Directive is at a minimum to remove from any separately collected WEEE a number of identified substances, preparations and components. Those identified are to be disposed or recovered in accordance with the Waste Framework Directive*.	This list does not include any specific nanomaterials however as this is a non-exhaustive list other substances can be added to this list, thereby providing for the inclusion in the future for any new substances which may pose a particular concern.	
3. Re-use and treatment information	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,	At the current time, there is not the relevant level of nanomaterial data available to allow producers to comply fully with this provision.	However, once this information becomes available this requirement will assist with the disposal of WEEE containing nanomaterials.

	including the location of dangerous substances and preparations.		
4. Dangerous Substances & Preparations	Current definition of dangerous substances is any substance which is considered to be dangerous under Directive on Dangerous Substances[109], in the UK this will be any substance on the Approved Supply List	There is the potential for identifying products containing nanomaterials. However, this will be dependent on whether nanomaterials are classed as dangerous substances and therefore hazardous. At present no 'existing' nanomaterial substance on this list. If not classed as a dangerous substance or is incorrectly classed as non-hazardous, these substances may not be managed by the best available treatment, recovery and recycling techniques and thereby reducing any potential damage to human health and/or the environment. This may also extend to the handling of any WEEE with employers not providing the adequate health and safety measures for employees and thereby not complying with COSHH[110].	With the lack of available data on the potential risks posed by nanomaterials, it is advisable to apply the precautionary principle and class nanomaterials as hazardous thereby reducing any gaps that may occur throughout the regulatory framework.
5. Treatment Methods	1. The Directive requires that operators ensure that appropriate systems are available to provide for the treatment of WEEE using the best available treatment, recovery and recycling techniques. 2. The Directive also seeks to encourage the integration of recycled materials in new equipment.	1. None of the current specified treatment methods are intended to address the potential risks of nanomaterials. 2. With the lack of information on the reaction of nanomaterials to various processes, treatment methods may need to consider this requirement and additional research may be required.	This may need to be readdressed in time.
6. Private Household WEEE	1. The introduction of a take back scheme for EEE from domestic use to producer.	1. Potential gap may exist depending on the extent of the scheme if exemptions apply and the level of information available to the public to secure its effectiveness.	1. This should capture domestic WEEE, which may contain nanomaterials, this system is a step forward for domestic waste to reduce the amount of domestic waste containing nanomaterials being sent to landfill.

[109] Directive 67/548/EEC – Annex I lists about 5,000 substances with their classification and labelling.
[110] Control of Substances Hazardous to Health Regulations 2002

	2. Information – Distributor responsible for supplying information on the potential effects on human health and on the environment caused by the presence of hazardous substances in EEE.	2. With the current level of available information on nanomaterials it seems unlikely that distributors will be able to comply with this condition, resulting in a lack of available information being passed on to the public.	2. EPR may provide a step forward in closing the information gap loop, e.g. producers with a responsibility for ensuring the appropriate disposal of their products will also be responsible for providing the relevant reuse and treatment information.
Linked Legislation	**** - Waste Framework Directive***[111] - The essential objective of all provisions relating to waste disposal must be the protection of human health and the environment against harmful effects caused by the collection, transport, treatment, storage and tipping of waste – central to this is the reduction of the amount of waste disposed to landfill. ***Control of Substances Hazardous to Health Regulations 2002 –*** These will be applicable to the health and safety conditions of treatment facilities. ***List of Waste Regulations 2005 –*** identification and coding of WEEE included in the list of wastes, WEEE arriving at sites will be classified using these codes – to date none accommodate identification of nanotechnologies but if identified as hazardous should be covered by the list, however list may need to be revised due to the introduction of nanomaterials as a potential contaminant.		
Horizon Scanning	EC Communication **"Towards a European Strategy for Nanotechnology"** - In that communication, the EC stressed that nanotechnology must be developed in a safe and responsible manner. As such, the EC urged that any potential public health, safety, environmental and consumer risks be addressed up front by generating the data needed for risk assessment, integrating risk assessment into every step of the lifecycle of nanotechnology-based products, and adapting existing methodologies (and, as necessary, developing new ones) for the regulation of nanomaterials and nanoproducts. The explicit mention of 'lifecycle' approach leads to the important conclusion that products containing nanomaterials must be managed after use to ensure that none of these substances are disposed in a manner which results in damage to human health or the environment. ***Thematic Strategy on the prevention and recycling of Waste*** by the European Commission – seeks to encourage the use of waste as a resource and therefore increased recycling.		

Legislation: *Packaging (Essential Requirements) Regulations 2003*[112]			
Summary of Purpose: The main requirement of the regulation is that no person who is responsible for packing or filling products into packaging or importing packed or filled packaging into the United Kingdom may place that packaging on the market unless that packaging fulfils the Essential Requirements^ and is within the Heavy Metal concentration limits.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Essential Requirement – Manufacturing and	1. Design, production and commercialisation of packaging facilitates the potential to reuse, recover and recycle and should minimise the	1. This provision is sufficiently flexible to extend to any packaging containing nanomaterials. Nanomaterials are likely to be utilised in a number of packaging materials	Due to the scope of materials covered by the regulations there are a number of significant applications for nanotechnology.

[111] Council Directive 75/442/EEC
[112] As amended 2004 (SI 1188) and 2006 (SI 1492)

composition	impact on the environment when packaging waste or residues from packaging waste management operations is finally disposed. 2. The presence of noxious and hazardous substances and materials are minimised with regard to their presence in emissions, ash or leachate when packaging or residues from waste management are incinerated or sent to landfill[113].	e.g. plastic and nanomaterials whether classed as hazardous or not should be assessed as to their effectiveness to be disposed of via the waste management methods identified. 2. The aim of the regulations and the Packaging Directive is to reduce the amount of noxious metals and other substances as well as the potential toxicity of packaging waste and to limit their environmental impact. Nanomaterials are likely to be captured under this regulation if they are classed as a hazardous substance or material and if so any emissions will be minimised. As the regulations extend throughout the lifecycle of packaging including manufacturing; manufacturers will rely on information supplied to them by chemical suppliers who in turn will rely on data provided under NONS* notification. Potential gaps at these stages will therefore impact on other users. Hazardous packaging waste will be coded under the List of Waste Regulations 2005**.	In applying a lifecycle analysis approach the design, production and commercialisation requirements should ensure that the impact on the environment and human health are limited even where there are likely emissions and/or discharges*** as a result of the recovery process and the end disposal of any wastes resulting from the recovery. Currently, the lack of scientific information on the impacts of nanomaterials on human health and the environment is likely to prohibit a full lifecycle approach and as such to limit any potential harm from nanomaterials, it is recommended that they are classed as hazardous substances.
2. Regulated Metals	Aggregate heavy metal limits apply to cadmium, mercury, lead and hexavalent chromium in packaging or packaging components subject to some exceptions.	In the UK one of the main applications of nanotechnology is within metals and metal oxides – it is however, unlikely that the regulations do extend to metal components in their nanoform, particularly in terms of the applicable concentration values. If the nano-equivalent is classed as an 'existing' substance there is then the risk that the potential impacts will not be identified at the nanoscale but at the macro equivalent, thereby resulting in a gap in risk assessment and risk management. If the nano-equivalent is classed as a 'new' substance it may not be	If data indicated that the nanoscale form of heavy metals should be covered, this would be a simple alteration to the regulations.

[113] Under the provisions of the Hazardous Waste (England & Wales) Landfill Regulations 2005 – any hazardous packaging sent to landfill must be sent to one designated to receive hazardous waste.

		covered by the regulations.	
3. Exemption Criteria	The concentration levels of regulated metals shall not apply to plastic crates or plastic pallets on or before 4 March 2009 provided certain requirements are fulfilled.	This limits the entry of external materials into the recycling process to that which is technically feasible to control and that no regulated material shall be intentionally introduced. The technical specifications are unlikely to include any that are capable of addressing the identification of nanomaterials and the definition of intentionally introduced does not extend to the use of recycled material as feedstock where the recycled materials contains amounts of regulated metal. The exemption criteria are therefore unlikely to capture nanomaterials, which could be contained in recycled material.	
Linked Legislation	***^ - as outlined in Annex II of Directive 94/62/EC of the European Parliament and the Council on packaging and packaging waste*** **** - Notification of New Substances Regulations 1993*** – Determination of new substances and the hazard information necessary to reduce risks during use and disposal. ** - ***List of Waste (England & Wales) Regulations 2005*** – Currently only two hazardous codes available for contaminated packaging with one identified as a 'mirror' code requiring thresholds for hazardous properties to be met, as a consequence the threshold levels may be too high to ensure that packaging containing nanoparticles is identified as hazardous. ***Pollution Prevention and Control (England & Wales) Regulations 2000*** - Operators of the potentially most polluting processes ('prescribed processes' which are specified in the amended Environmental Protection (Prescribed Processes and Substances) Regulations 1991/472) have to apply for prior authorisation from the Environment Agency to operate the process. PPC requires operators to consider the total impact of all releases to air, water and land when making an application ***Consumer Protection Act 1987***		
Horizon Scanning			

Legislation: *Producer Responsibility Obligations (Packaging Waste) Regulations 2005*[114]
Summary of Purpose: The 2005 Regulations place obligations on certain businesses to register with the relevant competent authority in each jurisdiction within the UK or via a 'compliance scheme', to recover and recycle specified tonnages of packaging waste each year and to certify that this recovery and recycling has been achieved. Some businesses must also provide certain information about recycling to consumers. The UK has set a series of targets to be achieved each year to 2010. The obligation is placed on any business which handles more than 50 tonnes of packaging per annum and has a turnover of more than £2 million per annum if it is involved in manufacturing raw materials for packaging, converting raw materials into packaging, filling

[114] Implementing Council Directive 94/62/EC on packaging and packaging waste as amended Council Directive 2004/12/EC and 2005/20/EC

packaging, selling packaged goods as a service provider or importer.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	The primary aim is to reduce the overall quantity of packaging waste that is subject to final disposal and priority is given to the prevention of packaging waste and to reuse where possible.	The scope of the regulations is limited as they only apply to producers with a turnover of £2,000,000 and handled in aggregate more than 50 tonnes of packaging or packaging materials. Small producers using nanomaterials will not be covered by the regulations and if nanomaterials are not classed as hazardous substances, the packaging can be disposed to landfill.	Irrespective of whether packaging contains nanomaterials, the purpose of the regulations is to reduce the amount of packaging being disposed to landfill and as such offers a means of reducing any potential impacts on the environment and human health from the final disposal of nanomaterials.
2. Recovery and Recycling Obligations	Producers are required to take reasonable steps to carry out specified tonnages of recovery & recycling of packaging waste. Recovery includes recycling, composting and energy recovery****.	Many of the packaging materials listed are capable of being composed of nanomaterials – with the lack of available information on the potential impacts of nanomaterials it may be necessary to consider the potential impacts of the various disposal methods for this type of packaging materials if the nanomaterials are not classed as hazardous under the Dangerous Substances Directive**. Any emissions levels will require to be controlled under the PPC*** regulations, which include waste management facilities as specified activity, as long as they fulfil the tonnage requirements. Small waste management facilities may not be covered by the PPC regulations if they do not meet the tonnage levels.	There is little scope for classifying packaging waste as hazardous with only 'mirror' entry codes being available, which means that there is a scope for assessing whether the hazardous substance in terms of concentration thresholds and it is unlikely that nanomaterials will be captured by these concentration thresholds^.
3. Application for accreditation	Person seeking accreditation must provide information on the development of capacity for the collection and reprocessing of packaging waste and the development of new markets for materials or goods which have been made from recycled packaging waste and arrangements for the collection and separation of packaging.	Unlikely, in the present that such capacity will extend to the handling of nanomaterials or for the potential utilisation of recycled feedstock containing nanomaterials. At present it is unlikely that sufficient technical methods exist to separate nanomaterials from packaging.	
Linked	***Packaging (Essential Requirements) Regulations 2003 –*** The regulations provide a list of essential requirements for all packaging and provide concentration levels for regulated metals.		

Legislation	** - ***Dangerous Substances Directive*** - List I and List II substances contained in the ***Dangerous Substances Directive (76/464/EEC),*** however as part of the ongoing restructuring of the Community water policy, the **Directive on Dangerous Substances** is now integrated in the **Water Framework Directive** (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as **Directive 2006/11/EC** on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community. *** - ***Pollution Prevention and Control (England & Wales) Regulations 2000*** - Operators of the potentially most polluting processes ('prescribed processes' which are specified in the amended Environmental Protection (Prescribed Processes and Substances) Regulations 1991/472) have to apply for prior authorisation from the Environment Agency to operate the process. PPC requires operators to consider the total impact of all releases to air, water and land when making an application. Limited to specific processes. **** - ***Waste Framework Directive Annex II*** – Provides a list of recovery methods acceptable under the Directive. ***Environment Act 1995*** introduces the producer responsibility obligations. ***Waste Management Licensing Regulations 1994*** **^ - *List of Waste (England & Wales) Regulations 2005*** - Identifies substances as either 'Absolute' or 'Mirror' wastes. Absolute wastes are always hazardous. Mirror wastes may be hazardous or non-hazardous dependent on the concentration of dangerous substances.
Horizon Scanning	***Thematic Strategy on the Prevention and Recycling of Waste*** by the European Commission – seeks to encourage the use of waste as a resource and therefore increased recycling.

Legislation: *Control of Pesticides Regulations 1986*

Summary of Purpose: The Control of Pesticides Regulations 1986 sets out an approval scheme for non-agricultural pesticides. In 2001, Directive 98/8/EC (which establishes a regulated single European market in biocides based on risk evaluation and harmonised authorisation) was transposed in the Biocidal Products Regulations 2001. The Biocidal Products Regulations 2001 will replace the Control of Pesticides Regulations 1986, although the 1986 Regulations will remain in force until the safety of substances has been assessed under the 2001 Regulations. Currently most pesticides are regulated under the Control of Pesticides Regulations 1986. The 1986 Regulations prohibit the advertisement, sale, supply, storage and use of pesticides without an approval and a consent.

Content for Analysis	Summary of regulations	Gap or Potential Gap	Comment/Impact
I. Definition and scope	Regulation 3 provides that the Regulations apply to: - *any* pesticide; or - any substance, preparation or organism prepared or used for any of the following purposes, as if it	Note exemption in relation to R&D: The Regulations do *not* apply to … 'substances, preparations or organisms used in laboratories for the purpose of the micro propagation of plants or substances,	It is foreseen that nanomaterials will be used in the manufacture of pesticides falling within the Regulation 3. The Regulation 3(2)(f) exemption creates the possibility that nanomaterials will be

	were a pesticide: ▪ protecting plants or wood or other plant products from harmful organisms; ▪ regulating the growth of plants; ▪ giving protection against harmful creatures; ▪ rendering such creatures harmless; ▪ controlling organisms with harmful or unwanted effects on water systems; ▪ protecting animals against ectoparasites. 'Pesticide' is given the meaning assigned to it in section 16(15) of the Food and Environment Act 1985.	preparations or organisms used in the production of novel food' (3(2)(f)).	used specifically in relation to novel food R&D without prior approval (Regulation 5) or consent (Regulation 6). This has potential implications regarding workplace and environmental exposure to nanoparticles.
II. Approval and consent	Regulation 4 prohibits the advertisement, sale, supply, storage, and use of a pesticide without prior approval (Regulation 5) and consent Regulation 6). Regulation 5(3) provides that '[e]ach approval may authorise the use, supply and storage of the pesticide to which it relates'.	The question is whether the inclusion of nanoparticles in pesticides requires a new approval and consent irrespective of the fact that its non-nano form has already been authorised. If the inclusion of nanoparticles alters the nature of the pesticide to such an extent that it may be considered a 'new' pesticide for the purposes of the Regulations, separate approval and consent will be required. Regulation 5(2) provides that approval may be 'experimental' to enable further testing to be conducted to produce additional safety data before provisional/full approval is granted. If the inclusion of nanoparticles has no bearing on the nature of the pesticide so that it is still deemed to be the same pesticide product for the purposes of the Regulations, no new approval or consent will be required. The upshot is that nanoparticles might enter	The Biocidal Products Regulations 2001, which will replace the 1986 Control of Pesticides Regulations, establish a rigorous mechanism for risk assessment based on the toxicity of substances.

		onto the market without consideration of safety aspects specific to nanomaterials.	
III. Safety	The advertisement, sale, supply, storage and use of pesticides are prohibited unless conditions of consent set out in the Schedules to the Control Of Pesticides Regulations 1986 are met. - Schedule 1 (conditions relating to consent to advertisement of pesticides) - Schedule 2 (conditions relating to consent to sale, supply and storage of pesticides) - Schedule 3 (conditions relating to consent to use of pesticides) - Schedule 4 conditions relating to consent of use of pesticides by aerial application) Each of the Schedules sets out a number of safety requirements. Schedules 2 and 3, for example, set out a general safety requirement that any person who sells, supplies or stores a pesticide shall take all reasonable precautions, particularly with regard to storage and transport, to protect the health of human beings, creatures and plants, safeguard the environment and in particular avoid the pollution of water. Before a pesticide can be approved for sale and use, evidence is required of its	The question is whether current forms of risk assessment are designed to address the sort of risks posed by human/environmental exposure to pesticides containing nanoparticles.	It is likely that safety requirements are sufficiently broad to encompass potential risks associated with human or environmental exposure to pesticides. The Advisory Committee on Pesticides maintains that a precautionary approach to pesticide approval is adopted.[116] Pesticides in use are periodically reviewed, and companies are required to notify registration authorities if any new information becomes available raising safety concerns.

