Review of Environmental Legislation for the Regulatory Control of Nanomaterials

Final Report

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Final Report

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Acronyms

AFM	Atomic force microscopy
CPC	Condensation Particle Counter
COMMPS	Combined Monitoring-based and Modelling-based Priority Setting
CNT	Carbon Nanotubes
DMA	Differential Mobility Analyser
ELPI	Electrical Low Pressure Impactor
EQS	Environmental Quality Standards
MOUDI	Micro-orifice uniform-deposit impactor
MWCNT	Multi-walled Carbon Nanotube
OECD	Organisation for Economic Cooperation and Development
OPC	Optical particle counter
PCS	Photon Correlation Spectroscopy
PM	Particulate Matter
SEM	Scanning electron microscopy
SMPS	Scanning Mobility Particle Spectrometer/ Sizer
SWCNT	Single-walled Carbon Nanotube
TEM	Transmission electron microscopy
TEOM	Tapered Element Oscillating Microbalance
UFP	Ultrafine particles
WEEE	Waste Electronic and Electrical Equipment
XRD	X-ray diffraction spectroscopy

Executive Summary

Introduction

Background

In light of the rapid growth in the number and diversity of applications of nanomaterials in products, it can be expected that emissions of nanomaterials into the environment will increase through multiple exposure pathways. This was recognised in the European Parliament's Resolution of 24 April 2009, which explicitly calls on the Commission to evaluate the need to review waste legislation, emission limit values and environmental quality standards in air and water legislation to adequately address nanomaterials. DG Environment contracted Milieu Ltd and AMEC Environment & Infrastructure UK Ltd. to assess whether key EU environmental legislation adequately addresses nanomaterials. EU legislation addressed within the context of this review is presented in the box below.

Waste legislation	Water legislation	Other relevant legislation
• Waste Framework Directive 2008/98/EC; • The list of waste decision 2000/532/EC; • The landfill Directive 1999/31/EC; • Waste acceptance criteria in landfills in Decision 2003/33/EC; • Sewage sludge Directive 86/278/EEC; • WEEE and RoHS Directives 2002/95/EC, 2002/96/EC; • Directive on end-of-life vehicles 2000/53/EC; • Directive on packaging waste 94/62/EC	• Water Framework Directive 2000/60/EC; • Directive 2008/105/EC on environmental quality standards in the field of water policy; • Directive 2006/118/EC on the protection of groundwater against pollution and deterioration; • Urban waste water Directive 91/271/EEC; • Drinking water Directive 98/83/EC; • Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment;	• Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (Seveso II Directive) • Regulation (EC) No 66/2010 on the EU Ecolabel

Objectives of the study

The first objective of this study was to review environmental legislation for waste, water and other relevant acts as regards their legal coverage of nanomaterials and, where possible, implementation on the ground, using a systematic methodological framework.

The second objective was to identify and describe legislative and implementation gaps in environmental legislation, including details on whether gaps relate to a lack of legal coverage, limitations in technical capacities or dependences on other legislation.

A final objective was to hold a stakeholder workshop to act as a sounding board against which to test the conclusions of an Interim Report generated under the study, as well as gathering up-to-date information on Member State activities regarding nanomaterials and their potential environmental impacts. This workshop was held on 20th June 2011 at DG Environment, Brussels, Belgium and comments received at the workshop have been integrated into this Final Report.

Methodological Framework

The focus of the report is on possible releases of engineered nanomaterials into the environment, and the extent of coverage of these releases under EU environmental legislation. The study considers the potential risks associated with nanomaterials in general, while at the same recognising that there are differences in the potential risks posed by different nanomaterials.

The methodological framework for the analysis of legislation ensured a consistent and coherent approach to reviewing the legislation, at the same time as allowing for a degree of flexibility required given the range of legislative acts to be reviewed. The methodology involved two steps, the review of coverage and the subsequent identification of any challenges, including possible gaps in legislation or in implementation. In interpreting the results presented in this report, it is important to distinguish between the outputs of the two key steps in the methodology for the legal analysis. Step 1) serves to “map” coverage of nanomaterials under each piece of legislation, while step 2) identifies potential risks from nanomaterials that are currently not subject to control. Where the lack of control stems from a gap in legal coverage, this is considered a legislative gap. Where the lack of control stems from inadequate implementation or a lack of technical capacity, this is considered to be an implementation gap. The identification of gaps was hampered by the very limited availability of exposure data and hazard data for specific nanomaterials and nanomaterials in general, making an assessment of potential risks extremely difficult. In the absence of a clear picture of potential risks, the study focussed on identifying possible issues in the coverage of nanomaterials under EU environmental legislation.

Nanomaterials in the Environment

Potential Exposure Pathways

Rapid increases in production volumes of nanomaterials and their incorporation into multiple applications suggest that releases of nanomaterials into the environment have increased accordingly. The lack of efficient, cost-effective analytical methods for monitoring the presence of nanomaterials in environmental media means that estimates of occurrence in the environment have been based on modelling estimates of exposure over the life cycle of products containing nanomaterials.

Possibilities for exposure exist at each stage of a product life cycle, including the synthesis of nanomaterials, incorporation into the final product, product use and disposal. These potential exposure pathways are all subject to controls under EU environmental legislation, and are examined within the context of this report, the exception being emissions from industrial installations. Once nanomaterials enter the environment, the associated risk depends on their mobility within the parent material (i.e. their ability to disperse) and the inherent hazard, including their ability to serve as carriers to pollutants.

The scale of environmental exposure

Information on the volumes of nanomaterials being produced and placed on the market and the number and range of product application for nanomaterials should provides an insight into the scale of possible environmental exposure to nanomaterials. However, the availability of such information in the public domain remains very limited, making an assessment of the volumes of nanomaterials entering product life cycles difficult, if not impossible. Available data regarding both the number of products on the market containing nanomaterials and current and future estimates of the market value of the nanomaterials industry suggest that volumes are increasing rapidly.

Limitations in the availability of ecotoxicological data for nanomaterials

Information on the physico-chemistry of specific nanomaterials is essential to understanding their fate and behaviour in the environment, including uptake and distribution within organisms and interactions with other pollutants. Each specific nanomaterial has a distinct “footprint” resulting from its chemical composition, shape and structure, implying that nanomaterials exhibit unique behaviours in different environmental media, even when they are fabricated from the same bulk parent material.

However, such data is currently limited in a context where the number of studies that specifically examine the (eco)toxicology of nanomaterials is low. What studies there are suffer from a lack of consistency in method and approach, making cross-study comparisons difficult and slowing the development of a robust body of evidence. This highlights the need for standardized test methods for assessing the toxicology of nanomaterials.

The Working Party on Manufactured Nanomaterials (WPMN) of the Organisation for Economic Co-operation and Development (OECD) has published a number of outputs on the testing of nanomaterials, including a priority list of nanomaterials and a list of endpoints relevant for human health and environmental safety for which they should be tested; preliminary guidance on sample preparation and dosimetry; and revised guidance for the testing of manufactured nanomaterials. In a preliminary review of OECD test guidelines for their applicability to manufactured nanomaterials, the WPNM concluded that many of the OECD Test Guidelines are applicable, while the Ecotoxicity Test Guidelines are currently insufficient. The current state of knowledge regarding nanomaterials toxicity and exposure routes was found to preclude the development of new test guidelines. In addition, many of the tests included in the OCED Test Guidelines require that chemical substances be in solution, while nanomaterials tend to present in dispersion in liquid, a fundamentally different state with implications for observed test outcomes.

The potential role of the Precautionary Principle in regulating nanomaterials

In a context where concrete evidence is lacking regarding current concentrations of nanomaterials in environmental compartments, trends in concentrations and any related negative environmental impacts, the precautionary principle could provides the legal basis in EU legislation for action to manage potential risks from nanomaterials.

The precautionary principle is mentioned in the context of environmental protection in Article 191 (2) of the Treaty on the Functioning of the European Union[1] (ex Article 174 of the Treaty establishing the European Community) In 2000, the Commission issued a Communication (2000)1 on the precautionary principle[2], with the aim of outlining the Commission's approach to using the precautionary principle. The Communication notes that the precautionary principle is to be used by decision-makers in the management of risk to inform two aspects: the political decision of whether to act or not; and how to act.

Regarding recourse to the precautionary principle when taking the decision whether to act to manage a potential risk, the Commission explains that the precautionary principle specifically applies in cases where "*potentially dangerous effects deriving from a phenomenon, product or process have been identified*" and where "*scientific evaluation does not allow the risk to be determined with sufficient certainty*". The Communication also states that if action is deemed necessary, measures based on the

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[1] Treaty on the Functioning of the European Union, OJ C 115/47, 9.5.2008, 47-199

[2] Communication from the Commission on the Precautionary Principle, COM(2000)1,

precautionary principle should be proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action, subject to review in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

As such, the precautionary principle seems applicable to the management of the potential risks from nanomaterials. In the case of nanomaterials, the scientific knowledge needed to inform the scientific evaluation is currently limited, serving to increase the overall level of uncertainty and ultimately affect the foundation for preventative action. The precautionary principle could be applied to the management of the potential risks of nanomaterials in general, or to the management of potential risks from specific nanomaterials. In the case of some specific nanomaterials, the body of evidence that could feed into a risk assessment is expected to be somewhat larger, possibly creating a foundation for more stringent preventative action, such as product controls.

Waste Framework Directive 2008/98/EC

Wastes generated during the life cycle of products containing nanomaterials are expected to be the chief sources of nanomaterials into the environment. Critical questions for controlling releases to the environment centre around the handling, treatment and disposal of wastes containing nanomaterials. Overall, there is a need for material flow analysis to determine what kinds, qualities and volumes of nanowaste specific waste streams contain, with current estimates based upon production volumes or quantities of products on the market containing nanomaterials. A precondition for the appropriate management of wastes containing nanomaterials is awareness amongst waste operators of their presence in waste materials. The necessity of such information for specific nanomaterials depends upon whether they present a known hazard in the waste streams in which they occur.

Directive 2008/98/EC on waste[3] establishes the general framework for waste policies, including the definition of concepts such as waste, recovery and disposal and key requirements for waste management. Currently, wastes containing nanomaterials are treated as any other waste under the Waste Framework Directive without any specific requirements. There is no definition of waste containing nanomaterials and therefore no measures specifically designed to deal with the possible risks associated with nanomaterials in wastes. This is consistent given that the current discussion of possible risks associated with the presence of nanomaterials in wastes remains speculative, with no evidence of environmental harm to date.

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[3] Directive 2008/98/EC on waste, OJ L312 22.11.2008, 3-30

Specific concerns regarding the coverage of nanomaterials under the Waste Framework Directive include: uncertainties regarding the classification of specific nanomaterials as hazardous; and the presence of nanowaste in municipal waste streams.

The classification of wastes as non-hazardous or hazardous wastes is based on chemicals legislation, namely on Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation)[4]. The system for classifying wastes as hazardous is not tailored to the specific properties of nanomaterials and it is possible that, in the absence of *available* nano-specific data, nanomaterials will most likely be categorised according to the bulk form or even left unclassified due to the absence of the nano-specific information. Thus, in some cases hazardous properties may not be recognised.

The result of this is that requirements under the Waste Framework Directive that are triggered when wastes are categorised as hazardous may not apply to wastes containing specific nanomaterials, despite concerns regarding their toxicity. This includes the requirements to ensure traceability, prevent mixing with other categories of waste, package and label waste and maintain records.

The second principle concern relates to the disposal of consumer products containing nanomaterials in municipal waste streams, likely to be channelled for landfill or incineration. Currently, there are no obligations to label products as containing nanomaterials and no programmes established to separate out and collect end-of-life products containing nanomaterials for specific waste management procedures. As such, products containing nanomaterials will remain within the municipal waste stream, even when specific nanomaterials may have been classified as hazardous, since there is no basis for their separation. For example, zinc oxide is classified under the CLP Regulation as N, dangerous to the environment, and specifically as R50/53, very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Nano forms of zinc oxide are contained in a number of consumer products that can be expected to be disposed of in municipal waste streams, incluing sun screens, lipsticks, antibacterial lotions, paints and functional coatings on wood, plastics and fabrics. While life cycle assessments will have been undertaken for the bulk form of zinc oxide, the may not have taken into account the specific properties of the nanoform.

In reviewing the coverage provided by the Waste Framework Directive, a number of knowledge limitations were encountered. For example, information is lacking on the behaviour of nanomaterials in recycling and recovery processes, and very scarce regarding any possible release pathways through effluents and flue gases. The volumes of waste generated in the industrial synthesis of nanomaterials,

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[4] Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures, OJ L353 31.12.2008, 1-1355

their incorporation into products and the existence and volumes of any by-products generated by the various processes are unknown.

In conclusion, the main challenge in coverage of nanomaterials under the Waste Framework Directive relates to uncertainties surrounding the classification of specific nanomaterials as hazardous under the CLP Regulation. As such, this does not represent a legislative gap under the Waste Framework Directive, but rather points to possible deficiencies under EU chemicals legislation with regards to nanomaterials. A second issue relates to the disposal of consumer products containing nanomaterials in municipal waste streams, even if those nanomaterials had been identified as hazardous under CLP. Here, upstream product control offer a route for controlling releases of specific nanomaterials found to exhibit hazardous properties. However, it should be noted that this issue also exists for other hazardous substances that are incorporated into consumer products.

A number of options for managing nanowaste have been proposed by commentators and include elements such as: establishing a definition for nanowaste: including nanowaste as hazardous wastes in the List of Wastes; introducing “free nanoparticles” under Annex III of the Waste Framework Directive. However, in the absence of an obligatory labelling scheme for products containing nanomaterials, waste operators would not be in a position to identify nanowastes. End-of-pipe measures (including detection and sorting technologies) are not available and would be very costly to implement. In addition, it would be very difficult to monitor implementation of these provisions. The application to nanomaterials of existing hazard classifications under CLP on the basis of tailored tests would provide more effective up-stream control, and serve to generate an information flow down the value chain for products containing specific nanomaterials identified as hazardous. An assessment of the possible environmental impacts of a substance over its life cycle in all foreseen uses would identify any possible risks in the disposal phase. While such an assessment is included in the Chemical Safety Report under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[5], this is only required for substances placed on the market at volumes of 10 tonnes or more per year, implying that not all nanomaterials will be captured.

List of Wastes

The List of Waste established under Decision 2000/532/EC[6] serves to provide a common encoding of waste characteristics, including the classification of hazardous wastes. The current List of Waste does not mention wastes that contain nanomaterials in any form. In establishing the properties that led to

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[5] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1–849

[6] Commission Decision 2000/532/EC establishing a list of wastes, OJ L 226, 06/09/2000 p.3-2

the categorisation of a waste as hazardous, Article 2 of the Decision includes concentration thresholds for all properties other than thermal flash point. Mass-based thresholds may not be appropriate for hazardous nanomaterials, where hazard has been found to be less dependent of mass concentration but rather of concentration expressed in other metric such as the surface area.

Directive 2000/53/EC on end-of-life vehicles

Directive 2000/53/EC (the ELV Directive)[7] aims at reducing the quantity of waste arising from vehicles through the prevention of waste from vehicles and promoting the reuse, recycling and other forms of recovery of end-of-life vehicles and their components. Nanomaterials have an increasing number and range of applications in the design and manufacture of vehicles, including frames and body parts, engines and powertrain, paints and coatings, suspension and braking systems, lubrication, tyres, exhaust systems, catalytic converters and electric and electronic equipment.

An element of the Directive relevant to nanomaterials is Article 4 on prevention, which requires vehicle manufacturers to limit the use of hazardous substances in vehicles. The identification of hazardous substances is based on the CLP Regulation and hence subject to uncertainties regarding recognition of the nano-specific hazardous properties of specific nanomaterials. Again, this relates to the coverage of nanomaterials under CLP, rather than under the ELV Directive itself.

An additional aspect is the minimum technical requirements for the treatment of end-of-life vehicles. These requirements do not specifically consider any risks related to particular nanomaterials, which may be incorporated into vehicle parts or in traces of lubricants, oils and fuels on car parts. Further research would be required to justify and develop specific measures.

Landfill Directive 1999/31/EC

Directive 1999/31/EC[8] sets technical and operational requirements for dumping of waste in landfills with the aim of preventing or reducing negative effects on the environment, in particular the pollution of surface water, groundwater, soil and air. The key source of nanomaterials into landfills is the disposal of nanoproducts by consumers at the end of life phase of those products, their subsequent entry into the municipal mixed waste stream, and the channelling of that waste stream into landfill. Recent life cycle analyses suggest over 50% of nanomaterials produced will eventually reside in landfills.

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[7] Directive 2000/53/EC on end-of life vehicles, OJ L 269, 21.10.2000, p. 34–43

[8] Council Directive 1999/31/EC on the landfill of waste, OJ L 182, 16.7.1999, p. 1–19

Current knowledge regarding the long-term behaviour of nanomaterials in landfill is extremely limited. The release of nanomaterials incorporated in landfilled commercially-available products is probable, creating the possibility that nanomaterials may leach out of landfills and be released into groundwater and surface waters. It is also presumably possible that nanomaterials could be released from landfills to the air, with landfill gas, for example in the case of volatile nanomaterials. However, most nanomaterials are likely to be relatively non-volatile – for example C_{60} has a vapour pressure of around 6.7 x 10-4 [Pa] - making such releases less likely than releases in leachate.

The most significant issue in the potential for the Landfill Directive to address nanomaterials relates to whether hazardous nanowastes will be identified as hazardous according to the criteria set out in the CLP Regulation. As such, this is not a gap in waste legislation but rather a limitation in the capacity of the chemicals legislation to capture the potential risks of specific nanomaterials. In addition, information may not be available to landfill operators to allow for a basic characterisation of nanowaste upon arrival at landfills. A possible consequence is the dumping of hazardous nanowastes in landfills for municipal wastes.

Regarding the technical specifications in the Directive, leachate limit values have not been established with the particular characteristics and potentially increased toxicity of the nanoform in mind. It should be stressed that there is currently no evidence to suggest that nanomaterials are able to pass through the liners used to prevent leachate from passing into the environment, although this remains a subject of investigation.

WEEE Directive 2002/96/EC

The Waste Electronic and Electrical Equipment (WEEE) Directive[9], currently under the recast procedure, lays down requirements for the prevention of WEEE, for the reuse, recycling and other forms of recovery of such wastes so as to reduce their disposal. Nanomaterials are increasingly found in electrical and electronic equipment, being a key component in the new generation of computers and new compact energy sources such as lithium-ion batteries.

Impacts of nanomaterials on recycling processes for electrical and electronic equipment have so far not been reported. Releases of nanomaterials during these processes are possible.

The treatment requirements for WEEE do not currently address nanomaterials, nor is the removal of specific nanomaterials from WEEE required. The Commission may, however, include nanomaterials in the treatment requirements for WEEE in the future, if necessary.

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[9] Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), OJ L 37, 13.2.2003, p. 24–39

Directive 2002/95/EC on RoHS

The RoHS Directive[10] lays down rules on the restriction of use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste electrical and electronic equipment (WEEE). The recast of the RoSH Directive was published in the Official Journal on 1 July 2011 and will replace Directive 2002/95/EC on 2 January 2013.

The key issue for nanomaterials relates to the applicability of current substance concentration threshold values to nanomaterials, namely cadmium-based quantum dots. This is addressed in the recast of the Directive, where recital 16 backs the substitution of any hazardous substances, with specific reference to nanomaterials. No nanomaterials are as yet included under Annex II as restricted substances. Given the possibilities of releases of hazardous nanomaterials into the environment during recycling processes, this may be relevant.

Packaging and Packaging Waste Directive 1994/62/EC

Directive 1994/62/EC on packaging and packaging waste (the Packaging Directive) [11] lays down measures aimed, as a first priority, at preventing the production of packaging waste. Nanomaterials are increasingly used in packaging, with between 400 and 500 nano-packaging products thought to be in commercial use today.

Uncertainties relate to the possible impacts of nanomaterials on the reusability of packaging and on recycling processes, as well as possible emissions of nanomaterials from packaging during recycling and recovery processes. Should specific nanomaterials be found to impact on recycling processes, their upstream elimination from packaging may be considered, since additional sorting and collection schemes would be unrealistic in terms of the burden on the consumer.

In seeking to prevent the harmful effects of materials and substances used in packaging, the “prevention” mechanism relies on evidence of harm. In addition, the essential requirements for packaging set out in Annex II require that the presence of noxious and other hazardous substances in emissions, ash or leachate be minimized when packaging or residues from management operations or packaging waste are incinerated or landfilled. Robust evidence of harm or hazard is lacking for many nanomaterials despite indications from initial studies, making the application of these provisions to nanomaterials in packaging uncertain.

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[10] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), OJ L 174, 1.7.2011, p.88-110

[11] Directive 94/62/EC on packaging and packaging waste, OJ L 365, 31.12.1994, p.10-32

Sewage Sludge Directive 86/27/EEC

The aim of the Sewage Sludge Directive[12] is to encourage the spreading of sewage sludge from waste water treatment plants in agricultural fields and to prevent any harmful effects on soil, vegetation, animals and man. Nanomaterials may enter into sewage sludge during the generation of sludge in the waste water treatment plant, following the sedimentation of nanoparticles from waste waters. Possible sources of nanomaterials into waste waters include: washed off personal-care products; detergents and other cleaning products; releases from fabrics during washing; surface run-off of spilled lubricants, oils and fuels; and released from paints. Reports on the effectiveness of current waste water treatments in removing nanomaterials from waste waters are conflicting, although they agree that at least some of the nanomaterials present will be captured in sewage sludge. A recent study based on the modelling of nanomaterials in the environment suggested that nano-zinc oxide and nano-titanium dioxide tend to end up in soils through the spreading of sewage sludge, with titanium dioxide predicted to accumulate in the highest concentrations overall.

The Sewage Sludge Directive establishes limit values for heavy metals concentrations in soil (e.g. cadmium 1 to 3 mg/kg of dry matter), for heavy-metal concentrations of sludge for use in agriculture (e.g. cadmium 20 to 40 mg/kg of dry matter), for amounts of heavy metals which may be added annually to agriculture land based on a 10-year average (e.g. cadmium 0.15 kg per hectare per year). Limit values have been established for cadmium, copper, nickel, lead, zinc, mercury and chromium. There are no specific limit values for the nano-form of these heavy metals, or for any other specific nanomaterials. In addition, the requirements for analysis of sludge and soils do not cover nanomaterials.

Although a study suggests that for the EU the highest concentration of nanomaterials in environmental compartments will be found in sludge treated soil or sediment, the future establishment of limit values for nano concentrations in soil may not provide a solution for controlling releases. Firstly, there is no evidence base with which to establish thresholds below which no harm to human health of the environment can be foreseen. Secondly, mass-based limit values may not be adequate to ensure that the toxicity effects of nanomaterials are rendered negligible. Thirdly, the heterogeneous distributions of nanomaterials (in terms of shape, size, surface charge, composition and degree of aggregation or dispersion) mean that determining concentration within a given sample and deriving concentrations that accurately represent the characteristics of the whole is difficult. Finally, it is not currently technically feasible to monitor concentrations of nanomaterials in sludge.

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[12] Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, OJ L 181, 4.7.1986, p. 6–12

Water Framework Directive 2000/60/EC

Directive 2000/60/EC establishing a framework for Community action in the field of water policy[13] sets the legal framework for the protection and restoration of clean water across Europe, with the aim of ensuring its long term sustainable use. In protecting waters against pollution, the Water Framework Directive uses quality objectives to facilitate the management of concentrations of pollutants in surface waters and groundwater. These include the requirement for groundwater and surface waters to show good chemical status, and the requirement for surface waters to also meet good ecological status.

For surface waters chemical status is assessed with reference to EU Environmental Quality Standards (EQS) for priority substances (individual or group of pollutants posing a risk to or via aquatic environment) and other pollutants (substances regulated under previous piece of legislations), with concentrations below the EQS lending the water “good” chemical status. In setting the quality standards for European waters the Water Framework Directive works together with Directive 2008/105/EC on environmental quality standards in their field of water policy. However, the categorization of any specific nanomaterial as a priority substance is not currently feasible. There are significant problems with applying an approach based on quality standards to nanomaterials, given limitations in data on (eco)toxicology and problems in establishing mass-based thresholds for nanomaterials. In addition, categorisation would require evidence of the widespread contamination of European surface waters, with no evidence currently available on the concentrations of any nanomaterial in surface waters.

Complementary to the controls on priority substances, the Water Framework Directive also targets a number of other pollutants, as listed in Annex VIII. Metals and their compounds (point 7) and materials in suspension (point 10) are included under Annex VIII, implying that nanoforms of metals and metal compounds and nanomaterials that remain in suspension in water are covered, although this coverage is not specific to the nano-form. Inclusion under Annex VIII triggers the requirement to identify the significant pressures from point and diffuse sources of such pollutants, as well as the magnitude of the impact of these pressures at the water body level. In addition, achieving the good ecological status of surface waters requires that national EQS established for Annex VIII pollutants be met.

Monitoring programmes established for river basins under the Water Framework Directive are intended to identify pollutants and establish the source, in terms of both diffuse and point sources. However, monitoring nanomaterials in water is a challenging task, with a limited number of

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[13] Directive 2000/60/EC establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p1-82

specialised techniques restricted to university laboratories. Detection limits for most methods are too low to detect environmental concentrations of nanonmaterials, sample and analytical methods are not developed, and techniques cannot distinguish between engineered and naturally occurring nanomaterials. As such, the lack of cost-effective and reliable monitoring techniques across European river basins makes gathering data on the presence of nanomaterials in European surface waters currently impossible.

In principle, the Water Framework Directive provides coverage of nanomaterials, should they be detected as pollutants of European waters. Pollutants may be dealt with either as priority substances (where there is evidence of EU-wide pollution), or as Annex VIII pollutants (for specific river basins) and for both triggers exist for control measures, should relevant EQS be transgressed. In practice, however, there exist a number of problems with applying the current approach to nanomaterials. Firstly, major limitations in current capacities to detect and then perform ongoing monitoring of nanomaterials pollutants of waters mean that they will not currently be detected in surface waters. This creates a catch 22, whereby nanomaterials will not be detected as pollutants of surface waters, will not therefore be monitored and as a result there is no body of data to justify their inclusions are either priority substances or Annex VIII pollutantsSecondly, it is not possible to categorise any specific nanomaterial as a priority substance using current tools. Were nanomaterials to be detected, the Water Framework Directive includes triggers for action to reduce pollution from both point and diffuse sources. However, current end-of-pipe techniques may not be adequate to control point source emissions of nanomaterials, while the most effective means of controlling diffuse sources would likely be through up-stream controls on the applications of nanomaterials. Further research is required to assess the efficiency of a range of end-of-pipe controls in eliminating specific nanomaterials from waste waters.

Given that the literature identifies releases of waste water effluent as a key source of exposure of the aqueous environment to nanomaterials, the inability of current tools under the Water Framework Directive to identify and control these releases represents a gap. The gap exists firstly because of the infeasibility of applying the Combined Monitoring-based and Modelling-based Priority Setting (COMMPS) Scheme for identifying priority substances to nanomaterials, and secondly because of the inapplicability of an approach based on environmental quality standards to nanomaterials as pollutants of surface waters. The COMMPS procedure responds to Article 16 of the Water Framework Directive and is a tool developed to implement the Water Framework Directive. The inapplicability of this implementation tool to nanomaterials is therefore an implementation gap. This implementation gap could be addressed over time were the tool to be adapted to accommodate nanomaterials, although significant challenges relating to the lack of monitoring data on nanomaterials in surface waters remain. In the absence of specific requirements and technical competence for monitoring nanomaterials in river basins, the generation of such data is not foreseen.

Problems with the application to nanomaterials of an EQS-based approach to controlling pollutants represent a legislative gap in the coverage of nanomaterials, since they relate to the relevance to nanomaterials of the threshold-based approach taken by the Water Framework Directive to controlling pollutants. Finding a solution to this gap depends on an increased understanding of the (eco)toxicology of specific nanomaterials at different concentrations in the aqueous environment. Initial studies suggest that results can vary significantly depending upon multiple variables (both related to the specific nanomaterials and the environmental conditions), questioning the applicability of traditional approaches to building a body of robust evidence. Given the limitations in scientific understanding, the application of the precautionary principle to regulating the potential risks of nanomaterials in surface waters is relevant.

Directive 2008/105/EC on Environmental Quality Standards

Directive 2008/105/EC[14] lays down environmental quality standards (EQS) for priority substances and certain other pollutants as required under Article 16 of the Water Framework Directive. Currently, no nanomaterial has specifically been included as a priority substance in Annex I of Directive 2008/105/EC, although the EQS set for Cadmium and Nickel would also apply for the nanoform.

A key question in regard to Directive 2008/105/EC and Directive 2000/60/EC is whether nanomaterials are possible candidates as priority substances. For now however, the inclusion of some nanomaterials as priority substances under the Water Framework Directive remains a theoretical scenario. Application of the Combined Monitoring-based and Modelling-based Priority Setting (COMMPS) scheme with which priority substance are established to nanomaterials is hampered by a lack of data of the (eco)toxicology of nanomaterials, the unlikelihood of nanomaterials being detected by current monitoring techniques, and the lack of prior reference to nanomaterials as hazardous under other EU and international legislation.

Should a nanomaterial nevertheless be included on the list of priority substances, the establishment of the EQS for any given nanomaterial is hampered by the lack of ecotoxicological data on toxicity, persistency and bioaccumulation, which makes it virtually impossible to set an EQS for nanoparticles.

Finally, monitoring and long-term trend analysis is required for priority substances. This is not currently possible for nanomaterials due to technical challenges such as insufficiently low detection limits for most methods, high background of natural and unintentionally produced nanoparticles in environmental samples.

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[14] Directive 2008/105/EC on environmental quality standards in their field of water policy, OJ L 348, 24.12.2008, p84-97

Groundwater Directive 2006/118/EC

The Groundwater Directive[15] establishes common monitoring methodologies, including criteria for assessing good groundwater chemical status and criteria for the identification of significant and sustained upwards trends and for the definition of starting points for trend reversals. Furthermore, the Groundwater Directive establishes measures for preventing or limiting the inputs of pollutants to groundwater, in addition to those laid down under the Water Framework Directive. Specific provisions relate to the protection of groundwaters to be abstracted for drinking water.

The coverage issues identified for the Groundwater Directive are tightly linked with those for the Water Framework Directive and the EQS Directive, relating to the absence of techniques for the detection and monitoring of nanomaterials and problems with establishing quality standards. Firstly, the criteria for assessing groundwater chemical status may fail to capture nanomaterial pollutants as monitoring techniques not sufficiently developed to allow for reliable, low-cost monitoring of nanomaterials in groundwater. Secondly, were nanomaterials to be detected as pollutants, there is insufficient data on ecotoxicity of nanomaterials in the aquatic environment to establish threshold values for specific nanomaterials. Thirdly, knowledge is too limited to allow for an assessment of the risk from nanomaterial pollutants in groundwater to be abstracted for drinking water. Finally, the reliability of technical measures to prevent or reduce inputs of nanomaterial pollutants into groundwater from point and diffuse sources is uncertain. In addition, there is no basis for establishing starting points for trend reversal in concentrations, should nanomaterials be detected in groundwater.

As such, gaps in implementation relate mainly to a lack of scientific knowledge regarding the (eco)toxicology of nanomaterials and a lack of technical capacity for monitoring nanomaterials in the aqueous environment. In terms of a legislative gap, the question of applicability of mass-based threshold values to a number of nanomaterials is again relevant.

Urban Waste Water Directive 91/271/EEC

The Directive on urban waste water treatment[16] regulates the collection, treatment and discharge of urban waste water and the treatment and discharge of waste water from certain industrial sectors. Possible sources of nanomaterials into waste water include: washed-off cosmetics and personal care products; detergents and other cleaning products disposed of down the drain; nanomaterials released from fabrics during washing; surface run-off containing spilt lubricants, fuels and oils; nanomaterials released from paints; and direct applications into water, such as water purification.

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[15] Directive 2006/118/EC on the protection of groundwater, OJ L 372, 27.12.2006, p19-31

[16] Directive 91/271//EEC concerning urban waste-water treatment, OJ L 135, 30.5.1991, p. 40–52

The main question regarding coverage afforded by the Urban Waste Water Directive is whether the treatment requirements under this Directive are adequate to address nanomaterials in urban waste water. The technical requirements of the Urban Waste Water Directive do not specifically consider the presence of nanomaterials in urban waste water and do not provide for the monitoring of nanomaterials in wastewater effluent. Since the monitoring requirements do not include any other specific hazardous chemicals, but rather chemical oxygen demand in general, it would seem to be lending an undeserved focus to nanomaterials to include them before other hazardous substances for which evidence on hazard and exposure scenarios is considerably more robust. It is not, therefore, considered reasonable to identify this as a legislative gap, despite the identification of waste water as a major release path for nanomaterials into the environment (together with sewage sludge).

Regarding the efficiency of current water treatment techniques in removing nanomaterials from waste waters, there is no clear consensus in the scientific community on this issue. Laboratory studies have found removal rates into sludge vary depending upon the specific nanomaterials (e.g. 97% silver nanomaterials, 13% fullerol suspension). Given that these initial studies suggest that the efficiency of the removal of nanomaterials from wastewater is dependent upon the specific nanomaterials, further research should be conducted to determine which specific nanomaterials are being released into the environment from waste water treatment plants in order to inform decision making.

Drinking Water Directive 98/83/EC

Directive 98/83/EC on the quality of water intended for human consumption[17] sets out quality standards for drinking water, as well as specifying the parameters that must be monitored to ensure that quality is maintained. Limitations in the coverage of nanomaterials relate to the applicability of quality standards and the technical capacity for monitoring nanomaterials in drinking water.

The entry of nanomaterials into the aquatic environment through effluent releases from wastewater treatment plants, surface run-off, intentional release (i.e. water purification techniques using nanomaterails) and diffuse sources raises the concern that drinking water sources will become contaminated with nanomaterials and possibly lead to risks for human health. Some laboratory scale studies have been undertaken on the fate and behaviour of nanomaterials in drinking water and their potential removal, concluding that while most drinking water treatment processes have not been designed to remove nanomaterials, some removal may occur through coagulation, sedimentation and filtration. However, studies suggest a fraction (10-30%) of nanomaterials can be expected to remain in the drinking water.

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[17] Directive 98/83/EC on the quality of water intended for human consumption, OJ L 330, 5.12.1998, p. 32–54

The quality standards for drinking water are laid down for a range of parameters in Annex I, with Member States obliged to set values for water intended for human consumption that are equal or more stringent. Chemical parameters for which values are set include several substances for which nanoforms are currently in use (nickel, cadmium, copper). However, the associated parametric values have not been established with consideration of the intrinsic properties of the nanoforms. In addition, a large number of nanomaterials are not captured by the parameters under Annex I Part B, including some of the most commonly used such as carbon nanotubes, C_{60} fullerenes and a range of other metal and metal oxides.

Monitoring requirements are set for a range of parameters, including minimum requirements for monitoring programmes and methods for analysis. The requirements do not specifically mention nanomaterials, although again some nanomaterials would be captured under certain substances (cadmium, nickel, copper, iron). The Directive states that additional monitoring should be carried out for substances for which no parametric value has been set if there is reason to suspect that they are present in volumes that constitute a potential danger to human health. This affords a theoretical possibility for Member States to include nanomaterials, however in practice the required monitoring techniques are not available.