[115] See Advisory Committee on Pesticides (ACP), *A Guide to Pesticide Regulation in the UK and the Role of the Advisory Committee on Pesticides*, (DEFRA & HSE; London; 2003).
[116] Advisory Committee on Pesticides (ACP), *A Guide to Pesticide Regulation in the UK and the Role of the Advisory Committee on Pesticides*, (DEFRA & HSE; London; 2003).

	efficacy and that it will not pose an unacceptable risk to human health or the environment. Companies seeking approval must submit scientific data, which would usually include information about the physico-chemical properties of the pesticide, its potential toxicity in humans, exposure to operators and workers, and ecotoxicology.[115]		
Linked Legislation	***Food and Environment Protection Act 1985*** – established overarching legal framework for the control of pesticides in Great Britain which implemented through the Control of Pesticides Regulations 1986. ***Biocidal Products Regulations 2001*** – establishes a framework addressing the hazardous properties of non-agricultural pesticides and their classification, labelling, and risk management procedures. ***Plant Protection Products Regulations 2005*** ***Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs (England and Wales) Regulations 1999*** ***Chemicals (Hazard Information & Packaging for Supply) Regulations 2002*** ***Control of Substances Hazardous to Health Regulations 2002***		
Horizon Scanning			

Legislation: *Detergents Regulations 2005*[117]			
Summary of Purpose: The Detergents Regulations 2005 introduce measures to implement Regulation 648/2004 and establish a competent authority ('Pesticides Safety Directorate') in charge of enforcement. Regulation 648/2004 aims to improve the free market of detergents, modernise the detergents regime, improve environmental protection, and provide specific information to consumers on the content of detergents. It extends and tightens the testing of surfactant biodegradability, and requires the provision of more detailed information on detergent labels. It is an offence to place a detergent on the market in contravention with the Regulation.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition of 'controlled product' ▪ Regulation 2(1) Detergent	Regulation 2(1) of the Detergent Regulations 2005 is defined as 'a detergent or a surfactant'. Article 2 to Regulation 648/2004 defines 'detergent' as:	No gap identified.	

[117] Enforcing the Detergents Regulation (EC) No.648/2004.

Regulations 2005 ▪ Article 2 Regulation 648/2004	'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.' Auxiliary washing preparations, laundry fabric-softener, domestic cleaning preparations, and other cleaning and washing preparations also fall within the definition of 'detergent'. 'Surfactant' is defined as: 'any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.'		
II. Protection of human health, animal health and the environment ▪ Article 2 Regulation	The use of surfactants can only be authorised if they pass certain biodegradability tests.[118] Regulation 648/2004 introduces a two-tier system of safety testing: *primary* testing and *ultimate* testing. Article 2 to Regulation 648/2004 defines	<u>Stringency of safety assessment</u> The use of nanotechnology is expected to heavily impact the manufacture of detergents. It is likely that the use of nanomaterials in this context would not be precluded by the definitions of 'detergent' and 'surfactant' provided in Article 2 to Regulation 648/2004. The issue is whether the safety provisions set	Article 15 to Regulation 648/2004 establishes a safeguard clause to protect against unforeseen dangers. It enables Member States to impose provisional restrictions or prohibitions on the sale and/or use of a specific detergent if there are justifiable grounds for believing that the detergent poses a potential risk to

[118] Tests must be conducted in accordance with Article 10(5) of Regulation (EC) No.793/93.

648/2004	'primary biodegradation' as: 'the structural change (transformation) of a surfactant by micro-organisms resulting in the loss of its surface-active properties due to the degradation of the parent substance and consequential loss of the surface-active property'. 'Ultimate biodegradation' is defined as: 'the level of biodegradation achieved when the surfactant is totally used by micro-organisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water and mineral salts of any other elements present (mineralisation)'. Primary testing is measured by a series of tests set out in Annex II to the Regulation. Ultimate testing is set out in Annex III to the Regulation. Manufacturers wishing to place on the market surfactants or detergents containing surfactants that *fail* the ultimate biodegradability test but pass a primary biodegradability test are required to submit a derogation application pursuant to Articles 4 and 5 of Regulation 648/2004. An application for derogation must be accompanied by a technical file supplying information necessary for evaluating the safety of the surfactant in question, results of tests conducted pursuant to Annexes II and III, and a complementary risk assessment in accordance with stipulations in Annex IV.	out in the Regulation are capable of identifying potential risks associated with exposure to nanomaterials. The provisions in Annex IV require that the molecular and structural formula, and the composition of a surfactant are taking into consideration in an assessment of safety. It is likely that the Annex IV requirements are sufficiently thorough to identify possible threats arising from the use of nanomaterials. However, a complementary risk assessment is only required in relation to surfactants that fail the ultimate biodegradability test set out in Annex III. It is conceivable that primary and ultimate biodegradability testing fails to detect potential risks associated with exposure to nanomaterials which might be expected to be identified by a complementary risk assessment.	human or animal health, or to the environment. The safety requirements established under the overarching framework of the General Product Safety Regulations 2005 also applies to the placing on the market of detergents.

	Annex IV requires that a complementary risk assessment includes information regarding the societal value of the application, conditions of use, the availability and suitability of alternatives, and its environmental impact.		
Linked Legislation	General Product Safety Regulations 2004		
Horizon Scanning			

Legislation: *Cosmetic Products (Safety) Regulations 2004 (as amended)*[119]			
Summary of Purpose: The principle aim of the Cosmetic Products (Safety) Regulations 2004 is to safeguard public health. Cosmetic products are only permitted to contain safe ingredients. The Regulations set out a number of requirements in relation to conditions of use, the manufacture and supply of products, prohibitions and restrictions on ingredients, animal testing, and ingredient labelling and information. The regulatory regime works from the premise that a product cannot be marketed unless it is deemed to be safe not only under *normal* but also under *reasonably foreseeable* conditions of use. The Regulations contain lists of ingredients which are either prohibited or restricted, or positively listed as acceptable subject to certain conditions. The manufacturer (or person responsible for placing the product on the market in the EC) is responsible for ensuring that cosmetic products do not cause damage to human health. A safety assessment must be conducted by a suitably qualified person in relation to all cosmetic products before they are placed on the market, and the results made available to enforcing authorise. Specific safety assessment procedures must be adhered to in relation to cosmetic products intended for use by children under the age of three years and for cosmetic products intended for external intimate hygiene.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition Regulation 3(1)	The definition of a 'cosmetic product' comprises two parts, both of which must be satisfied. The definition is set out in Regulation 3(1). First, in order to fall within the definition, a substance or preparation must have one of the following six functions: (i) to clean; (ii) to	No gap identified.	It is likely that the definition of 'cosmetic product' pursuant to Regulation 3(1) is sufficiently broad to capture current and future uses of nanomaterials in the cosmetics sector. Products supplied to consumers that fall outside the scope of the Regulation 3(1) definition are likely to

[119] Implementing Cosmetics Directive 76/768/EEC (as amended).

	perfume; (iii) to change the appearance; (iv) to protect; (v) to keep in good condition; or (vi) to correct body odours. Secondly, the field of application of the said substance or preparation must include one or more of the following: (i) the epidermis; (ii) the hair system; (iii) the nails; (iv) the lips; (v) the external genital organs; (vi) the teeth; or (vii) the mucous membranes of the oral cavity. A 'cosmetic ingredient' is defined as any substance or preparation of synthetic or natural origin used in the composition of a cosmetic product.		fall within the scope of the General Product Safety Regulations 2005[120] which establishes a framework for ensuring that intended for or likely to be used by consumers under normal or foreseeable conditions are safe.
II. General Safety Requirement Regulation 4	The supply of a cosmetic product liable to cause damage to human health under *normal* or *reasonably foreseeable* conditions of use is prohibited. This safety requirement does not cover the misuse of a cosmetic product.	No gap identified in relation to damage to *human health*.	The general safety requirement is limited to an assessment of risk in relation to human health. Normal or reasonably foreseeable uses of cosmetic products containing nanoparticles posing little or no threat to human health might at the same time create potential hazards at other stages of the lifecycle – for example, to the environment following product disposal.
II. Prohibited and Restricted Ingredients Regulations 5	Regulations 5(1) and 5(2) prohibit or restrict the use of groups of cosmetic ingredients listed in Schedules 3 to 7: <u>Schedule 3</u> Prohibited substances <u>Schedule 4</u> Restricted substances	<u>Whether Schedules of prohibited or restricted substances cover substances containing nanomaterials</u> Prohibition or restriction in Schedules 3 to 7 is based on the *type* of substance rather than their *method of production*. Determining if substances containing nanoparticles fall within	It is recommended that the list of prohibited and restricted substances, and weight and concentration thresholds of restricted substances, contained in Schedules 3 to 7 are examined with reference to specific characteristics of nanoparticles.

[120] 'Product' is defined by the General Product Safety Regulations 2005 as 'a product which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them and which is supplied or made available, whether for consideration or not, in the course of a commercial activity and whether it is new, used or reconditioned and includes a product that is supplied or made available to consumers for their own use in the context of providing a service.'

	Schedule 5 Hair colourants subject to restrictions Schedule 6 Preservatives subject to restrictions Schedule 7 UV filters subject to restrictions Schedules 4 to 7 stipulate the maximum weight and concentration of substances permitted in cosmetic products. Regulation 5(15) prohibits the supply of cosmetic products containing carcinogens, mutagens or as substances toxic to reproduction. Regulation 6 sets out procedures for obtaining authorisation for use of ingredients not listed in the Schedules. Colouring agents (excluding hair dyes), antimicrobial preservatives, and UV filters can only be used if they are positively listed in Schedules 5, 6 or 7. If a manufacturer wishes to use a cosmetic ingredient which is normally subject to positive listing but which is not listed in the Schedules to the Regulations, authorisation ('Prior National Approval') must be obtained.	the scope Schedules 3 to 7 depends on whether listed substances and those containing nanoparticles can be considered to be *equivalent* for the purposes of the Regulations. If substances containing nanomaterials are deemed to be equivalent to their non-nanomaterial counterpart whose use is *restricted*, the issue is whether the weight and concentration limits specified are appropriately set to account for risks associated with human/environmental exposure to nanoparticles. It is conceivable that nanoparticles have the same chemical composition as ingredients whose use is permitted absolutely (by virtue being positively listed under Regulation 6) or partially (owing to restrictions imposed by the Schedules to the Regulations) but whose toxicity profile is markedly different thus posing a greater threat to human health and the environment. If the inclusion of nanoparticles in substances listed in the Schedules in some way alters the chemical structure of that substance, it is conceivable that the use of the substance in cosmetic products will *not* be covered by Schedule 3 to 7.	
III. Safety Assessment Regulations 9(1)(d) and (e)	The manufacturer of cosmetic products is obliged to keep information on its products readily accessible to the competent authorities. Regulation 9(1)(d) requires that a safety	Incomplete knowledge base The safety assessment requirement raises the most issues in relation to nanomaterials. The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP),[121] which advises the	It is recommended that detailed guidelines are developed on the risk assessment of nanomaterials in the light of paucity of information in a number of key areas. Should the Regulation 9 risk assessment

[121] Committee has since been replaced by Scientific Committee on Consumer Products (SCCP), Scientific Committee on Health and Environmental Risks (SCHER), and Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

	assessment is conducted in relation to the finished product and made available to the competent authority. Regulation 9(1)(e) sets out the same requirement in relation to products intended for use on children under the age of three and to cosmetic products intended exclusively for use in external intimate hygiene. Regulation 9(2) stipulates that safety assessments must be conducted in accordance with principles of good laboratory practice referred to in Article 1 Directive 2004/10/EC, taking into account: ▪ 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.	European Commission, has stipulated in its Guidance Notes[122] that the precise chemical nature of the ingredient and its structural formula, if known, should be identified in the safety assessment file. The evaluation of a cosmetic ingredient should be conducted in relation to its physical, chemical, and physio-chemical properties. Although there are no specific requirements relating to nanomaterials in cosmetic products, it is unlikely, given incomplete information about the implications of human/environmental exposure to nanomaterials, that a full safety evaluation could be conducted on cosmetic products containing nanoparticles. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has noted that existing methods for assessing the toxicity of substances might not be sufficiently robust to cover potential hazards arising from the use of nanomaterials.[123] In particular, information necessary for the risk assessment of dermal exposure to nanoparticles is lacking. It is conceivable that the use of nanomaterials in cosmetic products will be authorised in line with the safety requirements set out in Regulation 9, notwithstanding the fact that relatively little is known about the toxicological profile of nanoparticulate ingredients and exposure characteristics.	requirement fail to identify threats to human health posed by nanomaterials contained in a cosmetic product, and evidence of this risk becomes available once the product has been placed on the market, Regulation 9 of the General Product Safety Regulations 2005 require producers or distributors to notify the competent authority of the said risk.

[122] Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation Should Contain Specific Safety Evaluation Procedures for Nanomaterials (SCCNFP/0690/03.

[123] SCENIHR, *Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies*, SCENIHR/002/05.

IV. Animal Testing Ban Regulations 5(7) to 5(13)	The Regulations introduce a two-stage ban on the testing of cosmetic ingredients on animals. This ban applies to any testing undertaken in order to satisfy compliance with the Cosmetics Directive 76/769/EEC or with the Regulations. ▪ Prior to 2009 it will be illegal to test any cosmetic ingredient on animals in order to satisfy requirements of the Regulations *if* an alternative test method exists and has been validated at Community level. ▪ After 2009 it will be illegal to test any cosmetic ingredient on animals *irrespective* of whether an alternative test method exists.	<u>Animal testing ban restricts level to which ingredients can be tested for safety</u> There is concern that certain toxicological conclusions could not be drawn without the testing of cosmetic ingredients on animals.[124] It is worth noting, however, that the REACH regulations specify the use of animals for testing.	
Linked Legislation	General Product Safety Regulations 2005		
Horizon Scanning			

[124] See Oral Evidence (23 February 2004) presented to the Royal Society and the Royal Academy of Engineering (Report: *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*), Dr. Ian White (Chairman at the time of the Scientific Committee on Cosmetic and Non-Food Products) (http://www.nanotec.org.uk/evidence/WhiteIWcomments.pdf, accessed October 2006).

Legislation: *General Product Safety Regulations 2005*[125]			
Summary of Purpose: The General Product Safety Regulations 2005 implement the General Product Safety Directive 2001/95/EC, and are designed to ensure the safety of all products intended for consumer use. They are complementary to specific sector provisions with safety requirements. The Regulations came into force on 1 October 2005, replacing the General Product Safety Regulations 1994. The 2005 Regulations ensure consumer product safety by requiring that products placed on the market or supplied by producers and distributors are deemed to be safe and establishing a framework for safety assessment. The Regulations cover the supply of all new and second-hand products,[126] including clothing, medicines, machinery, tools and equipment, household goods, chemicals and pesticides, and motor vehicles.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition Regulation 2	A 'product' is defined by the Regulations as a product which is intended for consumer use or *likely*, under reasonably foreseeable conditions, to be supplied or made available for consumer use. The Regulations also cover products that were originally intended for professional use, but have since 'migrated' to the consumer market. A 'safe product' is defined as a product which, under normal or reasonably foreseeable conditions of use *does not present any risk or only the minimum risks compatible with the product's use*, considered to be acceptable and consistent with a high level of protection for the health and safety of consumers.	<u>Definition of risk</u> The Regulations do not provide a clear definition of 'risk' in this context.[127] This has potential implications for the assessment of product safety, discussed below.	The Regulations apply to consumer products irrespective of whether a product contains nanoparticles. The Regulation's definition of 'product' can be held to be sufficiently broad to cover current and potential applications of nanotechnology in consumer goods. Although there is no legal definition of 'risk', it is clear that the Regulations only extend to cover risks to human health and safety. Potential environmental risks fall outside the scope of the Regulations.
II. General Safety Requirement Regulation 5	Regulation 5 provides that no producer shall supply or place a product on the market unless the product is deemed to be safe.	<u>Adequacy of safety standards</u> The question is whether the methods of safety assessment adequately deal with potential dangers posed by the use of nanoparticles in	Compliance with voluntary standards does not guarantee that a product will be deemed to be safe if it fails to establish appropriate safety levels in respect of

[125] Implementing Directive 2001/95/EC on General Product Safety.
[126] Although note that the following are excluded: (i) products supplied for repair or reconditioning prior to use; and (ii) the sale of antiques.
[127] Although note that 'serious risk' is defined by Regulation 2 as a serious risk, including one the effects of which are not immediate, requiring rapid intervention.

	An assessment of the safety of a product is made on the basis of a number of factors, including its characteristics; packaging; instructions for assembly and maintenance, use and disposal; effect on other products with which it might be use; labelling and other information provided for the consumer; and categories of consumers at risk. Specific product regulations or national safety laws are also taken into account in determining safety. Where there are no applicable product or national regulations, safety is assessed according to voluntary EU 'harmonised' standards;[128] Community technical specifications; national standards; industry codes of practice; and the state of the art and technology.	consumer products. The Regulations introduce a presumption of conformity with the general safety requirement if a product conforms with the UK transposition of a voluntary European standard insofar as the risk is covered by that standard.[129] Harmonised standards are European standards, adopted by CEN, CENELEC, or ETSI following the issuing of a mandate by the European Commission after Member State consultation. Standards published to date include those relating to a number of sectors of current and potential applications of nanotechnology, including: active implantable medical devices; in vitro diagnostic medical devices; medical devices; radio and telecom terminal equipment; machinery; toy safety; construction products; and packaging and packaging waste. Compliance with harmonised standards, however, remains voluntary.	nanomaterials. Standards, therefore, can be seen to provide a *de minimis* threshold of safety. It is recommended that harmonised standards that take into account the characteristics of nanoparticles are developed. Note also the RAPEX (Community Rapid Information System) procedure set out in Regulation 33. An obligation is placed on producers and distributors to notify the enforcement authority of a product (other than a pharmaceutical product) posing a serious risk to consumers which requires urgent action.
Linked Legislation			

[128] Council Resolution, 7 May 1985, 'New Approach to Technical Harmonization and Standards'.
[129] For a list of standards, see Official Journal of the European Union, European Commission website: http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html, accessed October 2006.

Horizon Scanning	In April 2006 the European Commission called for the establishment of CEN Technical Committee on nanotechnologies based on business plan set out by CEN Technical Board Working Group 166 and emphasised need to ensure cooperation with CENELEC.[130] Consumer Policy Committee of the International Organization for Standardization is calling for the development of an International Standard that would provide guidance on how to identify, assess and eliminate or reduce risks associated with consumer products to all those involved in the supply chain. ISO Technical Committee 229 has been set up to promote standardisation in the field of nanotechnologies, specifically in relation to classification, terminology and nomenclature, basic metrology, characterisation, including calibration and certification, risk and environmental issues. [Change font style/colour]

Legislation: *Contaminants in Food (England) Regulations 2006*[131]			
Summary of Purpose: Legislation on contaminants in foodstuffs is made under the overarching framework established by Regulation (EC) No.315/93. The Regulation sets out procedures for contaminants in food, and applies to contaminants which are not covered by other specific Community provisions. Regulation (EC) No.466/2001 was enacted under Regulation 315/93 as a measure to harmonise the setting of maximum quantities of contaminants in foodstuffs across Member States, facilitate trade by removing competition distortion, and achieve greater levels of consumer protection. Regulation 466/2001 is enforced by separate, parallel provisions in each of the devolved administrations of the UK. Regulation 3 of the Contaminants in Food (England) Regulations 2006 make it an offence to place on the market food breaching requirements of Regulation 315/93.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition of 'contaminant' ▪ Article 1(1) Regulation (EC) No.315/93	Article 1(1) to Regulation 315/93 defines a contaminant as: 'any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of	No gap identified.	It is likely that the definition of contaminant provided in Article 1(1) will cover a wide range of applications of nanotechnology in food manufacturing.

[130] European Commission (Enterprise and Industry Directorate-General) *Action Plan for European Standardisation*, April 2006, final, http://ec.europa.eu/enterprise/standards_policy/action_plan/doc/standardisation_action_plan.pdf, accessed October 2006.
[131] Implementing Regulation (EC) No. 466/2001 setting maximum levels for certain contaminants in foodstuffs.

	environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this definition.'		
II. Maximum contaminant thresholds ▪ Article 2 Regulation (EC) 315/93 ▪ Article 1 Regulation (EC) No.466/2001 ▪ Regulation 3 Contaminants in Food (England) Regulations 2006	Article 2 to Regulation 315/93 stipulates that food containing a contaminant in quantities that pose an *unacceptable* threat to public health must not be placed on the market. Article 1 to Regulation 466/2001 requires that foodstuffs indicated in Annex I must not, when placed on the market, contain contaminant levels higher than those specified in the Annex. Regulation 3 of the Contaminants in Food (England) Regulations 2006 makes it an offence to place on the market foodstuffs containing contaminants specified in Regulation 466/2001 at levels exceeding those specified.	<u>Appropriateness of threshold levels</u> It is unclear whether the thresholds specified in the Annex to Regulation 466/2001 are set at appropriate levels to control potential risks arising from applications of nanotechnology in this context. Taking into account recognised properties of nanomaterials, such as increased toxicity, it is conceivable that the maximum level thresholds specified provide inadequate protection to consumer health.	The toxicology of contaminants is continually evaluated by the Commission in cooperation with Member States to review the limits set. The flexibility of the regime is reflected by the fact that Regulation 466/2001 has undergone a number of amendments. Maximum thresholds can be adjusted, should it transpire that the migration of nanomaterials to foodstuffs results in unacceptable levels of contaminant. Furthermore, Part I of the Food and Environment Protection Act 1985 enables Ministers to make emergency orders where they consider that circumstances exist, or may exist, which are likely to create a risk to human health through the consumption of contaminated food. The regulatory regime relating to contaminants in food is underpinned by more general frameworks that establish basic safety principles, such as Regulation (EC) No.178/2002 and the Food Safety Act 1990. Foodstuffs also fall within the scope of the General Product Safety Regulations 2005.
Linked Legislation	Regulation (EC) No.466/2001 setting maximum levels for certain contaminants in foodstuffs General Principles of Food Law Regulation (EC) 178/2002 Food Safety Act 1990 General Product Safety Regulations 2005		
Horizon Scanning			

Legislation: *Food Additives Directive 89/107/EEC*[132]			
Summary of Purpose: Broadly speaking, the regulatory regime in relation to food additives sets out lists of permitted additives, the food products in which they can be used, and maximum levels of use. The Food Additives Directive 89/107/EEC establishes an overarching framework for the authorization of the use of additives in food products. Only those food additives listed in the Directive may be used in the manufacture or preparation of foodstuffs and only under specified conditions of use. The Directive, which provides the umbrella framework of food additive regulation, is supplemented by a number of other specific provisions.*			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definitional Aspects Article 1 and Annex I	A 'food additive' is defined by Article 1 of Directive 89/107/EEC* as: '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'. Accordingly, food additives are used (or intended to be used) as ingredients during the manufacture or preparation	No gap identified.	It is likely that current applications of nanotechnology in the manufacture of food additives will fall within the definition of 'food additive' in Article 1 and the categories set out in Annex I.

[132] Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorised for use in foodstuffs intended for human consumption (as amended).

	of food product and are present in the final product, even if in altered form.[133] Annex I of the Directive lists the following categories of food additives which may be used in the manufacture or preparation of foodstuffs: ▪ Colour ▪ Preservative ▪ Anti-oxidant ▪ Emulsifier ▪ Emulsifying salt ▪ Thickener ▪ Gelling agent ▪ Stabiliser ▪ Flavour enhancer ▪ Acid ▪ Acidity regulator ▪ Anti-caking agent ▪ Modified starch ▪ Sweetener ▪ Raising agent ▪ Anti-foaming agent ▪ Glazing agent ▪ Flour treatment agent ▪ Firming agent ▪ Humectant ▪ Sequestrant ▪ Enzyme ▪ Bulking agent ▪ Propellent gas and packing gas		
II. Safety Assessment Article 2 and Annex II	Annex II sets out general criteria for the use of food additives. In addition to other requirements, it stipulates that additives must not present a hazard to consumer health at level of use	<u>No specific assessment of additives containing nanomaterials</u> Safety assessment requirements make no reference to nanomaterials, or indeed to particle size. The question is whether, on the	Despite the fact that the Directive does se out specific criteria for the assessment of nanomaterials, it is likely that the provisions are sufficiently broad to protect consumer health from potential dangers

[133] Note that the Directive does not cover: (i) processing aids; (ii) substances used in the protection of plants and plant products in conformity with Community rules relating to plant health; (iii) flavourings for use in foodstuffs, which fall within the scope of Directive 88/388/EEC; and (iv) substances added to foodstuffs as nutrients.

	proposed, so far as can be judged on the scientific evidence available. It goes on the note that: '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.'	basis of the criteria given, the effect of nanoparticles is likely to be covered by the Directive.	arising from applications of nanotechnology. The Directive itself contains a number of 'safety net' provisions: ▪ Annex II provides that all food additives must be continually observed and re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. ▪ Annex II stipulates that authorisation of food additives must be limited to the lowest level of use necessary to achieve the desired effect (Annex II). ▪ Article 5 states that when granted, authorisation is limited to period of two years. ▪ Article 4 enables a Member State to temporarily suspend or restrict the application of provisions should it have grounds to believe that, as a result of new information or re-evaluation of existing information, an additive poses a potential risk to human health.
Linked Legislation	* Sweeteners in Food Regulations 1995 (as amended);[134] Colours in Food Regulations 1995 (as amended);[135] Miscellaneous Food Additives Regulations 1995 (as amended);[136] Smoke Flavourings (England) Regulations 2005.[137]		
Horizon Scanning			

[134] Implementing Directive 94/35/EC on sweeteners for use in foodstuffs and Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.
[135] Implementing Directive 94/36/EC on colours for use in foodstuffs (as amended).
[136] Implementing Directive 95/2/EC on food additives other than colours and sweeteners (as amended) (which has to be read with Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption).
[137] Implementing Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods.

Legislation:

- ***Food Additives Regulations:***
- ***Sweeteners in Food Regulations 1995 (as amended)***[138]
- ***Colours in Food Regulations 1995 (as amended)***[139]
- ***Miscellaneous Food Additives Regulations 1995 (as amended)***[140]

Summary of Purpose: In 1995, three sets of Regulations were adopted under the broad framework of the Food Additives Directive 89/107/EEC and the Food Safety Act 1990 to control the use of principal categories of food additives. This group of Regulations operates under the broad framework of the Food Additives Directive* controlling the use of specific substances as additives in foodstuffs. Each of the three Regulations implement a Community Directive which lists permitted food additives and their conditions of use. In addition, they implement Directives setting out purity criteria for the additives listed. They establish a pre-market approval regime which requires that all additives positively listed undergo safety assessment.

Content for Analysis	Summary of regulations	Gap or Potential Gap	Comment/Impact
I. Scope of Regulations	Directive 89/109/EEC does *not* extend to cover: ▪ Flavourings;** ▪ Extraction solvents.*** The Sweeteners in Food Regulations 1995 define 'sweetener' as any food additive which is used or intended to be used (a) to impart a sweet taste to food, or (b) as a table-top sweetener. It goes on to define 'food additive' as: '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	Use of nanomaterials as additives in categories falling outside scope of specific Regulations It is conceivable that nanomaterials will be used in the manufacture of types of food additives falling outside the scope of the three specific Regulations cited. Although it is difficult to predict future applications of nanotechnology, evidence from research and development suggests that uses of nanomaterials will feature heavily in food production.	Should the use of nanomaterials in foodstuffs fall outside the definitions provided in the aforementioned Regulations, it is likely that the Food Additives Directive* is sufficiently broad to encompass all known, and likely future, applications of nanotechnology in this context. The use of flavourings and extraction solvents as food additives is covered by separate, specific provisions (see ** and ***). The broad framework established General Product Safety Regulations 2005 extends to cover food products placed on the

[138] Implementing Directive 94/35/EC on sweeteners for use in foodstuffs and Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

[139] Implementing Directive 94/36/EC on colours for use in foodstuffs (as amended) and Directives 95/45/EC and 2001/50/EC laying down specific purity criteria concerning colours for use in foodstuffs.

[140] Implementing Directive 95/2/EC on food additives other than colours and sweeteners (as amended) (which has to be read with Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption); Directive 2001/5/EC on food additives other than colours and sweeteners; and Directives 96/77/EC and 2001/30/EC laying down specific purity criteria on food additives other than colours and sweeteners.

	a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may reasonably be expected to result, in it or its by-products becoming directly or indirectly a component of such foods'. The Colours in Food Regulations 1995 covers any food additive which is used or intended to be used for the primary purpose of adding or restoring colouring in a food. The crucial test for determining whether a substance is a 'colour' for the purposes of the Regulations is set out in Regulation 2(1)(b). The substance must have undergone 'selective extraction' for the prime function of colouring. The Miscellaneous Food Additives Regulations 1995 cover food additives other than colours and sweeteners ('miscellaneous additives') that perform one or more of the following functions, set out in Regulation 2(1). A 'miscellaneous food additive' is defined as: 'any food additive which is used or intended to be used primarily as an acid, acidity regulator, anti-caking agent, anti-foaming agent, antioxidant, bulking agent, carrier, carrier solvent, emulsifier, emulsifying salt, firming agent, flavour enhancer, foaming agent, gelling agent, glazing agent, humectant, modified starch, packaging gas, preservative, propellant, raising agent, sequestrant, stabiliser or thickener, but does not include any processing aid'.		market for consumer use.

II. Purity Criteria	Each of the three Regulations stipulate that specific purity criteria must be satisfied before an additive is used in foodstuffs. Directive 95/31/EC sets out purity criteria in relation to additives falling within the scope of the Sweeteners in Food Regulations 1995. Directives 95/45/EC and 2001/50/EC set out purity criteria in relation to the Colours in Food Regulations 1995. Directives 96/77/EC and 2001/30/EC set out purity criteria in relation to the Miscellaneous Food Additives Regulations 1995.	<u>Limited restriction of small particles in additives</u> The only additives whose use in food or food ingredient is restricted on the basis of particle size is microcrystalline cellulose[141] and powdered cellulose.[142] This restriction is set out in Directive 96/77/EC, and so applies only to miscellaneous food additives. The use of small microcrystalline cellulose and powdered cellulose (not less than 5µm) is limited because their safety is uncertain.	It is recommended that particle size is included in the purity criteria as standard practice. By refining safety assessment tools to allow for consideration of the effects of small particles, threats posed by nanomaterials are likely to be identified and managed prior to marketing. This anticipatory approach is consistent with the precautionary principle, which is cited by the General Principles of Food Law Regulation**** as a central element of food safety. Should nanomaterials satisfy the purity criteria (owing to their failure to assess impact of particle size), but still pose a danger to human health, the Food Additives Directive* establishes a sufficiently broad safeguards. The Directive imposes an overarching obligation to ensure that additives present no hazard to consumer health at the level of use proposed, so far as can be judged on the scientific evidence available.
Linked Legislation	* Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorised for use in foodstuffs intended for human consumption (as amended). ** Flavourings in Food Regulations 1992[143] *** Extraction Solvents in Food Regulations 1993[144] **** General Principles of Food Law Regulation (EC) 178/2002 General Product Safety Regulations 2005		
Horizon Scanning	The Food Standards Agency has called for an assessment consumer safety and regulatory implications of potential applications of nanotechnology in the manufacture of food additives and other novel food ingredients.[145] Directive 2004/19/EC (amending Directive 2002/72/EC) requires the creation of a positive list of additives permitted in the		

[141] Defined in Directive 96/77/EC as 'purified, partally depolymerised cellulose prepared by treating alpha-cellulose, obtained as a pulp from natural strains of fibrous plant material, with mineral acids'.
[142] Defined in Directive 96/77/EC as 'purified, mechanically disintegrated celluslose prepared by processing alpha-cellulose obtained as a pulp from natural strains of fibrous plant materials'.
[143] Implementing Directive 88/388/EEC concerning flavourings for use in foodstuffs.
[144] Implementing Directive 88/344/EEC on extraction solvents used in the production of foodstuffs.

	manufacture of food contact plastics. The Commission is required by 31 December 2007 to confirm when the list of additives will become a positive list.

Legislation: *Food Safety Act 1990*			
Summary of Purpose: The Food Safety Act 1990 is principally an enabling piece of legislation establishing a consumer protection regime ensuring the safety of products including (i) drinks; (ii) articles and substances of no nutritional value which are used for human consumption; (iii) chewing gum and other products or a like nature and use; (iv) and articles and substances used as ingredients in the preparation of food. The Food Safety Act 1990 (Amendment) Regulations 2005 enacted under the European Communities Act 1972 align the definition of 'food' with that in the General Principles of Food Law Regulation 178/2002. The Food Safety Act 1990 sets out general enforcement provisions, and creates specific offences and penalties.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
I. Food safety	Section 7 establishes that it is an offence to render injurious to health food intended to be sold for human consumption. 'Injury' is defined in this section as including any impairment, whether permanent or temporary. Section 18 provides that Ministers may by regulations make provision for prohibiting the carrying out of commercial operations with respect to novel foods, or food sources from which such foods are intended to be derived. A 'novel food' is defined as any food which has not previously been used for human consumption in Great Britain, or has been so used only to a very limited extent. Food safety obligations extend to those working in the production, processing, storage, distribution and sale of food. The Food Safety Act 1990 sets out a	<u>Meaning of 'novel food'</u> It is unclear whether the uses of nanomaterials in foodstuffs will bring the food product within the meaning of 'novel food'. Given that reference is made to the novelty of the food product rather than to its process of manufacture or composition, it is conceivable that the production of foodstuffs using nanotechnology is insufficient to render it 'novel' for the purposes of section 18 of the Act.	Even if food products were to fall outside the scope of section 18, the regime established by the Food Safety Act 1990 is still sufficiently broad to cover potential dangers arising from the use nanotechnology in relation to foodstuffs in general. Products falling outside the definition of 'food' set out in section 1 will be caught by overarching frameworks such as the General Principles of Food Law Regulation (EC) No.178/2002 and the General Product Safety Regulations 2005.

[145] FSA, Draft Report of FSA Regulatory Review, March 2006.

	general responsibility to take precautions to ensure compliance with its provisions. See also industry standards relating to Good Manufacturing Practices, and Hazard Analysis and Critical Control Point, for example.		
Linked Legislation	General Principles of Food Law Regulation (EC) No.178/2002 General Food Regulations 2004 General Product Safety Regulations 2005		
Horizon Scanning			

Legislation: ***General Principles of Food Law Regulation (EC) 178/2002***			
Summary of Purpose: The Regulation sets out general principles and requirements of food law, and lays down procedures relating to food safety. Its primary objective is to ensure the protection of human health. Regulation 178/2002 is enforced by the General Food Regulations 2004.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Safety Assessment	Paragraph 18 of the Preamble emphasises the centrality of scientific risk assessment in decision-making. It stipulates that: '[i]n order for there to be confidence in the scientific basis of food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.' Article 6 also makes reference to the scientific underpinnings of risk analysis. The scientific and technical basis to of Community legislation relating to food	<u>Incomplete information base</u> The most significant problem arising from the Regulation's emphasis on scientific risk assessment is the lack of knowledge in relation to the implications of nanotechnology on food safety. The upshot is that safety assessments of nanomaterials in food products are based on incomplete information, and might not accurately reflect the likely effect of nanotechnology. It is likely that applications of nanotechnology will be deemed to represent an 'emerging risk' pursuant to Article 50. Given the novelty of nanotechnology and the lack of complete knowledge about its implications, the feasibility of thorough risk assessment is thwarted by scientific uncertainty.	The Regulation establishes a broad framework of food safety that will extend to cover threats posed by applications of nanotechnology in foodstuffs. In particular, the Regulation makes reference to situations in which lacking information renders it is impossible to conduct a full scientific risk assessment. The precautionary principle is cited as the primary guiding tool to decision-making. Paragraph 19 of the Preamble: 'It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should

	safety is bolstered by the setting up of the European Food Safety Authority (EFSA), pursuant to the Regulation. Paragraph 50 of the Preamble: 'Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of Member States and the Community in the exercise of its policy. It is therefore necessary to assign to the Authority an anticipatory task of collecting information ad exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.' In making an assessment of food safety, Article 14 requires that the following factors are taken into account: ▪ Normal conditions of use by the consumer and at stages of production, processing and distribution; ▪ Information available to the consumers concerning the avoidance of specific adverse health effects from a particular food; ▪ Probable immediate and/or short-term and/or long-term effects of a particular food on the health of the person consuming it and on subsequent generations; ▪ Probable cumulative toxic effects; ▪ Particular health sensitivities of a specific category of consumers where a food is intended for that category of consumers. Article 34 deals specifically with the identification of emerging risks. It states		legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.' Paragraph 21 of the Preamble: 'In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.' Article 7 reiterates the significance of the precautionary principle in situations where, following an assessment of available information, the possibility of harmful effects on health is identified but 'scientific uncertainty persists'. Article 17 extends safety requirements to all stages of production, processing and distribution, requiring that Member States monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators. It is anticipated that threats posed by nanotechnology will be adequately managed under the broad safety framework established by the Regulation.

	that EFSA shall establish monitoring procedures for searching for, collating and analysing information in order to identify emerging risks in relation of foodstuffs.		
Linked Legislation	General Food Regulations 2004		
Horizon Scanning			

Legislation: *Materials and Articles in Contact with Food (England) Regulations 2005*[146]			
Summary of Purpose: Regulation 4 of the Materials and Articles in Contact with Food (England) Regulation provides for the enforcement of Regulation (EC) No. 1935/2004 which sets out a general framework of consumer protection. Regulation 1935/2004, amongst other things, requires that materials and articles are manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health. National regulations in each of the devolved administrations of the UK through enforce the Regulation. Regulation 1935/2004 revoked the previous framework Directive 89/109/EEC[147] and the Materials and Articles in Contact with Food Regulations 1987. Some parts of the 1987 Regulations which implemented Directive 78/142/EEC on vinyl chloride monomer and Directive 93/10/EEC on regenerated cellulose film[148] remain in force.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition Articles 1 and 2 Regulation (EC) No.1935/2004	Article 1 provides that the Regulation applies to materials and articles, including active and intelligent food contact materials, which in their finished state: ▪ Are intended to be brought into contact with food; or ▪ Are already in contact with food and were intended for that purpose; or ▪ Can reasonably be expected to be brought into contact with food or to	No gap identified.	The Regulation extends to the application of new technologies in food contact materials in the form of 'active' and 'intelligent' systems. This is significant because it is anticipated that nanotechnology will be used in this context to develop active and intelligent materials and articles.