In addition, Article 8(3) of the Drinking Water Directive requires that Member States ensure that any supply of drinking water that constitutes a danger to human health is prohibited or its use restricted until action is taken to protect human health. Should nanomaterials, or a specific nanomaterial, be found to pose a significant threat to human health and be detected in drinking water, this provision would then require that action be taken. Given current limitations in technical capacities to effectively remove nanomaterials from drinking water, it would seem that upstream controls of point and diffuse sources would be required. Such measures could be enacted under Article 7 of the Water Framework Directive, where Member States are required to ensure the necessary protection of bodies of water used for the abstraction of drinking water. Given the importance of protecting human populations from potential risks, it is relevant to apply the precautionary principle to the enactment of measures to control the entry of specific nanomaterials into drinking water.

In theory, the Drinking Water Directive provides legal mechanisms by which the presence of specific nanomaterials in drinking water could be controlled, including establishing quality standards and remedial action and restrictions in use. However, in practice both mechanisms would require that the nanomaterials are first detected in drinking water, which is considered unlikely given the absence of specific monitoring requirements and the lack of technical capacity. In addition, the applicability to nanomaterials of an approach based on quality standards is again called into question, in a context where data with which to establish threshold concentrations at which nanomaterials pose no threat to human health is lacking. Although these issues represent possible areas of concern, there is currently no evidence to suggest that drinking water is contaminated with nanomaterials. As such, a first step would be to conduct testing using standardised approaches in order to provide a coherent body of evidence for decision making.

Seveso II Directive 96/82/EC

The safety of chemical facilities at EU level is directly addressed by Council Directive 96/82/EC on the control of major-accident hazards, the so-called SEVESO-II Directive[18]. The Directive aims at the prevention of major-accident hazards involving dangerous substances and the limitation of the consequences of such accidents for man and the environment, if they do occur. A review of the SEVESO-II Directive has recently been concluded and, on 21 December 2010, the Commission adopted a proposal for a new Directive that would repeal and replace the current Directive by 1 June 2015. The SEVESO-II Directive takes a tiered approach to requiring safety measures at facilities based on the volumes of dangerous substances present at facilities. As such, dangerous substances are defined in Annex I, together with the thresholds for each substance that trigger requirements.

In general, the provisions of the SEVESO II Directive provide coverage of nanomaterials. The application of SEVESO II to hazardous nanomaterials depends upon their being effectively classified as hazardous under the CLP Regulation, this being subject to some constraints as discussed previously. Article 4 of the Commission Proposal provides a channel for introducing nanomaterials under Annex I, should a Member State identify major-accident risks associated with specific nanomaterials. It would then be necessary to develop thresholds for these nanomaterials.

A potential concern comes with the application of the volume thresholds for categorising sites as upper or lower tier, since the hazard associated with nanomaterials relates less to the mass of the substance and more to other charcteritics such as surcace area concentration. However, at this stage, there is insufficient data available to define appropriate thresholds for nanoforms of substances categorised under Annex I Part 1 or Part 2.

Air Quality Directive 2008/50/EC

Directive 2008/50/EC[19] defines and establishes objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment. The risk management measures on ambient air quality under this Directive apply to specific targeted pollutants which are

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[18] Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (OJ L 10, 14.1.1997, p. 13)

[19] Directive 2008/50/EC on ambient air quality and cleaner air for Europe, OJ L 152, 11.6.2008, p. 1-44

sulphur dioxide, nitrogen dioxide and oxides of nitrogen, lead, benzene, carbon monoxide and particulate matter (PM_{10} and $PM_{2.5}$). Risk management measures for PM_{10} and $PM_{2.5}$ are of relevance to nanomaterials.

Nanomaterials and ultrafine particles only represent a small fraction of the ambient $PM_{2.5}$ or PM_{10} mass but may make up a large proportion of airborne particles by number. Significant sources include: road and other transport; residential/commercial combustion; industrial combustion and industrial process emissions; power generation; and agriculture.

A lack of information on the toxicity of nanomaterials to human health when inhaled through ambient air makes it difficult to assess the coverage provided by the Air Quality Directive. While it may seem desirable to have limit values and assessment thresholds, the data required to allow for their establishment is not available. In addition, the current reference measurement methods are not applicable and no appropriate standards exist.

Whilst the existing Directive does not specifically cover nanomaterials or ultrafine particles and the test methods used do not specifically identify the nano-fraction, a portion of the PM_{10} and $PM_{2.5}$ fractions will be ultrafine particles and hence subject to indirect control/coverage by the Directive.

There exists the potential to introduce new pollutants into the Directive. The Directive therefore provides a potential legal mechanism for reducing pollution to levels which minimise harmful effects on human health in relation to nanomaterials and/or ultrafine particles. However, given the level of data currently available, further work would be required to develop appropriate metrics for dose and monitoring/characterisation strategies and relevant limit values or target values, if appropriate. There would also need to be further work related to determining appropriate sampling locations; approaches for dealing with contributions from natural sources; and the techniques that would need to be used within Member States in developing plans and programmes to achieve reductions in ambient concentrations.

EU Ecolabel Regulation No. 66/2010

This Regulation[20] lays down rules for the establishment and application of the voluntary EU Ecolabel award scheme. It applies to any goods or services that are supplied for distribution, consumption or use on the Community market whether in return for payment or free of charge. The issue is whether products containing potentially dangerous nanomaterials for health and/or the environment (e.g. detergents containing nanosilver) could still be granted an EU Ecolabel.

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[20] Regulation (EC) No 66/2010 on the EU Ecolabel, OJ L 27, 30.1.2010, p. 1–19

A common approach to nanomaterials has been consistently applied in the recent revision of EU Ecolabel criteria for three product categories, and will now be consistently applied to the review of criteria for specific product categories. The product groups for which decisions for the EU Ecolabel criteria have been taken include hand dishwashing detergents, all-purpose cleaners and sanitary cleaners, and lubricants. The new criteria specify that nanoforms of hazardous substances classified as such under the CLP Regulation shall be excluded from products awarded the EU Ecolabel at any concentration. This recognises the fact that the risks associated with nanomaterials may not be directly linked to mass concentrations. In addition, a requirement to provide data specific to substances in the nanoform should serve to generation information on the applications of nanomaterials, if only within products seeking registration under the EU Ecolabel.

As with most other EU environmental legislation (excluding water legislation) the EU Ecolabel relies on the categorisation of substances under the CLP Regulation as hazardous when excluding hazardous substances from EU Ecolabel products. As discussed previously, some nanomaterials that exhibit hazardous properties not seen in the bulk from may not be captured under the CLP criteria.

Summary of Feedback from Member States on Activities on Nanomaterials

Initiatives towards the establishment of national databases for nanomaterials are being undertaken in Italy, Belgium and France. These initiatives sit within the context of a common project “Towards harmonization of national databases for nanomaterials on the market”. France is the only country to have taken legal action to require the declaration of the production, importation or placing on the market of nanoparticles or materials that may emit such substances, although the requirement is not yet in force. In addition, a number of other Member States have initiated discussions regarding possible national nanomaterials databases. Other action taken by Member States to date regarding nanomaterials has mainly involved studies and analyses to determine the legislative coverage of nanomaterials, assess applications on the market and investigate specific technical questions.

Conclusions

In undertaking a review of EU environmental legislation on waste, water and three other legislative acts (namely the SEVESO II Directive, the Air Quality Directive and the EU Ecolabel Regulation) for their coverage of nanomaterials, this report identifies those environmental exposure pathways for nanomaterials relevant to each piece of legislation and assessed the level of control afforded over possible releases of nanomaterials. The identification of gaps in the coverage of nanomaterials under EU environmental legislation and its subsequent implementation required an understanding of the potential risks associated with environmental exposure to nanomaterials. This understanding drew on possible environmental exposure pathways for specific nanomaterials and for nanomaterials in general and on data on the possible hazards associated with specific nanomaterials that were identified in the literature. Although a wide range of possible exposure pathways were identified, concrete evidence of releases was only found to support some of these pathways, notably releases of treated waste waters into surface waters and into soil through sewage sludge and treated effluent from sewage plants. For other pathways, either the very limited number of studies or the complete lack of studies made the identification of possible exposure more speculative. Regarding hazards, there is a lack of ecotocicological data even for the most tested nanomaterials such as fullerenes, carbon nanotubes, nano titanium dioxide, nano zinc oxide, and nano silver. The wide range of different nanomaterials and the subsequent diversity of their environmental footprints mean that general statements cannot be made concerning the hazards associated with nanomaterials.

Limitations in both exposure data and hazard data for specific nanomaterials made it extremely difficult to assess the potential risks of nanomaterials. In turn, the lack of a clear and comprehensive overview of the risks posed by nanomaterials made the identification of both implementation and legislative gaps challenging. In assessing each piece of legislation against potential risks, a distinction was made between the kinds of gaps in coverage that were identified, be they gaps in implementation or actual gaps in the legislative framework. Issues relating to limitations in data, a lack of technical capacity, or the inapplicability of implementation tools were considered to be implementation gaps, since these gaps could be addressed through further research and/or technical developments. The identification of a legislative gap required that an environmental risk from nanomaterials that is flagged as high in peer-reviewed scientific articles is not captured by the legislative framework. This could be either because approaches to identifying and controlling emissions employed under specific legislation are considered inappropriate for nanomaterials, or because the legislation does not provide for the control of specific release pathways. Where the discussion of possible pathways for environmental exposure was speculative rather than being based on evidence, the study nevertheless flagged potential issues in the interest of being comprehensive, without going so far as to label these issues as gaps.

In terms of the level of coverage afforded to nanomaterials, all the legislation reviewed could be considered to address nanomaterials in principle. However, several pieces of legislation were found to have some limitations in the coverage of nanomaterials, resulting generally from a lack of knowledge and technical capacity (in particular monitoring and detection techniques) and in some cases from the inapplicability of existing legal mechanisms (such as concentration thresholds to control the presence of pollutants).

In particular, the water legislation is considered limited in providing for the control of nanomaterials as pollutants in surface waters, groundwater and drinking water. Limitations stem from a lack of technical capacity to detect and monitor nanomaterials in aqueous environment and a lack of reliable data on the ecotoxicology of nanomaterials to feed into risk assessments, representing implementation gaps. In addition, there are questions surrounding the applicability of a threshold-based approach to controlling pollutants, in a context where the potential adverse effects associated with nanomaterials are not solely dependent on exposure in terms of the mass concentration.

Concerns regarding the coverage of nanomaterials under waste legislation reflect uncertainties surrounding the classification of specific nanomaterials as hazardous under the CLP Regulation. In common with the water legislation, a number of limitations that fall under the scope of the waste legislation relate to the applicability of threshold-based limit values to nanomaterials, for example under the Lits of Waste, Sewage Sludge Directive, Landfill Directive and RoHS Directive. It should be noted that environmental exposure pathways for nanomaterials in waste have received less attention under scientific studies than those in water, and this made it difficult to assess coverage and identify specific gaps.

A number of cross-cutting issues were identified that limit the effectiveness of environmental legislation in addressing nanomaterials in practice and these are discussed below. Firstly, a high proportion of the legislation is depended upon the CLP Regulation for the identification of hazardous substances. In the absence of *available* nano-specific data, nanomaterials will principally be categorised according to the bulk form and in some cases hazardous properties may not be recognised. This would imply that operative provisions across a range of environmental legislation that serve to control releases of hazardous substances into the environment would not be triggered for specific nanomaterials.

Limitations in the availability of cost-effective monitoring techniques have significant implications for the detection of pollutants under water legislation. The detection of pollutants in surface waters (under the Water Framework Directive) and groundwater (under the Groundwater Directive) under specific monitoring programmes serves to trigger measures to control these pollutants. Without the capacity to monitor nanomaterials in water there will be no data, hence measures will not be triggered, even in cases where nanomaterials are present as pollutants. Further research is required to investigate the future feasibility and relevance of monitoring the concentrations of nanomaterials in different environmental compartments.

Another cross-cutting issue relates to questions regarding the applicability of mass-based thresholds to nanomaterials. The specific properties of nanomaterials mean that concentrations given in mass terms and used to establish thresholds are not accurate for nanomaterials, since toxicology studies indicate that toxicity increases with decreased dimensions for nanomaterials. Further research is required on the fate and behaviour of nanomaterials in the environment, as well as on their toxicology, to determine whether it will be possible in the future to establish threshold values for specific nanomaterials with confidence.

Finally, the implementation of legislation suffers from the lack of data regarding the intrinsic properties of specific nanomaterials and their behaviour in environmental compartments, in particular when considering their large variety stemming also from differences in size distribution and particle coating. It implies that both regulators at the EU level and practitioners on the ground are struggling to manage a risk that remains essentially unquantifiable.

Given the particular emphasis on managing limitations in scientific knowledge, recourse to the precautionary principle would seem to be particularly relevant to the regulation of nanomaterials.

1. Introduction

1.1 Background to the study

A review of the current applications of nanomaterials and the rapid growth of the nanomaterials and nanotechnology industry over the past decade suggest that emissions during the life cycle of these applications will generate multiple sources of nanomaterials into the environment. A number of commentators have flagged the need for a prompt regulatory response to avoid harm to human health and the environment through the inappropriate and inadequate control of the entry of nanomaterials into the environment[21]. Current EU legislation has been developed without consideration of the specific properties of nanomaterials and how they might behave in waste materials and management processes. This raises questions regarding the adequacy of the existing frameworks to respond to the potential risks posed by nanomaterials.

The European Parliament's Resolution of 24 April 2009[22] commenting on the Commission Communication on regulatory aspects of nanomaterials[23] explicitly calls on the Commission to evaluate the need to review waste legislation, emission limit values and environmental quality standards in air and water legislation to adequately address nanomaterials. In response, DG Environment contracted[24] Milieu Ltd and AMEC Environment & Infrastructure UK Ltd. to assess whether key EU environmental legislation adequately addresses nanomaterials. EU legislation addressed within the context of this review is presented in Box 1. Here, it is relevant to note that releases of nanomaterials and ultra-fine particles from industrial installations were addressed in a parallel study[25]

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[21] NanoKommission "Verantwortliche Umgang mit Nanotechnologien" (2011) BMU, Germany, available at: http://www.bmu.de/files/pdfs/allgemein/application/pdf/nano_schlussbericht_2011_bf.pdf; Musee, N., "Nanowastes and the environment: Potential new waste management paradigm." (2011) Environment International 37, 112- 128, Franco, A., Hansen, S.F., Olsen, S.I. and Butti, L. 2007, "Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials," Regulatory Toxicology and Pharmacology, 48, 171-183

[22] European Parliament resolution on "Regulatory aspects of nanomaterials," (2008/2208(INI))

[23] COM (2008)366 final. Regulatory aspects of nanomaterials, and SEC (2008) 2036 final

[24] Contract № 070307/2010/580540/SER/D3

[25] Tender reference no. ENV.C.4/SER/2010/0006 "Industrial emissions of nano- and ultrafine particles" undertaken by AMEC Environment & Infrastructure UK Ltd.

Box 1: EU environmental legislation to be reviewed within the scope of this project

Waste legislation	**Water legislation**	**Other relevant legislation**
• Waste Framework Directive 2008/98/EC; • The list of waste decision 2000/532/EC; • The landfill Directive 1999/31/EC; • Waste acceptance criteria in landfills in Decision 2003/33/EC; • Sewage sludge Directive 86/278/EEC; • WEEE and RoHS Directives 2002/95/EC, 2002/96/EC; • Directive on end-of-life vehicles 2000/53/EC; • Directive on packaging waste 94/62/EC	• Water Framework Directive 2000/60/EC; • Directive 2008/105/EC on environmental quality standards in the field of water policy; • Directive 2006/118/EC on the protection of groundwater against pollution and deterioration; • Urban waste water Directive 91/271/EEC; • Drinking water Directive 98/83/EC; • Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment;	• Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (Seveso II Directive) • Regulation (EC) No 66/2010 on the EU Ecolabel

1.2 Objectives of the study

The key objectives of this study are identified below.

- Develop a methodological framework that allows for a coherent assessment of the coverage of nanomaterials across different pieces of legislation, including both a legal analysis and a review of existing implementation set ups.
- Review all the relevant legislation listed in Box 1 as regards their coverage of nanomaterials.
- Identify and describe legislative and implementation gaps in environmental legislation as regards their coverage of nanomaterials. In particular, the report should identify whether the gap is due to, *inter alia*:
    - nanomaterials not being covered by the general objective of the legislation;
    - nanomaterials being covered by the general objectives but explicitly excluded from the scope (e.g. not on the list of regulated pollutants);
    - nanomaterials being covered in principle but not effectively addressed (e.g. issue of metric or measurement method, monitoring criteria etc.); or

  - nanomaterials being ineffectively covered due to implementation gaps or critical dependence on other legislation.
- Hold a stakeholder workshop to act as a sounding board against which to test the conclusions of a draft report, as well as providing up to date information on Member State activities regarding nanomaterials and their potential environmental impacts.

Regarding the final objective of the study was to hold a stakeholder workshop with the aim of gathering additional information from Member States on national approaches to regulating the environmental exposure of nanomaterials, including both legal and implementation measures. This meeting was held on 20th June 2011 at DG Environment, Brussels, Belgium. The workshop was attended by approximately 25 participants, with representatives from Belgium, Denmark, France, Germany, Italy, Latvia, the Netherlands, Poland and the UK, as well as representatives from the following Commission Services: DG Environment, DG Enterprise and Industry, DG for Health and Consumers (DG SANCO) and DG Employment, Social Affairs and Inclusion.

The objectives of the workshop were to gather expert feedback on the conclusions presented in an earlier draft of this Final Report and to gain an insight into policy initiatives and activities undertaken on the ground in Member States regarding the potential environmental impacts of nanomaterials. Workshop participants listened to presentations on each of the pieces of legislation addressed under this study, as well as on a number of cross-cutting issues identified during the analysis, including limitations in the availability of (eco)toxicology data on nanomaterials; techniques for monitoring nanomaterials *in situ*; and end-of-pipe control techniques for controlling point source emissions of nanomaterials. In addition, the interface between environmental legislation and the classification of substances as hazardous under Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation)[26] was addressed. Participants had an opportunity to discuss the conclusions presented in a draft version of this final report and to provide updates on relevant activities at Member State level. Discussions on the coverage of nanomaterials provided by each piece of legislation are summarised in text boxes at the end of each section of this report.

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[26] Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures, OJ L353 31.12.2008, 1-1355

1.3 Methodological framework

This section provides a summary of the methodological framework applied in the analysis of the coverage of nanomaterials under EU environmental legislation, including a legal analysis and implementation set-ups.

Scope and approach

Regarding the scope of the study, the focus throughout is on possible releases of engineered nanomaterials (referred to simply as nanomaterials) into the environment. Where the study addresses releases of naturally occurring nanomaterials, their origin as natural is specific mentioned.

This study has taken a general approach to assessing whether the risks associated with nanomaterials are covered by relevant legislation. Particular attention was paid to areas where nanomaterials are covered in principle due to assumptions about their being similar to the respective substances at the bulk scale. However, is it recognised that there are differences in the potential risks posed by different nanomaterials due to differences in their intrinsic properties and the exposure pathways that result from the life cycles of products containing specific nanomaterials. In addressing these differences, the report includes text boxes on some of those nanomaterials that make up the bulk of the volume of nanomaterials present in consumer products the market today, namely: nano silver, nano titanium dioxide, nano zinc oxide, carbon nanotubes, C_{60} fullerenes and nano tungsten disulphide.

Step 1) Analysis of coverage of nanomaterials

The methodological framework ensured a consistent and coherent approach to reviewing the legislation, at the same time as allowing for a degree of flexibility required given the range of legislative acts to be reviewed. The analysis of the coverage of nanomaterials under each piece of legislation was framed by a number of key regulatory questions, namely:

1. Are nanomaterials covered in the general objectives?
2. Does the legislation rely on a list of substances and are nanomaterials included in the list?
3. What are the tools used to control releases or environmental concentrations? Environmental Quality Standards (EQS), Emission Limit Values (ELVs)? Are they also effective for nanomaterials?
4. Are thresholds/limits applicable to nanomaterials in terms of volume and associated risks? Can sources of nanomaterials be identified?
5. What are the relevant exposure pathways and are they controlled?

6. Are there examples of any specific nanomaterials that can be associated with these sources and exposure pathways?
7. Are monitoring requirements applicable to nanomaterials in terms of volume and associated risks (consider any criteria, measurements requirements, thresholds, regularity, who monitors, is there control by an authority or self monitoring)? Is it possible to apply the monitoring requirements to nanomaterials?

In conducting the investigation we went beyond a dry legal analysis and to review actual implementation on the ground, to the extent possible. As such, we also sought to address questions regarding the capacity amongst Member State authorities to apply provisions to nanomaterials, where relevant.

1. How much do authorities managing waste or wastewater treatment know about nanomaterials? What is the expertise in agencies in Member States expected to enforce this legislation? Do they have relevant measuring equipment?
2. What are the penalties for non compliance and are they relative to the risks from nanomaterials? Can the polluter be identified in the case of nanomaterials in waste?
3. How is the legislation being implemented, are there issues of concern regarding the application of legislation to nanomaterials?

In practice, answering these questions proved difficult due to the lack of information available, a result in itself. In including information on practice on the ground in our review, we also drew on feedback from Member States at the workshop. In addition, we sent out a written request for information channeled through the Commission to Member State authorities. The information request specific asked Member States to address the questions listed above. Responses were received from five Member States, namely Denmark, France, Portugal, Estonia and Sweden. These responses are presented in section 19 of this report.

In examining each piece of legislation we have sought to be comprehensive in reviewing the extent of coverage of nanomaterials provided. The results of this stage of the analysis are presented in the body of each chapter of specific pieces of legislation. **Where we have stated that nanomaterials are not explicitly covered, it should be noted that it is not our intention to suggest that this is necessarily a legislative gap but rather to map coverage of nanomaterials under the relevant legislation.**

Step 2) Identification of gaps in legislation and implementation

The identification of gaps in the coverage of nanomaterials under EU environmental legislation and its subsequent implementation required an understanding of the potential risks associated with environmental exposure to nanomaterials. This understanding drew on possible environmental exposure pathways for specific nanomaterials and for nanomaterials in general and on data on the possible hazards associated with specific nanomaterials that were identified in the literature. This picture of potential risks was compared against the coverage provided by each piece of legislation, allowing for the identification of any possible gaps. It is important to note here that data on environmental exposure pathways and hazards was very limited. Therefore, an important element of the methodological framework was the approach taken to identifying exposure pathways and assessing the hazards posed by nanomaterials in the light of limited information. There were no studies available that provided a clear quanitification of the risks posed by environmental exposure to nanomaterials, rather the estimation of risks tended to be speculative and qualitative in nature (i.e. ranking risk in terms of low, medium or high).

Our approach in identifying possible exposure pathways was to identify potential pathways for the release of nanomaterials along the life cycle of a product containing nanomaterials. In doing so we referred to the existing literature on nanomaterials, including studies of actual exposure, simulation studies and studies that use modelling to estimate environmental exposure. Where we found evidence of releases of nanomaterials into the environment from specific exposure pathways, we have cited this evidence. Where commentators have suggested that nanomaterials may enter into the environment through specific pathways but there is no evidence to date, we have included the pathway as a possible route of environmental exposure but explicitly highlighted the lack of evidence. Any discussion of possible issues of coverage relating to exposure routes for which no evidence has been found remains speculative.

Regarding hazards, there is a lack of ecotocicological data even for the most tested nanomaterials such as fullerenes, carbon nanotubes, nano titanium dioxide, nano zinc oxide, and nano silver. This study does not seek to comprehensively review the evidence on the potential hazards associated with specific nanomaterials. Rather it draws on studies to illustrate the hazards associated with specific nanomaterials and highlighted possible exposure pathways for these nanomaterials, with this material presented in the text boxes on specific nanomaterials. As such, the information on hazards is limited to specific examples that serve to illustrate the general discussions. The wide range of different nanomaterials and the subsequent diversity of their environmental footprints mean that general statements cannot be made concerning the hazards associated with nanomaterials.

The abovementioned limitations in both exposure data and hazard data for specific nanomaterials made it extremely difficult to asses the potential risks of nanomaterials. In turn, the lack of a clear and comprehensive overview of the risks posed by nanomaterials made the identification of both implementation and legislative gaps challenging. In assessing each piece of legislation against potential risks, a distinction was made between the kinds of gaps in coverage that were identified, be they gaps in implementation or actual gaps in the legislative framework. Issues such as the absence of monitoring techniques to allow for the identification of nanomaterials pollutants in water were considered to be implementation gaps. Aspects of legislative acts that can be modified under comitology procedures were also considered implementation gaps. In addition, an inapplicability of the tools developed to implement legislation was considered an implementation gap. The identification of a legislative gap required that an environmental risk from nanomaterials that is flagged as high in peer-reviewed scientific articles is not captured by the legislative framework. This could be either because approaches to identifying and controlling emissions employed under specific legislation are considered inappropriate for nanomaterials, or because the legislation does not provide for the control of specific release pathways. Where the discussion of possible pathways for environmental exposure was speculative rather than being based on evidence, we nevertheless flagged issues in the legislation in the interest of being comprehensive, without going so far as to label these issues as gaps.

Interpreting the results: distinguishing between coverage issues, legislative and implementation gaps

In interpreting the results presented in this report, it is important to distinguish between the outputs of the two key steps in the methodology for the legal analysis, 1) the review of coverage of nanomaterials and 2) the subsequent identification of legislative and implementation gaps. Step 1) serves to "map" coverage of nanomaterials under each piece of legislation, while step 2) identifies potential risks from nanomaterials that are currently not subject to control. Where the lack of control stems from a gap in legal coverage, this is considered a legislative gap. Where the lack of control stems from inadequate implementation or a lack of technical capacity, this is considered to be an implementation gap. The distinction between the outputs of step 1 and 2 is critical and has policy implications, since an identified coverage issue does not imply that legislative action is required, while evidence of a legislative gap suggests that some action, possibly legislative, should be considered. In addition, the increased resources and technical capacity needed to solve implementation gaps may not necessarily be provided by legislative action, although legislative can be used to prioritise an issue and catalyse innovation.

1.4 Structure of the report

Following this introduction, the report opens with a discussion of nanomaterials in the environment under section 2. This includes a discussion of potential exposure pathways for nanomaterials and presents studies that have modelled environmental concentrations. The scale of environmental exposure is considered, followed by a review of limitations in the ecotoxicological data for nanomaterials. The section ends with a review of the potential role of the precautionary principle in regulating nanomaterials.

Sections 3-18 of the report present the results of the review of EU Environmental legislation, with each piece of legislation granted its own section. Sections 3-10 deal with the waste legislation, while sections 11-15 address legislative acts in the field of water. Sections 16-18 then address other relevant legislation, including the SEVESO-II Directive, the Air Quality Directive and the Regulation on the EU Ecolabel.

A summary of Member State activities on nanomaterials and environmental legislation is presented in section 19.

Finally, the report presents overall conclusions and identifies cross-cutting issues in section 20.

2. Nanomaterials in the Environment

2.1 Potential exposure pathways and environmental concentrations of nanomaterials

Given the rapid increases in production volumes of nanomaterials and their incorporation into multiple applications, it can be reasonably assumed that releases of nanomaterials into the environment have increased accordingly[27]. Given the lack of efficient, cost-effective analytical methods for monitoring the presence of nanomaterials in environmental media, estimates of occurrence in the environment have been based on other sources of information, namely the usage of nanomaterials in commercial products and modelling estimates of exposure over the life cycle of those products[28].

For example, Gottschalk et al (2009) modelled predicted environmental concentrations of engineered nanoparticles based on a probabilistic material flow analysis from a life-cycle perspective of nanomaterial containing products[29]. They modelled nano-TiO2, nano-ZnO, nanoAg, carbon nanotubes (CNT), and fullerenes for the U.S., Europe and Switzerland. The simulated models range from 0.003 ng L^{-1} (fullerenes) to 21 ng L^{-1} (nano-TiO2) for surface waters and from 4 ng L^{-1} (fullerenes) to 4 µg L^{-1} (nano-TiO2) for sewage treatment effluents.

A similar study by Mueller and Nowack (2008) modelled releases of three nanomaterials (nanosilver, titanium dioxide and carbon nanotubes) into the environmental in Switzerland in a complex analysis with numerous uncertainties. Under a realistic scenario, predicted concentrations in water were as follows: 0.03µg/L for nanosilver; 0.7 µg/L for nano titanium dioxide; and 0.0005 µg/L for carbon nanotubes[30].

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[27] Reijinders L “Cleaner technology and hazard reduction of manufactured nanoparticles” Journal of Cleaner Production (2006) 67(1) p87-108

[28] Tuccillo ME, Boyd G, Dionysios D and Shatkin JA “Challenges and opportunities of nanomaterials in drinking water” (2011) Web Report No. 4311, Water Research Foundation, USA, available at: http://collab.waterrf.org/Workshops/nanowksp/Document%20Library/Nanomaterials%20White%20Paper.pdf

[29] Gottschalk, F, Sonderer, T, Scholz, RW and Nowack, B. “Modelled Environmental Concentrations of Engineered Nanomaterials (TiO2, ZnO, Ag, CNT, Fullerenes) for Different Regions” (2009) Environmental Science and Technology 43, 9216-9222

[30] Mueller NC and Nowack B “Exposure modeling of engineered nanoparticles in the environment” (2008) Environmental Science & Technology 42, 4447-4453

A recent UK report measured the presence of nano silver in both the influent and effluent from nine sewage treatment plants. The mean concentration of colloidal (2-450 nm) silver was found to be 12 ng/L in the influent and 6 ng/L in the effluent. For particulate silver (>450 nm) the mean values were 3.3 µg/L for influent and 0.08 µg/L for effluent. The report went on to use these results to model concentrations of nano silver in the rivers of England and Wales with results in the range of 0-3 ng/L, taking into account dilution as the major fate process[31].

The figure below provides an overview of the different stages of a product life cycle at which nanomaterials could enter the environment.The boxes in yellow represent the various stages in the life cycle of a product containing nanomaterials, from the synthesis of the specific nanomaterials, its incorporation into a product, the product use phase and final disposal. The boxes in blue all represent different waste management options, including incineration, landfill, waste water treatment and recycling. The boxes in green represent possible emissions to the environment, including emissions to air, releases of treated waste water effluent and leachate from landfills.

During the production or synthesis of nanomaterials as a raw material, industrial wastes may be generated. Such wastes may either be channeled for landfill or they may serve as by-products for other industrial processes. There is a paucity of information available on the amounts of wastes generated in the production of nanomaterials and byproducts. A know example of byproducts is the use of soot generated in the production of C_{60} fullerenes by the lubricants industry.

Raw nanomaterials will then be incorporated into a product or application by the manufacturing industry. Spillages or leakages are possible, should the raw material be transported between two industrial sites. During manufacturing, nanomaterials may be released into air during processes such as coating or in industrial waste waters, for example where fullerenes are included in paper products. In addition, some industrial wastes will be generated, for example where carbon nanotubes are incorporated into resins, some waste resin will result and will be channeled for specific waste management procedures.

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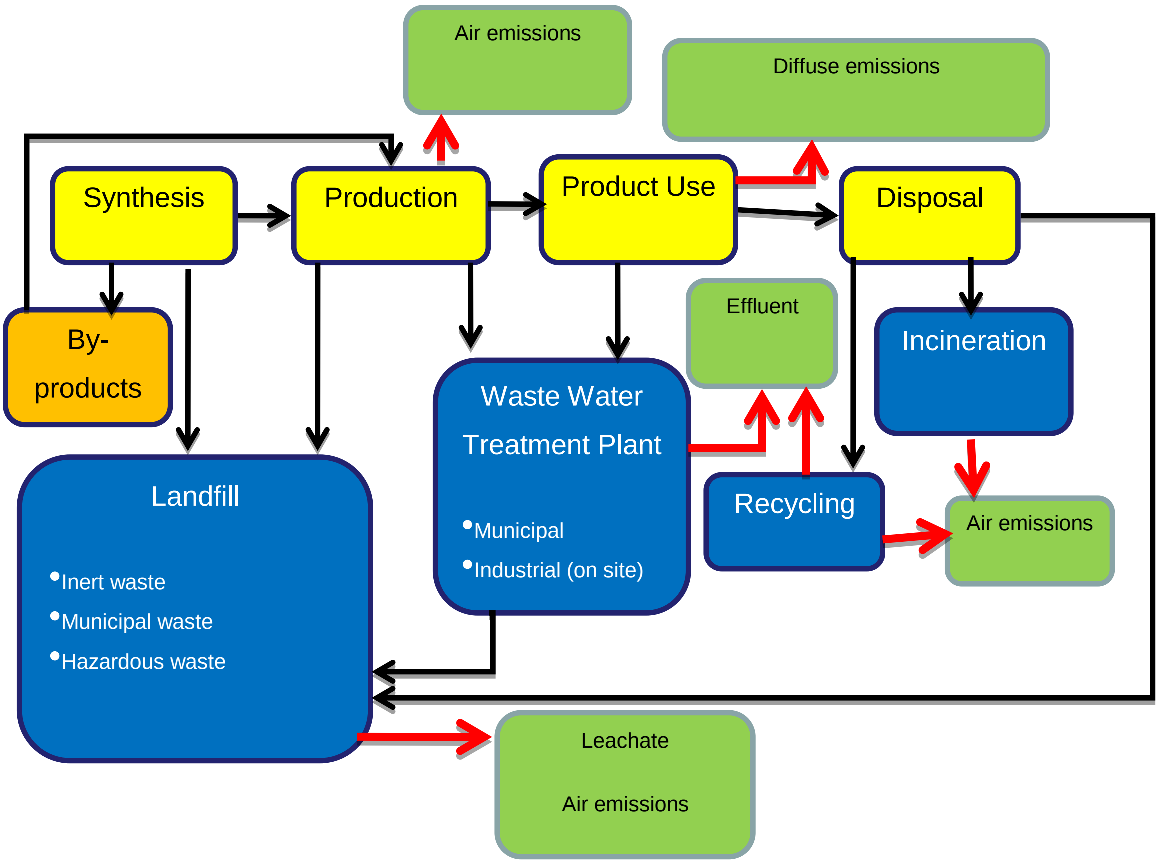
[31] Centre for Ecology and Hydrology (CEH) “Exposure assessment for engineered silver nanoparticles throughout the rivers of England and Wales” (2011) CEH, UK

Figure 1: Environmental exposure pathways for nanomaterials



Releases during product use will depend upon the mobility of the nanomaterials within the product, in particular where they are relatively immobile within a solid matrix, more easily dispersed within a liquid or even set for intentional release. It is expected that release will be most significant from creams and cosmetics that contain nanomaterials and that are washed off into sewage systems following use, as well as from washing textiles that contain nanomaterials and detergents and washing machines that use nanosilver. In addition, spillages of oils, fuels and lubricants containing nanomaterials provide a likely exposure pathway onto roads, with wash-off into sewage systems, soil and surface waters likely. Releases of nanomaterials from solid matrices through wear and tear are considered less significant in terms of volume. In addition, there are some applications of nanomaterials where their release into the environment is inherent to their function – soil remediation, water purification, cleaning etc.

Sewage waters will then be treated in urban waste water treatment plants, with nanomaterials either collecting in sewage sludge or passing through the treatment processes and out into surface waters with the release of treated effluent. Sewage sludge spread on agricultural land may then contaminate soils with nanomaterials.

With regards to the disposal phase of the product life cycle, the likelihood of environmental exposure will be influenced by the mobility of the nanomaterials in the waste product and the waste treatment process applied. Incineration may result in emissions of nanomaterials to air and ashes containing nanomaterials that have not been degraded (such as carbon nanotubes). There is also the possibility of nanomaterials entering landfill passing into leachate and entering groundwater, particularly in older landfill sites that may not be lined.

These potential pathways are all subject to control under EU legislation, most of which are addressed in this report with the exception of industrial emissions which are addressed in a related study[32]. The exposure pathways and the coverage provided by relevant legislation are discussed in greater detail under the sections on relevant legislation.

With regard to releases of nanomaterials over the product life cycle, it seems important to distinguish between applications that are inherently dispersive (e.g. nanomaterials in liquids) and applications that are not inherently dispersive (e.g. nanomaterials in a solid matrix).[33].

Once nanomaterials have entered the environment, the associated degree of risk will depend upon the mobility of the nanomaterials in the parent matrix as well as potential hazard characteristics, as shown in box 2 below. When considering the stringency of possible controls, the dispersive nature of the nanomaterials should feed into the analysis.

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[32] Tender reference no. ENV.C.4/SER/2010/0006 “Industrial emissions of nano- and ultrafine particles” undertaken by AMEC Environment & Infrastructure UK Ltd.

[33] Reijnders L “Cleaner nanotechnology and hazard reduction of manufactured nanoparticles”(2006) Journal of Clean Production 14, 124–133

Box 2: Risks levels associated with nanowaste in different forms

<table>
<tr><td colspan="4">Lower risk → Higher risk</td></tr>
<tr><td>Solid materials with imbedded nanomaterials</td><td>Solid materials with nanomaterials fixed to the surface</td><td>Nanomaterials suspended in liquids</td><td>Dry, dispersible engineered nanoparticles, agglomerates, or aggregates</td></tr>
<tr><td>Nanomaterials do notbreak free
Very low potential for contamination</td><td>Nanomaterials can be dissolvedinto solution</td><td>Capable of going down a drain
May evaporate leading to airborne nanomaterials
Contact contamination</td><td>Mobile/airborne
Highest contamination potential</td></tr>
<tr><td colspan="4">Lower controls → Stringent controls</td></tr>
</table>

2.2 The scale of environmental exposure

Information on the volumes of nanomaterials being produced and placed on the market and the number and range of product application for nanomaterials should provides an insight into the scale of possible environmental exposure to nanomaterials. However, the availability of such information in the public domain remains very limited, making an assessment of the volumes of nanomaterials entering product life cycles difficult, if not impossible.

Available information sources that can contribute to a picture of what nanomaterials are on the market, in which products and in what volumes include product registers that list products that voluntarily declare a nano content and estimates of current market size and market forecasts.

As an example of the first, the Woodrow Wilson International Centre for Scholars has developed an online inventory of consumer products labelled as containing nanomaterials[34]. As of March 10, 2011, the nanotechnology consumer products inventory contains 1,317 products or product lines that voluntarily declare a nano content.

Regarding market estimates, an OECD report notes that the nanotechnology industry is still at an early phase of development, making its future hard to forecast[35]. A report published by Global Industry Analysts in 2010 forecasts that the global market for nanomaterials will reach US$6.2 billion (€4.26 billion) by 2015.[36] In addition, the report predicts that the carbon nanotube industry in Western Europe will reach US$43.1 million (€29.64 million) by 2012. Research from UK consulting firm Cientifica Ltd. indicates that the market for nanotechnology-enabled products, excluding semiconductors and electronics due to uncertainties, will reach US$ 1.5 trillion (€1.03 trillion) in 2015[37].

Feedback from the Stakeholder Workshop

Pointing to recent reductions in investments in the nanomaterials industry, a participant questioned high future projections for the production of nanomaterials. He explained that investment has slowed as a consequence of concerns regarding health and environmental impacts and the costs of regulation.

2.3 Limitations in the availability of ecotoxicological data for nanomaterials

Many of the challenges in regulating nanomaterials emerge from the fact that nanomaterials typically have novel properties compared to the bulk form. The physico-chemistry of specific nanomaterials is essential to understanding their fate and behaviour in the environment, including uptake and distribution within organisms and interactions with other pollutants. These properties will affect the pathways through which nanomaterials can enter the environment, their environmental fate (including how they might change in form or composition) and their impacts on biota. Each nanomaterial has a distinct "footprint" resulting from its chemical composition, shape and structure, implying that

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[34] Woodrow Wilson international Centre for Scholars, inventory of nanotechnology-based consumer products on the market, available at: http://www.nanotechproject.org/inventories/consumer/

[35] OECD "Nanotechnology: An overview based on indicators and statistics" (2009) STI Working Paper 2009/7, OECD, Paris, France, available at: http://www.oecd.org/dataoecd/59/9/43179651.pdf

[36] Global Industry Analyst "Nanomaterials - A global strategic business report" (2010)

[37] Industry Week.com, last accessed 07.06.11 at: http://www.industryweek.com/articles/nano-growth_14395.aspx

nanomaterials exhibit unique behaviours in different environmental media, even when they are fabricated from the same bulk parent material[38]. For example, different nanomaterials exhibit diverse transport behaviours in the environment resulting from their different properties[39]. This implies that specific nanomaterials should be treated on a case-by-case basis.

Characterising the potential risk from environmental exposure to nanomaterials requires data on the intrinsic properties of specific nanomaterials and an understanding of their fate and behaviour in the environment. (Eco)toxicological data is fed into risk assessments and includes data on:

- aquatic toxicity (hazard to aquatic animals and plants);
- degradability (persistence in the environment, based on molecular structure or analytical testing); and
- bioaccumulation (accumulation in living organisms based on calculations or bio-concentration factor (BCF) studies using fish)[40].

However, such data is currently limited in a context where the number of studies that specifically examine the (eco)toxicology of nanomaterials is low. While existing data on biological effects show that specific nanonmaterials can be toxic to bacteria, algae, invertebrates and fish species, as well as mammals, data is limited and detailed investigations of absorption, distribution, metabolism and excretion (ADME) remain to be performed.[41] In addition, there is a lack of standardization in the studies that make up the existing body of evidence and of coherent examination of endpoints. Studies vary in the species tested, techniques for particle preparation; means of dispersions; dose range; and duration of exposure. These variants have been found to strongly influence the effects observed for specific nanomaterials, inhibiting the comparison of results. Many studies do not adequately characterize the nanomaterials that they examine, in terms of size, shape, crystal structure, surface charge, surface chemistry and solubility[42]. In the current context, regulators are therefore expected to take decisions regarding whether to control releases of nanomaterials into the environment in the absence of a full understanding of the potential risks.

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[38] Pal S, Tak YK, Song JM "Does the antibacterial activity of silver nanoparticles depend on the shape of the nanoparticle?) (2007) Applied Environmental Microbiology 73, 1712-20

[39] Lecoanet Leocanet HF, Bottero J-Y, Wiesner MR "Laboratory assessment of the mobility of nanomaterials in porous media"(2004) Environmental Science and Technology 38(19) 5164-9

[40] UNECE (2004) Globally Harmonized System of classification and labeling of chemicals (GHS), Annex 8, Guidance on hazards to the aquatic environment

[41] Handy RD, Owen R and Valsami-Jones E "The ecotoxicology of nanoparticles and nanomaterials: current status, knowledge gaps, challenges, and future needs" (2008) Ecotoxicology 17(5) 315-25

[42] Hansen SF, Larsen BH, Olsen SI, Baun A "Categorization framework to aid hazard identification of nanomaterials" (2007) Nanotoxicology 1, 243-50

This highlights the need for continued work to develop an understanding of the implications for ecosystems of different exposure levels for nanoparticles in environmental systems[43]. In order to allow for effective comparisons across studies that assess the impacts of nanomaterials in environmental compartments and the building of a body of evidence, standardised approaches for nanomaterial hazard identification and more thorough characterisations of the exposed particles are required. In addition, there is a need for the advancement of tools and techniques that can accurately quantify uptake of nanoparticles into biological tissues[44]. There is also a need to identify what the most appropriate dose metric might be when assessing the ecotoxicology of nanomaterials, since the dose metric applied for bulk materials may not be relevant. The answer might be multiple and material specific. Measuring and testing the properties of specific nanomaterials for the purpose of risk evaluation requires the application of specific test procedures and metrology that recognise properties such as:

Feedback from the Stakeholder Workshop

Participants at the workshop questioned whether the release of nanomaterials into the environment represents a real problem entailing known risks, or whether it is rather the lack of data that generates uncertainties.

- extremely large surface area in relation to mass;
- surface reactivity and insolubility;
- potential to agglomerate or change particle size in different media;
- potential to distribute in media and possible to persist and accumulate in different ways to the bulk form; and
- potential to carry other environmental pollutants across media (“Trojan horse” effect).

In 2007, the Working Party on Manufactured Nanomaterials (WPMN) of the Organisation for Economic Co-operation and Development (OECD) responded to the need for a coordinated approach to reviewing existing test methods in order to assess their applicability to nanomaterials by launching a Sponsorship Programme on the Testing on Manufactured Nanomaterials. The programme seeks to pool expertise and to fund the safety testing of specific manufactured nanomaterials. The WPMN has already generated a number of valuable outputs that serve to frame ongoing and future research on nanomaterials, including a priority list of nanomaterials and a list of endpoints relevant for human

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[43] Boxall AB, Tiede K and Chaudhry Q “Engineered nanomaterials in soils and water: how do they behave and could they pose a risk to human health?” (2007) Nanomedicine 2(6) 919-27

[44] Scown TM, van Aerle R and Tyler CR “Review: Do engineered nanoparticles pose a significant threat to the aquatic environment?” (2010) Critical Review of Toxicology 40(7) 653-70

health and environmental safety for which they should be tested[45]; preliminary guidance on sample preparation and dosimetry[46]; and revised guidance for the testing of manufactured nanomaterials[47]. Important further output is scheduled for 2012.

The OECD's "preliminary review of OECD test guidelines for their applicability to manufactured nanomaterials"[48] concluded that many of the OECD Test Guidelines are applicable, with conditions in some cases, to testing manufactured nanomaterials while some are inadequate. It should however be noted that the OECD furthermore concluded that 24 of OECD Ecotoxicity Test Guidelines guidance on preparation, delivery, measurement, and metrology is currently insufficient for testing of nanomaterials. The current state of knowledge regarding nanomaterials toxicity and exposure routes was found to preclude the reviewers from making specific recommendations regarding the development of new test guidelines. In addition, many of the tests included in the OCED Test Guidelines require that chemical substances be in solution, while nanomaterials tend to present in dispersion in liquid, a fundamentally different state with implications for observed test outcomes.

The EU has funded a number of projects aiming to increase the understanding of the toxicological impacts of nanomaterials on human and environmental health (e.g. IMPART-NanoTOX). Under the NanoReTox project, a number of studies are being undertaken to further characterise the toxicity and ecotoxicity of specific engineered nanoparticles[49].

2.4 The potential role of the Precautionary Principle in regulating nanomaterials

A number of factors combine to generate concern regarding the potential risks of nanomaterials, including the increasing global production volumes, the growing number and diversity of applications, the subsequent wide range of possible exposure pathways through which nanomaterials may enter the environment and initial evidence regarding the (eco)toxicity of specific nanomaterials. At the same

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[45] OECD, No. 27 - ENV/JM/MONO(2010)46 "List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision" (2010) OECD, Paris

[46] OECD, No. 24 - ENV/JM/MONO(2010)25 "Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials" (2010) OECD, Paris

[47] OECD, No. 25 - ENV/JM/MONO(2009)20/REV a Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision" (2010) OECD, Paris

[48] OECD, No. 15 - ENV/JM/MONO(2009)21 Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials" (2010) OECD, Paris, France

[49] See www.nanoretox.eu - work includes 'in vitro' toxicity studies considering issues of bioavailability and whether the nature of particles and/or the biological trait of the organism affect that uptake, as well as the stress responses of selected aquatic species to nanoparticles accumulation. It also includes 'in vivo' toxicity studies (on CUo and TiO2) to harmonise the data generation for future possible comparison between different studies.

time, concrete evidence is lacking regarding current concentrations of nanomaterials in environmental compartments, trends in concentrations and any related negative environmental impacts *in situ*. As such, current regulatory action to control emissions of nanomaterials into the environment would be undertaken in a proactive fashion to avoid perceived potential future risks. The precautionary principle provides the legal basis in EU legislation for such action.

The precautionary principle is mentioned in the context of environmental protection in Article 191 (2) of the Treaty on the Functioning of the European Union[50] (ex Article 174 of the Treaty establishing the European Community) In 2000, the Commission issued a Communication (2000)1 on the precautionary principle[51], with the aim of outlining the Commission's approach to using the precautionary principle. In addition, the Communication aims to build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, as such its content is relevant to the question of whether or how to regulate environmental releases of nanomaterials.

The Communication clarifies that, in practice, the scope of the precautionary principle is "*specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community*". In addition, the Communication notes that the precautionary principle is to be used by decision-makers in the management of risk to inform two aspects: the political decision of whether to act or not; and how to act.

Feedback from the Stakeholder Workshop

At the Stakeholder Workshop, the potential application of the precautionary principle to the regulation of nanomaterials was discussed. In light of the limitations that the paucity of data sets on accurately assessing risk, the precautionary principle was identified as providing a possible basis for legal action. In particular, a participant suggested that it could be used to justify a case-by-case approach to address the risks posed by specific nanomaterials, for example through product controls.

Regarding recourse to the precautionary principle when taking the decision whether to act to manage a potential risk, the Commission explains that the precautionary principle specifically applies in cases

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[50] Treaty on the Functioning of the European Union, OJ C 115/47, 9.5.2008, 47-199

[51] Communication from the Commission on the Precautionary Principle, COM(2000)1,

where “*potentially dangerous effects deriving from a phenomenon, product or process have been identified*” and where “*scientific evaluation does not allow the risk to be determined with sufficient certainty*”.

The scientific evaluation should entail a risk assessment, which consists of four components, namely: hazard identification, hazard characterisation, appraisal of exposure and risk characterisation. In the case of nanomaterials, the scientific knowledge needed to inform each of these components is currently limited, with evidence for hazard identification existing for some specific nanomaterials. These knowledge limitations serve to increase the overall level of uncertainty and ultimately affect the foundation for preventative action.

In informing how to act, the Commission Communication notes that recourse to the precautionary principle does not necessarily mean adopting legal instruments. Rather, a whole range of actions are available to policy makers, including funding research to increase the availability of information.

The precautionary principle could be applied to the management of the potential risks of nanomaterials in general, or to the management of potential risks from specific nanomaterials. In the case of some specific nanomaterials (i.e. carbon nanotubes, nano titanium dioxide), the available body of evidence that could feed into a risk assessment may be somewhat larger and more targeted, possibly creating a foundation for more stringent preventative action, such as product controls.

COM(2000)1 states that if action is deemed necessary, measures based on the precautionary principle should be proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action, subject to review in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

3. Waste Framework Directive 2008/98/EC

3.1 Introduction

Directive 2008/98/EC on waste[52] (hereafter the Waste Framework Directive) establishes the general framework for waste policies, including the definition of concepts such as waste, recovery and disposal and key requirements for waste management. Requirements include the obligation for an establishment or undertaking carrying out waste management operation to have a permit or to be registered, and the obligation for Member States to draw up waste management plans. Member States should take measures to treat waste in line with the waste hierarchy, and ensure that waste management is not harmful to human health or the environment.

The Waste Framework Directive 2008/98/EC repealed and replaced Directive 2006/12/EC, with the aim of modernising and streamlining its provisions clarifying definitions and laying down waste management principles such as the "polluter pays principle" or the "waste hierarchy", thus promoting waste recovery and use. In addition, the provisions of Directive 91/689/EEC on Hazardous Waste were integrated into the new Directive 2008/98/EC. Accordingly, the properties that render waste hazardous are laid down in Regulation No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Currently, wastes containing nanomaterials are treated as any other waste under the Waste Framework Directive without any specific requirements. There is no definition for nanowastes and therefore no measures specifically designed to deal with the possible risks associated with nanomaterials in wastes. A particular concern relates to the disposal of consumer products containing nanomaterials in municipal waste streams, likely to be channelled for landfill or incineration. Currently, there are no obligations to label products as containing nanomaterials and no programmes established to separate out and collect end-of-life products containing nanomaterials for specific waste management procedures. As such, products containing nanomaterials will remain within the municipal waste stream, even when specific nanomaterials may have been classified as hazardous, since there is no basis for their separation.

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[52] Directive 2008/98/EC on waste, OJ L312 22.11.2008, 3-30

Classification of wastes as non-hazardous or hazardous wastes is based on chemicals legislation, namely on Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation)[53]. Given that the CLP Regulation does not include specific provisions for nanomaterials, the system for classifying wastes as hazardous does not explicitly take the specific properties of nanomaterials into consideration. Specific wastes categorised as hazardous are listed under Decision 2000/532/EC establishing a List of Wastes[54], as last amended by Decision 2001/573/EC. There are no nanowastes included in the List of Wastes that are specifically identified as being of nanoscale. The result of this is that, even for non-municipal waste streams, requirements under the Waste Framework Directive that are triggered when wastes are categorised as hazardous may not apply to wastes containing specific nanomaterials, despite possible concerns regarding their toxicity.

3.2 Exposure pathways for nanomaterials in waste

The management and final disposal of waste represents a principal channel through which pollutants enter our environment. With regards to nanomaterials, a review of the current applications of nanomaterials and the rapid growth predicted for the future suggest that wastes generated during the life cycle of these applications will be the chief sources of nanomaterials into the environment. A number of commentators have flagged the need for a prompt regulatory response to avoid harm to human health and the environment through the inappropriate and inadequate management of wastes containing nanomaterials[55]. Powell *et al.* identify current and future applications of nanomaterials as the most significant sources of large quantities of nanomaterials into the waterways through waste streams[56]. On the basis of expectations for dramatic increases in production rates for nanomaterials, Musee concludes that the types and quantities of wastes containing nanomaterials will also increase rapidly, posing challenges for the existing waste management paradigm and increasing the potential exposure of humans and ecological systems to nanomaterials through waste streams[57]. Already in

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[53] Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures, OJ L353 31.12.2008, 1-1355

[54] Commission Decision 2000/532/EC establishing a list of wastes, OJ L 226, 06/09/2000 p.3-24

[55] Musee N "Nanowastes and the environment: Potential new waste management paradigm" (2011) Environment International 37, 112- 128; Franco A, Hansen SF, Olsen SI and Butti L "Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials" (2007) Regulatory Toxicology and Pharmacology 48, 171-183

[56] Powell MC, Griffin MPA and Tai S "Bottom-up risk regulation? How nanotechnology risk knowledge gaps challenge federal and state environmental agencies" (2008) Environmental Management 42, 426–43

[57] Musee N "Nanowastes and the environment: Potential new waste management paradigm" (2011) Environment International 37, 112- 128

2004, the Royal Academy noted that the risk of releases of nanomaterials into the environment would be greatest during disposal, destruction or recycling[58].

Current EU waste legislation has been developed without consideration of the specific properties of nanomaterials and how they might behave in waste materials and management processes. This raises questions regarding the adequacy of the existing frameworks to respond to the potential risks posed by wastes containing nanomaterials. Critical questions for controlling releases to the environment centre around the handling, treatment and disposal of wastes containing nanomaterials (Breggins and Pendergrass, 2007)[59]. As pointed out by a recent Dutch study, a precondition for the appropriate management of wastes containing nanomaterials is awareness of their presence in waste materials[60].

In order to allow for an effective review of the coverage of nanomaterials under existing EU legislation on waste and the subsequent identification of any possible implementation or legislative gaps, a number of key questions need to be addressed. These include:

- How can wastes containing nanomaterials be defined?
- What are the key sources?
- What volumes are generated?

These issues will be discussed briefly in turn below before we proceed with an analysis of the pieces of EU waste legislation identified above.

Nanomaterials may be present in waste materials in a number of different forms. In some cases the waste may be comprised entirely of nanomaterials, for example where excess production from a facility producing nanomaterials is stored and eventually discarded. Items used to control spillage, for storage or to protect workers during production processes may become contaminated with nanomaterials and subsequently be disposed of. Nanomaterials may be contained in liquid suspension. Finally, nanomaterials may coat a solid bulk waste material, or be contained within a matrix of host waste material.

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[58] The Royal Academy of Engineering “Nanoscience and nanotechnologies: opportunities and uncertainties,” (2004) Last accessed 1/3/11 at: http://www.nanotec.org.uk/finalReport.htm

[59] Breggin LK, Pendergrass J “Where does the Nano Go? End-of-life Regulation of Nanotechnologies” (2007) Woodrow Wilson International Center for Scholars, Washington

[60] Vogelezang-Stoute EM, Popma JR, Aalders MVC and Gaarthuis JV, “Regulating uncertain risks of nanomaterials” English summary of “Regulering van onzekere risico’s van nanomaterialen. Mogelijkheden en knelpunten in de regelgeving op het gebied van milieu, consumentenbescherming en arbeidsomstandigheden” (2010) STEM, Netherlands

Should regulators choose to adopt an end-of-pipe approach to managing nanomaterials in general in wastes, agreeing upon a legal definition of wastes that contain nanomaterials, or "nanowaste" would be an important first step. This would serve as a basis for the identification of nanowastes by end-users and waste managers and allow for their separate collection and treatment. While adopting an end-of-pipe approach to managing nanowastes in municipal wastestreams (i.e. discarded consumer products containing nanomaterials) would be less efficient than upstream controls, it may be relevant to identify nanowastes from industrial sources and establish controls, should they prove to be necessary. As yet, there is no formally agreed consensus around one particular definition of nanowaste. A review of the literature finds general consensus around the definition put forward by the British Standards Institute (BSI), presented in Box 2 below.

Box 2: BSI Definition of Nanowaste

Definition of Nanowaste provided by the British Standards Institute

Nanowaste (nanomaterials-bearing waste)

1. pure nanomaterials (i.e. nanoparticles and rods or NPR);
2. items contaminated with nanomaterials, such as containers, wipes and disposable personal protective equipment (PPE);
3. liquid suspensions containing nanomaterials; and
4. solid matrices with nanomaterials that are friable or have a nanostructure loosely attaches to the surface such that they can reasonably be expected to break free or leach out when in contact with air or water, or when subjected to reasonable foreseeable mechanical forces.

BSI PD 6699-2(2007): Guide to safe handling and disposal of manufactured nanomaterials

Regarding sources of nanowaste, wastes containing or composed of nanomaterials may be generated at different points along the life cycle of products containing nanomaterials, including manufacturing, use, waste management and final disposal.

Firstly, the manufacturing process is likely to be multi-stage, including the production of the raw nanomaterial, possible purification and incorporation into the final product for the commercial market, often involving different manufacturers. Each stage may result in the generation of production residues that contain nanomaterials and may become waste or "production by-products". The possible commercial value of by-products containing nanomaterials is determined by their potential uses and whether they meet the legal criteria to be defined as "by-products" rather than waste. Data from the Woodrow Wilson Center indicates that the manufacture of some nanomaterials is energy intensive and itself highly polluting, for instance, in the manufacture of fullerenes, only 10% of materials was usable and the rest was sent as waste to landfill (RCEP, 2008)[61].

Secondly, nanomaterials may be released into the environment during the use phase. The release of nanowaste during product use is most likely for products where nanomaterial are contained within a liquid matrix that is intentionally applied, spilled or other otherwise released during use. Examples of products might include detergents, lubricants, fuel additives, catalysts, cosmetics and personal care products. Mueller and Norwack has estimated that 95% of the nanomaterials in cosmetics and personal care products will end up in wastewater treatment plants through releases during run-off, abrasion and liquid entrapment during use[62]. It can generally be assumed that detergents containing nanomaterials would pass into the municipal sewage system, and hence fall under the Urban Waste Water Directive 91/271/EEC addressed in section 14. Nanomaterials in lubricants, fuel additives and catalysts may be released into the environment from non-point sources such as spillage, leakage from vehicles, or they may enter sewage systems through drainage systems. For example, cerium oxide is used as a fuel additive and tungsten disulphide and fullerenes are used in lubricants. For more details on exposure pathways for tungsten dioxide in lubricants see box 3 below. Alternatively, residues of fuel and lubricants may adhere to the metal of the vehicle and eventually follow the waste path of the vehicle, so covered by Directive 2000/53/EC on End-of Life Vehicles addressed in section 5 of this report. Nanomaterials that are fixed within a solid matrix (i.e. incorporated into a resin) are generally stable and are not expected to leach out during use[63].

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[61] Royal Commission on Environmental Pollution “Novel Materials in the Environment: The case of nanotechnology” (2008) RCEP, UK

[62] Müller NC and Nowack B “Exposure modelling of engineered nanoparticles in the environment” Environmental Science and Technology’ (2008) 42(12) 4447–53

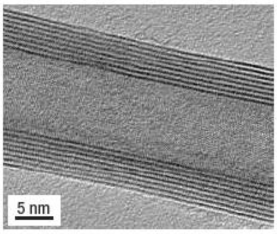
[63] Musee N, “Nanowastes and the environment: Potential new waste management paradigm” (2011) Environment International 37, 112- 128

Box 3: Summary of the environmental risks and legislative coverage for tungsten disulphide (WS_2)

Properties and applications

In the 1990s, it was found that stable structures in the layered semiconductor tungsten disulphide (WS_2) could be formed (Tenne, 1992). WS_2 adopts a layered structure related to molybdenum disulfide (MoS_2) nanoparticles. The compounds have been termed inorganic fullerene-like (IF) structure and inorganic nanotubes (INT). They come in a variety of forms and shapes, such as multi-wall and single-wall nanotubes (Figure 1) and nested fullerene-like structures. After the heating of thin tungsten films in the presence of hydrogen sulphide, transmission electron microscopy (TEM) reveals a variety of concentric polyhedral and cylindrical structures growing from the amorphous tungsten matrix. The bonding within the S–W–S sandwich is covalent, while weak van der Waals forces hold the sandwich together resulting in interlamellar mechanical weakness. Thus, under a shearing force the basal planes slide back and forth over one another.

Figure 1 A TEM image of a portion of a multi-wall WS_2 nanotube with eight cylindrical and concentric layers



Source: Reproduced from Tenne et al. (2006) by permission of Prof. Reshef Tenne.

WS_2 nanostructures have been shown to exhibit superior tribological behaviour, particularly under high loads. Their quasi-spherical shape and inert sulphur-terminated surface means that they serve as superior solid lubricants in the form of additives to lubrication fluids, greases and for self-lubricating coatings (Rapoport, 2005). With a coefficient of friction at 0.03, it offers excellent dry lubricity, reportedly unmatched by any other substance. It can also be used in high-temperature and high-pressure applications. Load bearing property of coated film is extremely high at 300,000psi. Applications include the automotive and aerospace industries, home appliances and medical technology, and are summarised in the table below.

Additives	**Other**
• Composites (multiple applications e.g. reinforcing polymer matrices) • Catalysts • Engine oil additives • Dry lubricant • Low friction coating	• Scanning electron microscope probe tip
Bio-medical applications	**Energy storage**
• Improved orthodontic wire • Coatings for artificial joints • Biofunctionalization of WS_2 opens new opportunities like drug delivery, cancer therapy and medical-relevant coatings (Wu et al., 2011)	• Hydrogen fuel cell storage • Lithium storage battery technology

Production volumes and projected growth

Data on production volumes are very limited. No reliable data has been identified.

Pathways for environmental exposure

IF and INT WS_2 nanoparticles have been synthesised using solid precursors, by reaction of the corresponding metal oxide nanopowder, sulphur and a hydrogen-releasing agent ($NaBH_4$ or $LiAlH_4$), achieved either by conventional furnace heating up to ~900 °C or by photothermal ablation at far higher temperatures (Wiesel et al., 2009). Exposure pathways for WS_2 nanoparticles along the product life cycle will be determined by the application. In this example, we focus on the application of WS_2 in lubricants to illustrate uses, environmental exposure/effects and the impacts of legislation.

There are three main lubricant categories: automotive lubricants (including petrol-engine crankcase lubricants, diesel-engine crankcase lubricants, transmission lubricants, greases and shock absorber fluids); hydraulic fluids; and metal-cutting fluids. Release may occur during various phases of the product life cycle.

Firstly, release may occur during formulation of additive packages. Typically blending of lubricant additives is carried out in a batch operation involving up to twenty components, mainly in liquid form and supplied to the process in bulk or drums (OECD ESD, 2004). Additive blending is generally carried out at elevated temperatures which may create emissions to atmosphere. Secondly, releases may occur during formulation of lubricants. Emissions may occur under three categories, namely emissions to the atmosphere, aqueous discharges to drain and solid waste. Thirdly, possible losses may occur during the product use phase. For automotive lubricants, unintended spillage losses may occur during charging; leakages may occur during use; and losses may occur during recycling or disposal of used oil. Hydraulic oils are used in a wide range of applications, which makes generalisation difficult. Losses will be to soil or to (surface or ground) water depending on the application and the location of the release.

Finally, the end-of-life stage may lead to releases of lubricants through disposal (at landfill or incineration) or recycling. No studies were found that specifically address exposure pathways for WS_2 nanoparticles. However, it is known that WS_2 exhibits high temperature resistance, suggesting that it will not degrade easily in incinerators

Toxicity and ecotoxicity

Studies on the ecotoxicology of IF and INT WS_2 are limited and the number of tested taxa are few. Preliminary toxicology tests of WS_2 nanoparticles reveal that the material showed no apparent toxic reaction after an oral administration test in rats and no sensitization in lymph nodes following a topical dermal application (Tsabari, 2005; Haist, 2005). More recent inhalation tests have shown that the material has no toxic effects in rats (Moore, 2006). In Canada, however, tungsten disulphide has been found to be persistent and inherently toxic to aquatic organisms (CEPA CCR). Further toxicity tests on WS_2 are currently being undertaken[1].

WS_2 is not classified according to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Dangerous Substances.

Monitoring options

Quantification of WS_2 is usually performed at the laboratory scale using microscopy methods. No in-situ monitoring methods have been identified.

Existing legislative coverage and possible future approaches

There is a lack of information on production volumes for WS_2, concentrations of WS_2 in lubricant products and the likely behaviour and possible exposure routes along the life cycle of lubricant products containing WS_2. A full understanding of the volumes of WS_2 that are in use is a critical first step towards taking decisions as to whether, and if so how, to regulate them, as is further information on hazardous properties. However, for the main uses in lubricants, it is clear that existing legislation does already offer a level of control, regardless of whether this substance is ultimately found to pose a risk.

In relation to the presence of IF and INT WS_2 in lubricants, the following can be concluded:

- The paucity of toxicity and ecotoxicity data on IF and INT WS_2 nanoparticles means that it cannot be concluded whether they are likely to pose a risk to health or the environment.
- WS_2 (regardless of whether nano-scale or not) is not classified under the CLP Regulation meaning that various other legislation that relies on CLP will not be triggered.
- There are already substantial generic controls on the management of oils that will cover oils (and lubricants) containing WS_2, including waste oil provisions under the Waste Framework Directive and on removal of liquids/oils under the ELV Directive.
- It is unlikely that WS_2 nanoparticles will be detected in water bodies using currently available monitoring equipment and protocols in place to monitor for regulatory purposes. Therefore, they are unlikely to be identified as pollutants (such as under the Water Framework Directive), even if they were to be present.

Footnotes:

1) Personal communication with Professor Reshef Tenne on 31st May 2011.

References

Haist I "Test for Sensitization (Local Lymph Node Assay – LLNA) with Inorganic Fullerene-like WS2 Nanospheres" (2005) Project No. 052052, BSL Disservices, Germany.

Moore G "Acute inhalation toxicity study in rats – limit test" (2006) Product safety laboratories study number 18503, Dayton, New Jersey, USA

OECD "Series on emission scenario documents number 10: emission scenario document on lubricants and lubricant additives" (2004) Online version last accessed 27/5/2011 at: http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2004)21&doclanguage=en

Rapoport L *et al.* "Applications of WS_2 (MoS_2) inorganic nanotubes and fullerene-like nanoparticles for solid lubrication and for structural nanocomposites" (2005) Journal of Materials Chemistry 15, 1782-1788

Scharf TW *et al.* "Growth, structure, and tribological behaviour of atomic layer-deposited tungsten disulphide solid lubricant coatings with applications to MEMS" (2006) Acta Materialia 54, 4731-4743

Tenne R "Inorganic nanotubes and fullerene-like nanoparticles" (2006) Nature 1, 103-111

Tsabari H, Final report, Batch no. HP6, (2005) Harlan Biotech, Rehovot, Israel

Wiesel I *et al*. "Synthesis of WS_2 and MoS_2 fullerene-like nanoparticles from solid precursors" (2009) Nanoresearch 2, 416-424

Wu H et al. "Biocompatible Inorganic Fullerene-Like Molybdenum Disulfide Nanoparticles Produced by Pulsed Laser Ablation in Water" (2011) ACSNano 5(2) 1276-1281

Regarding disposal, commercial goods containing nanomaterials in a solid matrix or in residues (i.e. cosmetic packaging) are most likely to enter the municipal waste stream and eventually be disposed of either in landfills or incinerators. An example of the industrial utilisation of nanoparticles is the Silver Nano product line introduced by Samsung[64]. It is composed of fridges, vacuum cleaners, washing machines and air conditioning systems. The antibacterial effect is reached through the release of silver

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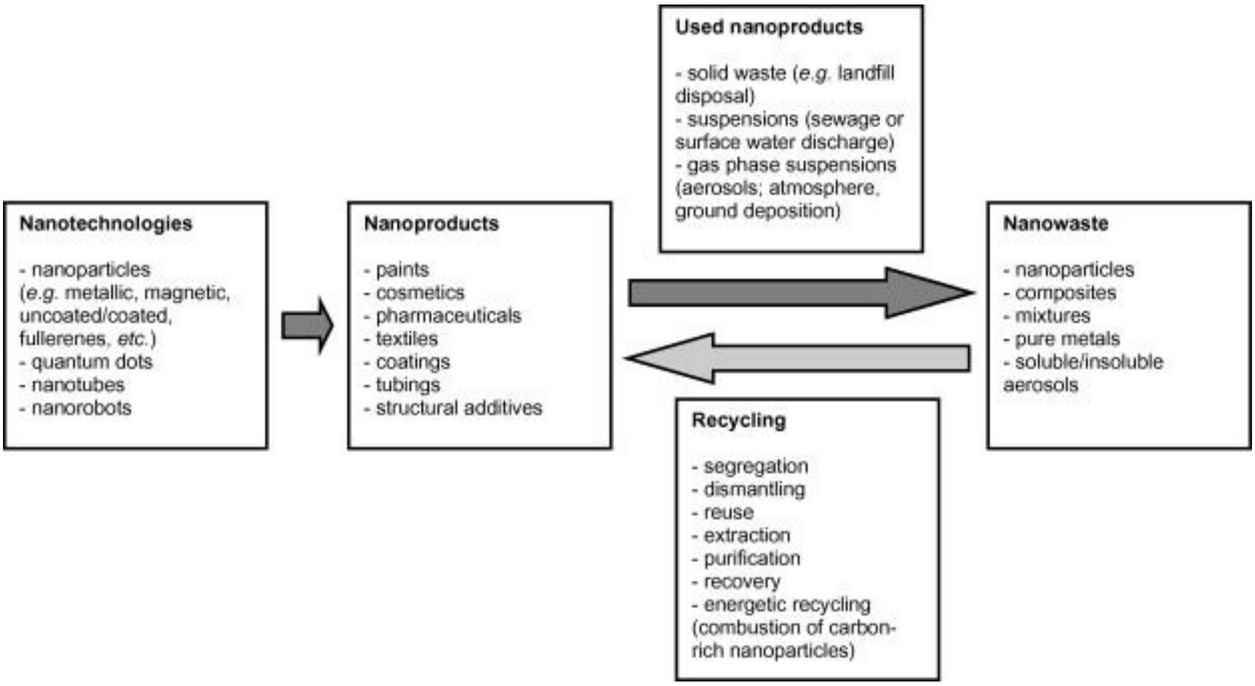
[64] Samsung website: http://www.samsung.com

ions due to silver electrolysis or desorption from the nanoparticle-coated walls. It is expected that the oxidised silver released in the washing machine will eventually reach the municipal waste water system. The fate of waste containing nanomaterials may include reuse, landfill, incineration, recycling or composting, and these processes can be expected to have different effects on the integrity of the host materials, its degradation, subsequent potential modification of the nanomaterial and its release into the environment. Figure 1 below illustrates how "nanowaste" may arise from the use, recycling and final disposal of products containing nanomaterials.