[146] Implementing the Materials and Articles in Contact with Food Regulation (EC) No. 1935/2004.
[147] Directive 89/109/EEC on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.
[148] Directive 93/10/EEC has since been amended by Directive 2004/14/EC.

	transfer their constituents to food under normal or foreseeable conditions of use. 'Active food contact materials and articles' is defined in Article 2 as materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. 'Intelligent food contact and articles' is defined in Article 2 as materials and articles which monitor the conditions of packaged food or the environment surrounding the food.		
II. Active and Intelligent Materials and Articles Article 4 Regulation (EC) No.1935/2004	The intended migration of constituents from active and intelligent food contact materials and articles is permitted, provided that safeguards are complied with. Article 4 sets out special requirements in relation to these categories of food contact material. It notes that active and intelligent materials may bring about changes in the composition or organoleptic characteristics of food, provided that those changes comply with other Community provision relating to food safety.	<u>Migration of nanomaterials to foodstuffs</u> Given that it is anticipated that nanomaterials will be used in the manufacture of active and intelligent materials and articles, the migration of nanomaterials to foodstuffs is likely.	Although the migration of nano-constituents to foodstuffs is potentially permitted by the Regulation, Article 4 requires pre-market authorisation of substances deliberately incorporated into active materials and articles to be released into food or the environment surrounding food shall be authorised and used in accordance with the relevant Community provisions relating to food safety. A safety assessment is required as part of the authorisation application (see safety assessment, below).
III. Authorisation and safety assessment Articles 8 and 9 Regulation (EC) No.1935/2004	Article 8 provides that no substance shall be authorised unless it has been demonstrated that, when used under the conditions set in specific measures, the final material or article satisfies requirements of Article 3 (general requirements), and where they apply, Article 4 (special requirements for active and intelligent materials and articles,	<u>Incomplete knowledge base about migration of nano-constituents</u> Given that there are recognised knowledge gaps relating to the effect of nanomaterials on food safety, comprehensive safety assessments are likely to be difficult to conduct. Under the 2001 Scientific Committee on Food Guidelines, the toxicological dataset required to determine	It is unlikely that full safety assessments are possible in relation to the migration of nanomaterials to foodstuffs. The General Principles of Food Law Regulation (EC) 178/2002 framework, however, imposes an overarching obligation to adopt a precautionary approach to scientifically uncertain risk.

[149] Guidance published by the European Food Safety Authority can be found at: http://www.efsa.europa.eu/en/science/afc/afc_guidance/722.html

	see above). Article 3 requires that materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health. Article 9 sets out requirements for application for authorisation of new substances. As part of the application procedure, an applicant must submit to the competent authority a technical dossier containing information specific in the guidelines for the safety assessment of a substance.[149] An assessment of both the toxicological data indicating the potential hazard and the likely human exposure data is required.[150] Furthermore, an application for authorisation must include information on the identity of the substance in question, its physical, chemical and microbiological properties, and intended use. Guidelines of the Scientific Committee on Food published in 2001[151] state that, as a general principle, the greater the	safety depend on migration values. It is conceivable, given the novelty of applications of nanotechnology, datasets are insufficiently 'extensive' to establish the safety of food contact materials containing nanoparticles falling within the 'high migration' category. Establishing the safety of food contact materials containing nanoparticles falling within the 'low migration' category, however, poses less of an evidential challenge. Given that only a limited dataset is required in relation to low migration constituents, it is conceivable that materials and articles containing nanoparticles are deemed to be 'safe' and marketed before more robust datasets on human and environmental exposure are developed. The Scientific Committee on Food Guidelines do not consider environmental impact of food contact materials.	Furthermore, Article 18 of Regulation 1935/2004 establishes safeguard measures that enable a Member State, following the receipt of new information or a re-evaluation of existing information that leads it to conclude that the use of a material or article endangers human health, to temporarily suspend or restrict the application of the Regulation.

[150] See also Scientific Committee on Food, Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation, SCF/CS/PLEN/GEN/100 Final, 19 December 2001.
[151] See also Scientific Committee on Food, Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation, SCF/CS/PLEN/GEN/100 Final, 19 December 2001.
[152] See also Scientific Committee on Food, Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation, SCF/CS/PLEN/GEN/100 Final, 19 December 2001, at pages 2-3.

	exposure through migration, the more toxicological information will be required. [152] In relation to high migration (5-60mg/kg/food), an extensive data set is required in order to establish safety. In relation to migration between 0.05-5mg/kg/food, a reduced data set may be sufficient. In relation to low migration (<0.05mg/kg/food), only a limited data set is required.		
Linked Legislation	General Principles of Food Law Regulation (EC) 178/2002 Food Contact Ceramics Directive 2005/31/EC[153]		
Horizon Scanning	In December 2005 the Department of Trade and Industry published a consultation document on proposals to implement Directive 2005/31/EC. The Directive will replace the Ceramic Ware (Safety) Regulations 1988. Draft Regulations are being made pursuant to the Food Safety Act 1990, ensuring consistency with other specific provisions on food contact materials and articles. The consultation closed in February 2006. The DTI is currently in the throes of implementing the Directive.		

[153] Directive 2005/31/EC amending Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs.

Legislation: *Novel Foods and Novel Food Ingredients Regulations 1997*[154]			
Summary of Purpose: The Novel Foods Regulations 1997 establishes an approval system for all novel foods and processes before the food or food ingredient is placed on the market. Novel foods and food ingredients are those that have not been used within the European Community to any significant degree before 15 May 1997. Before being placed on the market in the Community, novel food and novel food ingredients are subject to a single safety assessment through Community procedure. If, however, if a food falling within certain categories set out in the Regulations they are 'substantially equivalent' to food already on the market, they are subject to a simplified procedure of assessment. Applications for the placing on the market of a novel food or food ingredient must be made to the Food Standards Agency (FSA). The FSA will consult the independent Advisory Committee on Novel Foods and Processes, DEFRA, the Department of Health, and other relevant departments on product safety, and consumer and ethical concerns. The overriding objective is to protect human health.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
I. Definition Regulation 2 (Novel Food and	'Novel food' and 'novel food ingredients' are defined in Article 1 of Regulation (EC) No.258/97 as food and food ingredients:	<u>Whether use of nanotechnology in food and ingredients satisfies 'novelty' threshold</u> It is conceivable that the use of nanoparticles in foods *already* on the market will fail to	It is likely that applications of nanotechnology in food production will satisfy the novelty test set out in part (e) opposite. Should applications of

[154] Implementing the Novel Foods Regulation (EC) 258/97.
[155] Except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use.

Novel Food Ingredients Regulations 1997); Article 1 (Regulation (EC) No.258/97)	a. produced from, but not containing, genetically modified organisms; b. which present a new or intentionally modified primary molecular structure; c. which consist of micro-organisms, fungi or algae; [155] d. which consist of or are isolated from plants or isolated from animals; and e. to which a production process not currently used has been applied, and where that process gives rise to significant changes in their composition or structure. Regulation 3 stipulates that the marketing of food or food ingredients falling within the scope of the Regulations must be authorised. An application must be submitted to the Member State in which the product is to be placed on the market for the first time (see III below).	satisfy the novelty test set out in Article 1. It is unlikely that the novelty threshold has been tested in relation to the use of nanomaterials in food, given that nanotechnologies in this context are still in the research and development stage.[156] The question is whether the use of nanoparticles in existing products render those products 'novel' and requiring authorisation before being marketed.	nanotechnology in this context fall outside scope of Regulations, they will be caught by the EC Regulation on General Principles of Food Law* which establishes mechanisms to ensure the safety of food placed on the market.
II. Substantial equivalence Article 3(4) (Regulation (EC) No.258/97)	The concept of 'substantial equivalence' was introduced by WHO and OECD, with particular reference to foods produced by modern biotechnology. Commission Recommendation 97/618/EC notes that: 'If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to	<u>Whether food or food ingredients produced using nanomaterials are 'substantially equivalent' to those already on market</u> It is conceivable that a food or ingredient produced using nanotechnology will be deemed to be 'substantially equivalent' to food products that have a history of consumer use. Article 3(4) notes that the substantial equivalence test applies only in relation to certain categories of food and food ingredients: ▪ foods and food ingredients produced from, but not containing, genetically modified	It is unlikely that current and potential applications of nanotechnology identified will fall into any of these categories to which Article 3(4) applies.

[156] See Food and Drink Federation, *Response to FSA Draft Report of Regulatory Review of the Use of Nanotechnologies in Relation to Food* http://www.fdf.org.uk/responses/fdf_response_nano.pdf, accessed October 2006.

	compare a potential new food with its conventional counterpart.' (paragraph 3.3) Accordingly, the substantial equivalence test can be extended to assess foods from novel sources and processes. Analysis of the composition of a novel food or ingredient is essential to the substantial equivalence evaluation.	organisms; ▪ foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; and ▪ foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use.	
III. Safety Assessment Regulation 3 (Novel Food and Novel Food Ingredients Regulations 1997) Articles 4, 6 and 7 (Regulation (EC) No.258/97)	Manufacturers wishing to place a novel food or novel food ingredient on the market are required to submit an application in accordance with Commission Recommendation 97/618/EC 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. Amongst other things, the application must contain information to demonstrate that the following conditions (as set out in Article 3(1)) are satisfied. Foods and food ingredients falling within the scope of the Regulation must not: ▪ present a danger for the consumer; ▪ mislead the consumer; ▪ differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer. Article 6 provides that, upon receipt of application, the Member State shall ensure that an initial safety assessment	<u>No specific assessment criteria for nanomaterials</u> The Regulations do not explicitly set out specific criteria to assess the safety of novel foods on the basis of particle size. A finding of 'substantial' or 'partial' equivalence has implications for safety assessment requirements. In the case of the former, no further toxicological testing is required. In the case of the latter, toxicological testing required only in relation to novel traits.	It is likely that safety assessment requirements are sufficiently broad to cover potential risks arising from food products manufactured using nanomaterials. Commission Recommendation 97/618/EC, however, requires that a compositional and toxicological analysis is conducted in an assessment of safety, with reference to the identity, chemical structure and physico-chemical properties of the novel food, as well as aspects such as source, composition, potential intake based on the proposed use in the general diet, potential exposure of particularly vulnerable population groups, and the likely effects of processing. A finding of substantial (or partial) equivalence would create a potential loophole for the safety assessment of foods containing nanomaterials, although as noted above, it is unlikely that current applications of nanotechnology in this context fall within Article 3(4).

	is conducted by the competent food assessment body. In the UK, this function is carried out by the Food Standards Agency. In the event that an additional assessment is required pursuant to Article 7, the Commission, together with the Standing Committee for Foodstuffs, shall decide whether to authorise the food or ingredient in question by having regard to: ▪ the conditions of use of the food or food ingredient; ▪ the designation of the food or food ingredient, and its specification, ▪ specific labelling requirements.		
Linked Legislation	* Regulation (EC) No.178/2002 on General Principles of Food Law		
Horizon Scanning	European Commission launched consultation in June 2006 on the revision of Novel Food Regulation (EC) No.258/97. The consultation seeks input from the public, stakeholders, and Member States in order to conduct an impact assessment for a future revision to the Regulation. The principal objectives of the consultation include: to develop a more streamlined authorisation procedure and a more adjusted safety assessment system; and to clarify the definition of 'novel' and the scope of the Regulation. One of the main issues open to discussion was whether the Regulation should continue to employ uniform criteria for the safety assessment of all types of food or whether specific criteria should be developed for specific types of food that are proportionate to the potential risks posed. Arguments for specific safety criteria might have particular resonance in relation to the use of nanotechnology in food. The consultation closed on 1 August 2006.		

Legislation: ***Plastic Materials and Articles in Contact with Food (England) Regulations 2006***[157]			
Summary of Purpose: The Plastic Materials and Articles in Contact with Food (England) Regulations 2006 revoke the Plastic Materials and Articles in Contact with Food Regulations 1998. The 2006 Regulations prohibit specified activities in relation to any plastic material or article which fails to meet the appropriate required standards set out in the Regulations, and specify the required standard relating to overall migration limits from plastic materials or articles to food. The Regulations implement a number of Directives relating to food contact materials. Directive 2002/72/EC establishes the overarching framework in relation to plastic materials and articles intended to come into contact with foodstuffs.			
Content for Analysis	**Summary of regulations**	**Gap or Potential Gap**	**Comment/Impact**
I. Definitional Aspects Article 1 Directive 2002/72/EC	Article 1 of the Directive defines 'plastics' as: 'the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules.' The following substances are not regarded as 'plastics' for the purpose of the Directive: ▪ varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC; ▪ elastomers and natural and synthetic rubber; ▪ paper and paperboard, whether modified or not by the addition of plastics;	<u>Use of nanomaterials in categories falling outside definition of 'plastics'</u> It is anticipated that certain uses of nanomaterials in the manufacture of food contact materials will fall outside the scope of 'plastics' as defined in Article 1. A scoping exercise of current and future applications that nanotechnology will be used to produce rubber, paper, and surface coatings, particular in the food packaging field. These applications are not covered by the consumer protection afforded by Directive 2002/72/EC.[158]	Whilst it is conceivable that certain materials falling outside the Article 1 definition of 'plastics' could pose a threat to human health, this potential gap is covered by the general framework established by Regulation 1935/2004* which stipulates that materials and articles shall be manufactured in compliance with good manufacturing practice so that they do not transfer their constituents to food in quantities which could endanger human health (Article 3).

[157] Implementing Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs; Directive 85/572/EEC laying down the list of stimulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs; and Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. The 2006 Regulations also provide for the enforcement of Regulation (EC) No.1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

[158] This is confirmed by Directive 2004/19/EC.

	▪ surface coatings obtained from: (i) paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes, or (ii) mixtures of the waxes listed in the first indent with each other and/or with plastics, ▪ ion-exchange resins; ▪ silicones. Regulation (EC) No.1895/2005** provides that 'material and articles' are: ▪ materials and articles made of any type of plastics; ▪ materials and articles covered by surface coatings; and ▪ adhesives.		
II. Restricted migration of constituents Regulation 9	Regulation 3 prohibits specified activities in relation to any plastic material or article which fails to meet the appropriate required standards set out in the Regulations. The Regulations stipulate that plastic materials and articles shall not transfer their constituents in quantities exceeding specific limits. Regulation 9 sets standards relating to overall migration limits. It stipulates that the overall migration must not exceed 60 milligrams of constituents released per kilogram of food in the case of any plastic material or article comprising: ▪ an article which is a container or comparable to a container or can be filled, with a capacity of not less than 500 millilitres and not more than 10 litres; ▪ an article which can be filled and for	<u>Whether migration thresholds are sufficient to manage potential dangers posed by nanomaterials</u> Given that the Regulations not differentiate between nanomaterials and materials and articles produced by 'traditional' means, it is uncertain whether this migration threshold would provide adequate protection against threats posed by nanoparticles.	Even if the thresholds are inappropriately set in respect of nanomaterials, the overarching framework of consumer safety established by Regulation 1935/2004* and the General Product Safety Regulations 2004 apply. If the maximum thresholds are set at too high a level, thus enabling potentially toxic plastic materials and articles containing nanoparticles to enter onto the market, a number of waste provisions might apply. If the plastic materials and articles are used in the manufacture of packaging, the Packaging (Essential Requirements) Regulations 2003 and the Producer Responsibility Obligations (Packaging Waste) Regulations 2005 might apply. Packaging waste is also listed as 'hazardous waste' by the List of Wastes (England) Regulations 2005 for the purposes of the Hazardous Waste (England and Wales) Regulations 2005.

	which it is impracticable to estimate the surface area in contact with food; or ▪ cap, gasket, stopper or similar device for sealing. In the case of any other plastic material or article, the overall migration limit is set at 10 milligrams per square decimetre of the surface area of the plastic material or article.		
III. Restriction of use of certain substances Regulations 4 and 5	Regulation 4 restricts the use of monomers in the manufacture of plastic materials and articles. Schedule 1 to the Regulations lists restricted monomers, and stipulates maximum permitted quantities and migration thresholds. Regulation 5 restricts with use of additives in the manufacture of plastic materials and articles. Schedule 2 to the Regulations list restricted additives, and stipulates maximum permitted quantities and migration thresholds. Regulation 10 and Schedule 4 set out similar provisions in relation to the migration of primary aromatic amines.	<u>Appropriateness of set thresholds</u> Thresholds set in Schedules 1, 2, and 4 are based on weight or percentage concentration. It is unclear whether the maximum limits specified provide adequate protection against potential risks associated with exposure to nanoparticles.	See above.
Linked Legislation	* Materials and Articles in Contact with Food Regulation (EC) No.1935/2004 ** Regulation (EC) No.1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food Contaminants in Food Regulation (EC) No. 315/93 Packaging (Essential Requirements) Regulations 2003 Producer Responsibility Obligations (Packaging Waste) Regulations 2005 Hazardous Waste (England and Wales) Regulations 2005 List of Wastes (England) Regulations 2005		
Horizon Scanning			

Legislation: *Environmental Protection Act 1990*[159]^			
Summary of Purpose: Provides the main statutory framework for environmental protection including the management of waste, statutory nuisance and contaminated land^.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Waste Disposal - Duty of Care*	Section 34 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.	1. Potential gaps exist in the regulating of nanomaterials, in particular in understanding the potential risks posed by waste products containing nanomaterial, in assessing the most effective form of management/disposal; and if specialised management/disposal is required, identifying waste products containing nanomaterials amongst other waste streams e.g. domestic, commercial and industrial. 2. 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. However, identification of waste is via the ***List of Waste Regulations 2005*** and no codes exist that will specifically identify nanomaterials. In addition a number of the potential applications for nanomaterials, e.g. food production, have no available hazardous waste code, if nanomaterials are classed as dangerous substances and therefore hazardous no current code under this Chapter will provide identification of the hazardous properties.	To ensure the proper disposal of nanomaterials further information is required on the most appropriate methods, which will result in the least amount of damage to human health and the environment. It is recommended that due to the lack of available scientific information on the impacts of nanomaterials, wastes resulting from the development, manufacture, supply and use of nanoparticles are classed as hazardous.
3. Contaminated Land**	1. Part IIA provides a definition of contaminated land and how it is to be identified and dealt with:	Potential problems relating to the role of nanomaterials in contaminated land is the availability of appropriate scientific and	The current lack of knowledge on the health and environmental impacts of nanomaterials means that land where

[159] As amended Environment Act 1995 and Waste Management (England & Wales) Regulations 2006

	"*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*". 2. Remediation	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. It is unlikely that because of the nanoscale properties, nanomaterials in contaminated land will satisfy the definition and criteria for assessing significant harm.	nanomaterials are released is likely to fall outside the Part IIA regime, pending future developments in scientific knowledge.
4. Control of Substances	Power to prohibit or restrict the importation, use, supply or storage of injurious substances or articles if it is considered that such prohibition or restriction will prevent the cause of pollution of the environment or damage to human health.	No gap identified.	This power can be use to introduce regulations where it may be necessary to control identified nanomaterial, if it is considered that certain nanomaterials are considered to impose a particular pressure on the environment or damage human health.
5. Hazardous Substances	Powers to obtain information about potentially hazardous substances for the purpose of assessing their potential for causing pollution of the environment or harm to human health.	This may be a valuable power for the regulator allowing the relevant authority to collect information on products or articles containing prescribed substances, the requirement to conduct tests of substances and furnish results from the tests.	However, at present owing to current scientific and technical limitations it is unlikely sufficient information and assessment capability is available to comply with any regulations implemented under this power.
Linked Legislation	**^ - *Environment Act 1995 –*** amends the EPA, establishes the relevant environment protection agencies in the UK and introduces into the EPA Part IIB on contaminated land and also producer responsibility obligations e.g. ***Producer Responsibility Obligations (Packaging Waste) Regulations 2005*** ***Waste Management (England & Wales) Regulations 2006 –*** amends certain sections of Part II of the EPA. ***Pollution Prevention and Control (England & Wales) Regulations 2000*** – replaces the pollution control regime established under Part 1 of the EPA. **** - Waste (Household Waste Duty of Care) Regulations 2005*** – Householders must ensure that any waste disposal is collected by an authorised waste collector. ** - ***Contaminated Land (England) Regulations 2000*** - deal with various procedural details such as the description of special sites, public registers, remediation notices and appeals. ***Waste Management Licensing Regulations 1994*** – These regulations in combination with Part II of the EPA transposed the ***Waste Framework Directive***[160] ***Groundwater Regulations 1998*** – covers the disposal of substances covered under the Regulation in cases where a waste management licence under Part II of the ***EPA*** is not already required.		

[160] *Directive 75/442/EEC*

	Water Industry Act 1991 - 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 discharge consent from the competent body, discharge consents are regulated under the Water Industry Act.
Horizon Scanning	**Directive 2004/35/EC on Environmental Liability –** covers environmental damage from activities, it includes damage to land and soil where there is serious harm to health and water pollution leading to a decline in water quality. There may be defences 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. Consequently any damage from nanomaterials assessed according to the best available scientific and technical knowledge would not be covered if they were classed as non-harmful.

Legislation: *Pollution Prevention and Control (England and Wales) Regulations 2000[161](PPC)^*			
Summary of Purpose: The Regulations implement into the UK the *Directive 96/61/EC on Integrated Pollution Prevention and Control*, which sets down measures to either prevent or reduce emissions to air, water and land from prescribed activities.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	1. Scope extends to traditional unit operations and unit processes. 2. Threshold Capacity – Activities are subject to a capacity before IPPC permits are required. For example, plants for the pre-treatment or dyeing of	1. 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 nanomaterials produced using solely by physical production routes[162]. 2. Many of the sectors under which nanomaterials may be produced are unlikely to meet these thresholds and therefore be exempted under the Regulations. These thresholds mean that small scale sites, as well	However, even if the production of nanomaterials does not fall under the Regulations, it is also likely that the listed activities will incorporate the use of nanomaterials.

[161] As amended 2001 (SI 503), 2002 (SI 275 & SI 1702), 2003 (SI 1699 & SI 3296), 2006 (SI 2311), Pollution Prevention and Control (England and Wales) (Amendment) and Connected Provisions Regulations 2004 SI 3276, Pollution Prevention and Control (Unauthorised Part B Processes) (England and Wales) Regulations 2004, SI 434 and Pollution Prevention and Control (Public Participation)(England and Wales) Regulations 2005 SI 1448

[162] A scoping study to identify gaps in environmental regulation for the product and application of nanotechnologies, Final Report, DEFRA, 200

	fibres or textiles are excluded where the treatment capacity is below 10 tonnes per day.	as all research and development activities, are not covered by the IPPC Directive and national legislation.	
2. Definition - pollutant	Is any substance, vibration, heat or noise released as the result of an emission which may be harmful to human health or quality of the environment and which may damage material property or impair or interfere with amenities. A substance is defined as a chemical element and its compounds and any biological entity or micro-organism.	<u>Are nanomaterials 'pollutants'?</u> May depend on a number of factors including whether the nanomaterial has been classed as a new substance or as an existing one in terms of its macro equivalent*. There is no requirement in the definition for a substance to be a dangerous substance** merely that as a result of an emission it may be harmful – consequently, nanomaterials if classed as a new substance could be captured whether or not it was considered dangerous. However, a list of pollutants is provided and nanomaterials if classed as new substances* are not captured under this list. If classed as an existing substance, any analysis may be based on the impacts of the macro scale form, which is likely to be inappropriate for the nanoscale form of the substance.	This will impact on the means of assessing the likely risks and the methods used for evaluating the appropriate emission level values.
3. Emission Level Values (ELV)	1. May be set in permit for all pollutants likely to be released 2. ELVs to apply when pollutants are likely to be emitted in significant quantity?	<u>If considered an existing substance</u> – ELV estimated on the basis of the environmental risks of the macro equivalent, which may be different from the nanomaterial due to the different reactions of materials at the nanoscale. <u>If not considered an existing substance</u> - the term 'significant quantities' may exclude consideration of nanomaterial emissions, unless it was assessed in relation to the environmental significance of the nanomaterial itself. <u>2. What is significant quantity?</u> It is unlikely that nanomaterials will satisfy any 'significant quantity' threshold, as what is significant at the macro scale is not comparable to that at the nanoscale.	As the regulations provide for reviewing the emission levels, as new information becomes available and the scientific knowledge on the impact of nanomaterials is collected and collated, new levels can be set which are applicable to nanomaterial emissions.

	3. Levels to be based on the best available techniques for the type of installation.	3. Best Available Technique? With the lack of scientific data available, nanomaterials may escape capture under this method of assessing emissions, however, there is scope for stricter limits to be set under the regulations and nanomaterials may need to be covered under this standard.	
4. Permit Information	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.	Given the current uncertainty in relation to the potential impacts of nanomaterials on human health and/or the environment in relation both to the potential effects and the level at which these effects might occur, it may not be possible to assess the impacts of many nanomaterials. Based on current scientific knowledge, there may be a number of issues in determining an acceptable level of emissions, the appropriate preventative measures or the Best Available Technology (BAT). The general lack of scientific knowledge on the management of nanomaterials may itself mean that the definition of BAT cannot extend to nanomaterials.	The regulations do provide for conditions which are supplemental or incidental to other conditions to be applied to a permit, there is the potential to capture nanomaterials via these supplemental conditions. Whilst the Secretary of State has the power to ask for specific conditions to be included in a permit.
5. Environmental Assessment Levels	ELVs are set so that environmental assessment levels (EALs) are not exceeded.	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	
6. Monitoring	Assuming that ELVs could be established, it would be necessary to monitor industrial emissions for nanomaterials to ensure compliance.	Based on current evidence about the relative toxicity of nanomaterials 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.	As commented in the Defra scoping study report - while methodologies to measure these parameters are available, they have not yet been applied to stack measurement. It is unlikely, that the

		However, the current means of measuring and monitoring the emissions is unlikely to be applicable to monitoring any emissions resulting from nanomaterial pollutants. It is possible that they could be based on an alternative metric such as particle number or surface area within an appropriate size range. It is likely that similar problems will arise in monitoring nanomaterials in effluent discharges.	systems as currently available would be well suited to this type of environment, particularly in terms of robustness and ability to tolerate temperature extremes[163].
Linked Legislation	**^ - *Environment Protection Act 1990 (EPA)* –** PPC Regulations replaces the pollution and control regime established under Part 1 of the EPA. *** - *Notification of New Substances Regulations*** - requires standardised testing of hazardous properties of new chemical substances, those substances identified as new feed into EU level and Annex I of the Dangerous Substances Directive **** - *Directive 2006/11/EC*** on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, this directive codifies and replaces ***Directive on Dangerous Substances 76/464/EEC***, which provided a list of List I and II substances **** - *Environment Protection (Prescribed Processes and Substances) Regulations 1991*** - lists a number of List I substances whose releases to water are prescribed for Integrated Pollution Control. PPC Regulations will revoke the prescribed process regulation following full implementation of the PPC regime. ***Packaging (Essential Requirements) Regulations 2003*** ***Producer Responsibility Obligations (Packaging Waste) Regulations 2005*** ***Control of Major Accident Hazard Regulations 1999*** ***Groundwater Regulations 1998 –*** ***Urban Waste Water Treatment (England & Wales) Regulations 1994*** ***Water Resources Act 1991*** ***Hazardous Waste (England & Wales) Regulations 2005*** ***Landfill (England & Wales) Regulations 2002*** ***Waste Incineration (England) Regulations 2002***	
Horizon Scanning	Regulation (EC) No 166/2006 concerning the establishment of a ***European Pollutant Release and Transfer Register*** and amending Council Directives 91/689/EEC and 96/61/EC - tool for encouraging improvements in environmental performance, for providing public access to information on releases of pollutants and off-site transfers of pollutants and waste, and for use in tracking trends, demonstrating progress in pollution reduction, monitoring compliance with certain international agreements, setting priorities and evaluating progress achieved through Community and national environmental policies and programmes. Applies to any chemical element and its compounds and applies to any introduction of pollutants into the environment as a result of any human activity, whether deliberate or accidental, routine or non-routine, including spilling, emitting, discharging, injecting, disposing or dumping, or through sewer systems without final waste-water treatment. Directive applies to a list of prescribed activities as well as a list of prescribed substances with specific thresholds. It is likely that the thresholds have been set at a level too high to cover the		

[163] A scoping study to identify gaps in environmental regulation for the product and application of nanotechnologies, Final Report, DEFRA, 200

	release of nanomaterials.

Legislation: Air Quality (England) Regulations 2000[164] & Air Quality Limit Values Regulations 2003[165]			
Summary of Purpose: The purpose of these regulations is to protect human health and the environment by restricting or preventing the potential harm from pollutants being released into the air.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	Regulations relate to a prescribed list of pollutants including: sulphur dioxide, nitrogen dioxide, fine particulate matter (PM10), suspended particulate matter, lead, benzene, carbon monoxide, polycyclic aromatic hydrocarbons (PAHs) (benzo-a-pyrene as indicator), cadmium, arsenic, nickel compounds and mercury.	For each of these pollutants, the effects on human health and the environment are known, hence the reasons for their control as such it is unlikely that these regulations will extend to nanomaterials given that the effects on human health and the environment are at present generally unknown. A potential gap exists as the regulations are unlikely to extend to the nanoscale form.	The regulations oblige industry to reduce the quantity of dust, fumes, acid gases and volatile organic compounds emitted to the atmosphere. The general intention is that industry will achieve this either by altering procedures or by installing appropriate treatment or separation systems. On a practical level even if nanomaterials were covered by the relevant regulations, the relevant technical systems may not currently exist.
2. Limit Values	The 2003 Regulations provide prescribed limit values for each of the prescribed pollutants.	Again the limit values are set at a level based on the specific knowledge of the effects of the prescribed pollutants and do not relate to any potential impacts from the nanoscale form. Even if the nanoscale form was covered under the prescribed list, a potential gap is likely to arise as a result of the specific limit values.	
3. Testing	Requirement to assess ambient air quality via measuring stations supplying representative data on concentrations.	As identified against other regulations, the main issue will be whether current testing methods can be adapted to measure the presence of nanomaterials. At present it is unlikely that current testing standards and methods are likely to be able to detect the nanoscale form of substances.	

[164] As amended 2002 (SI 3043)
[165] As amended 2004 (SI 2888)

Linked Legislation	**Pollution Prevention and Control (England & Wales) Regulations 2000** – controls industrial emissions to air from prescribed substances emitted from prescribed activities. **Clean Air Act 1993 –** consolidated existing legislation which control smoke emissions, the intallation of furnaces and the height of chimneys.
Horizon Scanning	**Commission's Thematic Strategy on Air Pollution 2005** - The strategy focuses on reducing emissions from five key pollutants as well as ground-level ozone **by 2020** including particulate matter (PM) with a diameter of 2.5, which the Strategy recognises for particular attention as 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. Proposed **Ambient Air Quality Directive** - would require reductions in average $PM_{2.5}$ concentrations throughout each Member State and set a cap on concentrations in the most polluted areas.

Legislation: *Control of Pollution (Oil Storage) (England) Regulations 2001*			
Summary of Purpose: The Regulations 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*. 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.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	Regulations apply to oil of any kind except waste oil as defined in the Waste Management Licensing Regulations, within any kind of container which is being used and stored above ground and situated outside a building and on any premises except those specifically listed.	The aim of the regulations is to reduce the number of significant oil pollution incidents by 50%[166] - this target may need to be reviewed in light of the presence of nanomaterials if it is discovered that the potential polluting impacts are increased due to the presence of these nanoscale materials.	There are a number of potential applications for nanotechnology in the manufacture and supply of oil products e.g. frying oil and motor fuel and synthetic oils.
2. Design Requirements	The Regulations set minimum design standards for all new and existing above ground oil storage facilities. The key requirement is the provision of secondary containment (a 'bund' or 'drip tray') to ensure that any leaking or spilt oil cannot enter controlled waters.	There may need to be a requirement to ensure that the minimum design standards are sufficient for oils containing nanoscale substances or materials e.g. the base of containers must be impermeable to water and oil – however nanomaterials may react differently.	The regulations as a whole should provide sufficient flexibility to ensure that oils containing nanomaterials are regulated in a way so as to prevent pollution resulting from any escape.

[166] Environment Agency http://www.environment-agency.gov.uk/ourviews/857255/880418/?version=1&lang=_e

3. Risks	A notice may be served on a person with custody or control of oil, requiring person to carry out works, take precautions or other such action to minimise the risk of oil-related water pollution.	Where oil contains nanomaterials, which may (depending on available research) cause a potential risk, person with custody or control will be reliant on the available safety data provided by supplier under CHIP**, if said nanomaterials have been classed as hazardous. Persons with obligations under these regulations will only be in a position to take precautions or minimise potential risk if they are supplied with the appropriate hazard data.	New potential risks may also need to be considered particularly in terms of the potential hazards from heat exposure or fire.
Linked Legislation	**** - Water Resources Act 1991 –*** outlines those water courses considered to be controlled water for the purposes of the Act. ***** - Chemical (Hazard Information & Packaging Supply) Regulations*** - CHIP requires suppliers of chemicals to decide whether they are 'dangerous' and in what way, and then provide information to their customers in the form of warning labels and safety data sheets. The chemicals must also be packaged properly. ***The Building Regulations 1991 -*** may be amended to include provisions for pollution prevention measures at new build private dwellings, similar to the new oil storage regulations. The EA can use existing anti-pollution powers to tackle individual existing private dwellings heating oil storage tanks where pollution of controlled waters is likely to occur.		
Horizon Scanning			

Legislation: *Control of Pollution (Silage, Slurry and Agricultural Fuel Oil) Regulations 1991* [167]			
Summary of Purpose: These Regulations require persons with custody or control of a crop being made into silage, livestock slurry or certain fuel oil to carry out works and take precautions and other steps for preventing pollution of waters which are controlled waters.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Agricultural Fuel Oil	A person who has the custody or control of agricultural fuel oil must store it in a prescribed manner under the regulations as contained in Schedule 3. The design requirements for the bund and base of storage must be impermeable and designed to a quality that with proper maintenance will have	The regulations introduce a secondary containment system (a bund) which should cover the control of pollution from agricultural fuel oil whether nanomaterials are present or not. However, they are minimum prescriptive standards and only capture those that store over 1,500 litres of fuel.	