Figure 1: A schematic pathway from nanotechnology to nanowaste



Source: Bystrzejewska-Piotrowska *et al* "Nanoparticles: Their potential toxicity, waste and environmental management" (2009) Waste Management 29, 2587-2595

Overall, there is a need for material flow analysis to determine what kinds, qualities and volumes of nanowaste specific waste streams contain. Given that nanowastes are currently managed without specifically being registered as nanowastes, current studies have estimated volumes of nanowaste by extrapolating from data on the volumes of nanomaterials on the market, either as raw materials or in products[65]. For example, the Royal Society and Royal Academy of Engineering estimated that quantities of engineered nanomaterials are anticipated to increase to 58,000 tonnes per year between

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[65] Musee N "Nanowastes and the environment: Potential new waste management paradigm" (2011) Environment International 37, 112- 128

2011 and 2020[66]. Commentators suggest that such statistics provide insights into the likely rapid increase in the types and quantities of nanowastes[67].

A major obstacle to addressing the management of nanowastes is caused by the production of several derivatives of the same material based on different manufacturing processes. In effect this raises the possibility of generating nanowastes of different physical-chemical properties (size, shape, composition, etc) which ultimately exhibit a range of possible toxicological and ecotoxicity characteristics[68]. This implies that nanowastes containing different nanomaterials may require a different waste management approach. This is strikingly different from the conventional large-scale treatment of wastes.

3.3 General Objectives and Scope

The objective of the Waste Framework Directive is to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste. Where releases of nanomaterials during waste generation and management are known to entail adverse affects on the environmental and human health, they can be assumed to be implicitly included in this scope. A number of exclusions detailed in Article 2 are either not considered to be of relevance to sources of nanomaterials, or are covered by other legislation (namely gaseous effluents and waste waters).

Article 2 does provide for the laying down of specific rules for the management of particular categories of waste under individual directives, an opportunity that could be used with regards to wastes containing nanomaterials. This could provide an opportunity to develop and lay down rules for the management of wastes composed of or containing nanomaterials, should a definition be established.

An additional objective is to reduce the overall impacts of resource use and improve the efficiency of use. This objective highlights the need to take a life cycle approach to the applications and products

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[66] Royal Society and Royal Academy of Engineering "Nanoscience and nanotechnologies: opportunities and uncertainties" (2004) Royal Society and Royal Academy of Engineering, UK

[67] Oelofse S and Musee N "Hazardous waste management and emerging waste streams: A consideration of key emerging issues that may impact on the state of the environment" (2008) Department of Environmental Affairs and Tourism, South Africa

[68] Thomas K and Sayre P "Research strategies for safety evaluation of nanomaterials, Part I: Evaluating human health implications for exposure to nanomaterials" (2005) Toxicology Science 87(2) 316–321; Oberdörster G, Oberdörster E and Oberdörster J "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles" (2005) Environmental Health Perspective 113(7):823-839.

arising from nanotechnologies, to ensure that any savings in resources consumptions during use are not offset by increases in resource consumption during production, and in this case, disposal[69,70]. Life cycle assessments need to be conducted for different classes of nanoparticles and nanoproducts, so as to predict the real threat of nanowaste (Bystrzejewska-Piotrowska et al., 2009). At present, however, it is impossible to conduct a full-spectrum life cycle assessment for nanomaterials in products due to insufficient knowledge about the detailed inputs and outputs.

There are no specific mentions of nanomaterials or nano-wastes within the Waste Framework Directive. As such, nano-waste is covered by waste legislation implicitly rather than explicitly, and in a non-specific way.

3.4 Definitions

The definition of waste under Article 3(1) includes any substance or object which the holder discards or intends or is required to discard. Thus the definition includes any discarded substances or objects which contain nanomaterials or be comprised of nanomaterials.

The definition of “waste oils” has relevance as this serves to capture a possible source of waste containing nanomaterials through exhausted lubricants (e.g. oil lubricants containing C_{60}).

The definition of hazardous waste under Article 1(2) includes wastes that display one or more of the hazardous properties listed in Annex III of the Directive. The attribution of these properties is made according to criteria laid down in Annex VI of CLP Regulation 1272/2008/EC, discussed in the section below.

In the case of a waste that may not be hazardous in itself, but that contains nanomaterials that would be categorised as hazardous under Article III, this waste would be considered hazardous were it capable of yielding the nanomaterials (e.g. through leaching). For a nanowaste to be captured by this, an understanding of the specific behaviour of the nanomaterials within the bulk material would be required. Specific information on the behaviour of nanomaterials within solid matrices over time is not

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[69] Royal Society and Royal Academy of Engineering “Nanoscience and nanotechnologies: opportunities and uncertainties” (2004) Royal Society and Royal Academy of Engineering, UK

[70] Curran MA, Frankl P, Heijungs P, Köhler A and Olsen SI “Nanotechnology and Life Cycle Assessment: A system approach to Nanotechnology and the Environment” (2007) Woodrow Wilson International Center for Scholars, Washington, US

available for nanoproducts as there is no requirement for the producers to generate this information and make it publically available.

3.5 Categorisation as Hazardous Waste

As specified in paragraph 14 of the Preamble of the Waste Framework Directive and reiterated under Annex III, wastes are classified as hazardous according to the criteria in chemicals legislation, in particular concerning the classification of preparations as hazardous, including concentration limit values used for that purpose. The relevant legislation is the CLP Regulation, as mentioned above. While the properties of waste which render it hazardous are set out in Annex III to the Waste Framework Directive, the specific attribution of the hazardous properties “toxic” (and “very toxic”), “harmful”, “corrosive”, irritant”, “carcinogenic”, “toxic to reproduction”, “mutagenic”, and “eco-toxic” is made on the basis of criteria laid down in Annex VI of the CLP Regulation, with test methods described in Annex V.

It is important to stress that no distinction between bulk and nano form is made within the CLP Regulations (as amended), indeed, the pre-fix *nano* does not appear in the CLP regulation. However, there is a requirement under CLP to consider the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. The Commission has stated that the CLP Regulation covers nanomaterials. In 2009 the Commission concluded that:

- If substances are producer/imported both at nanoscale and as bulk, a separate classification and labelling may be required if the available data on the intrinsic properties indicates a difference in hazard class between the nano form and the bulk form (REACH, Article 10(a)[71]).
- The classification of nanomaterials has to be done on a case-by-case basis under the CLP Regulation.
- Hazard classification should be based on *available data* on the intrinsic properties that relate specifically to the forms or physical states.[72]

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[71] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1–849

[72] CA/90/2009 Rev 2 of 3 December 2009

These conclusions are set forth in a document intended to summarise the state of discussions and provide guidance to stakeholders. It is not, however, a legally binding document and as such stakeholders are not legally obliged to follow the interpretations set out therein.

Whilst there may be a lack of available (eco)toxicology data that is specific to nanomaterials, there should be data based on the bulk form which may also apply to the nanomaterials. Zinc oxide provides an example of a nanomaterial for which certain bulk forms are classified as hazardous, with the powder form of both standard and low grade zinc oxide classified as hazardous under CLP. This implies that the powder form of nano-scale zinc oxide should also be classified as hazardous. It should be noted that there is considerable uncertainty regarding the application of hazard information on bulk materials to the nanoform. In addition, companies are expected to make use of information available in registrations submitted under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). According to CLP Article 8 (1-2), companies are also expected to conduct additional testing where required for physico-chemical properties.

There might, therefore, be an expectation that companies will increasingly need to identify whether there are different (eco)toxicological properties at the nanoscale for substances placed on the market. These might then be translated into differences in (eco)toxicological data on nanomaterials present in wastes. While this suggests that nanomaterials are covered in theory, it remains too early to determine how effective this will be in practice.

Following Article 40(1) of CLP, suppliers were obliged to notify to the European Chemicals Agency (ECHA) by 3 January 2011 substances placed on the market and meet the criteria for classification as hazardous or are subject to registration in accordance with REACH (see box 4 below). ECHA is currently compiling an inventory of nanomaterials included in the REACH registration dossiers and CLP notifications for the European Commission and intends to deliver the inventory by the end of June 2011. REACH registration dossiers submitted by the 30 November 2010 deadline are for substances manufactured or imported at 1,000 tonnes or more per year, a volume threshold that can be assumed to exclude many nanomaterials due to their small scale and relatively small markets when compared to bulk form chemicals. According to an ECHA spokesperson, three registration dossiers have been found and 14 CLP notifications in which “nanomaterial” was selected as the form of the substance[73]. ECHA expects to be able to identify 50-60 REACH registration dossiers that include information on nanomaterials. These will be sent to the Joint Research Centre for assessment under a

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[73] Nanotechnology Law Blog “ECHA preparing nano inventory from REACH and CLP submissions” Bergenson & Campbell, last accessed 2/6/11 at: http://nanotech.lawbc.com/2011/05/articles/international/echa-preparing-nano-inventory-from-reach-and-clp-submissions/

separate project to address if and how information on nanomaterials is included in REACH registration dossiers.

Box 4: Substances requiring notification under CLP, irrespective of their quantities:

- Substances which are subject to registration under REACH (≥ 1 tonne/year) and placed on the market. This will include substances on their own, substances contained in mixtures and certain substances contained in articles where REACH Article 7 provides for their registration. Notification of these substances is not necessary where a manufacturer, importer or Only Representative (OR) has already registered the substance with the classification and labelling according to CLP when its notification in line with CLP Article 40(1) is due. In particular, notification is not required for the importers covered by a registration that has already been done by an OR on their behalf. However, importers will have to notify a substance placed on the market on 1 December 2010 where the OR will submit the registration later than 3 January 2011;

- Substances classified as hazardous under CLP and placed on the market irrespective of the tonnage. This includes substances which are classified as hazardous under CLP, but which are exempted from registration, e.g. polymers referred to in REACH Article 6(3); and

- Substances classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC, where relevant, which results in the classification of the mixture as hazardous, and where the mixture is placed on the market.

Source: ECHA website, Frequently Asked Questions, last accessed 5/6/11 at:
http://echa.europa.eu/clp/clp_help/clp_faq_en.asp

An additional concern regarding the classification of nanomaterials as hazardous under CLP is that the criteria against which hazardous properties are assessed were established without consideration of the specific properties of nanomaterials. As such, test methods have not been specifically tailored to capture the possible specific hazardous properties of nanomaterials. Metrology tools are under development and there are no agreed dose units that can be used in hazard and exposure assessments for nanomaterials. Consequently, (eco)toxicology data and exposure limits cannot be established with the existing methodologies[74].

Under the OECD's Working Party on Manufactured Nanomaterials (WPMN), work is underway to undertake safety testing and risk assessment of manufactured nanomaterials through a "sponsorship programme". A list of representative manufactured nanomaterials and a list of end-points for initial testing has been agreed[75].

The OECD's test guidelines are a key source of information used under the CLP Regulation. As discussed in the introduction, some questions remain regarding the application of the OECD test guidelines to nanomaterials and as such substantial work is still required before the properties of nanomaterials can be specifically addressed and hence before they can be explicitly recognised and distinguished from non-nanomaterials under the CLP Regulation. This has knock-on implications for the extent to which nanowastes may be identified as hazardous.

Feedback from the Stakeholder Workshop

The issue of the coverage of nanomaterials under the CLP Regulation received considerable attention at the Stakeholder Workshop. A participant stated that CLP provides an effective mechanism for assessing the risks associated with specific substances on a case-by-case basis, stressing that a horizontal approach for nanomaterials is not required. One participant described the default situation, whereby nanomaterials would be classified according to the properties of the bulk form, as preferable to their not being classified at all due to lack of available nanomaterial specific information.

An additional barrier to the identification of hazardous properties associated with specific nanomaterials is that under the CLP Regulation, producers are not required to generate any additional information where data already exists. In the case where data exists for the bulk form, under the CLP producers are not legally required to conduct additional tests. However, it is often not possible to predict the properties of nanoscale materials from current knowledge of the counterpart bulk parent

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[74] Franco, A., Hansen, S.F., Olsen, S.I. and Butti, L. 2007, "Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials," Regulatory Toxicology and Pharmacology, 48, 171-183

[75] See list of manufactured nanomaterials and list of endpoints for phase one of the sponsorship programme for the testing of manufactured nanomaterials: revision (OECD, December 2012). The nanomaterials include fullerenes; single-walled and multi-walled carbon nanotubes; silver, gold and iron nanoparticles; oxides of aluminium, cerium, zinc and silicon; dendrimers and nanoclays. There are various endpoints covering NM identification, physical-chemical properties, environmental fate, ecotoxicology, mammalian toxicology and material safety.

material (an example being the relatively benign bulk form of gold and the seemingly more toxic nano-gold)[76]. In the absence of a specific requirement to conduct tailored tests to investigate the properties of the nanoform, nanoform-specific information on hazards would not be provided. This has led some authors to conclude that nanomaterials will not readily be categorised as hazardous[77]. It would seem that companies have little incentive under CLP to test nanoforms for additional hazard-related information given the costs of carrying out such tests.

Specific wastes categorised as hazardous are listed under Decision 2000/532/EC establishing a List of Wastes, as last amended by Decision 2001/573/EC. There are no nanowastes included in the List of Wastes that are specifically identified as being of nanoscale.

For reasons discussed above, it is unlikely that nanowastes will be categorised as hazardous under the Waste Framework Directive unless the waste is already classified as hazardous on the basis of the bulk form._This conclusion agrees with an analysis of existing European waste legislation conducted by the German Chemical Industry Association (VCI) who found there is no specific examination of nanomaterials under the current provisions[78]. Bystrzejewska-Piotrowska et al. (2009) find that, so far, no nanowaste has been regulated as hazardous waste[79]. This suggests that unless the nanomaterials is already classified as hazardous on the basis of the bulk form, for example in the case of zinc oxide, it is unlikely that nanowastes will be captured under provisions in the Directive that serve to regulate the management of hazardous waste.

However, since many commercial products are expected to enter the end of life stage of the life cycle as nanowaste in municipal waste streams, under Article 20 they would anyway be exempt from the specific requirements. For example, zinc oxide is classified under the CLP Regulation as N, dangerous to the environment, and specifically as R50/53, very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment[80]. Nano forms of zinc oxide are contained in a number of consumer products that can be expected to be disposed of in municipal waste streams, incluing sun screens, lipsticks, antibacterial lotions, paints and functional coatings on wood, plastics and fabrics.

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[76] Royal Commission on Environmental Pollution “Novel Materials in the Environment: The Case of Nanotechnology” (2008), RCEP, UK

[77] Franco, A., Hansen, S.F., Olsen, S.I. and Butti, L. 2007, “Limits and prospects of the “incremental approach” and the European legislation on the management of risks related to nanomaterials,” Regulatory Toxicology and Pharmacology, 48, 171-183

[78] VCI “Guidance for the safe recovery and disposal of waste containing nanomaterials” (2009) VCI, Germany

[79] Bystrzejewska-Piotrowska G, Golimowski J and Urban PL “Nanoparticles: Their potential toxicity, waste and environmental management” (2009) Waste Management 29 (9) 2587-2595

[80] UMICORE website, last accessed 31.7.11 at:
http://www.zincchemicals.umicore.com/ZincMetalPigment/ZMPhse/ZMPhseClassify.html

The only stage at which requirements could be triggered for municipal waste that had been classified as hazardous on the basis of nanowaste content (or on the basis of any other hazardous content) would be once they had been accepted for collection, disposal or recovery by a waste management operation with a permit. This would depend upon the individual Member State having established specific separation, collection and waste management procedures for municipal waste containing nanowastes. This is not the case in any Member State to date and it remains uncertain as to whether there is sufficient evidence regarding the possible hazards from nanomaterials in different waste streams to warrant such an approach given the considerable cost it would entail.

An example of a scheme that is the systems set up in Member States to promote and maximise the separate collection of waste batteries and accumulators and to prevent their being thrown away as unsorted municipal refuse in order to meet the requirements of Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators[81]. Member States must make arrangements enabling end-users to discard spent batteries and accumulators at collection points in their vicinity and have them taken back at no charge by the producers. Collection rates of at least 25% and 45% have to be reached by 26 September 2012 and 26 September 2016 respectively.

3.6 Controls on hazardous waste

The categorisation of a waste as hazardous waste under the Framework Directive on Waste is important as it then triggers a number of additional requirements regarding the management of hazardous wastes. These additional requirements are summarised in box 5 below.

Since the majority of nanowaste resulting from the disposal of consumer products containing nanomaterials can be expected to be sourced through municipal waste streams, the specific conditions for hazardous waste will not apply (as according to Article 20), unless the nanowastes have been characterised as hazardous according to the CLP Regulation and specific separation and collection schemes have been established at the Member State level by authorised waste management operators (registered and with permits). Exemption from Article 17 is particularly relevant, since Article 17 stresses the need for action to ensure that production, collection, transportation, storage and treatment of hazardous waste is carried out in conditions that provide protection for the environment and human

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[81] Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators, OJ L 266, 26.9.2006, p. 1–14

health. The more general provisions of Article 13 providing for the protection of human health and the environment still apply, but the generality affords a less rigorous approach.

Box 5: Requirements on the management of hazardous waste

Article 17: ensuring that the production, collection, transportation, storage and treatment are carried out in conditions that provide protection for the environment and human health, including traceability.

Article 18: Hazardous waste shall not be mixed with other categories of hazardous waste, waste substances or materials, unless the mixing in carried out by an establishment or undertaking with a permit, adverse effect on the environment is not increased and best available techniques are employed.

Article 19: In the course of collection, transport and temporary storage, hazardous waste must be packaged and labelled in accordance with international and Community standards in force. Hazardous waste that is transferred within a Member State shall be accompanied by an identification document.

Article 35: Establishments or undertakings producing, collecting, transporting or dealing in hazardous wastes shall keep records of the quantity, nature and origin of the waste, and where relevant of the destination, frequency of collection, mode of transport and treatment methods foreseen. Records for hazardous waste are to be preserved for at least three months, with a minimum duration of 12 months. The information shall be made available to the competent authorities upon request.

Sources of nanowaste exhibiting hazardous properties that could be subject to specific control include industrial wastes. Again, since it is likely that not all nanowastes that exhibit hazardous properties will be recognised as hazardous wastes according to the criteria laid down in Annex VI of CLP Regulation 1272/2008, some nanomaterials that demonstrate different (eco)toxicological profiles at the nanoscale will slip through and requirements will not apply.

The Trojan horse effects of nanomaterials, whereby some nanomaterials have been found to pick up and transport other more hazardous substances[82], are relevant when considering the requirement under Article 18 to avoid mixing hazardous wastes with other waste types, unless the mixing is carried out by an establishment or undertaking with a permit, adverse effect on the environment is not increases and best available techniques are employed. The ability of nanomaterials to transport other environmental pollutants, whereby the toxicity of those pollutants is then increased, suggests that nanowaste should not be mixed with hazardous wastes under any conditions. This would be particularly relevant for liquid nanowastes, where the mobility of the nanomaterials is higher. Avoiding the mixing of nanomaterials with hazardous waste requires both that:

- Nanowaste that has been categorised under the CLP Regulation as hazardous should not be mixed with other hazardous wastes, waste substances or materials **under any conditions**; and
- Hazardous wastes should not be mixed with municipal wastes that can be assumed to contain nanowastes.

3.7 The Waste Hierarchy

With regards to the impact of nanowastes on the capacity of waste managers to apply the waste hierarchy (as required under Article 4), further understanding of the behaviour of nanowastes within the various processes involved is required. There are two key questions regarding nanowastes in waste management processes,

- their effect on the integrity of the process; and
- their release as free nanoparticles into the environment.

However, due to a paucity of research on the end of life of nanomaterials, the behaviour of different nanomaterials in waste management processes and the degree of release into the environment is not yet fully understood. Initial results suggest that behaviour within process is determined by the specific properties of the nanoparticles in question, with different nanoparticles exhibiting a wide range of

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[82] Baun A, Sørensen SN, Rasmussen RF, Hartmann N, Bloch I, Koch CB “Toxicity and bioaccumulation of xenobiotic organic compounds in the presence of aqueous suspensions of aggregates of nano-C60” (2008) Aquatic Toxicology 86 (3) 379-387; Hartmann N, Bloch I and Baun A “The nano cocktail – ecotoxicological effects of engineered nanoparticles in chemical mixtures” (2010) Integrated Environmental Assessment and Management 6, 311-313; Baun A, Hartmann NB, Grieger K and Kusk KO "Ecotoxicity of engineered nanoparticles to aquatic invertebrates: a brief review and recommendations for future toxicity testing" (2008) Ecotoxicology 17(5) 387-95

behaviours, making it more complicated to regulate nanowastes as a group of substances. In 2008 in the EU-27, 5.4 % of waste was incinerated, 45.7 % was recovered and 48.9 % was disposed of[83].

In terms of preventing the generation of waste, industry claims that future applications of nanomaterials will serve to reduce overall resource use by allowing the development of nanoscale functions that require much reduced raw material inputs. For example, boron nitride nanotubes (BNNTs) are expected to find application in nanoscale electronic and optoelectronic devices. These devices are expected to have smaller dimension, cost fewer resources and less energy to fabricate, and consume less energy due to minimum electron scattering in their ideally defect-free tubular structures[84]. Another example is the use of stronger, lighter nanomaterials such as composite wood/nonwood nanoscale biomaterials being developed which could decrease fuel and material use[85]. Furthermore, nanotechnology promises to make current wastewater treatment processes more energy efficient by using single-stage treatment methods that can remove biological and chemical contaminants in treated wastewater (e.g. Kamat et al, 2002).

Engineered nanomaterials may also reduce the amount of harmful substances produced during reactions, such as heavy metals. For instance, BASF's "NanoSelect" catalyst is an alternative for select hydrogenation catalyst which eliminates the presence of toxic lead[86]. While reduced material input and reduced waste generation need not necessarily correlate positively, it can be posited that with a significant reduction in raw material input, a reduction in waste generation would follow.

3.8 Reuse

With regards to possibilities for the re-use of wastes containing nanomaterials a complete picture of likely re-uses is not currently available. Access to information on the quantitative and qualitative characteristics of possible non-waste by-products generated during the production of nanomaterials and their subsequent use is limited by non-disclosure policies. The legal status of possible non-waste

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[83] Eurostat "Waste statistics" Data from 2010, last accessed 3/6/11 at: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Waste_statistics#Waste_generated_by_households

[84] Ming X "Synthesis and characterization of advanced nanomaterials for energy applications" (2010) MTI, US http://proquest.umi.com/pqdlink?Ver=1&Exp=03-06-2016&FMT=7&DID=2159206911&RQT=309&attempt=1&cfc=1

[85] e.g. Berglund et al (2004) Cellulose nanocomposites. In Mohanty M (ed) Natural fibers, biopolymers and their biocomposites. CRC Press, Boca Raton, FL

[86] BASF 'NanoSelect' Catalyst: http://www.catalysts.basf.com/Main/process/chemical_catalysts/fine_and_specialty_chemicals/selective_hydrogenation.be

by-products is considered in a 2007 Commission Communication on the Interpretative Communication on waste and by-products[87], which serves to elucidate the distinction between waste and non-waste within the context of the production process. The Communication indicates that should the use of a by-product have a higher environmental impact than an alternative materials that it replaces, this can affect the decision as to whether the waste can be categorised as a by-product. The distinction is important as should a waste material containing or contaminated with nanomaterials with hazardous properties cease to be a waste and be considered a by-product, it then falls outside of waste legislation.

With regards to the possible toxicity of by-products, a study by Templeton *et al.* suggests that the by-products generated in the manufacture of single walled carbon nanotubes may potentially cause deleterious effects[88]. Noting that different manufacturing processes will generate different nanoscale derivatives from the same material, Musee notes that these nanowastes may then exhibit different toxicological and ecotoxiocological properties and as such require different waste management approaches, as yet undeveloped[89].

A known example of the re-use of by-products generated in the production of nanomaterials is found in the use of low purity C_{60} fullerene soot in the lubricants industry. It can, however, be expected that this use would in turn generate residues[90]. An example where reuse remains in the experimental phase is the recovery and reuse of scandium nanomaterials from waste containing scandium generated in the production of metallic nitride fullerene nanomaterials, where Wynne *et al*. have demonstrated safe method to recover and reuse the scandium content in the waste.[91]

It would serve the regulatory purpose to have further information from industry on the possible by-products that are currently generated and could in the future be generated in the production of nanomaterials. Such information would allow for an informed assessment of whether it would be

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[87] Communication from the Commission to the Council and the European Parliament on the Interpretative Communication on waste and by-products, 2007, COM(2007) 59 final

[88] Templeton RC, Ferguson PL, Washburn KM, Scrivens WA, Chandler GT "Life-cycle effects of single-walled carbon nanotubes (SWNTs) on an estuarine meiobenthic copepod" (2006) Environmental Science and Technology 40(23) 7387–93

[89] Musee N, "Nanowastes and the environment: Potential new waste management paradigm" (2011) Environment International 37, 112- 128

[90] Franco A, Hansen SF, Olsen SI and Butti L "Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials," (2007) Regulatory Toxicology and Pharmacology 48, 171-183

[91] Wynne J, Buckley J, Coumbe P, Phillips J and Stevenson S "Reducing hazardous material and environmental impact through recycling of scandium nanomaterial waste" (2008) Journal of environmental sciences and health: Part A, Toxic/hazardous substances and environmental engineering 43 (4) 357-360

relevant to adopt measures establishing criteria under Article 5 of the Waste Framework Directive for by-products containing specific nanomaterials for which concerns have been identified.

3.9 Recycling

In terms of the ease of recycling wastes containing nanomaterials and their possible effects on recycling processes, knowledge remains limited. Some commentators have raised concerns that the mechanics of the recycling process, including crushing, cutting and grinding, may serve to liberate significant amounts of nanomaterials[92]. Simulation studies could provide a useful data source on potential releases of nanomaterials during recycling processes. Typically such studies attempt to simulate, often at worse cases a process which may lead to a release. An example may be found in a study by Gohler et al. (2010), which measured emissions from a sanding simulation using polyurethane coating and architectural paint containing two types of nanoparticles[93].

Should this prove to be the case, high quality recycling as required under Article 11 may ultimately require the elimination of wastes containing nanomaterials from household waste collection (and where relevant from other sources). In particular, there are applications for nanomaterials in paper and food packaging, both product types that may then be channelled for recycling by households. In addition, plastic containers may be contaminated with nanomaterials. For example a plastic bottle for a detergent that contained nanomaterials in liquid suspension would then be contaminated with some residue of nanomaterials. Pre-treatments of recycled wastes such as shredding may serve to liberate nanomaterials from host materials and introduce them into effluents following washing processes.

The discussion of measures by which to manage the waste streams channelled for recycling remains speculative until such time as a greater understanding can be gained of the impacts of nanomaterials on recycling processes for paper and plastics and possible release pathways during these processes. Given that it can be expected that many consumer products containing nanomaterials will be disposed of in municipal waste, controlling the entry of nanowaste into waste streams targeted for recycling

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[92] International Council on Nanotechnology "Advancing the eco-responsible design and disposal of engineered nanomaterials: An international workshop," held March 9-10, 2009, Rice University, Houston, Texas, USA, Last accessed 14/05/11 at: http://cohesion.rice.edu/centersandinst/icon/emplibrary/ICON_Eco-Responsible_Design_and_Disposal%20of_Engineered_Nanomaterials_Full_Report.pdf

[93] Göhler D, Stintz M, Hillemann L and Vorbau M "Characterization of nanoparticle release from surface coatings by the simulation of a sanding process" (2010) The Annals of Occupational Hygiene 54, 615-24

would be a challenging task. A decision to control the entry of nanowastes into municipal waste streams would involve measures including: an agreed definition of nanomaterials; clear labelling of nanoproducts (including nanoproducts produced outside of the EU); consumer awareness raising regarding the presence of nanomaterials in products and the need to separate out nanowaste; and programmes for the separation and collection of nanowastes from municipal wastes at the level of the household. Implementing such measures would have considerable technical and economic implications, as well as knock-on effects on other policy objectives. For example, the removal of packaging materials contaminated with nanowastes from packaging waste streams targeted for recycling would then have implications for the achievement of overall recycling goals for those materials, as discussed below. In the absence of data regarding the volumes of nanoproducts on the market and their life cycles, it is not possible to currently estimate the impact on recycling goals of removing all nanoproducts from waste streams channelled to recycling.

3.10 Recovery

With regards to energy recovery through incineration, there is speculation as to whether incineration of wastes containing nanomaterials may lead to the generation of gaseous emissions containing nanomaterials. It is unknown what fraction of nanomaterials remains in the slag and what fraction enters flue gases[94]. The thermal properties of specific nanomaterials will determine their behaviour within incinerators and ultimately whether nanoparticles are degraded or are released into the environment through gaseous emissions or in disposal of slag. Modern waste incineration plants are equipped with different types of filters, including electrofilters, flue gas scrubbers, catalytic NO_x/furan/dioxin removers and in some cases fabric filters. Burtscher et al found such filters to reduce the concentration of particles less than 100nm by around 99%[95]. The efficiency of wet scrubbers has been found to vary significantly for particles less than 5,000nm (see figure 2)

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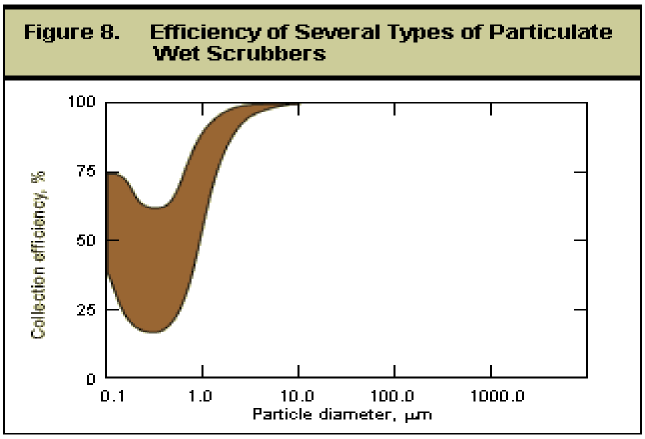
[94] Som C, Berges M, Chaudry Q, Dusinska M and Fernandes T “The importance of life cycle concepts for the development of safe nanoproducts” (2010) Toxicology 269, 160-169

[95] Burtscher H, Zürcher M, Kaspar A and Brunner M “Efficiency of flue gas cleaning in waste incineration for sub micron particles” In Mayer E “Procedures of an international ETH conference on nanoparticle management” (2002) BUWAL

Figure 2: Efficiency of wet scrubbers in removing nanoparticles



Source: US EPA, 2010, Air Pollutants and Control Techniques - Particulate Matter - Control Techniques.

Charged wet scrubbers have been demonstrated to have over 99% efficiency for removing particles in the range 100-2,500nm. A study by Cataldo demonstrated that the thermal properties of nanomaterials derived from the same bulk material can vary considerably, with C60 fullerenes showing a much greater thermal reactivity and hence degradability than carbon nanotubes, which remain stable until very high temperatures[96]. Understanding of the behaviour of specific nanomaterials under conditions within an incinerator remains very limited. Once waste is channelled for incineration, it ceases to fall under the remit of waste legislation and instead subsequent emissions are regulated under Directive 2010/75/EU on Industrial Emissions[97]. The Nano Working Group of the Swiss Federal Office of the Environment recommends avoiding the incineration of wastes with a high content of free nanoparticles in municipal waste incinerators, due to the paucity of knowledge regarding the behaviour of high concentrations of nanoparticles in an incinerator[98].

With regards to the possibility of the recovery of nanomaterials, Liu et al have proposed several techniques for the treatment and disposal of solid nanowastes generated from industrial sludge,

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[96] Cataldo, F, 2002, "A study on the thermal stability to 1000°C of various carbon allotropes and carbonaceous matter both under nitrogen and in air." Fullerene Nanotubes and Carbon Nanotubes, 4 (20), 293-311

[97] Directive 2010/75/EU on Industrial Emissions, OJ L334, 17.12.2010, 17

[98] Swiss Federal Office of the Environment "How to treat nanowaste: challenges and information needs along the disposal chain" (2010) last accessed 22.04.11 at http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/16_How_to_treat_Nanowaste.pdf

allowing for the reuse of nanomaterials in other applications[99]. However, industrial scale applications have not yet been implemented.

3.11 Waste Oils

Given the current use of nanomaterials in lubricants, it is likely that some waste oils will contain nanomaterials. Article 21 on waste oils recognises that Member States may give priority to the regeneration of waste oils. The possible impacts of nanomaterials on oil regeneration are not known. There are no requirements specific to waste oils that contain nanomaterials. Following Article 21 (1)(c), the mixing of oils of different characteristics should be avoided if this mixing impedes their treatment. This raises two key questions:

- Do nanomaterials impede the treatment process for waste oils?
- Is it technically and economically feasible to separate out waste oils that contain nanomaterials?

To date, no publicly available report has indicated that nanomaterials currently present in waste oils affect the treatment processes. No research has however addressed the first question, implying that the possible effects of nanomaterials on waste oil treatment processes are unknown. Regarding the separation of waste oils containing nanomaterials from other waste oils, this would require the imposition of a number of measures on oils containing nanomaterials, including but not limited to: an agreed definition of nanomaterials; clear labelling; consumer awareness raising; techniques for separate storage, collection and disposal.

3.12 Permits

Under the Waste Framework Directive, Member States are required to issue permits to waste treatment facilities, based upon the types of wastes being treated and specifying technical and safety

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[99] Liu W-Z, Xu X-J, Wang J-Y-J, He Z, Zhuo N, Huang F *et al,* “Treatment of Cr(VI) containing nanowastes via the growth of nanomaterial” (2010) Chinese Science Bulletin 55(4-5) 373-7

requirements. Again, since some nanomaterials that exhibit hazardous properties may not be recognised as such (since they are not hazardous at the bulk scale) and there are no nanoscale wastes included in the List of Waste, it is unlikely that permits will include specific requirements for managing wastes containing nanomaterials.

3.13 Waste Management Plans

Member States are obliged to establish waste management plans that analyse the current waste management situation in the country and support the objectives of the Waste Framework Directive. Given the lack of any mention of wastes containing nanomaterials in the Waste Framework Directive, it is unlikely that Member States will include information on the specific management of nanomaterials.

3.14 Penalties and Enforcement

With regards to inspections by competent authorities of establishments or undertakings that produce waste containing nanomaterials, no inspections will be specifically required on the basis of the nano-content of the waste, although inspections will take place under the general duty. Such inspections would be required where the waste to be categorised as hazardous, which then returns to the uncertainties regarding the specific properties of nanomaterials versus the bulk form, questions regarding the applicability of test methods under the CLP Regulation and the appropriateness of thresholds in the List of Waste.

Penalties established at the discretion of the Member States for the dumping of wastes containing nanomaterials may not reflect the actual potential for harm. In addition, Member States authorities may not have the appropriate equipment to allow them to recognise waste containing nanomaterials.

3.15 The coverage of nanomaterials under the Waste Framework Directive

In the discussion above, a number of issues were identified in the legislative coverage provided for nanomaterials entering the waste management stage of the life cycle, as regulated by the Waste

Framework Directive. These issues are summarised in table 1 below, together with a summary of the possible implications. In addition, knowledge gaps and limitations in technical capacities for measuring nanomaterials were highlighted and these are summarised in box 6. The most significant gaps related not to the Waste Framework Directive itself but rather to question regarding the classification of nanomaterials as hazardous under the CLP Regulation.

To summarise, provisions established to identify and separate hazardous wastes and channel these wastes for specific treatment are unlikely to capture all hazardous nanowastes, due to limitations in applying the procedures under the CLP Regulation for the identification of hazardous properties to nanomaterials. It is possible that some nanowastes will have fundamentally different hazard profiles to those of the equivalent bulk form and that these characteristics may be overlooked due to the lack of a specific legal requirement to investigate them. Were the hazardous properties of specific nanomaterials to be identified under CLP, this would serve to trigger specific management procedures for wastes recognised and labelled as containing those hazardous nanomaterials, such as industrial wastes and possibly wastes from medical establishments.

However, the disposal of most consumer products containing nanomaterials is likely to be exempt from requirements on hazardous waste because such products will be channelled through municipal waste streams. Controlling the entry of nanowastes from consumer products into municipal waste streams is currently not possible. Were procedures and supporting technologies to be developed to

Feedback from the Stakeholder Workshop

The validity and relevance of interpreting a lack of specific coverage of nanomaterials under waste legislation as legislative gaps was called into question at the stakeholder workshop. A participant stressed that attempting to regulate the potential adverse effects of nanonmaterials at the end of their life represents an end-of-pipe approach. Greater efficiency would be achieved by addressing any potential risks at source, i.e. at the point of their registration under REACH. Annex I of REACH sets out the general provisions for assessing substances and states that the assessment shall include all stages of the life cycle of the substance resulting from the manufacture and identified uses. However, it should be noted that the requirement to conduct a chemical safety assessment applies only to those substances subject to registration in quantities of 10 tonnes or more per year per registrant. The majority of nanomaterials on the market will not be captured under this tonnage threshold, implying that possible exposure scenarios along the life cycle of possible uses will not be described in the registration dossier.

allow for the identification and separation of nanomaterials, their implementation would be challenging and costly, as discussed above.

It would therefore appear to be more efficient to identify those specific nanomaterials that pose hazards to the environment and employ upstream product controls to prevent their entry into product life cycles and ultimately into waste streams. Although the systematic identification of the hazard profiles of different nanomaterials is currently subject to data limitations, it can be expected that concerted efforts driven by regulatory requirements could redress those limitations.

Feedback from the Stakeholder Workshop

Given the challenges in separating out wastes containing nanomaterials and the lack of knowledge regarding appropriate treatment, specific measures addressing waste containing nanomaterials were considered to be unenforceable and therefore redundant. Any environmental risks related to nanomaterials should be addressed upstream under chemicals legislation. The participant went on to stress that EU chemicals legislation should be amended to ensure that any hazardous properties of nanomaterials are captured and that this information then ensures their correct treatment as hazardous waste.

Table 1: Summary of issues relating to the coverage of nanomaterials under the Waste Framework Directive and the associated implications and uncertainties

Issues	**Article**	**Type of gap, implications and uncertainties**
Wastes that contain nanomaterials that display hazardous properties that are not seen in the bulk form may not be classified as hazardous under Annex VI of CLP Regulation No 1272/2008 because: • Criteria against which hazardous properties are assessed were established without consideration of the specific properties of nanomaterials, with concentration thresholds not applicable to nanomaterials • Test methods in Annex V are not tailored to nanomaterials • Data on the intrinsic properties of nanoforms may not be readily available and there is no obligation under CLP to generate new data.	CLP Regulation	Legislative gap: Nanowastes that display hazardous properties may not be recognised as such and would therefore be exempt from provisions applying to hazardous wastes, including: Article 17 protecting the environment and human health, traceability; Article 18: mixing ban; Article 19: packaging and labelling; and Article 35: records. Possible practical implications for nanowastes when hazardous properties are not recognised under CLP include: • Possible releases into the environment during the waste management chain • No traceability • Mixing with other categories of hazardous waste with possible Trojan horse effects in transferring environmental pollutants • Possible environmental contamination from management without proper packaging and labelling • No records collected
Municipal waste is expected to be one of the largest sources of nanowaste into the environment and is exempt from a number of provisions that establish specific requirements for hazardous waste	Article 20	Potential limitation: Nanowastes displaying hazardous properties may be channelled through municipal waste streams into: • Landfills for non-hazardous waste • Recovery through Incineration • Recycling processes • Re-use as by-products Evidence regarding the behaviour of nanomaterials in these waste management processes, associated exposure pathways and possible negative effects on the environment is lacking. In addition, similar concerns exist for non-nano hazardous substances in consumer products.
No specific provisions for waste oils containing nanomaterials	Article 21	Potential imitation: There exists uncertainty regarding the characteristics of waste oils containing nanomaterials and their possible effect on waste oil treatment techniques – this remains speculative at this stage. Given the Trojan horse effect of nanomaterials and the mobility of nanomaterials in liquids this should be the subject of research.
There is no definition of nanowaste in the Waste Framework Directive and no mechanism for generating information on the nanowaste content in different waste streams	n/a	Potential limitation: No basis for ensuring that waste managers are aware of the nanowaste content in specific waste streams, even nanowaste from industrial sources. No basis for applying any specific waste management techniques to nanowaste, should this be deemed necessary. No basis for controlling the entry of nanomaterials into waste streams targeted for recycling, should this be deemed necessary
Permits waste management facilities do not consider any specific practice for the management of nanowaste	Article 23	Potential limitation: Nanowastes are currently managed without any specific requirements, there is currently no evidence to suggest that specific requirements are necessary or what such requirements might be.
No requirements regarding the management of nanowaste in waste management plans	Article 28	Potential limitation: No information generated on the management of nanowaste in Member States for consideration at EU level

Box 6: Summary of knowledge gaps and limitations in technical capacities relating to waste

Knowledge gaps:

- Information on which products contain nanoparticles and what concentrations are present.
- Life cycle analysis for nanoparticles and products containing nanomaterials.
- Information on which waste streams contain nanowaste.
- Whether concentration by mass is the most appropriate metric to report the presence of nanomaterials.
- Specific information on the behaviour of nanomaterials within solid matrices over time is not available for nanoproducts (as there is no legislative requirement for the producers to generate this information and make it publically available).
- Information on possible re-uses of nanomaterials to reduce waste.
- Information on possible uses of nanowaste as by-products and the associated environmental impacts.
- Information on the impact of nanomaterials on recycling processes.

Limitations in technical capacities:

- Test methods that specifically address the properties of nanomaterials
- Authorities unlikely to have technologies that would allow then to identify wastes containing nanomaterials, even if monitoring for nano content in waste were required.
- Separation technologies for wastes containing hazardous nanomaterials

Below, some of the approaches towards managing nanowastes that have been discussed by commentators are briefly outlined.

A number of commentators have called for the establishment of a definition of nanowastes[100]. Certainly, should it be desirable or necessary to specifically identify wastes as nanowastes, then a definition would be required. Given that there is concern from some quarters about the potential risks of nanomaterials in general (rather than because of a specifically identified risk), it may be that specific identification of wastes that contain nanomaterials would be desirable from a policy perspective. However, there would presumably be very significant cost implications and this could lead to an inconsistent/unwarranted focus on nanomaterials to the detriment of other types of wastes.

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[100] Franco A, Hansen SF, Olsen SI and Butti L “Limits and prospects of the “incremental approach” and the European legislation on the management of risks related to nanomaterials,” (2007) Regulatory Toxicology and Pharmacology 48, 171-183; Musee N “Nanowastes and the environment: Potential new waste management paradigm” (2011) Environment International 37, 112- 128

With regards to establishing a definition for nanowastes, in the case where the waste material is entirely composed of nanomaterials the categorisation is clear. However, the more likely scenario is that waste materials will contain a certain percentage of nanomaterials bound within a host material. The legal challenge will be to establish a practical definition of nanomaterials in a waste material that leads it to be categorised as "nanowaste" that can capture nanoproducts, residues of nanomaterials in products and containers.

A BSI publication entitled the "Guide to safe handling and disposal of manufacture nanomaterials"[101] stresses that in the absence of knowledge regarding the risks associated with nanomaterials it is inappropriate to assume that a nanoparticle form of a material has the same hazard potential as in the bulk form. It goes on to recommend that all nanomaterials be considered potentially hazardous unless sufficient information to the contrary is obtained. Since evidence suggests that nanomaterials can display hazardous properties when released into the environment, Franco et *al* recommend introducing "free nanoparticles" under Annex III of the Waste Framework Directive, which lists the properties of a waste that render it hazardous (Franco *et al*, 2007). Achieving categorisation of nanowaste as hazardous under the Waste Framework Directive comes up against the barriers discussed above, relating to data availability, test methods and metrology. In order to circumvent these barriers, a revision to the List of Wastes could be used to classify nanowastes as hazardous. Führ *et al* (2006) recommend the separate listing of nanomaterials under the List of Wastes, with a specific waste code[102].

Feedback from the Stakeholder Workshop

Referring to a Dutch report due to be published this summer (2011) on nanomaterials and waste, a participant noted that awareness of nanomaterials amongst operators at waste management facilities was found to be non-existent. This raises concerns regarding both health and safety and environmental exposure and underlines the fact that nanowastes will not receive any specific waste treatment. Participants stressed the need for specific guidance on how to manage wastes that contain nanomaterials and awareness-raising amongst waste operators.

However, the effect of categorising nanowaste as hazardous under Annex III of the Waste Framework Directive or the List of Wastes would be somewhat limited given that consumer products containing nanomaterials are disposed of in municipal waste streams and they are not labelled for their nano content. Sources of nanowaste that would be affected include industrial wastes, such as solid wastes (including nanomaterials in

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[101] British Standards Institute "Guide to safe handling and disposal of manufactured nanomaterials" (2007) BSI, UK

[102] Führ M, Hermann A, Merenyi S, Moch K And Möller M "Legal appraisal of nano technologies" Final Report (2006) Öko-Institu/Sofia, Darmstadt, Germany

powder form that have a high potential for dispersal, e.g. carbon nanotubes soot), materials contaminated with nanomaterials and possibly sludges from waste water treatment plants. However, currently operators of waste treatment facilities do not know which waste streams contain nanowaste and there is no obvious source of this information. There is no legal obligation for the producers of nanoproducts or nanowaste to transfer information on the nano content of their product or waste down the value chain to waste managers. In addition, techniques allowing for the identification of nanowaste within specific waste streams are not available.

Alternatively, if the OECD test methods are refined such that they can be applied separately to nanomaterials (where appropriate), the existing hazard classifications under CLP could be applied to nanomaterials based on those tests. The requirement under CLP to then communicate hazard information down the supply chain would serve to generate an information flow for products containing specific nanomaterials identified as hazardous, allowing subsequent hazardous nanowastes to be processed under current procedures for the management of hazardous wastes.

4. Decision 2000/532/EC on the List of Waste

4.1 Introduction

This list serves to provide a common encoding of waste characteristics, including the classification of hazardous wastes. The assignment of waste codes then determines the procedures to be imposed when transporting different wastes, the granting of installation permits for the processing of specific wastes, and decisions about the recyclability of waste materials. The current List of Waste does not mention wastes that contain nanomaterials in any form.

In addition, in establishing the properties that led to the categorisation of a waste as hazardous, Article 2 of the Decision includes concentration thresholds for all properties other than thermal flash point. The specific properties of nanomaterials mean that concentrations given in mass terms and used to establish thresholds may not be best suited for nanomaterials, since for example toxicology studies indicate that toxicity of some nanomaterials increases with decreased dimensions of particles[103].

Article 7 provides that should a Member States consider a waste as hazardous, even though it does not appear on the list of waste, the Member States shall notify the Commission and include information in their report on implementation of the Directive. This provides a channel through which information on the possible hazard status of specific nanomaterials could reach the Commission. These nanomaterials could then be considered by the technical committee charged with reviewing the List of Waste.

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[103] European Commission, Health and Consumer Protection Directorate General, 2004, “Nanotechnologies: a preliminary risk assessment on the basis of a workshop” European Commission, Brussels, Belgium

4.2 Coverage of nanomaterials under the List of Waste

Possible issues in the coverage of nanomaterials under the List of Waste and the associated implications are summarised in table 2 below.

Table 2: Summary of issues relating to the coverage of nanomaterials under Decision 2000/532/EC on the List of Waste and their implications

Issues	**Article**	**Type of gap, implications and uncertainties**
No mention of wastes containing nanomaterials	n/a	Potential limitation: Nanowastes have no categorisation and are not "recognised" by waste managers
Mass-based concentration thresholds are given for all hazardous properties (other than thermal flashpoint). In some cases, this may not be appropriate for nanomaterials.	Article 2	Potential limitation: A hazardous nanowaste may still involve risk at concentrations below the thresholds established in the list of waste. If hazardous nanowastes are identified, specific thresholds could be introduced in Article 2.

5. Directive 2000/53/EC on end-of-life vehicles

5.1 Introduction

Directive 2000/53/EC (the ELV Directive) [104] aims at reducing the quantity of waste arising from vehicles through the prevention of waste from vehicles and promoting the reuse, recycling and other forms of recovery of end-of-life vehicles and their components. It encourages vehicle manufacturers and importers of vehicles to limit the use of hazardous substances in new vehicles, to design and produce vehicles which facilitate re-use and recycling and to integrate recycled materials in vehicles (Article 4). The Directive states that collection systems for waste shall be established and end-of-life vehicles shall be transferred to authorised treatment facilities. A certificate of destruction is to be provided to the owner/holder of the end-of-life vehicle (Article 5). The Directive states that end-of-life vehicles shall be stored and treated in accordance with the requirements of the Framework Directive on waste (Article 6). The rate of re-use and recovery should reach 95% by average weight per vehicle per year no later than 1 January 2015. The rate of re-use and recycling should reach 85% by average weight per vehicle per year no later than 1 January 2015 (Article 7). Producers shall use material and component coding standards, allowing the identification of the various materials and components and facilitating the dismantling of end-of-life vehicles (Article 8). This Directive does not refer to the treatment, recycling or recovery of nanomaterials that may potentially be contained in different parts of end-of-life vehicles.

The automotive industry supply chain has traditionally been organised into several tiers. The roles in the supply chain include:

- OEMs: Design, manufacturing of components and assembling of the car;
- First tier: Manufacture and supply of products and components directly to the car manufacturer (e.g. fuel pump);
- Second tier: Production of simpler, individual parts to be included in a product or component manufactured by a first tier (e.g. housing of a fuel pump); and
- Third and fourth tiers: Mostly raw materials or manufacturers of sub-components.

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[104] Directive 2000/53/EC on end-of life vehicles, OJ L 269, 21.10.2000, p. 34–43

However, in recent years car manufacturers have gradually moved from procurement of discrete parts to procurement of integrated or modular systems from larger and often global firms. There are, however, many thousands of suppliers for typical vehicle manufacturers, something which is likely to make later identification of nanomaterials present in vehicles problematic at the end-of-life, if no information is disseminated on such presence. It is possible that the automotive industry's 'International Material Data System' or the 'Global Automotive Declarable Substance List' could be used to communicate information on nanomaterials present in vehicles, however at present it does not include appropriate data elements.

5.2 Potential presence of nanomaterials in end-of-life vehicles

A report concerning the use of nanomaterials in the automotive sector notes that the automotive industry can benefit from nanomaterials in almost all parts of vehicles including frames and body parts, engines and powertrain, paints and coatings, suspension and braking systems, lubrication, tyres, exhaust systems, catalytic converters and electric and electronic equipment (see Table 3)[105]. The global revenue from nanotechnologies in the automotive sector is predicted to increase from $404m in 2007 to $7,134m in 2015[106].

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[105] Steinbeis-Europa-Zentrum, FFG, "Nanomaterial Roadmap 2015, SWOT Analysis, Concerning the Use of Nanomaterials in the Automotive Sector" Sixth Framework Programme funded by the European Commission

[106] UK Department for Business, Innovation and Skills "UK Nanotechnologies Strategy: Small technologies, great opportunities"(2010), UK

Table 3: Examples of nanomaterials currently used in vehicles:

Domains of application	**Nanomaterials used at an industrial scale**
Frame and body	Polymer nanocomposite (e.g. clay nanocomposite olefin plastics for exterior parts)
Engine and powertrain	Polymer nanocomposite (e.g. used to replace metals in motor vehicles because much lighter) Nanocrystalline structures (e.g. fuel injector for diesel engine integrating thin diamond like carbon coatings)
Paints and coatings	Nanocoating applications (e.g. Iridescent coatings, carbon nanotube based paints, corrosion protection coatings, scatch-proof, transparent coatings, fluoropolymer composites allowing water-and dirt-repellent effect, photochromic and electrochromic window coating, surface disinfectants, thermal spray coatings, electroconductive polymers)
Lubrication	Nanotechnology-based solid lubricants (e.g. new cooling fluids and ferrofluids)
Suspension and breaking system	Injection of nano iron-based particles into certain fluids
Tyres	Carbon black improves mechanical properties of car tyres

5.3 Coverage

According to Article 3, the ELV Directive shall cover vehicles and end-of-life vehicles including their components and materials. In principle therefore, any nanomaterials contained in end-of-life vehicles are covered by the general scope of the ELV Directive. This implies that the operative Articles of the ELV Directive that are discussed below apply to nanomaterials in end-of-life vehicles.

5.4 Prevention (Requirements to limit the use of hazardous substances in vehicles)

Article 4(1)(a) requires vehicle manufacturers, in liaison with material and equipment manufacturers, to limit the use of hazardous substances in vehicles from the point of initial conception of the vehicle onwards, so as to prevent their release into the environment, to facilitate recycling and avoid the need to dispose of hazardous waste. Hazardous substances are defined under Article 2(11) as any substance which fulfils the criteria for the hazardous classes set out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

As already mentioned in the analysis on the Waste Framework Directive, any specific nanomaterials are unlikely to be categorised as hazardous substances under the CLP Regulation unless the bulk substance of the nanomaterials is considered a hazardous substance[107]. Therefore Article 4(1)(a) of the ELV Directive will most likely only cover hazardous nanomaterials if the bulk form is also hazardous.

Pursuant to Article 4(2), materials and components in vehicles put on the market after 1 July 2003 shall not contain lead, mercury, cadmium, or hexavalent chromium. This provision could be a powerful tool to prohibit the use in vehicles of potentially dangerous nanomaterials in the future, if and when sufficient evidence exists that there are risks of sufficient concern.

5.5 Treatment

Pursuant to Article 6(3) (b) of the ELV Directive, any establishment or undertaking carrying out treatment operations shall remove and segregate hazardous materials in a selective way so as not to contaminate subsequent shredder waste from end-of-life vehicles in accordance with Annex I. As the legislation currently stands, hazardous nanomaterials may not be identified as such unless the bulk form is also considered hazardous. Therefore this provision may not apply to specific nanomaterials that exhibit hazardous properties.

Annex I of the ELV Directive sets minimum technical requirements for the treatment of end-of-life vehicles. Technical requirements that have been identified as of possible relevance to containing the

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[107] Whilst there are provisions for the form in which the substance is supplied to be taken into account, it is not clear that the nano-form will, in practice, be differentiated from the bulk form when classification and labelling is decided upon and whether specific data will be available regarding the nano-form

risks from nanomaterials are presented in table 4 below. Article 6(6) of the ELV Directive provides that Annex I shall be amended according to technical and scientific progress by comitology. Annex I could therefore be amended to provide specific requirements for the storage and treatment of nanomaterials contained in end-of-life vehicles, if there was deemed to be sufficient risk from specific nanomaterials to make such an amendment. Evidence of risk is currently lacking, given the lack of research specifically in this area.

Table 4: Technical requirements for the treatment of end-of-life vehicles of possible relevance to nanomaterials

Technical Requirements	**Possible exposure pathways for nanomaterials**
<u>Site storage requirements</u> (Annex I (1)) • Impermeable surfaces for appropriate areas with the provision of spillage collection facilities, decanters and cleanser-degreasers, • Equipment for the treatment of water, including rainwater, in compliance with health and environmental regulations	Additional requirements for nanomaterials might be necessary, given that spillages of oils, lubricants or fuels released from vehicles may contain nanomaterials. In particular, the treatment processes for spent waters may need to consider the presence of nanomaterials.
<u>Site treatment requirements</u> (Annex I (2)) • Impermeable surfaces for appropriate areas with the provision of spillage collection facilities, decanters and cleanser-degreasers • Appropriate storage for dismantled spare parts, including impermeable storage for oil-contaminated spare parts • Appropriate containers for storage of batteries (with electrolyte neutralisation on site or elsewhere), filters and PCB/PCT-containing condensers • Appropriate storage tanks for the segregated storage of end-of-life vehicle fluids: fuel, motor oil, gearbox oil, transmission oil, hydraulic oil, cooling liquids, antifreeze, brake fluids, battery acids, air-conditioning system fluids and any other fluid contained in the end-of-life vehicles, • Equipment for the treatment of water, including rainwater, in compliance with health and environmental regulations.	Vehicles parts may be contaminated with oils, fuels or lubricants that contain nanomaterials. It may be relevant to examine the permeability of current storage facilities for dismantled spare parts to nanomaterials in oils, lubricants or fuels. Batteries may contain nanomaterials. It may be relevant to assess the permeability to nanomaterials of storage tanks for the containment of end-of-life vehicle fluids.

Treatment operations for depollution (Annex I (3)) - Removal of batteries and liquefied gas tanks, - Removal and separate collection and storage of fuel, motor oil, transmission oil, gearbox oil, hydraulic oil, cooling liquids, antifreeze, brake fluids, air-conditioning system fluids and any other fluid contained in the end-of-life vehicle, unless they are necessary for the re-use of the parts concerned.	Fuels, oil lubricants can contain nanomaterials. The removal of fuels and lubricants will therefore cover the removal of nanomaterials contained in these liquids. However, it is highly likely that there would still be traces of fuel/lubricant in parts of the vehicle because the ELV Directive stipulates that liquids must be removed only to the extent that no visible further draining of oil is occurring.
Treatment operations in order to promote recycling (Annex I (4)) - Removal of catalysts: - Removal of tyres and large plastic components (bumpers, dashboard, fluid containers, etc), if these materials are not segregated in the shredding process in such a way that they can be effectively recycled as materials. - Removal of glass.	According to Harper and Hollister (2002) the largest market for functional nanomaterials today is automotive catalysts (11,500 tonnes). Therefore the removal of catalysts should encompass the removal of any nanomaterials contained in these catalysts. Nanomaterials may be contained in tyres or plastic components. Nanomaterials are used in coatings on some glass windows. The removal of glass would therefore encompass the removal of any nanomaterials contained in coatings on glass components. The impact of nanomaterials coating on recycling processes should be investigated.

5.6 Recycling and recovering

Pursuant to Article 7 of the ELV Directive, Member States shall take the necessary measures to encourage the recovery of components which cannot be reused (e.g. energy recovery through incineration) and give preference to recycling when environmentally viable.

As mentioned in the section on the Waste Framework Directive, knowledge on the ease of recycling of wastes containing nanomaterials and their possible effects on recycling processes remains limited. With regards to energy recovery through incineration, there is speculation as to whether incineration of wastes containing nanomaterials may lead to the generation of gaseous emissions containing nanomaterials. When products are incinerated, the thermal properties of nanoparticles determine their fate.

5.7 Coding standards/ dismantling information

Pursuant to Article 8, Member States shall take the necessary measures to ensure that producers, in liaison with material and equipment manufacturers, use component and material coding standards to facilitate the identification of those components and materials which are suitable for reuse and recovery. They shall provide information on the location of hazardous substances and on dismantling, storage and testing of components which can be reused. These provisions should oblige producers to provide information on the nanomaterials contained in different parts of the vehicles.

To meet this legal obligation, the automotive industry developed a data base called the International Dismantling Information System (IDIS), which enables the dismantling and recycling industry to recognise materials suitable for reuse and recovery. It includes information about material composition and detailed dismantling instructions.

5.8 Reporting and information

Pursuant to Article 9(2) of the ELV Directive, economic operators shall publish information on the design of vehicles and their components with a view to the potential for recovery and recycling and the environmentally sound treatment of end-of life vehicles. In particular, operators should publish information on the removal of all fluids and dismantling, the development and optimisation of ways to reuse, recycle and recover end-of life vehicles and their components and progress achieved with regard to increasing the recovery and recycling rates to reduce waste.

This provision could thus be interpreted in such a way that the information to be published by economic operators should also cover nanomaterial components used in vehicles if there were sufficient information on the risks of specific nanomaterials to warrant this. In practice, it does not appear that economic operators provide such information today, presumably because of the relative lack of information on risks of nanomaterials.

5.9 Coverage of nanomaterials under the End-of-Life Vehicles Directive

The main issue as regards coverage relates to whether nanomaterials that exhibit hazardous properties will be recognised as doing so under the CLP Regulation, hence triggering relevant provisions under the ELV Directive on prevention and treatment. As such, this relates to EU chemicals legislation rather than to the ELV Directive. No specific legislative gaps in the coverage of nanomaterials were identified under the ELV Directive, rather a number of possible issues were flagged based on speculations regarding possible exposure pathways

A possible source of environmental contamination through nanomaterials from end-of-life vehicles that is not captured by the Directive is the release of nanomaterials into air from the incineration of vehicle parts containing nanomaterials in energy recovery. However, this exposure pathway remains speculative and further evidence is required as to the behaviour and degradability of nanomaterials under combustion conditions before sufficient risk can be identified to quality this as a legislative gap. Concerns regarding the application of technical standards for the treatment of end-of-life vehicles are also speculative, with further evidence required before specific treatment requirements for nanomaterials could be developed. The same applies to information on the use of nanomaterials in specific vehicle parts, with evidence required of emissions of nanomaterials from incineration or impacts on recycling processes.

Table 4 below provides a summary of the issues identified in the Directive on end-of-life vehicles with regards to the coverage of nanomaterials.

Table 4: Summary of issues relating to the coverage of nanomaterials under the Directive on end-of-life vehicles

Issues	**Article**	**Type of gap, implications and uncertainties**
Some hazardous nanomaterials may not be captured under the requirement to limit the use of hazardous substances in vehicles, as they will not be caught under the CLP Regulation.	CLP Regulation	Legislative gap: May lead to continued use of hazardous nanomaterials in vehicles and their subsequent release into the environment
Minimum technical requirements for the treatment of end-of-life vehicles do not specifically consider possible pathways for the release of nanomaterials. Particularly relevant for residues of fuel, oils and lubricants that are likely to contain nanomaterials.	Annex I	Potential limitation: Possible releases of nanomaterials to the environment from traces of oils, fuels and lubricants left on vehicles. Current requirements for the collection of spillages should capture liquids containing nanomaterials, although water treatment systems may not remove them.
Coding standards required of producers to facilitate dismantling and subsequent channelling for reuse or recovery do not specify those parts for which nanomaterials are used.	Article 8	Potential limitation: Parts containing nanomaterials may be channelled for recovery through incineration, leading to emissions of nanomaterials in flue gases. Further research required on behaviour of nanomaterials in incinerators.
No information on the use of nanomaterials in the design of vehicles and their components in order to promote environmentally sound treatment of end-of-life vehicles	Article 9(2)	Potential limitation: Such information may be relevant should nanomaterials be found to affect recycling processes, or should nanomaterials in flue gases from incineration be found to be a significant source of nanomaterials in the environment.

6. Landfill Directive 1999/31/EC

6.1 Introduction

Directive 1999/31/EC[108] sets technical and operational requirements for dumping of waste in landfills with the aim of preventing or reducing negative effects on the environment, in particular the pollution of surface water, groundwater, soil and air. The key source of nanomaterials into landfills is the disposal of nanoproducts by consumers at the end of life phase of those products, their subsequent entry into the municipal mixed waste stream, and the channelling of that waste stream into landfill. Recent life cycle analyses suggest over 50% of nanomaterials produced will eventually reside in landfills[109]. An example of the introduction of nanowaste from industrial sources into landfills can be found in the disposal of production residues from the manufacturing of fullerenes[110]. Box 7 provides a more detailed examination of possible entry points for fullerenes into landfills, as well as into environmental compartments.

Most industrial processes where nanomaterials are employed or produced are likely to lead to some release to landfill through, for example, internal waste in production of finished articles or nanomaterials deposited on floors and equipment, which is subsequently collected for disposal. There could be any number of examples of this, some of the most obvious of which could include soot/particles from industrial exhaust gas capture or TiO2 dust remaining in facilities producing/using the substance.

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[108] Council Directive 1999/31/EC on the landfill of waste, OJ L 182, 16.7.1999, p. 1–19

[109] Mueller NC and Nowack B "Exposure modeling of engineered nanoparticles in the environment" (2008) Environmental Science & Technology 42, 4447-4453

[110] Royal Commission on Environmental Pollution. 27th Report (2008) RCEP, UK

Box 7: Overview of environmental risks and possible legislative issues for C_{60} fullerenes

Properties and applications

Fullerenes are a class of carbon allotrope, together with graphite, diamond and amorphous carbon. Fullerenes are closed-caged carbon molecules structured as hollow spheres, ellipsoids or tubes. Different forms of fullerenes can have very different properties, depending upon the functionalization, or the synthesis and cleaning method. This has important implications for the associated environmental risk and any decisions regarding regulation. The most common form, C_{60}, act like micro ball-bearings, react readily with electron rich species and can be subject to extreme pressure and retain their original shape when pressure is released. When manufactured, the surface chemical composition can be altered, different organic chains can be added or they can be incorporated into carbon nanotubes. The hollow centre can be filled with substances and used in medical applications. C60 fullerenes have the following applications:

Vehicles • Enhanced durability • Lower heat build-up • Better fuel economy with use of fullerene black/rubber compounds	Polymer electronics • Organic field effect transisitors • Photodetectors • Organic photovoltaics	Additives • Composites (multiple applications) • polymer additives • catalysts • fuel additives • lubricants
Medicinal applications • Antioxidants • Biopharmaceuticals • MRI agents • Drug and gene delivery • Diagnostic application • Photosensitisers • Antiviral activities	Biohazard protection & water purification Cosmetics • Sunscreen • Personal care products	Energy storage • Proton exchange membranes for fuel cells • Flywheel energy storage • Batteries • ultracapacitors

Source: Yadav and Kumar (2008), nano-C, Bakry *et al.* (2007)

According to the inventory of the Woodrow Wilson International Centre for Scholars, fullerenes are referenced nanomaterials in 7 consumer products; all of them cosmetics (note that since labelling is not mandatory, this does not reflect the true number of products containing fullerenes).

Production volumes and projected growth

Data on production volumes are very limited and vary tremendously in scale. Estimates for worldwide production range from 10 t/yr for 2005, 5 t/yr for 2008 (Gottschalk *et al.* 2009) to 5 t/yr for 2008 (Sonderer, 2009). US production has been estimated at 2-80 tons/yr (Hendren *et al.* 2011). The Global Market was predicted to be worth USD 1.312 million by 2011, with an average annual growth rate of 70% (BCC, 2006).

Pathways for environmental exposure

Production processes for C_{60} include the combustion method and the arc method. The combustion method is energy intensive, with only 10% of the final output usable and the remaining soot either going to landfill as waste or channelled into the production of lubricants as a by-product (RCEP, 2008). Exposure pathways for C_{60} along the product life cycle will be determined by the application. For example, it is expected that C_{60} contained within a solid matrix (such as a badminton racket) will not be released during the product use phase, including eventual disposal in a municipal landfill. In contrast, the unintended release of free C_{60} nanomaterials in the life cycle of a liquid, such as a lubricant, is more likely, from spills, sublimation, oil changes, combustion and through final disposal of the vehicle (Franco *et al* 2007). Hence C_{60} could be expected to enter into water through surface run-off, into the air through combustion and sublimation and into waste streams through disposal of contaminated wastes. Following the Waste Framework Directive, oil lubricants should be channelled for regeneration and it may be possible to recover the C_{60} from exhausted oils, although further research is required to develop this process. C_{60} used in cosmetics are likely to be washed off the skin and enter the sewage system, ultimately passing through urban wastewater treatment plants and into sludge or wastewater emissions. The efficiency of the removal of fullerenes from wastewaters is not known, with considerable variation anticipated amongst different types of fullerene (Sonderer, 2009).

With regards to emissions into air, sources may include production processes, or combustion in engines (lubricants/fuels) or in incinerators for products disposed of in incinerators. C_{60} have been shown to have a greater thermal reactivity than carbon nanotubes, suggesting that they will degrade in incinerators (Cataldo, 2002). Burscher *et al* (2001) demonstrated efficiency rates of 99.9% for the removal of ultra fine particles from flue gases by filter systems, supported by Lind *et al* (2007) who found a 99.9% efficiency in the removal of PM1.0 from flue gases from waste incineration plants using selective non-catalytic reduction (SNCR) for NO_x control together with novel integrated flue gas desulfurization (NID). Should fullerenes be released to air, the persistence of C_{60} in ambient air is related to ozone concentrations, with ozone promoting the degradation of C_{60} (Chibante and Heymann 1993).

Environmental fate and behaviour

Modelling estimated future environmental concentrations of fullerenes to be 0.003µg/l for surface waters and 4µg/l for sewage treatment effluents in the EU. Risks to aquatic organisms were not expected from these predicted concentrations (Gottschalk *et al.* 2009). Boxall *et al* (2008) predicted exposure levels for the UK of 0.31µg/l for water and 13.1µg/kg for soil. C_{60} fullerenes have been found to act as transporters of other pollutants, exhibiting Trojan horse effects (Baun *et al,* 2008). C60 fullerenes remain suspended in water, where they form aggregates at the nanoscale, the behaviour of which depends on the ion concentration of the water. Ionic strengths typical of natural waters and the presence polysaccharide-based natural organic matter will tend to favor deposition and reduced potential for exposure (Espinasse *et al.* 2007).