[167] As amended in 1996 (SI 2044), 1997 (SI 547). The regulations were implemented under Section 92 of the Water Resources Act 1991.

	a life span of 20 years. No part of the fuel storage area should be within 10 metres of any inland or coastal waters.		
Linked Legislation	***Water Resources Act 1991*** – regulations were implemented under Section 92 of this Act. ***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. ***The Protection of Water Against Agricultural Nitrate Pollution (England and Wales) Regulations 1996*** ***Action Programme for Nitrate Vulnerable Zones (England & Wales) Regulations 1999*** ***Protection of Water Against Agricultural Nitrate Pollution (England and Wales) (Amendment) Regulations 2006, SI 1289***		
Horizon Scanning			

Legislation: *Environmental Protection (Prescribed Processes and Substances) Regulations 1991*[168]			
Summary of Purpose: list a number of List I substances whose releases to water are prescribed for Integrated Pollution Control			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Prescribed Processes	Extends to the processes and activities covered by the Pollution, Prevention and Control Regulations.	The production and manufacture of nanomaterials are unlikely to meet the IPPC activity descriptions, generally because the activities fall under the tradition unit process.	Whilst the production may not fall under the prescribed processes, those processes that are identified are likely to utilise nanomaterial substances in their production process.
2. Prescribed Substances	Three different lists of prescribed substances for water, air and land must be prevented or restricted.	<u>Will nanomaterials be classed as a prescribed substance?</u> Whether nanomaterials will be covered by the regulations will depend on whether they can be classed as a prescribed substance. <u>1. Water</u> It is unlikely that nanomaterials are at present included under the identified substances but there is the potential to include nanomaterials	In relation to nanomaterials, 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 nanomaterials). Some nanomaterials may need to be considered independently of the macro equivalent due to unknown effects of nanoscale form. However, any potential to be captured

[168] As amended 1992 (SI 614), 1993 (SI 1749 & SI 2405), 1994 (SI 1271 & SI 1329), 1995 (SI 3247), Environmental Protection (Prescribed Processes and Substances) (Amendment) (Hazardous Waste Incineration) Regulations 1998, SI 767 and Environmental Protection (Prescribed Processes and Substances Etc.) (Amendment) (Petrol Vapour Recovery) Regulations 1996, SI 2678.

		in particular metal and its compounds if they are classed as existing substances[169] – which means that the nanoscale substance is measured and assessed to the same standards as the macro, which may fail to identify the specific issues of the nanoscale. However, other nanomaterials will not be covered. 1. Air The list could include nanomaterials but as outlined above much will depend on whether nanoscale is considered as an existing or a new substance. Again potential for a number of nanomaterials not to be covered by the regulations if the macro scale equivalent does not require inclusion on the list. 3. Land A number of the listed substances have the potential to include nanomaterials in particular pesticides.	under the lists will be if the nanomaterial is classed as an existing substance. To ensure a consistent approach to nanomaterials and to ensure assessment of their particular risks and effects, it has been recommended in other assessments that nanomaterials are classed as new substances and as such there is the potential gap that they will not be covered by the lists of prescribed substances.
Linked Legislation	* As part of the ongoing restructuring of the Community water policy, the Directive 76/464/EEC on Dangerous Substances is now integrated in the Water Framework Directive (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as **2006/11/EC** on pollution caused by certain dangerous substances discharged into the aquatic environment of the community. ***Pollution Prevention and Control (England & Wales) Regulations*** - Operators of the potentially most polluting processes ('prescribed processes' which are specified in the amended Environmental Protection (Prescribed Processes and Substances) Regulations 1991/472) have to apply for prior authorisation from the Environment Agency to operate the process. PPC requires operators to consider the total impact of all releases to air, water and land when making an application. These Regulations revoke the prescribed process regulation following full implementation of the PPC regime. ***Water Industry Act 1991*** - occupiers of trade premises may not discharge any trade effluents into a public sewerage unless authorised by the competent body.		
Horizon Scanning			

[169] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

Legislation: ***Groundwater Regulations 1998***[170]			
Summary of Purpose: The regulations require the relevant authority to prevent the direct or indirect discharge of list I substances to groundwater and to control pollution resulting from the direct or indirect discharge of list II substances, this is achieved via a requirement for an authorisation for the disposal, or tipping for the purposes of disposal, of list I or II substances in cases where a waste management licence under Part II of the ***Environmental Protection Act 1990*** is not already required.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Definition – pollution	The Regulations place a duty on the Environment Agency (the relevant authority in England) to protect groundwater, in effect by prohibiting discharges of List I substances to groundwater, and preventing pollution of groundwater by List II substances.* Pollution is defined as discharge substances, directly or indirectly into groundwater which can result in damage to human health, water supplies, living resources or aquatic ecosystem.	<u>Will nanomaterials be classed as a substance under the regulation?</u> Whether nanomaterials will be covered by the regulations will depend on whether they can be classed as a List I or List II substance. 1. If they are classed as a List I substance systems will be required to prohibit their discharge into groundwater. It is unlikely that nanomaterials are at present included under the identified substances in List I. Substances in List I do have the potential to include nanomaterials in particular metal and its compounds, if they are classed as existing substances – meaning that the nanoscale substance is measured and assessed to the same standards as the existing macro substance identified on the List. Such a comparison may fail to identify the specific impacts and/or effects of a material at the nanoscale. In addition, the majority of the remaining nanomaterials will not be covered. If the nanoscale substance is classed as a 'new substance' – this raises a new issue as	In general nanomaterials are currently unlikely to fall under either of the Lists and even if some can be captured due to comparison with the macro equivalent – any risk assessments derived from the effects of the macro scale are unlikely to capture the potential risk effects of the nanoscale form. To ensure a consistent approach to nanomaterials and to ensure assessment of their particular risks and effects, it has been recommended in other assessments that nanomaterials are classed as new substances and as such would not be included in the Lists. It is foreseeable that due to the purpose of the introduction of the lists, e.g. List I is to cover pollutants which were selected because of their persistence, toxicity and bioaccumulation – any nanomaterials which fulfil these requirements can be added to the list.

[170] Implements Council Directive 80/68/EEC^ as amended by Directive 91/692/EEC.

		to whether a new substance at the nanoscale is still covered by the regulation. 2. A number of the substances in List II are available at the nanoscale. Again it will depend on whether they are classed as existing substances and subject to the same issues outlined in terms of List I.	
2. Exception	Even if nanomaterials were captured under List I or List II, the regulations include exceptions, which extend to discharge of substances in list I and II but in very small quantities and concentrations.	This is not a numeric standard and the European Court has held that were quantity of substances in List I or II contained in discharges of other substances is such that the threat of pollution cannot automatically be excluded, the Directive is applicable[171]. It is likely that nanomaterials discharged will be in small quantities, however with the lack of scientific knowledge on the potential impacts, it may be necessary to consider including them under the regulations by considering them as pollutants which constitute a pressure. However, this will require adequate monitoring tools to capture the presence of nanomaterials.	The introduction of the proposed Directive on Groundwater+ is likely to introduce threshold values for all pollutants identified as putting groundwater at potential risk. Thresholds in other legislation (e.g. REACH) have generally been set at a level too high to include nanomaterials and this may need to be addressed at an early stage. Pollutants for which limits must be set include: ammonium, arsenic, cadmium, sulphate, trichloroethylene and tetrachloroethylene.
3. Risk Assessment & Information	1. Prior to granting authorisations to permit certain discharges, the Environment Agency must assess the risk of the discharge polluting or altering the quality of the groundwater. 2. Assess the purifying powers of soil & subsoil and the risk of pollution and alteration of the quality of the groundwater	1. This may be assessed by using current techniques and these standard tests may not capture the different level of pressures, effects and potential risks introduced by nanomaterials. 2. Again this will be dependent on current scientific knowledge, where this is not available it may not be possible to assess the reaction of soil and subsoil to effluents containing nanomaterials.	Does not extend to List I substances, the discharge of which cannot be authorised, except where this is permitted under the regulations.
4. Terms of Authorisation	Authorisations will include the essential precaution required for the potential substance that may be present in the effluent and the maximum quantity of	It is unlikely that due to the lack of available scientific data that the relevant precautions can be evaluated and this lack of information can extend to the maximum quantity of any	

[171] Department of the Environment, Transport & Regions, Guidance on the Groundwater Regulations 1998, 2001

	such substance.	nanoscale substance that may be permitted to be discharged.	
Linked Legislation	^ -***Directive 80/68/EEC*** – directive on pollution caused by certain dangerous substances discharged into groundwater, this amended Directive 76/464/EEC, by removing the protection of groundwater from its remit. - List I and List II substances contained in the ***Dangerous Substances Directive (76/464/EEC),*** however as part of the ongoing restructuring of the Community water policy, the **Directive on Dangerous Substances** is now integrated in the **Water Framework Directive** (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as **Directive 2006/11/EC** on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community. ***Environment Protection (Prescribed Processes and Substances) Regulations 1991*** - lists a number of List I substances whose releases to water are prescribed for Integrated Pollution Control. ***Water Resources Act 1991 -*** provides the power to modify discharge consents ***Pollution Prevention and Control (England & Wales) Regulations 2000 -*** Operators of the potentially most polluting processes ('prescribed processes' which are specified in the amended Environmental Protection (Prescribed Processes and Substances) Regulations 1991/472) have to apply for prior authorisation from the Environment Agency to operate the process. PPC requires operators to consider the total impact of all releases to air, water and land when making an application.		
Horizon Scanning	**+ -** Groundwater protection against pollution under the Water Framework Directive - The European Commission adopted a proposal for a new Directive to protect groundwater from pollution on 19th September 2003 (***COM(2003)550***). Based on an EU-wide approach, the proposed Directive introduces, for the first time, quality objectives, obliging Member States to monitor and assess groundwater quality on the basis of common criteria and to identify and reverse trends in groundwater pollution. A final text was agreed in October 2006. On 17 July 2006, the Commission adopted a proposed Directive **(Surface Water Protection against Pollution under the Water Framework Directive)** setting environmental quality standards for the priority substances which Member States must achieve by 2015, to ensure "good chemical surface water status". The proposal also requires progressive reduction of emissions, losses and discharges of all priority substances, and phase-out or cessation of emissions, losses and discharges of priority hazardous substances within 20 years.		

Legislation: *Surface Waters (Dangerous Substances) (Classification) Regulations 1997 & 1998*			
Summary of Purpose: These Regulations prescribe a system for classifying the quality of inland freshwaters, coastal waters and relevant territorial waters with a view to reducing the pollution of those waters by the dangerous substances. The regulations establish water quality objectives.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**

1. Dangerous Substances	The substances listed in both regulations are substances within List II of the Dangerous Substances Directive*.	A number of the substances in List II are available at the nanoscale. Again it will depend on whether they are classed as existing substances[172] - which means that the nanoscale substance is measured and assessed to the same standards as the macro. Such a comparison may fail to identify the specific issues of the nanoscale substance. In addition, other nanomaterials will not be covered.	To ensure a consistent approach to nanomaterials and to ensure assessment of their particular risks and effects, it has been recommended in other assessments that nanomaterials are classed as new substances and as such would not be included in the Lists.
2. Limits	An annual mean concentration for each dangerous substance is listed in both regulations. The mean concentration assists in the classification of the water source ensuring that the concentration of the dangerous substance does not exceed that listed.	With the low levels associated with nanomaterials it is foreseeable that in a number of occasions, they will, if classed as a dangerous substance, fall below these threshold limits.	New concentrations limits may need to be considered in light of nanomaterials and this would support a need for them to be considered as new substances.
3. Sampling	The Environment Agency is required under the regulations to monitor the effects on the designated waters of discharges containing the prescribed dangerous substances.	It is likely that the current standards for monitoring and sampling techniques of water status will not capture the pressures introduced by nanomaterials.	
Linked Legislation	* - List II substances contained in the ***Dangerous Substances Directive (76/464/EEC),*** however as part of the ongoing restructuring of the Community water policy, the **Directive on Dangerous Substances** is now integrated in the **Water Framework Directive** (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as **Directive 2006/11/EC** on pollution caused by certain dangerous substances discharged into the aquatic		
Horizon Scanning	On 17 July 2006, the Commission adopted a proposed Directive **(Surface Water Protection against Pollution under the Water Framework Directive)** setting environmental quality standards for the priority substances which Member States must achieve by 2015, to ensure "good chemical surface water status". The proposal also requires progressive reduction of emissions, losses and discharges of all priority substances, and phase-out or cessation of emissions, losses and discharges of priority hazardous substances within 20 years.		

[172] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

Legislation: *Trade Effluents (Prescribed Processes and Substances) Regulations 1989*[173]			
Summary of Purpose: These regulations specify two categories of trade effluent, which is any effluent (liquid waste) that is discharged from any premises used for carrying on a trade or industry. Consent must be obtained to permit any discharge of trade effluent.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Prescribed Substances	Prescribed substances as contained in Section 1 are controlled if present in prescribed concentrations.	Potential for nanomaterial to be covered under the list, however much will depend on whether the nanoscale form is classed as an existing or new substance. If an existing substance[174], it might be categorised as a prescribed substance but would then be assessed against the same standards as the macro, which may fail to identify the specific issues of the nanoscale. Nanomaterials, which do not fall under the prescribed substances list, will not be captured.	Trade effluent can include waste chemicals, including oils, liquid process wastes, detergents, condensate water from compressed air installations, cooling water, biodegradable liquids, wash water, liquid wastes or wash waters, other than domestic sewage, discharged using sinks, basins or toilets, and contaminated mine or quarry water. It therefore, has a high likelihood of containing nanomaterials
2. Prescribed Processes	Trade effluent that derives from a prescribed process as contained in Section 2, which contains asbestos or chloroform if present in prescribed concentrations.	Potential for inclusion in the list but subject to the same issues discussed above.	To ensure a consistent approach to nanomaterials and to ensure assessment of their potential risks and effects, it has been recommended in other assessments that nanomaterials are classed as new substances and as such there is the potential gap that they will not be covered by the lists of prescribed substances.
Linked Legislation	***Water Act 1989*** – Section 74 provides for the control of exercise of trade effluent functions as applied in these regulations. ***Environmental Protection (Duty of Care) (England & Wales) Regulations 2000*** - Any effluents that the Sewerage Undertaker will not permit you to discharge to the foul sewer will be classed as Waste or Hazardous Waste. Wastes must be handled and disposed of according to the duty of care regulations. ***Water Industry Act*** – Definition of trade effluent - "...any liquid, either with or without particles of matter in suspension in the liquid, which is wholly or partly produced in the course of any trade or industry carried on at a trade premises.." 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.		
Horizon			

[173] As amended 1990 (SI 1629) and 1992 (SI 339)
[174] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

Scanning	

Legislation: ***Urban Waste Water Treatment (England and Wales) Regulations 1994***[175]			
Summary of Purpose: is to ensure that all significant discharges of sewage are treated before they are discharged either to inland surface waters, groundwater, estuaries or coastal waters. The regulations also provide conditions to be followed by those providing waste water treatment facilities.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Classification of specific water bodies.	Regulations set down various criteria to identify sensitive areas. Schedule 1 provides elements, which might be taken into account when considering which nutrient should be reduced by further treatment	The criteria are not prescriptive but make recommendations as to which types of nutrients should be reduced by further treatment. With its limited coverage it is unlikely that these regulations will extend to nanomaterials.	
2. Standards	1. Collecting Systems - Sets minimum standards for the design, construction, operation and maintenance of collecting systems 2. Treatment Facilities – standards in design, construction, operation and maintenance are required to ensure that performance will meet achieve compliance of the treatment standards. The minimum treatment required (primary, secondary or tertiary) is related to the sensitivity classification. Urban waste water entering collecting systems is subject to treatment. Generally secondary is the most common but more stringent treatment is required for waters identified as "sensitive areas".	1. The standards recommended are based on conventional systems and these standards may not capture the different level of pressures, effects and potential risks introduced by nanomaterials. 2. The regulations specify treatment methods for specific substances, whether nanomaterials are captured by the regulations will depend on whether they are included within the specified substances due to the lack of nanomaterials in waste water are unlikely to be captured.	1. To ensure that the standards meet the requirements of nanomaterial, information on the potential risks associated with the discharge nanomaterials will be required. 2. There are a number of potential products containing nanomaterials that will be disposed into waste water, in particular cosmetics, detergents and medicines.
3. Thresholds	Discharge concentrations are provided	As the regulations provide concentration level	There is sufficient scope within the

[175] Implement Council Directive 91/271/EEC concerning urban waste water treatment.

	for specific substances.	for specific substances, nanomaterials will not be captured and even if they were captured under the regulations, unlikely that the concentration levels would be appropriate.	regulations and within the Water Resources Act to introduce new substances and or conditions including concentrations.
4. Conditions	1. Conditions can include the provision of apparatus for the purpose of measuring or recording the volume, rate of flow, nature, composition or temperature of any waste water. 2. Other conditions can be attached to fulfil any duties identified under the Water Resources Act^ e.g. discharges of biodegradable industrial waste water from specified industrial sectors are subject to conditions appropriate to the nature of the industry.	Given the current uncertainty in relation to the potential impacts of nanomaterials on human health and/or the environment in relation both to the potential effects and the level at which these effects might occur, it may not be possible to assess the impacts of many nanomaterials. As a consequence it may prove difficult to attach appropriate conditions to a discharge consent, which will deal with any specific considerations arising from the presence of nanomaterials.	As above the regulatory framework provides for the relevant authority to impose conditions, which are appropriate for the nature of the industry conducting the discharge, therefore scope exists, where necessary to include specific conditions relating to the discharge of nanomaterials in urban waste water – this will depend on any practical treatment elements to treat nanomaterials.
5. Monitoring	Condition on competent authority or appropriate body to monitor discharges for composition of sludges and to verify that discharges are not having a negative effect on the environment.	Monitoring is required for specific substances of which nanomaterials are not included. Even if nanomaterials were included under the regulations it is unlikely that the current monitoring techniques would capture the presence of nanomaterials and therefore unlikely that the regulations would be able to regulate nanomaterials in waste water.	
Linked Legislation	***Water Industry Act 1991*** – The regulations bring into force the requirement under the Act for appropriate authority to secure that "collecting systems" are provided by specified dates, and to secure that urban waste water entering collecting systems is subject to treatment provided in accordance with the regulations. ***Urban Waste Water Treatment Directive 91/271/EEC*** - is to ensure that all significant discharges of sewage are treated, whether the discharge is to inland surface water, groundwaters, estuaries or coastal waters. ***Pollution Prevention and Control (England & Wales) Regulations*** – controls emission levels from certain type of prescribed activities. **^ - *Water Resources Act 1991*** - provides the power to modify discharge consents.		
Horizon Scanning			