(Eco)toxicity

Studies on the ecotoxicology of C_{60} fullerenes are limited and the number of tested taxa few. Studies on aquatic ecotoxicity involving various degrees of exposure of *Daphnia magna* to C_{60} fullerenes have found significant cellular damage alimentary canal (Yang, 2010), increase cumulative mortality and reduced offspring (Oberdöster *et al* 2006), and low toxicity (Lovern and Klaper 2006). The results of studies have been called into question due to concerns regarding the toxicity of substances use to disperse the C_{60} in aqueous solution. Further documented evidence is required. *In vivo* studies on the toxicological effects of C_{60} suggest that they induce oxidative stress in living organisms (Hristozov and Malsch 2009). While evidence regarding the biotoxicity of fullerenes are poor and contradictory (Fiorito *et al* 2006), $C_{60\ h}$as been found to reduce the viability of bovine alveolar macrophages (Hristozov and Malsch 2009), and to induce inflammatory responses in the lung of mice (Park *et al* 2010). In his characterization of the degree of hazard associated with different nanomaterials, Musee (2011) ranked fullerenes as posing a high degree of hazard.

Monitoring Options

Quantification of C_{60} is usually performed by UV-vis at the laboratory scale. HPLC is used for the detection of low concentrations of $C_{60.}$ A method in the very early stage of development involves direct analysis by electrospray time-of-flight mass spectrometry (Nowack and Bucheli 2007).

Existing legislative coverage and possible future approaches

Issues related to the legislative coverage of C_{60} are summarised below.

- The paucity of (eco)toxicology data on C_{60} means that their specific classification under CLP is uncertain as conducting risk assessments is currently difficult if not impossible. The bulk form, graphite, is not categorised as hazardous.
- No specific waste management practices are required for wastes containing C_{60}, other than those for specific waste categories such as oils and resins. Industrial wastes containing C_{60} (e.g. soot) are not included in the list of wastes.
- C_{60} are expected to enter wastewater treatment from release during the life cycles of liquid products such as cosmetics and lubricants. Monitoring of concentrations of C_{60} in treated urban wastewater and in sewage sludge is not required under the Urban Waste Water and Sewage Sludge directives.
- C_{60} fullerenes are not captured under the chemical parameters listed under Annex I Part B of the Drinking Water Directive, implying that testing for these substances in water destined for human consumption is not required.
- C_{60} will not be detected in water bodies under the Water Framework Directive using currently available monitoring equipment and hence will not be identified as a pollutant, were it to be present.
- The Best Available Technique Reference Documents do not specifically address the production of C_{60}, implying that there are no BAT for reducing releases to the environment during production.

There is a lack of key information on production volumes for C_{60}, characterisations of by-products, concentration of C_{60} in products, and the behaviour and possible exposure routes along the life cycle of products containing C_{60} (Franco *et al.,* 2007). An full understanding of the volumes of C_{60} that are being used and their applications is a critical first step towards taking decisions as to whether, and if so how, to regulate them. The stability of C_{60} in solid matrices over the product life cycle and presumably in landfills suggests that products containing C_{60} in solid matrix are not a key concern if sent to landfill. Initial evidence suggests that C_{60} degrade in incinerators and that filters on flue gases demonstrate a high efficiency in the removal of ultra fine particles.

Liquids containing C_{60} pose a much higher risk of environmental exposure and may warrant more comprehensive controls, be they efforts to label and collect spent liquids (measures are already in place for oils and lubricants) and degrade the C_{60} (possibly through incineration) or product controls to limit these applications.

Industrial waste containing C_{60} in the form of soot poses a significant risk due to the high potential for dispersion. Such wastes may not be captured by hazardous classification since the bulk form (graphite) does not exhibit hazardous properties. The addition of soot containing C_{60} to the list of wastes may be relevant to ensure that such wastes are management to reduce environmental exposure and resulting risks.

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6.2 Nanomaterials in landfills

Current knowledge regarding the long-term behaviour of nanomaterials in landfill is extremely limited. The fate of nanomaterials will most likely be a function of the mobility of the nanoparticles, together with their degradability and that of the host material[111]. It is considered that the release of nanomaterials incorporated in landfilled commercially-available products is probable[112]. The harsh environmental conditions found within landfills, such as low pH and strongly reducing conditions, will likely aid the release of nanomaterials bound in polymers. Furthermore, many manufactured nanomaterials have greater environmental mobility than “ordinary” materials[113]. Commentators have flagged concerns that nanomaterials may leach out of landfills and contaminate groundwater and surface waters[114]. For example, researchers have found that C_{60} fullerenes remain suspended in water, where they form aggregates at the nanoscale. The behaviour of the aggregates depends on the ion concentration of the water, with aggregates remaining suspended at a salt concentration equivalent to that of groundwater, but sink to the sediment after a couple of hours in solutions with a salt concentration similar to that of seawater[115]. This has implications for the transport of C_{60} fullerenes in leachate, and suggests that they would remain in suspension in most groundwater and hence be further dispersed, should leachate penetrate through the physical barriers lining landfills and enter the environment.

Nanomaterials could potentially increase the toxicity of other materials. For example, in tests with algae and daphnia, the presence of C_{60} aggregates was shown to increase the toxicity of some substances (e.g. phenanthrene) but to decrease the toxicity others (e.g. PCP)[116]. The presence of certain nanomaterials might thus, in theory at least, introduce additional level of hazard/risk that was not identified using the criteria under the CLP Regulation.

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[111] Franco A, Hansen SF, Olsen SI and Butti L “Limits and prospects of the “incremental approach” and the European legislation on the management of risks related to nanomaterials” (2007) Regulatory Toxicology and Pharmacology 48, 171-183

[112] Reinhart et al “Emerging contaminants: nanomaterial fate in landfills” (2010) Waste Management 30, 2020-2021

[113] Motzer “Nanomaterials: New Emerging Contaminants and Their Potential Impact to Water Resources” http://www.grac.org/Nanomaterials_and_Water_Resources.pdf

[114] Musee N “Nanowastes and the environment: Potential new waste management paradigm” (2011) Environment International 37, 112- 128

[115] Science Daily, “Fate Of Nano Waste: Researchers Study How To Make Nanomaterial Industry Environmentally Sustainable” March 29, 2005, Last accessed 11/03/11 at http://www.sciencedaily.com/releases/2005/03/050323143506.htm; Espinasse B, Hotze EM, Wiesner, MR “Transport and retention of colloidal aggregates of C_{60} in porous media: effects of organic macromolecules, ionic composition, and preparation method” (2007) Environmental Science and Technology 41 (21) 7396–7402

[116] Baun A, Sørensen SN, Rasmussen RF, Hartmann NB and Koch CB “Toxicity and bioaccumulation of xenobiotic organic compounds in the presence of aqueous suspensions of aggregates of nano-C_{60}” (2008) Aquatic Toxicology 86 (3) 379-387

It is also presumably possible that nanomaterials could be released from landfills to the air, with landfill gas, for example in the case of volatile nanomaterials. Nanomaterials in air could then be deposited on land in precipitation and resuspended in groundwater. However, most are likely to be relatively non-volatile – for example C60 has a vapour pressure of around 6.7 x 10^{-4} – making such releases less likely than releases in leachate.

Given the aim of preventing or reducing negative effects on the environment through essentially technical measures, the concerns regarding nanomaterials in leachate raises two key questions:

- Are current monitoring techniques capable of detecting nanomaterials in leachate from landfills?
- Are current technical and operational requirements (i.e. requirements for the lining of landfills) adequate to prevent leachate containing nanomaterials from entering the environment?

6.3 General objectives and scope

The aim of the landfill directive is to prevent or reduce as far as possible negative effects on the environment. Importantly for nanomaterials, the Directive places a particular emphasis on the pollution of surface water, groundwater, soil and air, as well as any resulting risk to human health. The Directive establishes stringent operational and technical requirements on the waste and landfills, which in turn provide for measures, procedures and guidance with the aim of preventing and reducing negative effects.

6.4 Definitions

As mentioned above, the major source of nanomaterials into landfills will be through municipal waste streams channelled for landfill. This is defined under Article 2(b) as “waste from households, as well as other waste which, because of its nature or composition, is similar to waste from households”.

The definition of hazardous waste under the Landfill Directive refers to Directive 91/689/EEC, now repealed and replaced by the Waste Framework Directive. As discussed under section 3 above, the classification of nanowastes as hazardous is unlikely unless the bulk form of the relevant substance is already classified as hazardous under the CLP Regulation. Under the current CLP rules, there is unlikely to be a distinction made in classification between nanomaterials and the bulk form in practice, due to the lack of availability of information specifically on the nanoform of a substance.

Given the reactivity of nanomaterials due to their relatively large surface area (when compared to the same mass of material produced in bulk form), it is perhaps less likely that they will be categorised as "inert waste" according to the definition provided in Article 2(e) than any corresponding materials in bulk form. Criteria and procedures for the acceptance of waste at landfills are discussed under section 6.8 below. However, it is possible that certain nanomaterials could be classified as inert in the form that they are disposed of, for example nanomaterials within waste composed of construction materials. In addition, the level of awareness of nanomaterials amongst waste operators is likely to be low, given the paucity of information and the lack of labelling. Hence, it is possible to conceive of a situation where industrial waste such as waste soot containing carbon nanotubes could be channelled to waste operators without be labelled, or labelled according to the bulk form as graphite dust, and disposed of as inert waste.

6.5 Classes of landfill and waste accepted

The Directive establishes three classes of landfill on the basis of the types of waste that they will receive, namely:

- Landfill for hazardous waste
- Landfill for non-hazardous waste
- Landfill for inert waste

This is important as the technical requirements in terms of monitoring waste inputs, controlling emissions and monitoring leachates differ from the different landfills, with requirements being most stringent for landfill for hazardous waste and least stringent for landfill for inert waste. Correspondingly, the waste acceptance procedures (discussed in section 6.8) are most stringent for landfills for inert waste and least stringent for landfills for hazardous waste, due to the increasing level of environmental protection that they afford.

As mentioned above, nanowastes are most likely to enter landfills for non-hazardous waste through municipal waste streams. Nanowaste may enter hazardous landfills through industrial waste streams. With regards to landfills for inert waste, concrete is often channelled from the construction industry to landfills. There are types of concrete now available on the market that contain nano-scale particles of silica in the concrete mix, in order to make the concrete denser, more water resistent and more durable. In addition, carbon nanotubes or nano clays are being used to make new lighter, stronger consutruction materials[117]. As such it is foreseable that some nanomaterials may end up in landfills for inert waste. It would be necessary to evaluate any possible risks on a case-by-case basis. However, generally a nanomaterial contained within a solid matrix is less likely to migrate and pose a risk through environmental exposure.

6.6 Waste and treatment not acceptable in landfills

Article 5 identifies types of waste that are not to be accepted in landfills, and specifically identifies waste that in the context of landfill is explosive, corrosive, oxidising, highly flammable or flammable. The criteria against which wastes will be judged are set out in Annex VI of CLP Regulation 1272/2008, with test methods described in Annex V. Problems with the application of these criteria to nanowastes have been discussed in the sections above, with the conclusion that some nanowastes might slip through when they do exhibit such characteristics but the relevant bulk forms do not. Given the current lack of understanding of the behaviour of specific nanomaterials in landfill, it is unlikely that nanowastes would be eliminated from landfills on the basis of this provision.

If it is found that nanoscale materials pose risks that are not adequately captured by current test methods in which the physical form is not typically taken into account, it may be necessary to assess whether new criteria should be developed to reflect these new risks. In the extreme, if it is identified that there are risks associated with certain nanomaterials that are so severe as warrant their complete exclusion from landfills (such as in the case of explosive and other properties), such risks would need to be addressed through upstream product controls. At present, however, there is no evidence to suggest that nanomaterials possess any such properties.

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[117] Nano&me website “Nano in construction” last accessed 2/6/11 at: http://www.nanoandme.org/nano-products/construction/

6.7 Permit conditions

One of the conditions for permit application when operating a landfill is the provision of information on the types and total quantity of waste to be deposited. Once granted, the permit for operation specifies the defined types and total quantities of waste authorised for deposition, following Article 9. Since nanowastes have no specific classification, they will not be specifically mentioned in the permit unless they are classified as hazardous under CLP due to properties exhibited in the bulk form (a possible example being industrial wastes from the production of nano-scale zinc oxide powder). In addition, no information will be collected on overall volumes of nanowastes entering landfills, since the majority of nanowastes cannot be identified as such. Even when waste originates from industrial production and is recognised as hazardous, as in the example mentioned above, it may not be specifically labelled as being in the nanoform.

In addition, permits are required to ensure compliance with the relevant requirements of Directive 1999/31/EC and its annexes. Annex I sets out the general requirements for the three classes of landfills. Regarding landfills that accept inert waste, the permeability requirements of the mineral layer that constitutes the base and sides of the landfill are $K \geq 1.0 \times 1.0^{-7}$ m/s. There are no requirements for leachate collections, artificial barriers (bottom or surface sealings) or aftercare for landfills that accept inert waste.

As mentioned above, the technical requirements for protecting soil and water are less stringent for landfills that accept non-hazardous waste than for those accepting hazardous waste. For instance, the thickness of the mineral layer that forms the base and sides of the landfill must be equal to or greater than 1m for landfills accepting non-hazardous waste versus 5m for a landfill accepting hazardous waste. The permeability requirements are the same ($K \geq 1.0 \times 1.0^{-9}$ m/s). Both landfill types are required to have an artificial sealing liner and a drainage layer in order to collect leachate. The Directive goes on to provide recommendations for surface sealings to prevent leachate formation, with an artificial surface sealing recommended only for landfills that accept hazardous waste. It is unknown how effective barrier technologies (e.g. landfill liners) would be at intercepting engineered nanomaterials. The ability of silver nanoparticles to migrate through such liners is being investigated by East Tennessee State University[118]. We are not aware of any evidence to suggest that the existing permeability requirements would be less protective for any nanomaterials than for the other toxic pollutants that can be present in landfill leachate and which the permeability requirements have been designed to be protective against.

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[118] http://nanoevolution-nanowaste.blogspot.com/2010/05/behavior-of-silver-nanoparticles-in.html

However, it must be emphasised that the implementation of these requirements remain at the discretion of the Member State competent authority, which may reduce the requirements for the protection of soil and groundwater. A key concern is that the hazard assessment may have been conducted without consideration of the potential risks from nanomaterials. Techniques that enable the detection of nanomaterials in leachate are not technically available; hence the detection of nanomaterials in leachate is highly unlikely. Were comprehensive and consistent data available on the presence and concentration of nanomaterials in products, the volumes of these products on the market, and exposure scenarios in the disposal phase of the product life cycle, as well as data on industrial wastes and by-products containing nanomaterials and their disposal pathways, it may be possible to make some assessment of the presence of nanomaterials in landfills based on input streams. However, this data is not currently available.

6.8 Waste acceptance procedures

The principal control of wastes entering the landfill is through waste acceptance procedures before or at time of delivery of the waste. General principles for the acceptance of waste are laid down in Annex II, with additional waste acceptance criteria laid down in Council Decision 2003/33/EC[119].

Importantly, Annex I of Decision 2003/33/EC states that municipal waste can be accepted at landfills for non-hazardous wastes without testing. Given that the major flows of nanowastes will be through the municipal waste stream, this implies that most nanowastes will not be subject to any testing prior to acceptance.

As mentioned above, industrial waste presents another possible source of waste to landfill. In such a case, the procedure for the acceptance of waste begins with a basic characterisation of the waste in order to determine which class of landfill the waste may be deposited in. Initial characterisation is based on an assessment of a range of basic information on the waste. However, for nanowastes some of this information is likely to be unavailable, in particular information on leachability, behaviour in landfills, options for treatment and characteristic properties. It is very likely that landfill operators will have limited information on the composition, leachability, long-term behaviour and characteristic properties of the nanowaste, casting doubt on the capacity of landfill operators to effectively assess nanowaste from industrial sources. As mentioned above, research on the mobility of nanomaterials in landfill is the subject of investigation of one known study at East Tennessee State University.

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[119] Council Decision 2003/33/EC, OJ L 11, 16.01.2003, 27-49

In addition, the waste should be tested and assessed against leaching limit values, which are most stringent for landfills for inert waste and least stringent for landfills for hazardous waste, with leaching limit values for landfills for non-hazardous waste falling in the middle. Decision 2003/33/EC establishes leaching limit values for a range of substances that are expressed in mg/kg dry substance. However, these limit values have been established based on the intrinsic properties of these substances in the bulk form, and do not take into account the particular characteristics (including potentially enhanced reactivity) of substances at the nano-scale and subsequent increased risk potential upon entry into the environment in leachate. Again, the use of a mass-based threshold is not likely to be appropriate for nanomaterials.

It is also important to note that it is not mandatory that all waste be tested; rather it is a "general rule", the interpretation of which is left open to the Member States. In addition, there are cases where testing is not required, one of which being "where appropriate testing procedures and acceptance criteria are unavailable". Nanowastes currently fall within this category. Thus it can be expected that nanowastes would most likely be allowed to enter inert and municipal waste landfills, either because their properties are equated with the bulk form or due to a lack of appropriate testing procedures.

6.9 Control and monitoring procedures in the operational phase

According to Article 12, landfill operators are obliged to carry out a control and monitoring programme in the operational phase and report results to the competent authority. In addition, should significant adverse environmental effects be revealed by monitoring, they must be reported to the competent authorities, who may then determine corrective measures.

The requirements for the control and monitoring programme are specified in Annex III to the Directive and include inter alia:

- sampling of leachate and measuring volume (monthly) and composition (quarterly);
- monitoring of surface water if present, one upstream and one downstream (quarterly); and
- sampling of groundwater level (every six months) and composition (site-specific).

Annex III references the ISO guidelines for sampling technology, namely ISO 5667-2 (1991) and ISO 5667, Part 11, 1993. These have been superseded by newer versions, namely ISO 5667-1 (2006) and ISO 5667-11 (2009) respectively. Nanomaterials are not specifically included in these guidelines. ISO 5667-1 sets out the general principles for, and provides guidance on, the design of sampling programmes and sampling techniques for all aspects of sampling of water (including waste waters, sludges, effluents and bottom deposits). It is very general in scope and does not include detailed instructions for specific sampling situations. Whilst there are no explicit provisions referring to nanomaterials, the objectives set out in section 5 are broad enough to include nanomaterials. ISO 5667-11 provides guidance on the sampling of groundwater. It informs the user of the necessary considerations when planning and undertaking groundwater sampling to survey the quality of groundwater supply, to detect and assess groundwater contamination and to assist in groundwater resource management, protection and remediation. Again, whilst there are no explicit provisions referring to nanomaterials, the guidance is general in scope and 'nanomaterials' may be covered by 'contaminants'.

Annex III also specifies that, in determining significant environmental effects that would need to be reported to competent authorities, trigger levels should be established and laid down in the permit, where possible. Specific substances are not listed, and rather this is left open to the Member States. It would therefore be possible for trigger levels to be established for concentrations of specific nanomaterials in groundwater, should the competent authorities consider this necessary based on evidence of toxicity. However, due to the physico-chemical properties of nanoparticles, their behaviour and potential adverse effects are not solely dependent on exposure in terms of the mass concentration. This throws into question the relevance of a mass-based threshold approach.

Monitoring of specific nanomaterials in leachate, surface waters and groundwater could be foreseen as a possible future requirement, although it is not currently technically feasible. The task of monitoring nanomaterials in waters is by no means easy[120]. Despite significant progress in recent years, reliable methods are not yet available to determine nanoparticle identity, concentrations and characteristics in complex environmental matrices. Two fundamental challenges currently exist in regard to developing a feasible monitoring methodology of nanoparticles in environmental samples. First, the detection limits for most methods are not sufficiently low. Second, environmental samples often contain a high background of natural and unintentionally produced nanoparticles and it is vital to be able to distinguish between the two since they may have different toxicological profiles. More consistent and comprehensive data on the risks of specific nanomaterials would presumably be required before any such action could be taken.

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[120] Baun et al (2009) "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?", *Journal of Environmental Monitoring*

6.10 Implementation

According to a Commission Report from 2009, the implementation of the Directive on the landfill of waste remains highly unsatisfactory, with a number of Member States having failed to transpose the Directive. There are a large number of illegal landfills operating without the authorisations required under the Landfill Directive. In addition, the majority of Member States failed to meet the 2009 deadline by which all sub-standard landfills (unless specifically derogated) that existed before the introduction of the Directive were obliged to comply with its requirements[121]. The existing failure to implement requirements, even with the degree of discretion afforded to the Member States within the Directive, suggests that should additional requirements be developed, their effect in limiting releases of nanomaterials to the environment from landfills may be limited in practice due to poor implementation.

6.11 Thecoverage of nanomaterials under the Landfill Directive

The most significant isquestions regarding the potential for the Landfill Directive to address nanomaterials relate to whether hazardous nanowastes will be identified as hazardous according to the criteria set out in the CLP Regulation, and as such, are not gaps in the Landfill Directive but rather limitations in the capacity of chemicals legislation to capture the potential risks of specific nanomaterials. The limitations associated with applying this approach to nanomaterials are discussed extensively in section 3.

Feedback from the Stakeholder Workshop

A participant at the workshop noted that the issues identified under the Landfill Directive are not gaps in the legislative coverage, but relate rather to a lack of knowledge regarding the potential risks from nanomaterials and their behaviour in wastes in landfills.

In addition, information may not be available to landfill operators to allow for a basic characterisation of nanowaste upon arrival at landfills. A possible consequence is the dumping of hazardous nanowastes in landfills for municipal wastes. Again, this cannot be seen as a legislative gap but rather represents a knowledge limitation in available data on

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[121] Commission legislation summaries, http://europa.eu/legislation_summaries/environment/waste_management/l21208_en.htm

the hazards and behaviours associated with specific nanomaterials.

Leachate limit values have not been established with the particular characteristics and potentially increased toxicity of the nanoform in mind. However, is should be stressed that there is currently no evidence to suggest that nanomaterials are able to pass through the liners used to prevent leachate from passing into the environment, although this remains a subject of investigation.

Table 5 below provides a summary of issues relating to the coverage of nanomaterials under the Landfill Directive, in a context where information is limited and nanomaterials may not be classified under CLP according to their intrinsic properties but rather according to the properties of the bulk form.

Table 5: Summary of issues related to the coverage of nanomaterials under the Landfill Directive

Issues	**Article**	**Type of gap, implications and uncertainties**
Some hazardous nanowastes may not be categorised as hazardous under CLP Regulation	CLP Regulation	Legislative gap: Some hazardous nanowastes may be treated as non-hazardous and be dumped into landfill for inert waste or municipal waste
Types of waste not acceptable in landfills do not consider nanomaterials. Criteria set out in Annex VI of CLP Regulation were not set with consideration of the specific properties of nanomaterials	Article 5	Potential limitation: Some specific nanomaterials may exhibit characteristics that would make them hazardous in landfills – but they would not be identified and excluded
Basic characterisation of nanowaste may not be feasible due to the lack of information available on the characteristics of specific types of nanowaste	Annex II	Implementation gap: Nanowaste may end up in an inappropriate landfill
Leaching limit values may not be appropriate for nanomaterials, which may have enhanced reactivity compared with the bulk form	Annex II	Implementation gap: Nanowaste may end up in an inappropriate landfill

7. WEEE Directive 2002/96/EC

7.1 Introduction

The WEEE Directive[122] lays down requirements for the prevention of waste electrical and electronic equipment (WEEE), for the reuse, recycling and other forms of recovery of such wastes so as to reduce their disposal. It also seeks to improve the environmental performance of all operators involved in the life cycle of electrical and electronic equipment. A recast of the WEEE Directive is currently underway.

7.2 Nanomaterials in electrical and electronic equipment

Nanomaterials are increasingly found in electrical and electronic equipment (EEE). They are a key component in the new generation of computers. One of the main areas for development of nanotechnology in WEEE is likely to be new compact energy sources such as lithium-ion batteries. Another area of current application is the use of nano-silver coating in domestic appliances to limit bacterial growth. Box 8 provides examples of current uses of nanomaterials in electrical and electronic equipment:[123]

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[122] Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), OJ L 37, 13.2.2003, p. 24–39

[123] Milieu, RPA, Information from Industry on Applied Nanomaterials and their Safety, Deliverable 1 prepared for European Commission DG environment (2009) available at: http://www.nanomaterialsconf.eu/documents/Nanos-Task1.pdf

Box 8: Examples of applications of nanomaterials in electrical and electronic equipment

- Fabrication of silver/tungsten nanowires using an E-beam on metal nanoparticles to form nano-gap electrodes.
- Use of zinc oxide nanorods to produce nano-piezotronic electronic components such as diodes.
- Use of silver nanocylinders as waveguides for nano-focusing of light.
- Use of zinc oxide nanofibres on a gallium arsenide, sapphire or flexible polymer substrate to create energy generator.
- Use of nanosized lithium particles to produce lithiun-ion batteries with enhanced properties.

This Directive sets as a priority the reuse and recycling of WEEE. Based on the precautionary principle, the following set of questions can be raised as regards recycling of WEEE under the WEEE Directive, some of them already covered by the analysis of the Waste Framework Directive:

- Does the presence of nanomaterials have an impact on the recyclability of WEEE?
- Does the presence of nanomaterials create potential occupational health risks for staff during the recycling process?
- Is there a significant release of nanomaterials during the recycling process which can have a relevant impact on human health or the environment?
- Are there any nanomaterials that should be removed from WEEE before being treated for recycling? If so, is technology available to separate and remove nanomaterials from WEEE?
- Would the requirements for treatment facilities need to be changed in order to take the above into account?

7.3 Recovery target

Article 7 of this Directive establishes targets for the recovery, recycling and reuse of WEEE, as summarised in table 6 below. As mentioned above, there currently is little information on the behaviour of different nanomaterials in incinerators and recycling processes. Specific research would be needed to confirm whether there are negative impacts on the recycling process, occupational health and health and the environment beyond the recycling process.

Table 6: Recovery and recycling reuse targets for the different categories of WEEE

a) For large household appliances (e.g. refrigerators) and automatic dispensers (e.g. for cold bottles): — the rate of recovery shall be increased to a minimum of 80 % by an average weight per appliance, and — component, material and substance reuse and recycling shall be increased to a minimum of 75 % by an average weight per appliance;
b) For telecommunications equipment (e.g. printer unit) and consumer equipment (e.g. radio set): — the rate of recovery shall be increased to a minimum of 75 % by an average weight per appliance, and — component, material and substance reuse and recycling shall be increased to a minimum of 65 % by an average weight per appliance;
c) For small house appliances (e.g. toaster), lighting equipment, electric and electronic tools, toys leisure and sport equipment, monitoring and control instruments (smoke detectors): — the rate of recovery shall be increased to a minimum of 70 % by an average weight per appliance, and — component, material and substance reuse and recycling shall be increased to a minimum of 50 % by an average weight per appliance;
d) For gas discharge lamps, the rate of component, material and substance reuse and recycling shall reach a minimum of 80 % by weight of the lamps.

6.4 Product design

Pursuant to Article 4 Member States shall encourage the design and production of EEE which take into account and facilitate dismantling and recovery, in particular the reuse and recycling of WEEE, their components and materials. Were nanomaterials in general or specific nanomaterials to be found to impact negatively upon recovery, this impact could be taken into account by Member States under this Article.

7.5 Recycling treatment

Pursuant to Article 6(1) first paragraph of this Directive, producers of EEE must set up systems to provide for the treatment of WEEE using best available treatment, recovery and recycling techniques. The treatment shall, as a minimum, include the removal of all fluids and a selective treatment in accordance with Annex II to this Directive.

Annex II to this Directive lists a number of substances, preparations and components that shall be removed from any separately collected WEEE (e.g. PCBs, mercury containing components, asbestos waste and components which contain asbestos). Annex II does not refer to any nanomaterials or substances in nanoforms at present. Article 6(1) second paragraph, however, provides for the possible amendment of Annex II, through comitology, to introduce other treatment technologies ensuring at least the same level of protection for human health and the environment.

Article 6(1) third paragraph allows Member States to set up minimum quality standards for the treatment of collected WEEE, for environmental purposes. If necessary, such quality standards could require that certain types of nanomaterials should be removed during the recycling treatment because of their potential impact on the environment.

No information has so far been identified on any specific nanomaterials that would warrant specific removal from EEE on the basis of potential amendment to Annex II.

Pursuant to Article 6(3) of the Directive, establishments or undertakings carrying out treatment, operations, must store and treat WEEE in compliance with the following technical requirements:

Sites for storage of WEEE:

- impermeable surfaces for appropriate areas with the provision of spillage collection facilities and, where appropriate, decanters and cleanser-degreasers,
- weather-proof covering for appropriate areas.

Sites for treatment of WEEE:

- balances to measure the weight of the treated waste,
- impermeable surfaces and waterproof covering for appropriate areas with the provision of spillage collection facilities and, where appropriate, decanters and cleanser-degreasers,
- appropriate storage for disassembled spare parts,
- appropriate containers for storage of batteries, PCBs/PCTs containing capacitors and other hazardous waste such as radioactive waste,

- equipment for the treatment of water in compliance with health and environmental regulations.

7.6 Information for users

Article 10(1)(d) of the Directive requires that users of EEE in private households are given the necessary information regarding the potential effects on the environment and human health as a result of the presence of hazardous substances in EEE.

Article 3(l) of the WEEE Directive defines dangerous substances or mixtures as any mixture considered dangerous under Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations[124] (to be replaced by the CLP Regulation in 2015), or any substance which fulfils the criteria for any of the hazard classes or categories set out in Annex I of the CLP Regulation.

As mentioned in the analysis on the Waste Framework Directive, it is unlikely that nanomaterials would be classified as hazardous under the CLP Regulation, at least where the bulk form is not already classified. Therefore, this information requirement for users of EEE would likely not include ‘dangerous’ nanomaterials in WEEE.

7.7 Information for treatment facilities

Pursuant to Article 11 of the Directive, producers must provide reuse and treatment information for each type of new EEE within one year after the equipment is put on the market. This information shall identify, as far as it is needed by reuse centres, treatment and recycling facilities in order to comply with the provisions of this Directive, the different EEE components and materials, as well as the location of dangerous substances and mixtures in EEE.

Since nanomaterials are considered materials, this provision could be interpreted in such a way that producers should provide reuse and treatment information of the nanomaterials in EEE as far as it is

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[124] Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.7.1999, 1–68

needed by reuse centres, treatment and recycling facilities. This is not currently the case because, as noted above, no specific impacts of nanomaterials on the recycling process have been identified, and because no specifc requirements have been laid down for dealing with nanomaterials in the process.

7.8 Adaptation to scientific and technical progress

Pursuant to Article 13 of the Directive, any amendments which are necessary in order to adapt Annex II on selective treatment for materials and components of WEEE (taking into account new technical developments for the treatment of WEEE) can be adopted through the comitology procedure. For example, Annex II point 4 was amended in 2008 in order to oblige the Commission to evaluate whether the entries regarding printed circuit boards for mobile phones and liquid crystal displays are to be amended[125]. The treatment requirements, as laid down in Annex II, have been excluded by the Commission from the ongoing recast procedure. However, the Commission can at any time in the future review the selective treatment requirements, including to take into account treatment requirements for specific nanomaterials if necessary. The possible goal of including selective treatment requirements for specific nanomaterials under Annex II in the future would clearly be subject first to the identification of significant negative impacts that need to be avoided, and secondly to the development of technologies allowing the removal of nanomaterials from WEEE.

7.9 Amendments of the European Parliament to the WEEE Proposal of the Commission

The European Parliament, in its resolution of 3 February 2011 on the Commission proposal for the recast of the WEEE Directive[126], provides for two new amendments referring to nanomaterials in WEEE (see Box 9 below).

Box 9: Amendments proposed by the European Parliament

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[125] Directive 2008/34/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), as regards the implementing powers conferred on the Commission, OJ L 81, 20.3.2008, 65–66

[126] European Parliament legislative resolution of 3 February 2011 on the proposal for a directive of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE) (recast) (COM(2008)0810 – C6-0472/2008 – 2008/0241(COD)

Recital 15 (a) (new)

15a) The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), in its opinion on ‘Risk Assessment of Products of Nanotechnology’ of 19 January 2009, stated that exposure to nanomaterials that are firmly embedded in large structures, for example in electronic circuits, may occur in the waste phase and during recycling. To control possible risks to human health and the environment from the treatment of WEEE containing nanomaterials, selective treatment may be necessary. It is appropriate for the Commission to assess whether selective treatment should be applied to relevant nanomaterials.

Article 8(4) (new):

In order to introduce other treatment technologies ensuring at least the same level of protection for human health and the environment, the Commission shall adopt, by means of delegated acts in accordance with Article 18a and subject to the conditions of Articles 18b and 18c, amendments to Annex II. The Commission shall evaluate as a matter of priority whether the entries regarding printed circuit boards for mobile phones and liquid crystal displays are to be amended. The Commission shall evaluate whether amendments to Annex II are necessary to address relevant nanomaterials.

These amendments would require that the Commission shall evaluate whether amendments to Annex II on selective treatment for materials and components of WEEE equipment are necessary to address relevant nanomaterials. The Council, in its agreement reached on 14 March 2011, did not follow the position of the European parliament and did not make any references to nanomaterials.[127] The Commission has indicated in its Communication[128] that the two amendments of the Parliament in box 9 are not subject to the recast procedure. The Commission may, however, include nanomaterials in the treatment requirement for WEEE in the future, if necessary.

7.10 The coverage of nanomaterials under the WEEE Directive

Little definite information is so far available on possible impacts of nanomaterials on the recycling of WEEE, on occupational risks during the recyclinig process, and on releases during that process affecting human health and environment in general. However, if in the future such impacts were

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[127] Political agreement of the Council of the European Union on the Proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE) - (recast) available at: http://register.consilium.europa.eu/pdf/en/11/st07/st07851.en11.pdf

[128] Commission Communication on the action taken on opinions and resolutions adopted by Parliament at the February I & II 2011 part-sessions, P(2011)2217, available at: http://www.europarl.europa.eu/oeil/DownloadSP.do?id=18680&num_rep=8311&language=en

identified, it is clear that the WEEE Directive already provides for a number of options for addressing them, by controlling nanomaterials in waste electrical and electronic equipment if necessary. The Directive is currently subject to a limited recast process, which excludes such changes. The Commission may, however, include nanomaterials in the treatment requirements for WEEE in the future, if necessary. If significant risks from nanomaterials in the treatment of WEEE were identified, they could be addressed by specific technical requirements or standards for the treatment of WEEE that contain nanomaterials. Further evidence of environmental and occupation exposure during the treatment of WEEE would be required before such steps were taken.

8. Directive 2002/95/EC on RoHS

8.1 Introduction

The RoHS Directive[129] lays down rules on the restriction of use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste electrical and electronic equipment (WEEE). This study reviews the recast of the RoSH Directive, which was published in the Official Journal on 1 July 2011 and will replace Directive 2002/95/EC on 2 January 2013.

8.2 Restricted substances in EEE

Pursuant to Article 4 of the RoHS Directive, certain hazardous substances shall not be contained in EEE placed on the market above the permissible maximum concentration limits (see Table 7).[130]

Table 7: Annex II list of substances and concentration value threshold in WEEE

Lead (0.1%)

Mercury (0.1%)

Cadmium (0.01%)

Hexavalent chromium (0.1%)

Polybrominated biphenyls (PBB) (0.1%)

Polybrominated diphenyl ethers (PBDE) (0.1%)

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[129] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), OJ L 174, 1.7.2011, p.88-110

[130] Including cables and spare parts for its repair, its reuse, updating of its capacity

There is the potential for some of these hazardous substances to also be available at the nanoscale e.g. cadmium-based quantum dots.

The thresholds of permitted concentrations of substances in RoHS have been established where there exists an extensive body of dose-response and exposure data (which is not the case for most nanomaterials). According to Frater et al. (2006) "*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*"[131].

This risk management measure could be an efficient tool to restrict the use of potentially dangerous nanomaterials in EEE. Recital 16 of the recast Directive explicitly refers to this possibility. It states that *"as soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined"*[132].

The review and amendment procedure of Annex II is covered by Article 6 of the recast Directive, which explicitly refers to substances of very small size or with a very small internal or surface structure.

8.3 Review and amendment of restricted substances in Annex II

Article 6 of the Directive requires that a review, based on a thorough assessment and amendment of the list of restricted substances in Annex II, must be considered by the Commission three years after the entry into force of the Directive.

The Commission for this review must take special account of whether a substance, including substances of very small size or with a very small or internal or surface structure, or a group of similar substances could:

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[131] Frater L, Stokes E, Lee R and Oriola T "An overview of the framework of current regulation affecting the development and marketing of nanomaterials" (2006) A report for DTI, Cardiff University, UK

[132] Recast Directive of 22 March 2011, available online at: http://register.consilium.europa.eu/pdf/en/10/pe00/pe00062.en10.pdf

e) have a negative impact on EEE waste management operations, including preparing for the reuse of WEEE or for recycling of materials from WEEE;
f) give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
g) lead to unacceptable exposure of workers involved in the WEEE collection or treatment processes;
h) be replaced by substitutes or alternative technologies which have less negative impacts.

This review must refer to publicly available knowledge obtained from the application of such legislation. In the context of nanomaterials used in EEE, the knowledge publicly available is still scarce about their potential impact on the environment and health so it is likely to be some time before sufficient evidence exists to include nanomaterials on the Directive.

The proposal to review and amend the list of restricted substances must contain, among others, references and scientific evidence for the restriction on the use of the substance or group of similar substances in EEE, information on detrimental effects and exposure, in particular, during WEEE management operations. However, data on the risks of specific nanomaterials is currently limited. Therefore, it would be difficult to provide the required information on nanomaterials that could potentially be included in Annex II of the RoHS Directive.

8.4 The coverage of nanomaterials under the RoHS Directive

To summarize, the key issue relates to the applicability of current substance concentration threshold values to nanomaterials, namely cadmium-based quantum dots. This is addressed in the recast of the Directive, where recital 16 backs the substitution of any hazardous substances, with specific reference to nanomaterials. No nanomaterials are as yet included under Annex II as restricted substances. The release of hazardous nanomaterials into the environment during recycling processes is a possibility that requires verification through targeted research. Should evidence of releases be found, the inclusion of specific hazardous nanomaterials under Annex II as restricted substances may be relevant. Table 8 provides a summary of these issues.

Table 8: Summary of issues related to the coverage of nanomaterials under the RoHS Directive

Issue	**Article**	**Type of gap, implications and uncertainties**
No nanomaterials included as restricted substances	Annex II	Potential limitation: Possible releases of nanomaterials into the environment during recycling processes

9. Packaging and Packaging Waste Directive 1994/62/EC

9.1 Introduction

Directive 1994/62/EC on packaging and packaging waste (the Packaging Directive)[133] lays down measures aimed, as a first priority, at preventing the production of packaging waste. Additional fundamental principles promote the reuse of packaging, recycling and other forms of recovering packaging waste and reducing the disposal of such waste.

9.2 Nanomaterials in packaging

Nanomaterials are increasingly used in packaging. Nanoparticles were first used in the food industry for packaging, with 8% of the nanoproducts on the market falling under the food and beverage product category[134]. It is estimated that within the next ten years nanotechnology will be used in 25% of food packaging products. In 2004, there were less than 40 packaging products containing nanomaterials (herein referred to as 'nano-packaging') on the market, however between 400 and 500 nano-packaging products are thought to be in commercial use today[135]. Nanotechnology can enable the structure of materials to be altered at a molecular scale which can lead to significant performance improvements. The incorporation of nanoparticles into a polymer matrix to be used for packaging can improve the mechanical bulk properties, surface properties, dimensional stability, thermal stability, surface appearance and decreased permeability to gases and water. Plastic polymers incorporating nanomaterials can provide anti-bacterial properties and nanosensors are key components in 'smart' packaging (e.g. nanobar codes, food deterioration sensors and light activated oxygen sensing ink).

It should be noted that nano-packaging is typically not passive in the way that conventional packaging is, but rather it is designed to actively maintain or improve conditions of the food. Silicate nanoparticles, metallic nanoparticles, ceramic nanoparticles, carbon nanofibres and nanotubes are

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[133] Directive 94/62/EC on packaging and packaging waste, OJ L 365, 31.12.1994, p.10-32

[134] Woodrow Wilson International Centre for Scholars, Inventory of nanotechnology-based consumer products, last accessed 21/04/11 at http://www.nanotechproject.org/inventories/consumer/analysis_draft/

[135] Reynolds, G. "Future nanopackaging market worth billions" Food Production Daily, 15 May 2007, last accessed 22/04/11 at: http://www.foodproductiondaily.com/Packaging/Future-nanopackaging-market-worth-billions-says-study

examples of nanomaterials used in packaging[136]. Table 9 provides further examples of the application of nanotechnology in packaging.

Table 9: Examples of application of nanotechnology in packaging[137]

- Nanoclay-based composite for packaging material
- Bio-nanomaterials in packaging
- Enzymes as nanoscale tools in biopolymer modification and functionalization
- Tools for brand protection
- Disposable power source
- Visual indicators for food packaging

Nanotechnology has the potential to assist in reducing packaging waste, for example, through the use of mono-layer films rather than multi-layer films, enhanced material performance meaning that less packaging is required to achieve the desired performance and the use of naturally occurring polymers with enhanced properties. This is important as the Directive states that “the best means of preventing the creation of packaging waste is to reduce the overall volume of packaging”. However, the impact that nano-packaging might have on recycling, recovery and disposal of packaging waste is not yet fully understood.

The use of nanomaterials in packaging poses a number of potential new health and environmental hazards. Nanomaterials in food and drink packaging may unintentionally migrate from the packaging into foods or drinks, and thereby increase the likelihood of nanomaterials ingestion (Chaudhry et al., 2008). These risks are not addressed within the scope of this report.

The European Food Safety Authority (EFSA) has been following developments in nanotechnology within its remit and, in May 2011, published “Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain”.[138] The document includes, *inter alia,* guidance on the physico-chemical characterisation requirements of engineered nanomaterials used as food contact materials and testing approaches to identify and characterise hazards arising from the nanoproperties. This guidance can serve to inform regulators of the types of nanomaterials likely to be found in food packaging and their chemical properties.

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136 G. Moore, Current and future opportunities for nanomaterials in packaging , presentation at Nanomaterials 2007, Sage Centre Gateshead, 30 April-1 May 2007

137 M. Smolander, Potential Nanotechnology Applications in Food Packaging, International Forum on Merging Technologies in Food Processing, University of Illinois Urbana, IL, USA, September 2009

[138] EFSA “Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain” (2011) EFSA, Italy, available at: http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm

Of relevance to nanomaterials is packaging is legislation enacted on food contact materials under Regulation No 1935/2004[139], which states that food contact materials shall be safe and shall not transfer their components into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the taste and odour of foodstuffs. For example, Regulation (EC) No 450/2009[140] sets down additional requirements for active and intelligent materials and articles to ensure their safe use and specifically mentions "nanoparticles". The legislation takes a precautionary approach, with the presence of nanoparticles in packaging separated from food by a functional barrier not permitted, due to the lack of information regarding the potential of nanoparticles to migrate through barriers.

Discussions surrounding the revision of the Novel Foods Regulation EC N° 258/97[141] had relevance to nanomaterials in packaging, although the file was ultimately dropped due to a failure to achieve consensus. The Commission Proposal for a Regulation of the European Parliament and of the Council on novel foods[142] mentioned nanotechnology and nanoscience as a novel food technology in the preamble. In their first reading of the proposal, the European Parliament proposed a number of amendments on the topic of 'nano', including that nanomaterials present in food packaging should be entered on a list of approved nanomaterials, accompanied by a limit on migration into or onto the food products contained in such packaging[143]. Following a lack of agreement in the conciliation procedure, the legislative process for the review of the Novel Foods Regulation appears to be suspended. It should be noted that the institutions had been able to reach agreement on a legal definition of nanomaterials and the mandatory labelling of nanomaterials in food products (not in packaging)[144]. In the absence of progress, the Novel Foods Regulation EC N° 258/97 remains in force.

9.3 Scope

The Packaging Directive covers all packaging placed on the market in the European Union and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used. Pursuant to Article 3 of the Packaging

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[139] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, OJ L 338 13/11/2004, 4-17

[140] Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food, OJ L 135, 30.5.2009, 3–11

[141] Novel Foods Regulation EC N° 258/97 OJ L 43, 14.2.1997, p. 1–6

[142] COM(2007)872: Proposal for a Regulation of the European Parliament and of the Council on novel foods

[143] Nanotechnology Industry Association website, last accessed 6/6/11 at http://www.nanotechia.org/news/global/european-parliament-to-vote-on-definition-and-labe

[144] MEMO/11/202 "Statement by Commissioner Dalli on the lack of agreement in the conciliation procedure on the Novel Food Regulation" 29/03/11

Directive, ‘packaging’ shall mean all products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. ‘Non-returnable’ items used for the same purposes shall also be considered to constitute packaging. As the definition refers to products of “any materials of any nature” it therefore covers packaging containing nanomaterials.

9.4 Reuse systems

Following Article 5, Member States may encourage reuse systems of packaging. Although nanomaterials are not known to be used extensively in reusable packaging, it is possible that in the future they might be. Further research is required to establish the mobility of nanomaterials in packaging and their compatibility with reuse systems for packaging.

9.5 Recovery and recycling

Article 6 of the Packaging Directive establishes targets for the recovery and recycling of packaging waste, as summarised in table 11 below. As mentioned in the section on the Waste Framework Directive, further research is required to fully understand the behaviour of different nanomaterials in incinerators, and in recycling processes, with a particular emphasis on those processes employed to recycle glass, paper and board, metals and plastics. There are currently unanswered questions regarding the possible impacts of nanomaterials on the efficiency of the recycling processes. In addition, further understanding is required of possible release pathways for nanomaterials channelled through recycling processes, with concerns that processes such as shredding and washing may lead to occupational and environmental health problems[145].

Were evidence to be found to the effect that specific nanomaterials impair recycling processes or that unacceptable environmental exposure results from specific hazardous nanomaterials passing through recycling processes in packaging waste, it may be relevant to pursue the elimination of specific nanomaterials from waste streams targeted for recycling. Although the Packaging and Packaging Waste Directive favours the recycling of packaging waste (with the requirement that 55-80% by weight be recycling by December 2008), it does not provide a legal mechanism for the elimination of specific materials from packaging because of their negative effects on recycling processes.

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[145] Som, C. Berges, M. Chaudry, Q. Dusinska, M. Fernandes, T. Olsen, S and Nowarck, B “The importance of life cycle concepts for the development of safe nanoproducts” (2010) Toxicology, 269, p160-169

Waste packaging containing nanomaterials in general or specific nanomaterials could be channelled for recovery through incineration, requiring some kind of labelling system to provide for the identification of these nanowastes. However, the incineration of packaging containing nanomaterials may then lead to environmental exposure through flue gas emissions where nanomaterials are not captured by end-of-pipe controls, or through the ultimate disposal of filters where they are captured.

An alternative mechanism would be to establish a scheme for the separation and collection of nanowaste from municipal waste streams. However this would encounter a number of significant challenges, including the need to label products containing nanomaterials, the unwillingness of consumers to separate out nanowaste in a context where waste separation requirements are already perceived as arduous, and how to subsequently treat and dispose of collected nanowaste. In addition, the separation of all wastes containing nanomaterials from waste streams channelled for recycling could be expected to impacts on the achievement of the recycling goals presented in table 10.

Feedback from the Stakeholder Workshop

It was noted at the workshop that further sorting of waste by consumers above existing requirements is unrealistic. Experience shows that requiring the sorting of too many waste streams can fail in delivering results as the consumer starts to perceive sorting as a burden.

In the absence of specific evidence regarding the potential release of nanomaterials during waste management processes, including recycling and incineration, discussions regarding possible controls remain speculative. Further research is required on the potential releases of potentially hazardous nanomaterials from packaging during waste management processes in order to inform regulatory decision making.

Table 10: Recovery and recycling targets for packaging waste (Directive 1994/62/EC)

a) No later than 30 June 2001 between 50 % as a minimum and 65 % as a maximum by weight of packaging waste will be recovered or incinerated at waste incineration plants with energy recovery;
(b) no later than 31 December 2008 60 % as a minimum by weight of packaging waste will be recovered or incinerated at waste incineration plants with energy recovery;
(c) no later than 30 June 2001 between 25 % as a minimum and 45 % as a maximum by weight of the totality of packaging materials contained in packaging waste will be recycled with a minimum of 15 % by weight for each packaging material;
(d) no later than 31 December 2008 between 55 % as a minimum and 80 % as a maximum by weight of packaging waste will be recycled;
(e) no later than 31 December 2008 the following minimum recycling targets for materials contained in packaging waste will be attained: (i) 60 % by weight for glass; (ii) 60 % by weight for paper and board; (iii) 50 % by weight for metals; (iv) 22,5 % by weight for plastics, counting exclusively material that is recycled back into plastics; (v) 15 % by weight for wood.

9.6 Identification system

In order to facilitate collection, reuse and recovery, including recycling, Article 8(2) requires that packaging shall indicate the nature of the packaging material used on the basis of Commission Decision 97/129/EC (1). This Decision establishes a voluntary numbering and abbreviation system for plastics (e.g. polypropylene, polystyrene), paper and fibreboard (e.g. corrugated fibreboard, non-corrugated), metals (steel and aluminium), wood materials (wood, cork), textile materials (cotton, jute), glass (e.g. colourless glass, brown glass), and composites (e.g. paper and fibreboard/plastic, plastic/aluminium). The system is intended as a tool for recyclers, to facilitate identification at automatic sorting facilities. The Decision does not refer to nanomaterials used in these different categories of packaging.

9.7 Minimizing negative impacts on the environment through releases during disposal

A number of provisions in the Packaging Directive collectively serve to ensure that environmental impacts of harmful, noxious, hazardous or dangerous substances released into the environment during the disposal of packaging waste are minimized, including Articles 3, 9, 10 and 11. The applicability of these Articles to nanomaterials is discussed in turn below.

Under Article 3(4), '*prevention*' is defined as "*the reduction of the quantity and of the harmfulness for the environment of materials and substances contained in packaging and packaging waste, and packaging and packaging waste at production process level and at the marketing, distribution, utilization and elimination stages*". This approach to prevention should then also apply to nanomaterials that are harmful to the environment and contained in packaging and packaging waste. Implementation of this approach will require evidence that such materials and substances are harmful to the environment as a prerequisite for action. While there is mounting evidence for the harmful environmental impacts of certain nanomaterials (i.e. nanosilver), for others data remains scarce. As with other legislation, this aspect is therefore significantly dependent upon regimes such as the CLP Regulation picking up risks of nanomaterials effectively.

Article 9 requires that packaging placed on the market complies with a number of essential requirements, set out in Annex II. According to Annex II, environmental impacts from the disposal of packaging waste or residues from packaging waste should be minimized through design, production and commercialisation of packaging. Packaging shall be so manufactured to minimize the presence of noxious and other hazardous substances in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled. Again, a clear definition of what is considered noxious or hazardous is lacking, and hence the type and quantity of evidence required for triggering action to minimize the presence of specific substances in packaging is uncertain. It should apply to nanomaterials that could be considered noxious or hazardous.

Pursuant to Article 10, the Commission has revised European Standards relating to methods for measuring and verifying the presence of heavy metals and other dangerous substances in the packaging and their release into the environment from packaging and packaging waste. "Dangerous substances" are not defined by reference to other legislation.

The CEN standard on prevention (EN 13428:2004) consists of two parts. The first covers "prevention by source reduction" (minimising weight and/or volume of the packaging) and the second "qualitative prevention" (minimising the presence of noxious and hazardous substances in packaging). The second part provides methods for measuring and verifying the presence of heavy metals and other dangerous substances in the packaging and their release into the environment. The standard does not specifically address nanomaterials. The standard does not list specific substances considered to be noxious or hazardous, but rather packaging producers must determine whether dangerous substances or preparations which have been used during the manufacturing process are present in the final packaging placed on the market. If so, the user must evaluate their possible release into the environment. If there is a risk of release, the user must demonstrate that the use of dangerous substances or preparations represents the minimum necessary. Even though ‘dangerous’ nanomaterials would be covered by these provisions, there are currently no available methods for verifying and measuring the presence of ‘dangerous’ nanomaterials in packaging and monitoring their release to the environment. It may be appropriate to list specific nanowastes, or categories of nanowastes, as hazardous substances explicitly if there is sufficient evidence to suggest that this is warranted on the basis of risks.

Article 11 sets out maximum concentration levels of lead, cadmium, mercury and hexavalent chromium which can be present in packaging. Should a specific nanomaterial be identified as posing a serious risk to the environment or human health, this provision could be amended and used to limit the concentration of certain nanomaterials in packaging waste. However, as discussed in section 3 on the Waste Framework Directive, the specific properties of nanomaterials mean that concentrations given in mass terms and used to establish thresholds are not accurate for nanomaterials, since toxicology studies suggest that – in some cases at least – toxicity may increase with decreased dimensions for nanomaterials[146].

9.8 Information systems

Article 12 of the Packaging Directive states that Member States shall establish databases that provide information on the toxicity or danger of packaging materials and components used for their manufacture. Commission Decision of 22 March 2005 establishes the formats of these databases[147]. Article 8(2) of this Decision states that information on concentration levels of heavy metals present in packaging and the presence of noxious and other hazardous substances and materials within the meaning of Annex II of the packaging Directive may be provided on a voluntary basis. There is no

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[146] European Commission, Health and Consumer Protection Directorate General, 2004, “Nanotechnologies: a preliminary risk assessment on the basis of a workshop. European Commission, Brussels”.

[147] Commission Decision of 22 March 2005 establishing the formats relating to the database system pursuant to Directive 94/62/EC of the European Parliament and of the Council on packaging and packaging waste (notified under document number C(2005) 854) (Text with EEA relevance) (2005/270/EC)

specific requirement for information on nanomaterials used in packaging waste and as such the reports are unlikely to generate data on the use of nanomaterials in packaging.

Pursuant to Article 19 of the packaging Directive, the formats of the databases can be amended through comitology to adapt them to scientific and technical progress. Therefore these formats could be amended in order to provide information on the types of packaging containing specific nanomaterials, were serious risks identified.

9.9 The coverage of nanomaterials under the Packaging and Packaging Waste Directive

In seeking to prevent the harmful effects of materials and substances used in packaging, the “prevention” mechanism relies on evidence of harm. In addition, the essential requirement for packaging set out in Annex II require that the presence of noxious and other hazardous substances in emissions, ask or or leachate be minimized when packaging or residues from management operations or packaging waste are incinerated or landfilled. Robust evidence of harm or hazard is lacking for specific nanomaterials despite indications from initial studies, making the application of these provisions to nanomaterials in packaging uncertain. As such, there are no gaps in the coverage of nanomaterials under the Packaging and Packaging Waste Directive. Rather, table 11 provides a summary of technical issues relating to identifying the presence of nanomaterials in packaging.

Table 11: Summary of issues relating to thecoverage of nanomaterials under the Packagin and packaging Waste Directive

Technical Issue	**Article**	**Type of gap, implications and uncertainties**
Nanomaterials do not have a category for identification when present in packaging	Article 8(2)	Potential limitation: Packaging containing nanomaterials cannot be identified by users or those collecting, reusing or recycling packaging
CEN standards for packaging do not consider nanomaterials. No methods for verifying and measuring the presence of dangerous nanomaterials in packaging	Article 10	Potential limitation: Waste packaging may contain dangerous nanomaterials and be channelled for recycling or energy recovery through incineration – leading to possible releases of nanomaterials to the environment.

10. Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when the sewage sludge is used in agriculture (Sewage sludge Directive)

10.1 Introduction

The aim of Directive 86/278/EEC[148] is to encourage the spreading of sewage sludge from waste water treatment plants[149] in agricultural fields and to prevent harmful effects on soil, vegetation, animals and man of this use. The Directive prohibits the use of untreated sludge on agricultural land (Member States can authorize this use only if untreated sewage sludge is injected or worked into the soil). The Directive requires that sludge should be used in such a way that takes into account the nutrient requirements of plants and does not impair quality of the soil and of the surface and groundwater.

Nanomaterials may enter into sewage sludge during the generation of sludge in the waste water treatment plant, following the sedimentation of nanoparticles from waste waters. Sewage sludge is thus a residue of treated waste waters.

10.2 Entry of nanomaterials into sewage sludge and subsequent exposure pathways

Possible sources of nanomaterials into waste waters include the following:

- Cosmetics entering domestic waste waters during washing or split during application
- Detergents and other domestic, commercial and institutional products that are disposed of

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[148] Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, OJ L 181, 4.7.1986, p. 6–12

[149] Sewage sludge is defined under Article 2(a) as: i) residual sludge from sewage plants treating domestic or urban waste waters and from other sewage plants treating waste waters of a composition similar to domestic and urban waste waters, ii) residual sludge from septic tanks and other similar installations for the treatment of sewage; and residual sludge other than the ones referred to in (i) (ii)

down the drain during use[150]

- Nanomaterials released from fabrics during washing
- Surface run-off of spilled lubricants, oils, catalysts from cars
- Nanomaterials released from paints used for indoor and outdoor applications.

In addition there has been the development of water remediation techniques based on the use of nanomaterials for wastewater treatment (e.g. zero-valent iron NPs and nanomembranes)[151].

Nanomaterials in waste waters may either end-up in sludge or in other environmental compartments following treatment in wastewater treatment plants (WWTPs). Technologies to remove nanomaterials from waste waters are not yet commercially available but many of the existing techniques are likely to lead to at least some of the nanomaterials present being captured in sewage sludge (although some will be present in the liquid effluent, as with other chemical contaminants). Kiser et al (2009) examined titanium at one WWTP and found that approximately 91% of titanium entering the waste water treatment plant was removed. Sixty percent of this was removed during the activated sludge process, resulting in sludge with an average titanium concentration ranging from 1.1 ± 0.42 mg Ti/g[152]. A recent UK report measured the presence of nano silver in both the influent and effluent from nine sewage treatment plants (CEH, 2011). The mean concentration of colloidal (2-450 nm) silver was found to be 12 ng/L in the influent and 6 ng/L in the effluent. For particulate silver (>450 nm) the mean values were 3.3 µg/L for influent and 0.08 µg/L for effluent. This represents removal rates of approximately 50% and 97% for colloidal and particulate silver respectively[153]. Reijnders (2006) suggests that standard wastewater treatment has limited effectiveness in capturing nanomaterials[154]. Musee has illustrated that the degree of removal of nanomaterials from waste waters depends upon the efficiency regime of the wastewater treatment plant. His review of the treatment of effluents containing nanowastes suggests that current wastewater treatment plants allow considerable volumes

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[150] For example, Kim et al (2010) recovered nanosized silver sulphide (α-Ag2S) particles from the final stage sewage sludge materials of a full-scale municipal wastewater treatment plant that they interpreted as reaction products formed from Ag NPs in waste water during wastewater treatment.

[151] Theron et al (2008) provide a summary of current research on different nanomaterials (nanostructured catalytic membranes, nanosorbents, nanocatalysts, and bioactive nanoparticles) and their application in water treatment, purification and disinfection

[152] Kiser et al (2010) "Release of Nanomaterials from Wastewater Treatment Plants" last accessed at: http://rivm.nl/rvs/Images/Kiser%20et%20al%202010-abstract_tcm35-69097.pdf

[153] Centre for Ecology and Hydrology (CEH) "Exposure assessment for engineered silver nanoparticles throughout the rivers of England and Wales" (2011) CEH, UK

[154] Reijnders L "Cleaner nanotechnology and hazard reduction of manufactured nanoparticles"(2006) Journal of Clean Production 14, 124–133

of nanomaterials into the aquatic and terrestrial environment[155]. Limbach et al find that surface charge and the addition of dispersion stabilising surfactants (routinely used in the preparation of nanoparticle derived products) exert a significant influence on particle removal efficiency[156]. Their study found that, whilst many of the nanoparticles could be captured through adhesion to clearing sludge, a significant fraction of the engineered nanoparticles escaped the plant's clearing system. Some studies suggest that functionalized (surface coated) nanoparticles are more likely to be removed from waste waters through sedimentation into sewage sludge than unfunctionalized (not surface-coated) nanoparticles, which may enter into the environment through treated effluent[157]. However, there is seemingly contradictory evidence on this subject as Kiser et al (2010) state that "nonfunctionalised engineered nanomaterials are more effectively removed from wastewater than functionalised engineered nanomaterials"[158]. This is a further indication of how uncertain much of the scientific basis is around nanomaterial risks and controls.

In the EU 55% of sewage sludge is applied to soils, 20% is channelled to landfill and 25% is incinerated[159]. The spreading of sewage sludge represents a significant pathway for the entry of nanomaterials into the environment[160]. A recent study based on the modelling of nanomaterials in the environment suggested that nano-zinc oxide and nano-titanium dioxide tend to end up in soils through the spreading of sewage sludge, with titanium dioxide predicted to accumulate in the highest concentrations overall. Nano-titanium dioxide concentrations in sludge treated soils were predicted to have risen to 0.5 mg per kg by 2012, up from 0.1 mg per kg in 2008. The environmental risks posed by these concentrations could not be accurately estimated, as there is a lack of toxicity data[161]. Box 10 provides further details on the pathways through which titanium dioxide enters the environment.

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[155] Musee N. Nanotechnology risk assessment from a waste management perspective: are the current tools adequate? J Human Exper Toxicol (in press)

[156] Limbach et al (2006) Removal of Oxide Nanoparticles in a Model Wastewater Treatment Plant: Influence of Agglomeration and Surfactants on Clearing Efficiency

[157] Jarvie PH, Al-Obaidi H, King SM, Bowes MJ, Lawrence MJ, Drake AF, et al. "Fate of silica nanoparticles in simulated primary wastewater treatment"(2010) Environmental Science and Technology, 43, 8622–8; Holt MS, Fox KK, Burford M, Daniel M, Buckland H. UK monitoring study on the removal of linear alkylbenzene sulphonate in trickling filter type sewage treatment plants. Contribution to GREATER project #2" (1998) Science of the Total Environment, 210(1–6) 255–69

[158] Kiser MA, Westerhoff P, Benn T, Wang Y and Ryu H (2010) "Release of Nanomaterials from Wastewater Treatment Plants" last accessed 6/6/11 at: http://rivm.nl/rvs/Images/Kiser%20et%20al%202010-abstract_tcm35-69097.pdf

[159] Blaser SA, Scheringe M, MacLeod M and Hungerbühler K "Estimation of cumulative aquatic exposure and risk due to silver: Contribution of nano-functionalized plastics and textiles" (2008) Science of The Total Environment 390, 396-409

[160] Sonderer T "Risk assessment of engineered nanoparticles based on [probabilistic material flow analysis" (2009) Master thesis, Swiss Federal Institute of Technology Zurich, last accessed 6/6/11 at: http://e-collection.library.ethz.ch/eserv/eth:306/eth-306-01.pdf

[161] Gottschalk F, Sonderer T, Scholz RW and Nowack B "Modeled Environmental Concentrations of Engineering Nanoparticles (TiO2, ZnO, Ag, CNT, Fullerenes) for Different Regions" (2009) Environmental Science & Technology 43, 9216-9222

Finally, it is important to note that nanomaterials released in wastewater may undergo transformation when ending in sludge. For instance several studies have found that some silver nanoparticles introduced to the wastewater treatment plants ended up as silver sulfide nanoparticles[162].

10.3 Definition of treated sludge

Article 2(b) of the Sewage Sludge Directive defines treated sludge as “sludge which has undergone biological, chemical or heat treatment, long-term storage or any other appropriate process so as to significantly reduce its fermentability and the health hazards resulting from its use”. Treated sludge could thus be interpreted as sludge that has undergone a treatment or process to significantly reduce health hazards from nanomaterials (if any such health hazards were identified). Treatment or processes to significantly reduce potential health hazard from nanomaterials contained in sludge are not yet available at an industrial scale. Techniques used to treat sludge, such as use of ultrasound (e.g. prior to use in biogas production) or breaking down organic matter and removal/reduction of disease-causing organisms in digesters could also potentially have an effect on levels of nanomaterials present (e.g. through the effect of high temperatures).

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[162] Potera C “Transformation of Silver Nanoparticles in Sewage Sludge” (2010) Environmental Health Perspective 118, 526-527; Kim et al. “Discovery and Characterisation of Silver Sulfide Nanoparticles in Final Sewage Sludge Products, Environmental Science Technology” (2010) 44(19) 7509-7514

Box 10: Overview of environmental risks and possible legislative issues for titanium dioxide

Properties and applications:

Titanium is the ninth most common element in the earth’s crust is a naturally occurring mineral that can exist in three crystalline forms, known as rutile, anatase, and brookite, and in amorphous form. Rutile is the most common form of titanium doxide (TiO_2) found in nature. TiO_2 has been used commercially since the early 1900s in numerous consumer and industrial applications, particularly coatings and pigments. One of the main differences between nano-TiO_2 and conventional TiO_2 is the much greater surface area of a given mass or volume of nanoparticles compared to an equivalent mass or volume of conventional TiO_2 particles (EPA, 2010). This greater relative surface area of the nano-TiO_2 particles affords a greater potential for properties such as catalytic activity and UV absorption at certain wavelengths (Shao and Schlossman, 1999). Several types of nano-TiO_2 are available with differing physicochemical properties. Commercially available brands of nano-TiO_2 can vary in particle size, surface area, purity (e.g., due to doping, coating, or quality control), surface characteristics, crystalline form, chemical reactivity, and other properties. Nano-TiO_2 is available in pure anatase, pure rutile, and mixtures of anatase and rutile. In general, anatase nano-TiO_2 is more photocatalytic than the rutile form, and nanoscale rutile is less photoreactive than either anatase and rutile mixtures or anatase alone (EPA, 2010). The new properties of nano-TiO2 have led to the development or use of nano-TiO2 for a wide variety of applications:

Drinking water treatment

- Arsenic removal (development stage)

Disinfection of pathogens (development stage) Cleaning products

- Anti-bacteria, and virus resistant

Sunscreen

- Transparent on the skin no milky white appearance

Absorption and scattering of UV light Coating

- Coating used to prevent bacteria, fungi and algae in computer hardware:
  - self-cleaning coating on glass

Source: (EPA 2010) (Nanotechproject inventories of nanomaterials website)

Production volumes and projected growth

The manufacture of nano-TiO_2 is a significant niche industry and demand for these materials is strong. 50, 400 tons of nano-TiO2 was produced in 2010, representing 0.7% of the overall TiO2 market. By 2015, production is projected to increase to 201,500 tons. (Future Market 2011)

Pathways for environmental exposure

Increasingly used in commercial products (e.g. sunscreen, cleaning products) nano-TiO_2 are entering municipal sewage and waste water treatment plants. A recent study showed that raw sewage nano-TiO_2 concentrations ranged from 181 to 1233 $\mu g\ L^{-1}$ (median of 26 samples was 321 $\mu g\ L^{-1}$) and that wastewater treatment plants removed more than 96% of the nano-TiO_2 and that their effluent had nano-TiO_2 concentration of less than 25 $\mu g\ L^{-1}$. This study concluded that some nano-TiO_2 will still pass through wastewater treatment plants and enter aquatic systems (Westerhoff *et al*, 2011)

Commercial products containing nano-TiO_2 (e.g. sunscreen cleaning products containers, glass and hardware coated with Nano-TiO_2) may either be recycled or disposed of and end up in landfills or incinerators. During recycling the nano-TiO_2 could be incorporated into recycled materials. The potential for leaching of nano-TiO_2 from landfill disposal of containers would depend on many factors, including the integrity of liners and leachate collection systems. Incineration of waste containing nano-TiO_2 raise the issues of whether Nano-TiO_2 could enter the stack and be released to air or become a trace contaminant in fly or bottom ash. (EPA 2010).

An occupational exposure study at a European nano-TiO_2 manufacturing facility that supplies the nanomaterials for sunscreens and cosmetics found that “outside the plant,” the airborne TiO_2 particle concentration was approximately 13,000 particles/cm3, with nearly 94% of particles 100 nm or less in size, and approximately 52% at 40-60 nm (Berges, 2007; Berges, 2008).

Sewage sludge from wastewater treatment plants is likely to contain nano-TiO_2. In the EU, this sludge may be spread on land (55%), incinerated (25%) or disposed of in landfills (20%) (Blaser *et al.* 2008). Nano-titanium dioxide concentrations in sludge treated soils are predicted to have risen to 0.5 mg per kg by 2012, up from 0.1 mg per kg in 2008 (Gottschalk et al 2009).

Environmental fate and behaviour

With regards to their behaviour in the aqueous environment, the sedimentation rates of particles with a diameter of 100 nm and 1000 nm are about 8 years and 1 month, respectively. One month can be regarded as a long time from a risk perspective, and thus sedimentation is shown not to be an important factor for the removal of titanium dioxide nanoparticles from the water compartment. However, preliminary results show that aggregation can reduce the predicted environmental concentration significantly in a short time. The aggregation is shown to depend mainly on the pH of the water compartment and the zero point charge of the particles (Arvidsson 2009). Nanoparticle dispersions were often stable for environmentally relevant conditions (e.g. pH, and ionic strength) suggesting that in the natural environment, TiO_2 dispersion might occur to a greater extent than predicted by laboratory results (Rickard Arvidsson 2009). Müller and Norwark (2008) found that nano- TiO_2 may pose a threat for organisms living in the aquatic environment.

In terms of their behaviour in soil, nano-TiO_2 particles and aggregates of nanoparticles in a stable dispersion might be highly mobile in the soil subsurface over a wide range of conditions. A study using soil samples from 11 different sites found that nano-TiO_2 could remain suspended in soil suspensions for 10 days (Fang et al., 2009). Furthermore, the calculated maximum travel distance for some soil samples was more than 30 cm, which suggested that nano-TiO2 might be transferred to deeper soil layers or even to ground water. In general, large soil particles and low ionic strength conditions favor nano-TiO_2 movement, while high clay content, dissolved organic carbon, and salinity conditions favor soil retention of nano-TiO_2. (EPA 2010).

Regarding the behavior of nano-TiO_2 in air, when nano-TiO_2 was dispersed for 0.5 hours in the air immediately next to thermal precipitators 1.5 m above the ground in various outdoor locations in the city of El Paso, Texas, USA, the collected nano-TiO2 particles were not only in agglomerate/aggregate form, but were also associated with other airborne nanoparticles, in particular, nanosilicate particulates (Murr et al., 2004).