Legislation: *Water Environment (Water Framework Directive) (England and Wales) Regulations 2003*
Summary of Purpose: The Regulations require a new strategic planning process to be established for the purposes of managing, protecting and

improving the quality of water resources. That process applies to river basin districts and the relevant authority must prepare river basin management plan.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Scope	The regulations deal with the identification of the pressures on the aquatic environment, the monitoring of water quality and the means to protect and improve the quality of water resources in these regulations river basins.	Nanomaterials could constitute a pressure on the water environment, however it will depend on a number of factors including whether available techniques exist to measure, monitor and capture nanaomaterials and it is possible to assess the impact of nanomaterials on water quality.	
2. Characterisation	In England & Wales the Environment Agency must conduct a review of the impact of human activity on the status of surface water and groundwater in each river basin district.	Nanomaterials, which have effects on the chemical or ecological quality of water could be considered a pressure – however in order to measure the pressure, standard tests need to be applied – current test procedures may not capture the different level of pressures introduced by nanomaterials.	This analytical and preparatory work must then inform the preparation by the Agency of proposals for environmental objectives and programmes of measures in relation to each river basin district. If the process does not capture the pressures from the release of nanomaterials subsequent actions may fail to address programmes of measures.
3. Monitoring Techniques	The Environment Agency must establish a programme for monitoring water status, part of which must cover ecological and chemical status. The new system, with five quality classes underpinned by monitoring a range of biological quality elements, will be supported by measurements of physico-chemistry, hydrology and morphology.	Again it is likely that the current standards for monitoring water status will not capture the pressures introduced by nanomaterials.	New monitoring techniques may be required with regard to threshold and techniques for measuring pressures on chemical and ecological quality of water.
4. Programme of Measures	A programme of measures must be produced for each river basin district.	The programme of measures is linked to the analysis identifying pressures, any lack of information or gaps at the analysis stage will impact on identifying the relevant programme of measures in particular those relating to prevention or control of the input of pollutants.	
Linked Legislation			
Horizon Scanning	***Water Framework Directive*** - The Directive establishes a new legal framework for the protection, improvement and sustainable use of surface waters, transitional waters, coastal waters and groundwater across Europe. Its aim is to prevent deterioration and enhance		

	status of aquatic ecosystems, including groundwater, promote sustainable water use, reduce pollution and contribute to the mitigation of floods and droughts.

Legislation: *Water Industry Act 1991*[176] *(includes amendments made under Water Act 2003)*			
Summary of Purpose: 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 Act has been amended by the Water Act 2003.^			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. 'wholesome' water	1. Secretary of State can prescribe specific characteristics of water and prescribe specific requirements as to the substances that should or should not be present in the water*. 2. Water undertaker to ensure that there has been no deterioration of water quality.	1. Such a provision can enable new regulations to be introduced which can extend to new substances, processes or products and therefore any nanomaterials, which it may be considered necessary to classify as a prescribed substance could be regulated for under new regulations. 2. Due to the current scientific knowledge available, any water that may be contaminated with nanomaterials that are deleterious to the environment or human health will not be detected due to the current technical standards available for monitoring water quality.	The definition of substances – includes micro-organisms, natural or artificial substances – to ensure that nanoscale substances are captured, the definition may need to include reference to the nanosize form otherwise it would be open to debate.
2. Trade Effluent	No effluent can be discharged into the sewer which may damage the sewer, injure the people working in it or	1. Definition – the definition of trade effluent is sufficiently wide to encompass liquid containing nanomaterials produced or used by	The Act permits the designation of a 'special category effluent' – these are substances prescribed under the Act and

[176] As amended by Water Industry Act 1999 and the Water Act 2003

	interfere with the working of the sewage treatment works	industry, as it is confined to trade it excludes domestic effluent, which is likely to contain disposal of nanomaterials via the sewer.	are present in effluent or within prescribed concentrations or derives from a prescribed process*. The provision however, will allow, if necessary, new regulations to extend to nanomaterials.
3. Trade Effluent consents – Water Act 2003^	The Water Act introduces a power which allows the Secretary of State to classify a specified liquid as trade effluent. The Act also requires that applications for consent should contain the steps to be taken to minimise the polluting effects of the discharge and the impact of the discharge on sewerage services.	While this provision may extend to trade effluent containing nanomaterials, at the current level of knowledge on the effects of nanomaterials it is unlikely that there is sufficient available information to fulfil the requirements to provide information on the impact of the discharge on sewerage services or the necessary steps to be taken.	
4. Discharge	1. The Act prohibit disposal to public sewers any chemical waste which is classed as dangerous, will cause a nuisance or is injurious to health (s.111). 2. Part III can provide consents to allow discharge to public sewers (including those regulated under s.111). Application to discharge to the sewer 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. 3. In granting a trade effluent consent the sewerage undertaker may impose conditions such as the volume of discharge, composition of the discharge (chemical oxygen demand, temperature, concentration of suspended solids) and the sewer into which it may be discharged.	1. Whether nanomaterials will be covered by the Act will depend on whether any are classed as dangerous and that information is available of the likely effects of nanomaterials in different circumstances are likely to cause a nuisance or be injurious to health. If, without evidence to prove their classification, they are not classed as dangerous, there would be no prohibition on their disposal to public sewer. 2. Consent applications are open for inclusion of nanomaterials to be identified in the composition of the trade effluent. 3. Special conditions may be applied to those substances classed as 'special category effluent' and prohibit disposal where necessary or require conditions. Currently prescribed substances are unlikely to cover nanomaterials at the general level and at the specific level only a few applications of nanomaterials are likely to be covered if they are classed as existing substances[177]	Applying a precautionary approach, nanomaterials which are not supported by research findings, should be classed as dangerous substances and prohibited from disposal to public sewers.
5. Testing	The regulations require tests to be conducted on the extent and quality of the water.	It is likely that the current standards for monitoring water status will not capture the effects of nanomaterials, if the presence of	

[177] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

		substances at the nanoscale is likely to affect the quality of water.	
Linked Legislation	**^ - *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. *** - *Trade Effluent (Prescribed Processes and Substances) Regulation 1989*** (as amended 1990 & 1992) - apply to companies which have, or are seeking, a consent to discharge specified trade effluents under the Water Industry Act. ***Water Supply (Water Fittings) Regulations 1999 –*** The regulations were made under section 74 of the Water Industry Act to prevent the waste, misuse, undue consumption, contamination or erroneous measurement of drinking water. The Regulations set requirements for the design, installation and maintenance of plumbing systems and water fittings. They are enforced by water companies in their respective areas of supply. ***Water Supply (Water Quality) Regulations 2000*** (as amended 2001 SI 2885) – Requires water undertaker to identify water supply zones for a given year. Regulations require water to meet 'wholesomeness' standards, which requires that micro-organisms and substances do not exceed set concentrations. Water must be monitored and samples taken from supply points and analysed. No substance or product to be introduced into water, which would impact on wholesomeness. Unlikely due to the prescribed concentration levels that nanomaterials will be addressed by these regulations. ***Environment Protection Act 1990*** - Processes which are regulated under Part I of the Environmental Protection Act 1990 also require a trade effluent consent from the sewerage undertaker.		
Horizon Scanning	***Water Framework Directive (Directive 2000/60/EC)*** – sets out a timetable for implementation of all aspects by 2027 and has key aims for improving water quality in the European Union including, expanding the scope of water protection to all waters, surface waters and groundwater, achieving "good status" for all waters by a set deadline, water management based on river basins and "combined approach" of emission limit values and quality standards.		

Legislation: *Water Resources Act 1991*[178] *(includes amendments made under Water Act 2003)*			
Summary of Purpose: The Act sets out the responsibilities of the Environment Agency in relation to water pollution, resource management, flood defence, fisheries, and in some areas, navigation. It regulates discharges to controlled waters, namely rivers, estuaries, coastal waters, lakes and groundwaters. This is distinct from the drainage of water or trade effluent from trade premises into a sewer. Discharge to controlled waters is only permitted with the consent of the Environment Agency. An aim of the Act is to ensure that the polluter pays the cost of the consequences of their discharges. The Act has been amended by the Water Act 2003*.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Classification of quality of water	Under the Act the Secretary of State has the power to introduce regulations prescribing a classification system for the quality of water.	Classification should consist of specific requirements as to substances that are present in or absent from the water. Current classifications under this Act has not extended to nanomaterials e.g. under the ***Water***	Nanomaterials, which have effects on the chemical or ecological quality of water could be considered a pressure on the quality, however in order to measure the pressure, standard tests need to be

[178] The Act came into force in 1991 and replaced the corresponding sections of the Water Act 1989 and implements part of the Groundwater Directive 80/68/EEC

		Environment (Water Framework Directive) Regulations.	applied – current test procedures may not capture the different level of pressures introduced by nanomaterials.
2. Monitoring of extent of pollution in controlled water	A duty is placed on the competent authority to monitor the extent of pollution in controlled water.	It is likely that the current standards for monitoring water status will not capture the pressures introduced by nanomaterials, therefore the presence of nanomaterials will not be captured by the Act or subsequent regulations made under the Act unless monitoring techniques are capable of capturing the relevant data.	
3. Offences of polluting	1. It is an offence to cause or knowingly permits a poisonous, noxious or polluting matter to enter any controlled water. 2. It is an offence to discharge any effluent or matter containing a prescribed substance or a prescribed concentration	1. Whether the Act covers nanomaterials will depend on whether individual nanomaterials are classed as poisonous, noxious or polluting matter. Currently, it is unlikely that nanomaterials will be covered by the Act as under various other regulations they have not be classed as dangerous substances unless a nanoscale substance is classed as an 'existing' substance[179] and therefore compared with its macro equivalent, a comparison which will not identify the specific effects and impacts of the nanoscale form. 2. Only a limited scope of nanomaterials could be captured under the existing list of prescribed substances and again only if they are classed as existing substances (e.g. metals). However, the majority of nanomaterials will not be captured and those that are, are subject to the limitations of being compared to the macro equivalent.	
4. Precautions against pollution	1. Power to enact regulations to ensure that necessary precautions are undertaken to prevent or control the entry of poisonous, noxious or polluting matter into controlled water.	Applying the relevant precaution depends on the availability of information on the potential effects of a substance in a variety of different circumstances. With the current dearth of scientific information on how nanomaterials	

[179] An "existing substance" is defined as one that is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

	2. Identification of water protected zones – where certain prescribed activities are prohibited or restricted.	may react in different environments will limit the applicability of introducing the necessary precautions to prevent or control entry of nanomaterials into controlled waters if they are classed as pollutants. This is also applicable to point 2.	
5. Consent to Discharge**	Conditions may be imposed in any consent to discharge for example relating to nature, origin, composition, volume and rate of discharge. Provisions for minimising the polluting effects, provision for tests and sample analysis	Even if nanomaterials qualified as a pollutant and triggered conditions on discharge consents. Again in order to be able to impose conditions, one requires appropriate and relevant information to ensure that appropriate volumes and rates can be applied.	At present it is therefore unlikely that condition could be complied with to the necessary level to ensure the minimisation of the polluting effects.
6. Information	Pollution Control Register – containing information on the samples of analysis.	If nanomaterials are classed as existing substances, those that qualify under this definition, the information recorded will only be that acquired for the macro scale substance and as such not necessarily appropriate for the particular effects of the nanoscale. Other nanomaterials will not be recorded.	This also raises questions in terms of the standards used for collecting and evaluating samples – as the current test procedures may not capture the different level of pressures introduced by nanomaterials
Linked Legislation	***The Anti-Pollution Works Regulations 1999*** - were enacted into Section 161A of the Act, to enable the Environment Agency to serve works notices on polluters or prospective polluters. The purpose of the regulations is to provide the Agency with additional powers to prevent water pollution. **** - Water Act 2003*** – amends the Water Resources Act and introduced statutory provisions for water companies to produce water resources plans. ***Water Resources (Environmental Impact Assessment) Regulations 2003*** - EIA must be carried out for water management projects for agriculture, including irrigation projects, involving the abstraction (taking) or impoundment (storage) of water, which we judge could have significant environmental effects ***** - Urban Waste Water Treatment (England & Wales) Regulations 1994 -*** ensure that all significant discharges of sewage are treated before they are discharged either to inland surface waters, groundwater, estuaries or coastal waters ***** - Pollution Prevention & Control Regulations*** – regulates discharges to controlled waters		
Horizon Scanning	***Water Resources Management Regulations*** – proposed regulations to implement the processes required for water resource management plans as required under the Water Act. ***Water Framework Directive (Directive 2000/60/EC)*** – sets out a timetable for implementation of all aspects by 2027 and has key aims for improving water quality in the European Union including, expanding the scope of water protection to all waters, surface waters and groundwater, achieving "good status" for all waters by a set deadline, water management based on river basins and "combined approach" of emission limit values and quality standards.		

Legislation: *Hazardous Waste (England & Wales) Regulations 2005*

Summary of Purpose: The main aim is to define hazardous waste and to ensure it is properly managed and regulated; the regulations control waste that can harm human health or the environment. Producers or consigners are required to register their premises with the Environment Agency, companies are required to document the movement of hazardous waste and consignees are required to keep records available for inspection. A major element of the regulations is that there is a general restriction on the mixing of hazardous wastes and where appropriate the separation of wastes is required.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Definition of Hazardous Waste*	The definition of hazardous waste in regulation 6 refers to the list of hazardous wastes set out in the List of Wastes (England) Regulations 2005*. For a list of the potential issues relating to the definition of hazardous waste – see the assessment of List of Wastes Regulations.	The issue is the identification and classification of wastes containing substances at the nanosize form. The main potential gap is if waste is not classified as hazardous. If waste containing nanoparticles is classified as non-hazardous? – The waste will be able to be mixed with other waste types and disposed to non-hazardous landfill* sites – where it will be mixed with a variety of other waste types. As there is little available information on the reaction of nanoparticles with other materials – this could lead to both damage to human health and the environment.	The lack of relevant information on the effects of nanosized substances entering the waste stream, means that wastes classed as non-hazardous will not be required to meet the stricter standards required for hazardous wastes. The identification of wastes as hazardous could lead to a potential increase in available data, the Hazardous Waste Regulations are linked to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002** for the determination of dangerous substance – the use of safety data sheets under these regulations could build up a knowledge base on disposal options.
2. Consumer Products and Domestic Waste	The regulations do not extend to domestic waste unless it has been separately collected. No direct obligations are placed on householders under these regulations.	Consequently, with the increase in the availability of consumer products containing substances at the nanosize form and with little information on the effects – there is a potential gap relating to the best waste management methods.	The existing framework cannot accommodate any specific requirements to manage domestic waste containing products with nanosized substances.
3. Radioactive Wastes	Radioactive waste is covered by this regulation is being transferred from a site under the conditions of an Environment Agency authorisation and contains other hazardous properties.	Potential problems may arise in the containment of nanomaterials/particles 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 potential risks posed by radioactive nanomaterials, which may have the ability to penetrate cell membranes and cause greater damage to cells due to their proximity to the DNA.	

4. Specific wastes to be treated as hazardous	The Secretary of State may determine in special circumstances that a waste may be treated for all purposes as hazardous.		It is recommended that this provision is considered in determining the classification of substances containing nanoparticles.
Linked Legislation	**** - List of Waste (England) Regulations 2005*** – Identifies substances as either 'Absolute' or 'Mirror' wastes. Absolute wastes are always hazardous, Mirror wastes may be hazardous or non-hazardous dependent on the concentration of dangerous substances. ***** - Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 -*** Dangerous Substance means a substance contained in the "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Seventh Edition)" (UK Approved Supply List) or if not on this list is one or more of the categories of danger contained in Schedule 1 of this regulation. ***Landfill (England & Wales) Regulations 2005*** - the classification of waste under the List of Waste will determine, where waste is disposed to landfill, the type of landfill to which the waste can be sent. ***Pollution Prevention & Control (England & Wales) Regulations 2000*** – controls emissions to land, air and water from prescribed activities.		
Horizon Scanning	Regulation (EC) No 166/2006 concerning the establishment of a ***European Pollutant Release and Transfer Register*** and amending Council Directives 91/689/EEC and 96/61/EC - tool for encouraging improvements in environmental performance, for providing public access to information on releases of pollutants and off-site transfers of pollutants and waste, and for use in tracking trends, demonstrating progress in pollution reduction, monitoring compliance with certain international agreements, setting priorities and evaluating progress achieved through Community and national environmental policies and programmes. Applies to any chemical element and its compounds and applies to any introduction of pollutants into the environment as a result of any human activity, whether deliberate or accidental, routine or non-routine, including spilling, emitting, discharging, injecting, disposing or dumping, or through sewer systems without final waste-water treatment. Directive applies to a list of prescribed activities as well as a list of prescribed substances with specific thresholds. It is likely that the thresholds have been set at a level too high to cover the release of nanomaterials.		

Legislation: *Landfill (England & Wales) Regulations 2002*[180]^			
Summary of Purpose: Governs the operation of landfill sites and sets out new requirements for the classification and management of these sites. Three types of landfill sites are defined – hazardous, non-hazardous and inert. Aims to reduce the amount of waste disposed to landfill by encouraging recycling and recovery.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Permits	Outline the management procedures for operating the landfill, including the types and quantity of waste authorised to be deposited. Before permit authorised, sites require to be classified into hazardous, inert or non-hazardous.	The provisions under this Regulation are such that many avenues of wastes containing nanoparticles (e.g. from research & development) cannot be disposed in landfill sites. It is not foreseen that the existence of nanomaterials in waste will result in gaps in	In general the lack of knowledge relating to the effects of nanomaterials within waste streams and their different properties and characteristics could lead to gaps because: a. They may be misclassified under the

[180] As amended 2004 (SI 1375) and 2005 (SI 1640)

		the permitting of landfill sites however, potential gaps may arise in terms of the types of waste disposed to certain landfill sites (see box 4 – Waste Sources) or the role of Waste Acceptance Criteria (box 2).	List of Waste b. As a consequence, if being disposed to landfill, sent to the wrong type of landfill c. Little knowledge on whether the current standards are adequate to provide sufficient containment from dispersal throughout the landfill site and escape into water courses.
2. Waste Acceptance Criteria (WAC)	Waste can only be disposed to landfill if it will not result in unacceptable emissions to groundwater, surface water or surrounding environment; jeopardise environmental systems; put at risk waste stabilisation processes or endanger human health. These general acceptance criteria are supported for additional criteria for each of the three independent landfill types including being listed on the List of Wastes.** Stable non-reactive hazardous waste means hazardous waste, the leaching behaviour of which will not change adversely in the long-term, under landfill design conditions or foreseeable	1. Non-hazardous Landfill Potential gap due to the lack of available data in terms of the effects of nanomaterials and their potential to travel through the landfill and therefore escape. A number of potential wastes particularly consumer products, can be disposed to this type of site. 2. Hazardous Landfill* Stricter standards are required and if nanomaterials are classed as hazardous waste, there is potential for large volumes to be disposed to these sites – wastes will need to be treated before disposal and need to meet higher WAC standards. Questions may still arise about the ability of nanomaterials to escape due to the general lack of available data. 3. Inert Landfill Construction materials containing nanoparticles if not coded as hazardous waste could be sent to inert landfill where it would still be required to meet the criteria outlined in box 3. Inert wastes containing nanoparticles may need to be treated prior to landfill disposal. 4. Stable non-reactive hazardous waste – can be mixed with non-hazardous waste in the same cell. Only permissible if prescribed waste types meet set leaching thresholds – likely that any nanomaterials would escape these values. There is also a potential gap in	The availability of data on the impacts of nanomaterials will be vital to enable wastes containing these substances can be disposed safely via the appropriate means.

	accidents.	scientific knowledge of the long-term impacts of nanomaterials and as such they may qualify as non-reactive hazardous waste due to the lack of information on long-term effects.	
3. Waste Acceptance Procedures	1. Operator to inspect waste at point of disposal to confirm waste meets description. 2. Detailed data to be held on the quantities, characteristics, source and in terms of hazardous – its location on the site.	1. If waste has been incorrectly classified it is unlikely that a visual inspection of wastes containing nanoparticles will be detected at this stage. 2. The current system should be capable of dealing with the disposal of nanomaterials if they are correctly classified particularly if classified as hazardous – the main concern may be the impact of domestic waste.	Domestic waste streams are a source of disposal for nanomaterials as many consumer products will and do contain nanomaterials. However, it may be difficult to separate wastes containing nanomaterials from those that do not. Current waste management systems for domestic waste unlikely to be able to deal with segregating out waste products with nanoscale particles.
4. Waste Sources	Waste arises from a number of different generating sources.	1. Domestic Waste Consumer products containing nanoparticles are currently disposed into domestic waste streams and therefore disposed to non-hazardous landfill sites. With the existing lack of knowledge about the impacts of substances at the nanosize scale - is there a danger of nanoparticles to move through a landfill and potentially enter any water supply. There may be a potential gap in meeting the waste acceptance criteria. If separately collected and hazardous disposed to hazardous landfill sites. 2. Research & Development Waste Banned from landfill disposal – as a consequence any nanomaterials generated from this sector will not be permitted disposal at any landfill. 3. Medical Waste While hospital and other clinical wastes which arise from medical or veterinary establishments and which are infectious are banned from disposal to landfill there may be a number of medical wastes containing nanomaterials, which are not infectious and	More research into the potential impacts is required. Classification and labelling of products will be a major step in ensuring that wastes containing nanoparticles are disposed of in way, which reduces any potential damage to human health and the environment. Further research is required on the impacts of nanomaterials in landfill and whether the current regime, which is designed to reduce the escape of contaminants into the environment, is adequate to deal with new nanosized substances.

		therefore can be sent to landfill for disposal. Due to the lack of data on the effects of nanomaterials in waste streams.	
Linked Legislation	*** - *Hazardous Waste (England & Wales) Regulations 2005*** - Definition of hazardous waste is linked to the List of Waste Regulations and after classification as a hazardous waste, these Regulations outline the procedures relating to the movement of hazardous waste, the mixture and separation of hazardous wastes. ****** - ***List of Waste (England & Wales) Regulations 2005 -*** Identifies substances as either 'Absolute' or 'Mirror' wastes. Absolute wastes are always hazardous, Mirror wastes may be hazardous or non-hazardous dependent on the concentration of dangerous substances. ***Environmental Protection (Duty of Care) (England) Regulations 1991*** – Landfill Regulations altered the Duty of Care by adding a requirement to identify the waste by reference to the appropriate category in the European Waste Catalogue, now the List of Wastes ***Environment Protection Act 1990*** – Provides the main statutory framework for environmental protection including the management of waste, statutory nuisance and contaminated land. **^ - *Pollution Prevention & Control (England & Wales) Regulations 2000* –** These regulations alter the PPC regime by bringing all landfill sites under this regime. As a result, the PPC system of controlling environmental impacts of industrial operations will apply to all landfill sites. However, regulations based on the current knowledge on the polluting effects of emissions, which may be different in terms of the effects of nanomaterials.		
Horizon Scanning	***Thematic Strategy on the Prevention and Recycling of Waste*** by the European Commission – seeks to encourage the use of waste as a resource and therefore increased recycling. Regulation (EC) No 166/2006 concerning the establishment of a ***European Pollutant Release and Transfer Register*** and amending Council Directives 91/689/EEC and 96/61/EC - tool for encouraging improvements in environmental performance, for providing public access to information on releases of pollutants and off-site transfers of pollutants and waste, and for use in tracking trends, demonstrating progress in pollution reduction, monitoring compliance with certain international agreements, setting priorities and evaluating progress achieved through Community and national environmental policies and programmes. Applies to any chemical element and its compounds and applies to any introduction of pollutants into the environment as a result of any human activity, whether deliberate or accidental, routine or non-routine, including spilling, emitting, discharging, injecting, disposing or dumping, or through sewer systems without final waste-water treatment. Directive applies to a list of prescribed activities as well as a list of prescribed substances with specific thresholds. It is likely that the thresholds have been set at a level too high to cover the release of nanomaterials.		

Legislation: *List of Wastes (England) Regulations 2005*[181]
Summary of Purpose: The List of Wastes, which replaces the European Waste Catalogue, provides for the classification of wastes and determines whether they are hazardous. The regulation is an integral component of the waste management system in England and Wales. Classification provides an identification of the appropriate waste management process for the coded waste type, it is the first means to ensure that those wastes classified as hazardous are treated prior to landfill disposal in a hazardous landfill site. The codes are an integral part of the waste management system including the duty of care in disposal of waste.^

[181] As amended 2005 (SI 1673)

Content for Analysis	Summary of regulation	Gap or Potential Gap	Comment/Impact
1. Definition of Hazardous Waste	Hazardous wastes are split into 2 categories 'Absolute' meaning the waste will always be classed as hazardous or 'Mirror' which allows for a determination as to whether the waste will be hazardous or non-hazardous depending on their actual composition and the concentrations of "dangerous substances" within the waste.	1. If waste containing nanoparticles is classified as non-hazardous? – The waste will be able to be mixed with other waste types and disposed to non-hazardous landfill* sites – where it will be mixed with a variety of other waste types. As there is little available information on the reaction of nanoparticles with other materials – this could lead to both damage to human health and the environment. 2. If waste containing nanoparticles is classified as hazardous? – A determination will be required on whether waste is an absolute or mirror type hazardous waste (see Section 3 – Properties & Characteristics of Dangerous Substances).	It is recommended that due to the lack of available scientific information on the impacts of nanomaterials, wastes resulting from the development, manufacture, supply and use of nanoparticles are classed as hazardous.
2. Dangerous Substance **	A substance is classed as dangerous if it falls under Reg. 2 of Chemicals (Hazard Information & Packaging for Supply) Regulations 2002*** – Schedule 1 of the Regulations outlines specific categories of danger.	Currently no existing substance in nanosized form has been through the EU system, which results in substances being entered onto the UK 'Approved Supply List'. ** The lack of data available may mean that substances in nanosized form will not be classed as a dangerous substance.	CHIP's Schedule 1 list of specific categories of danger does include substances and preparations which in very low quantities can cause damage to health. However, as identified in the report prepared by the HSE lack of available data may result in a failure to think through potential health hazards.
3. Properties & Characteristics of Dangerous Substances	Once a waste has been identified as possessing dangerous substances it must then be assessed as to whether it contains dangerous substances in concentrations at or above the appropriate threshold or a test shows a hazardous property. The thresholds applied are H1 to H14 located in the Schedule 3 of Hazardous Waste Regulations****.	1. If waste containing nanoparticles is classified as 'Absolute'? – Waste will not be allowed to be mixed with other waste streams and if it has been mixed due to a natural consequence of the process – where applicable waste should be separated. Waste, if to be sent to landfill, must be treated prior to disposal and only sent to registered hazardous landfill sites. 2. If waste containing nanoparticles is classified as 'Mirror'? - Determination will require to be undertaken as to whether the	Applying a precautionary approach – all nanoparticles should be treated as 'Absolute' hazardous wastes.

		necessary characteristics of danger are present. An assessment of the relevant thresholds is necessary to assess whether the levels will satisfy an assessment of substances at the nanosized form. If the thresholds are not at a sufficient level, substances at this size may not be correctly classified. 2(a) <u>If waste classed as hazardous?</u> – Wastes will be subject to all of the provisions outlined for 'Absolute' hazardous waste as in 1 above. 2(b) <u>If waste classed as non-hazardous?</u> – Waste can be mixed with other waste streams and disposed to landfill – due to lack of available data on the impact of nanoparticles this could result in damage to human health and to the environment.	
4. Specific Process or intended use	Waste types are allocated against an identified process or activity or in certain circumstances against an intended use. When a person is lassifying a waste type they are required to code the waste according to the source generating the waste type.	1. Currently no existing hazardous waste codes available within the chapter specifically identified for food preparation and production. Food wastes containing any nanoparticles or nanomaterials, which may be hazardous, will have no valid code for classification. Producers will have access to codes under the manufacture, formulation, supply and use of organic and inorganic chemicals. 2. Packaging containing nanoparticles or exposed to nanoparticles under the current List will only be able to be coded as a 'Mirror' entry as no 'Absolute' code exists. As a consequence the threshold levels may be too high to ensure that packaging contaminated with nanoparticles is identified with the relevant thresholds to be classed as hazardous. 3. The allocation of codes to a specific waste	1. This will not identify that the waste is a result of the process of food. This limits available data on the types of waste arising from specific sectors.

		is the responsibility of the producer when completing Waste Transfer Notes under the Duty of Care^ - with the lack of available information on nanoparticles, their existence in goods, products, resources may not be identified – many companies may code wastes incorrectly, which could lead to incorrect disposal.	
5. Up dating the List of Wastes	The Regulations contain a provision for regular review and up dating of the list of wastes.		It is recommended that wastes containing nanoparticles are introduced into the List of Wastes.
Linked Legislation	**^** - **Environmental Protection (*Duty of Care) (England) (Amendment) Regulations 2003*** – Requires that a transfer note is a document which must be completed and accompany any transfer of waste between different holders. The document must contain a description of the waste in words and also by a code from the List of Wastes. The identification of the waste under this classification will often determine they type of waste management treatment e.g. whether a waste should be disposed to a hazardous or non-hazardous landfill site. ***** - ***Landfill (England & Wales) Regulations 2002*** – the classification of waste under the List of Waste will determine, where waste is disposed to landfill, the type of landfill to which the waste can be sent. ******- ***Chemicals (Hazard Information and Packaging for Supply) Regulations 2002*** – Dangerous Substance means a substance contained in the "Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Seventh Edition)" (UK Approved Supply List) or if not on this list is one or more of the categories of danger contained in Schedule 1 of this regulation. ******* - ***Hazardous Waste (England & Wales) Regulations 2005*** –Definition of hazardous waste is linked to the List of Waste Regulations and after classification as a hazardous waste, these Regulations outline the procedures relating to the movement of hazardous waste, the mixture and separation of hazardous wastes. ***End of Life Vehicles Regulations 2003*** – ELV wastes coded using List of Waste codes to determine whether waste hazardous and therefore containing dangerous substances.		
Horizon Scanning			

Legislation: *Waste Incineration (England & Wales) Regulations 2002^*			
Summary of Purpose: 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[182]. It applies to incineration and co-incineration plants.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Emission Levels	Permits are required to operate a waste incinerator. Strict emission levels are set based on best available techniques. The Regulations set down: a. operating conditions including gas temperatures; b. emission level values for a range of substance to air and water including dioxins; c. emission monitoring requirements	1. In general the lack of knowledge relating to the effects of nanomaterials within different waste streams and their different properties and characteristics could lead to gaps in the regulation of emission levels. 2. Currently, no limits exist for fine particles, which may be a concern in terms of nanomaterials and as a consequence result in another gap in the control of any emissions from the incineration of certain nanomaterials. 3. Present levels reflect current knowledge on the polluting effects of emissions, which may be different in terms of the effects of nanomaterials.	The current levels may not be adequate to address any of the potential emissions from the incineration of nanomaterials.
2. Waste Types	Both hazardous and non-hazardous wastes can be disposed via this waste management method.	Biomass from e.g. agricultural waste exempted from the limits as it is considered clean fuel – however the potential application of nanomaterials in agriculture may alter this assumption. As a consequence potential gap may arise.	

[182] Directive 96/61/EC on Integrated Pollution Prevention and Control

Legislation: ***Waste Management Licensing Regulations 1994***[183]			
Summary of Purpose: Implement the requirements provided in Part II of the Environmental Protection Act 1990 and provide the provisions for a waste management licensing scheme.			
Content for Analysis	**Summary of regulation**	**Gap or Potential Gap**	**Comment/Impact**
1. Information & evidence on application form	An applicant must supply certain information and evidence when making an application for a waste management licence – (where landfill or lagoon) works to prevent or minimise pollution, monitoring data of the quality of surface water and groundwater	At present the information is likely to be based on standard tests and the current test procedures may not capture the different level of pressures introduced by nanomaterials.	New monitoring techniques may be required with regard to threshold and techniques for fulfilling this information and evidence requirement.
2. Waste Oils	Where a licence authorises the regeneration of waste oil, conditions must be applied to ensure that base oils resulting from regeneration do not constitute a hazardous waste[184].	At present nanomaterials are unlikely to be identified as a hazardous waste for a variety of reasons. The first issue is whether they are captured under List I or List II of the dangerous substances lists as discussed in box 3 below. Secondly, is the numerous issues of identifying nanomaterials as hazardous waste as discussed in the assessment of the List of Waste Regulations. Even if identified as hazardous, for many wastes a determination has to be made on whether the concentration of hazardous properties is met and it is unlikely that nanomaterials will meet these thresholds and therefore may be classed as non-hazardous.	As a consequence it is likely that many nanomaterials will not be classed as hazardous waste and will therefore not be required to meet any of the stricter conditions applied to hazardous wastes in the various regulations including this regulation relating to waste oils.
3. Groundwater*	1. The discharge of List I or List II** substances are subject to a prior investigation before authorisation of licence.	Whether nanomaterials are captured under List I or List II substances has been discussed under the assessment of ***Groundwater Regulations*.*** Of particular concern is whether nanomaterials are classed as existing or new substances. If classed as 'existing' any investigation into potential risks arising	

[183] As amended 1995 (SI 288 & SI 1950), 1996 (SI 1279), 1997 (SI 2203), 1998 (SI 606), 2002 (SI 674), 2003 (SI 595) and Waste Management (England & Wales) Regulations 2006.
[184] As amended by the Hazardous Waste (England & Wales) Regulations 2005

		from the presence of nanomaterials would be assessed to the same standards as the macro scale, thereby failing to address the particular risks and pressures associated with the nanoscale.	
	2. Conditions Where the substance is permitted to be discharged, conditions may be applied including quantity, relevant precautions, monitoring and quality of groundwater.	It is unlikely that due to the lack of available scientific data that the relevant precautions can be evaluated and this lack of information can extend to the maximum quantity of any nanoscale substance that may be permitted to be discharged. In addition, if assessed at the macro level any quantity conditions will reflect the level of pressure arising from the macro equivalent and not the nano.	Current technical standards may not capture the relevant data related to the particular issues and effects that may arise from the presence of nanomaterials or even detect their presence.
Linked Legislation	*- ***Groundwater Regulations 1998*** – nothing in the groundwater regulations apply to any activity for which a waste management licence (within the meaning of Part II of the Environmental Protection Act 1990) is required. ** - List I and List II substances contained in the ***Dangerous Substances Directive (76/464/EEC),*** however as part of the ongoing restructuring of the Community water policy, the **Directive on Dangerous Substances** is now integrated in the **Water Framework Directive** (2000/60/EC) which was adopted in September 2000, and Directive 76/464/EEC will be fully repealed in 2013. Directive 76/464/EEC has been codified as **Directive 2006/11/EC** on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community. ***Waste Management Licensing (Amendment) Regulations 1995 –*** The amendment introduces conditions for the disposal of scrap metal by setting down 7 day limits for the total tonnage of identified metals to be handled by a prescribed activity.		
Horizon Scanning			