(Eco)toxicity

A study showed that nano-TiO_2 induces genotoxicity, clastogenicity, oxidative DNA damage and inflammation in vivo in mice (B. Trouiller 2009). Sub-lethal effects of nano-TiO_2 include decreases in daphnid reproduction by photostable nano-TiO_2 (Wiench et al., 2007), as well as respiratory distress, pathological changes in gills and intestine, and behavioral changes in fish (rainbow trout) by photocatalytic nano-TiO2 (Federici et al., 2007). Several studies reported visible turbidity in nano-TiO_2 stock suspensions, and the actual nano-TiO2 concentration in the liquid phase might be different from the concentration calculated from added nano-TiO2 (Velzeboer et al., 2008; Zhang et al., 2006; Zhang et al., 2008). Given that natural organic matter in the environment can affect the extent of aggregation and deposition of nanoparticles or modify nanoparticle surface charges (Navarro et al., 2008) (Kim et al., 2009), the bioavailability and behavior of nano-TiO2 in the environment are likely to be different from bioavailability and behavior in pure water or simple media, although the direction of the difference is difficult to predict. (EPA 2010)

Photocatalytic nano-TiO2 decreased reproduction in the invertebrate C. elegans without affecting body length. Although increased growth in spinach following acute exposure to anatase nano-TiO_2 could be useful for agricultural purposes, the effects of such growth promotion in an ecological system remain unclear. Photocatalytic nano-TiO2 enhanced the uptake of arsenic and cadmium in fish, indicating the possibility of interactive effects between nano-TiO_2 and co-occurring toxic substances. (EPA 2010)

Monitoring Options

To characterize the morphology and presence of nano-TiO_2 in the waste water effluent, colloidal materials were isolated *via* rota-evaporation, dialysis and lyophilization. (Westerhoff, 2011)

Existing legislative coverage and possible future appraoches

- The bulk forms of titanium dioxide do not meet the criteria for classification as hazardous under CLP. As such it is uncertain whether nano-TiO_2 will be classified as hazardous, despite the initial evidence regarding toxicity as summarised above.
- While the concentration of nano-TiO_2 in treated sludge is predicted to increase dramatically, the Sewage Sludge Directive does not currently set any concentration requirements for nano-TiO_2 for treated sludge. 55% of sewage sludge is applied to soils in the EU.

This summary suggests that the most significant environmental exposure of nano-TiO_2 is predicted to be in the aqueous and soil environmental compartments through the disposal of sewage sludge (with spreading on soil leading to entry into surface wasters and groundwater) and to a lesser extent, through the release of effluent from wastewater treatment plants. Nano-TiO_2 are unlikely to be detected in water bodies using current available monitoring equipment, implying that such pollution will go unrecognised. Possible controls could limit the spreading of sewage sludge on soil, or involve upstream restrictions of the use of nano-TiO_2 in products that end their life in sewage systems (i.e. cosmetics).

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Zhang Y; Chen Y; Westerhoff P; Hristovski K; Crittenden JC (2008) “Stability of commercial metal oxide nanoparticles in water“. Water Res, 42: 2204-2212

10.4 Limit values

The Sewage Sludge Directive establishes limit values for heavy metals concentrations in soil (e.g. cadmium 1 to 3 mg/kg of dry matter), for heavy-metal concentrations of sludge for use in agriculture (e.g. cadmium 20 to 40 mg/kg of dry matter), for amounts of heavy metals which may be added annually to agriculture land based on a 10-year average (e.g. cadmium 0,15 kg per hectare per year). Limit values have been established for cadmium, copper, nickel, lead, zinc, mercury and chromium. There are no specific limit values for the nano-form of these heavy metals, or for any other specific nanomaterials. Likewise, however, there are no limit values for e.g. organic chemicals under the Directive. Revision of the limit values under Annex I is subject to the co-decision procedure. Several Member States have established stricter limit values for heavy metals and set requirements of other contaminants, although not for nano-forms.

Treated sludge can be used for agriculture purposes provided the limit values are not exceeded and that specific conditions are respected (e.g. sludge cannot be spread on soil in which fruit and vegetable crops are growing). However, according to a Swiss Report, simulations on concentration of nanomaterials in environmental compartments predict that the highest concentration of nanomaterials for the EU will be found in sludge treated soil or sediment[163]. Therefore, limit values for concentration of certain nanomaterials in treated sewage sludge and in soil might be necessary if risks are proven for human health and the environment (e.g. it is thought that nano-forms of silver, titanium dioxide and zinc oxide may pose a risk to aquatic life). The establishment of limit values would be subject to two principle challenges. Firstly, concentrations (or other parameters more specific to the risks of the nanomaterials in question) below which no harm to the environment or human health (given the use in agriculture) is foreseen would need to be established. As stated by the SCENIHR "*due to the physico-chemical properties of nanoparticles, their behaviour and potential adverse effects are not solely dependent on exposure in terms of mass concentration*"[164]. Hence, mass-based limit values may not be adequate to ensure that the toxicity effects of nanomaterials are rendered negligible. Furthermore, nanoparticles have heterogeneous distributions in terms of shape, size, surface charge, composition and degree of aggregation or dispersion. This means that determining concentration within a given sample and deriving concentrations that accurately represent the characteristics of the whole from a given sample is much more difficult in comparison to conventional dissolved chemicals. Aggregated

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[163] Gottschalk F, Sonderer T, Scholz RW and Nowack B "Modeled Environmental Concentrations of Engineering Nanoparticles (TiO2, ZnO, Ag, CNT, Fullerenes) for Different Regions" (2009) Environmental Science & Technology 43, 9216 9222

[164] SCENIHR, The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials. European Commission, Brussels, Belgium. 2007.

particles are often considered to be less bioavailable. Whilst the aggregation behaviour of engineered nanoparticles has not been established in environmental matrices, in the laboratory aggregation has been found to be concentration-dependent[165]. Baun et al (2009) argue that the lack of knowledge – not only in relation to ecotoxicity, degradability and bioaccumulation but also in terms of valid test systems – make it impossible to set limit values for nanoparticles now and in the foreseeable future.

Secondly, the technical and economic feasibility of monitoring concentrations of nanomaterials in sludge would need to be determined. Existing techniques for toxicity testing include bioassay-directed chemical-analysis protocols involve solid phase extraction (SPE), followed by chromatographic techniques, such as liquid chromatography-mass spectrometry (LC-MS) or gas chromatography-mass spectrometry (GC-MS)[166]. Baun et al (2009) suggest that current environmental monitoring tools are not yet sufficiently practical or robust.

10.5 Analysis and Sampling (Article 9)

Article 9, read in conjunction with Annex II A, II B and II C, establishes criteria and a methodology to be followed by Member States for the analysis and sampling of sewage sludge and soil. Pursuant to Annex II A point 3 of the Sewage Sludge Directive, analyses of sludge shall cover the following parameters: dry matter, organic matter, pH, nitrogen and phosphorus, cadmium, copper, nickel, lead, zinc, mercury, chromium. Pursuant to Annex II B point 3, analyses of soil shall cover the following parameters: pH, nitrogen and phosphorus, cadmium, copper, nickel, lead, zinc, mercury, chromium.

The analysis of sludge and soil under the Sewage Sludge Directive does not cover parameters related to the concentration of nanomaterials. The measurement techniques and instruments to analyse and take sample of the concentration of nanomaterials in sludge and soil are not sufficiently well developed. Furthermore, there does not seem to be sufficient information on the risks of nanomaterials that would warrant their inclusion in the Directive in preference, for example, to various organic chemicals of high (eco)toxicity.

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[165] Baun et al (2009) "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?", Journal of Environmental Monitoring

[166] Farre M and Barcelo D "Toxicity testing of wastewater and sewage sludge by biosensors, bioassays and chemical analysis" (2003) Trends in analytical chemistry 22 (5) 299-310

10.6 Article 13 on adaptation to technical and scientific progress (Article 13)

Article 13 of the Directive provides that the Commission shall adapt the provisions of the Annexes to technical and scientific progress, except for the parameters and values listed in Annexes I A-C, any factors likely to affect the evaluation of the values, and the parameters for analysis referred to in Annexes II A and B. This means that the Commission could not amend the sludge and soil analysis provisions of the Directive to require an analysis of the concentrations of specific nanomaterials (types of nanomaterials will have to be defined) in sludge, without undertaking a full revision of the Directive.

In general, there is insufficient information to indicate whether nanomaterials should be added to the Directive (because of the relatively paucity of information on specific risks through sewage sludge) and, if so, what materials should be included. However, the potential to incorporate materials that pose relevant risks – be they nanomaterials or other chemicals – seems to exist.

10.7 The coverage of nanomaterials under the Sewage Sludge Directive

Issues regarding the coverage of nanomaterials under the Directive on Sewage Sludge relate to uncertainties regarding the applicability of current limit values to nanoforms of required parameters, as well as the absence of any requirement for monitoring nanomaterials in sludge and soils (summarized in table 12). However, practically any requirement for monitoring or controls would be hampered by the absence of techniques that can effectively and reliable detect concentrations of nanomaterials in sludges and soils.

Table 12: Issues related to the coverage of nanomaterials under the Sewage Sludge Directive

Issues	**Article**	**Type of gap, implications and uncertainties**
Limit values for heavy metals do not take into consideration the nanoforms of these metals	Annex I A	Legislative gap: The current limit values may not be low enough to ensure that the toxicity effects of nanoforms are rendered negligible. However, this remains uncertain. Establishing limit values for nanomaterials would be subject to challenges due to limited data sets for nanomaterials.
Requirement for analysis and sampling of sewage sludge and soil does not cover concentrations of nanomaterials	Article 9, Annex II	Implementation gap: Uncertainty regarding the presence of nanomaterials in sewage sludge will persist in the absence of monitoring

11. Water Framework Directive 2000/60/EC

11.1 Introduction

Directive 2000/60/EC establishing a framework for Community action in the field of water policy[167] (hereafter the Water Framework Directive) sets the legal framework for the protection and restoration of clean water across Europe, with the aim of ensuring its long term sustainable use. It addresses surface waters (rivers, lakes, transitional waters and coastal waters) and groundwater. In protecting waters against pollution, the Water Framework Directive uses quality objectives to facilitate the management of concentrations of pollutants in surface waters and groundwater. These include the requirement for groundwater and surface waters to show good chemical status, the requirement for surface waters to also meet good ecological status, and the requirement for groundwater to also meet good quantitative status. The approaches towards surface waters and groundwater differ and are laid down in Article 16 and 17 respectively.

Regarding the scope of the current section, the focus of this section will be on surface waters only with the requirements for groundwater further elaborated under section 13 covering Directive 2006/118/EC on the protection of groundwater[168]. Requirements for waters used for the abstraction of drinking water are set out in Article 7 of the Water Framework Directive, with further quality requirements provided under Directive 98/83/EC on drinking water, addressed in section 15 of this report. Directive 76/464/EEC, as codified by Directive 2006/11/EC, on pollution caused by certain dangerous substances discharged into the aquatic environment[169], is due to be repealed in December 2013, with operative provisions already repealed. As such it is not considered within the context of this review.

For surface waters chemical status is assessed with reference to EU Environmental Quality Standards (EQS) for priority substances (individual or group of pollutants posing a risk to or via aquatic environment) and other pollutants (substances regulated under previous piece of legislations), with concentrations below the EQS lending the water “good” chemical status. In setting the quality

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[167] OJ L 327, 22.12.2000, p1-82
[168] OJ L 372, 27.12.2006, p19-31
[169] OJ L 64, 4.3.2006, p52-59

standards for European waters the Water Framework Directive works together with Directive 2008/105/EC on environmental quality standards in their field of water policy[170].

As such, a possible route for the control of specific nanomaterials in surface waters would involve their categorization as priority substances. The steps involved in employing this mechanism entail a number of challenges, including:

1. categorizing specific nanomaterials that act as pollutants in water as priority substances, when the relevant procedures were not designed for the nanoform (discussed in greater detail under section 12 on the EQS Directive);
2. establishing relevant EQS for those nanomaterials, in a context where the procedures established for setting EQS are designed for the bulk form and do not take the specific properties of nanoforms into account;
3. setting out measures for monitoring levels of pollution by nanomaterials when the technical capacity for monitoring nanomaterials in surface waters is limited; and, where EQS are transgressed; and
4. triggering action under other legislative acts to reduce or eliminate pollution by nanomaterials, in a context where control measures for source and diffuse emissions have not been specifically designed to reduce and/or eliminate nanomaterials.

The relevance to nanomaterials of the legal and technical procedures established under the Water Framework Directive for steps 3 and 4 and the challenges involved are discussed below. Challenges related to categorizing specific nanomaterials as priority substances and establishing EQS for nanomaterial are discussed under section 12 on Directive 2008/105/EC, where limitations in monitoring techniques also receive further attention.

Complementary to the controls on priority substances, the Water Framework Directive also targets a number of other pollutants, as listed in Annex VIII. Metals and their compounds (point 7) and materials in suspension (point 10) are included under Annex VIII, implying that nanoforms of metals and metal compounds and nanomaterials that remain in suspension in water are covered, although this coverage is not specific to the nano-form. Inclusion under Annex VIII triggers the requirement to identify the significant pressures from point and diffuse sources of such pollutants, as well as the magnitude of the impact of these pressures at the water body level. In addition, achieving the good

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[170] OJ L 348, 24.12.2008, p84-97

ecological status of surface waters requires that national EQS established for Annex VIII pollutants be met.

This section provides an overview of key mechanisms of the Water Framework Directive relevant to the control of pollutants and asks whether they could be applied, in principle, to the control of nanomaterials in European waters. It begins with a brief review of exposure pathways for nanomaterials entering waters.

11.2 Exposure pathways for nanomaterials entering European waters

Feedback from the Stakeholder Workshop

Referring to the low number of studies on environmental exposure pathways for nanomaterials as well as the suboptimal characterization of assessed nanomaterials, a participant noted that what studies there are often provide contradictory findings. This serves to undermine the reliability of existing evidence

It is inevitable that nanomaterials will be released into soils and waters through a number of exposure pathways[171]. These include point sources emissions of wastewater from industrial facilities manufacturing or using nanomaterials or nanoproducts, as well as effluent from urban wastewater treatment facilities. Regarding nanomaterials in urban wastewater, possible entry paths include cosmetics washed off the users' body or face[172], used or spilt detergents, the release of nanomaterials from textiles during washing[173] and from paints used on building facades[174], and the use of nanomaterials to disinfect water[175] and in wastewater treatment[176]. Possible examples of diffuse sources include nanomaterials leaching into groundwater and then into surface waters from landfills, run-off from agricultural land of pesticides that contain nanomaterials (these are known to be present

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[171] Boxall, AB, Tiede K and Chaudry, Q "Engineered nanomaterials in soils and water: how do they behave and could they pose a risk to human health" (2007) Nanomedicine 2(6) p919-27

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[173] Benn, T. and Westerhoff, P. "Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics" (2008) Environmental Science and Technology, 42(11) p4133-4139

[174] Kaegi R, Ulrich A, Sinnet B, Vonbank R, Wichser A, Zuleeg S, Simmler H, Brunner S, Vonmont H, Burkhardt M, Boller M. "Synthetic TiO2 nanoparticle emission from exterior facades into the aquatic environment" (2008) Environmental Pollution, 156(2) p233-9

[175] Li Q, Mahendra S, Lyon DY,Liga MV, Li D and Alvarez P "Antimicrobial nanomaterials for water disinfection and microbial control: Potential applications and implications" (2008) Water Resources 42 p4591-4602

[176] Nano Iron, Technical Data Sheet, NANOFER 25S, Rajhrad, Czech Republic, last accessed 3/5/11 at: http://www.nanoiron.cz/en/?f=technical_data,2009

in some pesticides in the US[177] and may also potentially be present in pesticides in the EU, although no specific examples have been identified) and from sewage sludge, and spilt lubricants that are washed off roads into storm water discharges. Atmospheric deposition of nanomaterials is also likely to be relevant. In addition, nanomaterials are employed in environmental remediation of soils and groundwater, an example being the injection of zero-valent iron nanoparticles into contaminated areas[178].

Once present in surface waters, nanomaterials will aggregate to some extent, they may associate with suspended solids and sediment and they may accumulate in living tissues. Their fate in the environment will depend upon the characteristic of the specific nanoparticle and the receiving ecosystem[179]. Once within the water environment, the particle size distribution of nanomaterials can potentially differ significantly from that of the original material released to the environment. Behaviour in the aquatic environment, including removal from suspension, is likely to depend on properties such as particle size, composition, surface characteristics, solubility, susceptibility to leaching, as well as on the chemical and physical conditions within the aqueous environment. Some settling of particles can depend on factors such as porosity, size, permeability and buoyant density[180]. It is clear, therefore, that factors such as aggregation, dissolution and settlement are likely to affect nanomaterials in the aquatic environment. It is also possible that nanomaterials in surface waters may enter waters used for the abstraction of drinking water.

11.3 Key objectives of the Water Framework Directive relevant to nanomaterials

Article 4 sets out the environmental objectives of the Water Framework Directive, several of which are of direct relevance to the pollution of waters by nanomaterials. In particular, surface waters are to achieve good water status by December 2015, meaning that both the chemical status and ecological status of the surface water are at least “good”. In addition, artificial and heavily modified bodies of water are to achieve good surface water chemical status by 2015. Regarding chemical status, this

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177 Nanotechnology and Pesticides, presentation by William Jordan (Office of Pesticide Programs, US EPA), Pesticide Program Dialogue Committee, April 29, 2010.

[178] Li X, Elliott DW and Zhang WX “Zero-valent iron nanoparticles for abatement of environmental pollutants: materials and engineering aspects.” (2006) Critical Reviews in Solid State and Material Science 31(4) 111-122

[179] Boxall, AB, Tiede K and Chaudry, Q “Engineered nanomaterials in soils and water: how do they behave and could they pose a risk to human health” (2007) Nanomedicine 2(6) 919-27

[180] Baalousha M, Lead JR, von der Kammer F and Hofmann T: Natural colloids and nanoparticles in aquatic and terrestrial environments, chapter in Environmental and Human Health Impacts of Nanotechnology (Lead JR and Smith E (Eds), Blackwell, 2009.

means that concentrations of priority substances are below the EQS established at EU level. In addition, there is to be a progressive reduction in pollution from priority substances and a ceasing or phasing-out of emissions, discharges and losses of priority hazardous substances. These objectives would only apply were a nanomaterial to be categorised as a priority substance.

The definition of good ecological status for surface waters includes conditions for the physico-chemical quality elements of surface waters. Of relevance to nanomaterials, the concentration of specific synthetic and non-synthetic pollutants should not exceed EQS established by the Member States for the pollutants listed under Annex VIII of the Water Framework Directive. As mentioned above, nanoforms of metals and metal compounds are already covered. However, it is likely that the threshold concentrations in EQS established by the Member States for Annex VIII pollutants are not applicable to the nanoform, where hazard is not always positively correlated with increased concentration. This is further explored in the section on EQS.

11.4 Nanomaterials as priority substances

The categorization of a substance or group of substances as a priority substance for their nanoforms is a critical step in determining whether the reduction of nanomaterial exposure in European water bodies receives particular attention. While the list of priority substance is subject to revision and adaptation every four years, the future inclusion of specific nanomaterials is inhibited by the difficulty of applying the established procedureto nanomaterials, as discussed below.

Directive 2000/60/EC introduces in Article 16(2) a scientifically based methodology for selecting priority substances on the basis of their significant risk to or via the aquatic environment. For instance, the risk-based assessment methodology takes particular account of:

- evidence regarding the intrinsic hazard of the substance concerned, and, in particular, its aquatic ecotoxicity and human toxicity via aquatic exposure routes;
- evidence from monitoring of widespread environmental contamination; and
- other proven factors which may indicate the possibility of widespread environmental contamination, such as production, use volume and use pattern of the substance concerned.

On this basis, the European Commission has developed a Combined Monitoring-based and Modelling-based Priority Setting (COMMPS) scheme, in collaboration with experts of interested parties. The applicability of the COMMPS scheme to nanomaterials is discussed in more details under section 12 on the EQS Directive. Based on the COMMPS, Decision 2455//2001/EC[181] establishes a list of priority substances, which currently list 33 substances including Cadmium and Nickel. Some nanomaterials are currently based on Cadmium and Nickel and the EQS set for Cadmium and Nickel would also apply to them. No nanomaterial has however until now been specifically included as a priority substance in the Annex I of this Directive. The list includes a category called "priority hazardous substances," which includes substances that have been selected from the priority substances due to their persistency, toxicity and liability to bioaccumulate (PTBs), or due to their exhibiting properties which give rise to "equivalent level of concern". Following Article 16(3) the selection of substances of concern undertaken in EU legislation on hazardous substances or relevant international agreements are to be taken into account when identifying priority hazardous substances.

No nanomaterial has been included in any international agreement on hazardous substances agreed for phase-out or for cessation of discharges, emissions and losses. Determining whether any nanomaterials give rise to an equivalent concern as PTB substances is currently hampered by lack of ecotocicological data even for the most tested nanomaterials such as fullerenes, carbon nanotubes, nano titanium dioxide, nano zinc oxide, and nano silver. For instance, the persistency (degradability) of C_{60} and carbon nanotubes and their ability to bioaccumulate in the aquatic environment remains to be studied making it virtually impossible to determine the PTB-profile for these two nanoparticles[182]. The reliability and interpretation of the available ecotoxicity data is furthermore impeded as a result of factors such as: particle impurities, suspension preparation methods, release of free metal ions, and particle aggregation[183].

Another manner in which nanomaterials could meet the criteria to be included in the list of priority substances is if there is *"evidence from monitoring of widespread environmental contamination".* However, detection and monitoring of widespread environmental contamination of nanomaterials in natural waters represents some profound challenges. Detection limits for most methods are not sufficiently low to detect environmentally relevant concentrations of nanomaterials and is to be considered virtually impossible as there are no information about initial background levels of nanomaterials in the environment and there is currently no manner in which one can tell the difference

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[181] Decision 2455//2001/EC establishing a list of priority substances, OJ L 331, 15.12.2001, p1-5

[182] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11, 1774-1781

[183] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11, 1774-1781; Hartmann NB, Von der Kammer F, Hofmann T, Baalousha M, Ottofuelling S and Baun A "Algal testing of titanium dioxide nanoparticles—Testing considerations, inhibitory effects and modification of cadmium bioavailability"(2010) Toxicology 269, 190–197; Stone V, Hankin S, Aitken R, Aschberger K, Baun A, Christensen F, Fernandes T, Hansen SF, Hartmann NB, Hutchinson G, Johnston H, Micheletti G, Peters S, Ross B, Sokull-Kluettgen B, Stark D and Tran L "Engineered Nanoparticles: Review of Health and Environmental Safety" (2010) (ENRHES) last accessed 1/2/10 at: http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report

between an engineered nanoparticles and a natural nanoparticles[184]. Widespread environmental contamination is however to be expected due to the widespread and diffuse use of nanomaterials in a range of consumer products along with the hazard characteristics of some nanomaterials such as functionalized carbon nanotubes, nano-scale silver and zinc oxide. Specific examples of exposure pathways for silver nanomaterials are provided in box 11, together with a review of possible issues relating to the legislative coverage of silver nanomaterials.

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[184] Tiede K “Detection and fate of engineered nanoparticles in aquatic systems”(2008) PhD Thesis, University of York, Environment Department & Central Science Laboratory; Hassellöv M, Readman JW, Ranville JF and Tiede K ”Nanoparticle analysis and characterization methodology in environmental risk assessment of engineered nanoparticles” (2008) Ecotoxicology 17, 344–361

Box 11: Summary of environmental risks and possible legislative issues for nano silver

Properties and applications

The nanoforms of silver are characterized by being spherical particles with a size of between 1-250 nm. Nanosilver is commercialized as powder, flakes, grains, ingots, etc. and is sold in suspension (in water, alcohol or surfactant), as a dry powder, in preparations (e.g. as a coating agent, in alloys, etc.) as well as in articles (electrodomestic appliances, in textiles, in food packages, etc.). Nanosilver is often surface modified with dextran, citrate, polysaccharide, hydrocarbon or polyvinylpyrrolidone (PVP) to avoid aggregation, and it may be deposited onto a substrate such as plastic, silica or polymers to lend a desired adhesion or electrical conductivity (Luoma *et al.* 2007, Nanowerk 2010, Pronk *et al.* 2009). The wide range of commercialized forms of nanosilver as well as variation in preparations and articles and surface modifications/coatings has important implications for the associated environmental risk and any decisions regarding regulation. Nanosilver has long been known for its antimicrobial properties and nanosilver is being incorporated into a wide range of articles such as wound dressing, personal care products, powdered colours, varnish, textile, paper, interior and exterior paints, printing colours, water and air-purification, polymer-based products and foils for antibacterial protection such as washing machines. It should be noted that some applications of conventional silver contain a naturally occurring nanosized fraction. Examples include products as pigments, photographics, wound treatment, conductive/antistatic composites, catalysts and as biocides, with some of these applications having been commercially available for over 100 years (Nowack *et al.*, 2011).

Nanosilver is the most referenced nanomaterials in consumer products, being labelled as present in 313 products (note that since labelling is not mandatory and may also be just a unsubstantiated claim, this does not reflect the true number of products containing nanosilver) (Woodrow Wilson International Centre for Scholars, 2011).

Production volumes and projected growth

Data on production volumes for nanosilver are very limited, but according to Hendren et al. (2011) estimated upper and lower bounds for U.S. production range somewhere between 2.8-20 t/yr. Müller and Nowack (2008) estimate that the worldwide production of nano-Ag is 500 t/yr. It is almost impossible to project growth in production volumes, but the number of consumer product listed in the Woodrow Wilson Center Consumer Product Inventory has more than ten-doubled over the course of 2006 to 2011 (Woodrow Wilson International Centre for Scholars, 2011b). The overall percentage of consumer products containing nanosilver is unknown at this point in time.

Pathways for environmental exposure

Exposure pathways for nanosilver along the product life cycle will be determined by the application. As nanosilver is use in for instance personal care products this will lead to environmental exposures through normal uses and household sewage. Nanosilver is also widely used in all kinds of textiles that have to be washed regularly and hence in all cases environmental releases from textiles seems plausible. If there is a sewage treatment system some of the nanosilver might be retained in the sewage treatment plant. A recent UK report measured the presence of nano silver in both the influent and effluent from nine sewage treatment plants (CEH, 2011). The mean concentration of colloidal (2-450 nm) silver was found to be 12 ng/L in the influent and 6 ng/L in the effluent. For particulate silver (>450 nm) the mean values were 3.3 µg/L for influent and 0.08 µg/L for effluent. This represents removal rates of approximately 50% and 97% for colloidal and particulate silver respectively. Nanosilver retained in sewage sludge might be distributed onto agricultural fields as sewage sludge is used in agriculture to conserve organic matter and complete the nutrient cycle. This again would lead to terrestrial exposure and nanosilver might subsequently be washed out from the soil to nearby aquatic reservoirs such as lakes, streams or groundwater reservoirs.

Environmental fate and behaviour

Boxall *et al.* (2008) estimated Predicted Environmental Concentrations for among other nanoAg in cosmetics and personal care products and reported PEC_{water} = 0.010 µ/l and PEC_{soil} 0.43 µ/kg. Luoma (2008) estimated mass release of silver from socks, washing machines and swimming pools, assuming that 10-30% of the US population use socks containing silver, that US households that are wealthy enough will buy silver wash machines and that 1 million pools use silver as a biocide. Silver discharges from socks in the two scenarios were estimated to be in the range of 6-930 kg and 180-2,790 kg respectively depending on the silver contents in the socks, whereas the contribution from silver wash machines was found to be 2,850 kg. The contribution from the swimming pools was estimated to be 30 tons. In another scenario, Luoma estimated the total future discharges to be 457 tons assuming that there will 100, 10, and 5 products in the future that resemble the silver discharged from the socks, wash machines and the swimming pools, respectively. After waste treatment this could be reduced to 128 tons provided that 80% of the discharges are treated sufficiently to remove 90% of the silver. Blaser *et al.* (2008) estimated the silver emission into wastewater by multiplying the amount of silver in biocidal plastics and textiles with the release rate of silver ions from these products and the period the products are in contact with water. Assuming that the removal in the STP was assumed to range between 99-85% wastewater removal Blaser *et al.* (2008) found that the predicted environmental concentration (PEC) for the STP would be 18 μg/L whereas PEC_{water} and $PEC_{sediment}$ would be 320 ng/L and 14 mg/kg, respectively.

Based on a material flow analysis made by Mueller and Nowack (2008), Gottschalk *et al.* (2010) derived a PEC values of 0.72 ng/l for surface water and PEC of 11.8 ng/l for sewage treatment plant effluents. The estimated and modelled PECs differ substantially from one study to the next and some of the difference could be related to the different assumptions being made about the extent to which nanoAg is retained in the sewage treatment plants. For instance Boxall et al. (2008) assume that no particles are retained, whereas Mueller and Nowack (2008) assumed that up to 97% is retained. Another key factor is how much nanoAg is actually released from textiles upon contact with water, but little information is available is this regard. Benn & Westerhoff (2008) have found that some socks leached almost all silver after contact with water whereas for others did not. In a simulation of the washing of silver-containing textiles, Geranio *et al.* (2009) found varying percentages of the total silver emitted during one wash, i.e. from less than 1% and up to 45%. Benn *et al.* (2010) measured the content of silver in textiles (in a shirt, a medical mask, a towel and a cloth), personal care products (toothpaste, shampoo), a detergent, a toy (teddy bear), and two humidifiers. They found silver concentrations from 1.4 to 270,000 µg Ag/g product. Upon washing in tap water they estimated the potential release of silver into aqueous environmental matrices in quantities up to 45 µg Ag/g product. By electron microscopy Benn *et al.* (2010) were able to confirm that nano-silver particles were present in the products, but also in the wash water samples. A recent CEH report estimated concentrations of nano Ag in the rivers of England and Wales to be in the range of 0-3 ng/L (CEH, 2011).

(Eco)toxicity

A number of ecotoxicity studies on nanoAg have been reported in the literature and it seems that the number of papers is rapidly increasing. In a 48 hour static tests, Griffitt *et al.* (2008) reported finding a LC_{50} of 7.07 (6.04-8.28) mg/l and 7.20 (5.9-8.6) mg/l on adult and juvenile zebrafish (*Danio rerio*), respectively . Using zebra fish embryos decreased dose-dependent hatching rates, weak heart beats, edema and abnormal notochords has been reported by Yeo and Kang (2008) after 48 hours exposure of 0.01 mg/l and 0.02 mg/l 10-20 nm Ag nanoparticles suspended in tap water. A number of short-term studies have been performed on Ag nanoparticles on pelagic crustaceans and algae. Griffitt *et al.* (2008) reported finding a 48 hour LC_{50} 0.040 (0.030-0.050) mg/l and 0.067 mg/l adult Daphnia pulex and Ceriodaphnia dubia neonates, respectively. For green algae (*P. subcapitata*) an EC_{50} of 0.19 mg l-1 was found after 96 hours. For another alga species (*Chlamydomonas reinhardtii*) EC50 ranged from 0.355 mg/l ± 0.062 mg/l after 1 hour, to around 0.092 ± 0.011 mg/l after 3-5 hours. Although LC50, EC50, NOEC and LOEC-values for nanoAg have been reported for aquatic species in the scientific literature, it is not clear whether the methods to establish these values provide meaningful and comparable results due to variations in sampling techniques.

Expressed as a function of free Ag+, EC_{50} was estimated to range from 3.6 ± 0.5 ug/l after 1 hour, to 0.9 ± 0.08 ug/l after 5 hours (Navarro *et al.* 2008). The study by Navarro et al. (2008) is important as it finds that the ecotoxicity of Ag cannot solely be explained by the free ion (Ag+). The antibacterial effect of nanoAg on the biomass in wastewater treatment plants is especially important as it might affect the proper functioning of the STPs. In studies of effects on nitrifying bacteria Choi and Hu (2008) and Choi *et al.* (2008) used microbial growth inhibition tests to study the effect of different sizes (9-21 nm) of Ag nanoparticles in concentrations of 0.05-1 mg/l. At exposure concentrations of 1 mg/l a significant inhibition of 86 ± 3% was observed for Ag nanoparticles compared to 42 ± 7%, and 46 ± 4% for Ag+ ions and AgCl colloids, respectively (Choi *et al.* 2008). A correlation was found between inhibition and the fraction of nanoparticles with sizes less than 5 nm and that nanoparticles caused a greater inhibition than the free Ag+ at the same total Ag-concentration. Although metal nanoparticles such as nanosilver are not degradable by definition, changes in the silver speciation can occur depending on redox conditions, salt content, etc. For ionic silver the speciation is the determining factor for bioavailability and ecotoxicity and although speciation is very likely to play an important in nanoAg ecotoxicity, speciation changes of the elemental silver are poorly documented and no general conclusion can be made (Stone *et al.* 2010).

An addition concern regarding nanosilver is the issue of bacterial resistance to silver following the increase in topical application of nano silver, although the clinical incidence of silver resistance remains low (Chopra 2007).

Monitoring options

Analytical methods to detect and quantify concentrations of nanoparticles in the environment have yet to become available (Muller and Nowack 2008, Luoma 2008). Determination of chemical elements such as Ag could be done by Atomic Absorption Spectroscopy or by Inductively Coupled Plasma Mass Spectrometry, but these methods are will only confirm the presence of silver and are not able to distinguish between naturally occurring bulk silver, naturally occurring nanoAg particles and engineered nanoAg particles.

Existing legislative coverage and possible future approaches:

This summary suggests that the key sources of nanosilver into the environment will be through treated wastewater and sludge, with the spreading of sludge on soil then further distributing the nanosilver in the environment.

- Limited data is available on the possible persistent, bioaccumulative and toxic properties of nanoAg and its hazard classification under CLP therefore remains uncertain. Although nano-silver has been used for over 120 years, the distinction between the bulk and the nano form has only been made recently, and as such we cannot determine which historic data is relevant to nanosilver. There is no nanosilver particle characterisation from the last 120 years that can allow us to interpret the historical data. In addition, the methods used for testing ecotoxicity in the past and still today where not designed for nanomaterials, hence derived data might be subject to questions regarding relevance and appropriateness.
- Regarding technical limitations, there is a lack of *in situ* monitoring techniques and lack of analytical methods to detect and quantify concentrations of nanoparticles in the environment, and lack of methods to distinguish between bulk silver and nanosilver as well as naturally occurring and engineered nanosilver. This implies that it is unlikely that nanosilver would be recognised as a pollutant, distinct from the bulk form of silver, by monitoring under the Water Framework Directive. In a context where the use of both bulk and nanoforms of silver is increasing, monitoring the two forms together renders an assessment of any increase in the concentrations of nanosilver and any associated impacts impossible. While some of the toxicity of nanosilver comes from s*ilver i*ons, this does not account for all the observed differences between the bulk and nanoform of silver.
- Regarding possible threshold values, it is not clear whether mass is the most proper metric to express the toxic potential of nanoAg as other metrics have yet to be explored

Control options include restricting the spreading of sludge on soil and upstream restrictions on relevant products.

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Some applications of nanomaterials furthermore involve direct contact with the water cycle, e.g. in relation to their use for water disinfection[185] and wastewater treatment[186] as well as in regard to the direct use to treat soil and groundwater contamination[187]. Currently the priority substances list is under review, involving the addition of new substances to the list. While the methodology for the selection of priority substances has been improved in comparison with COMMPS procedure, the inclusion of specific nanomaterials as priority substances remains practically implausible[188].

11.5 Controlling specific pollutants

An additional mechanism for controlling pollutants comes through the requirement for Member States to measure and address pollution from substances listed in Annex VIII in their river basin management plans. Given that Annex VIII includes metals and their compounds and materials in suspension, this provides coverage of nanomaterials as water pollutants, although not necessarily explicitly.

As a first step, Member States must characterize river basins according to Annex II. Included in the procedures for characterization is the requirement estimate and identify significant point and diffuse source pollution, in particular by Annex VIII substances, from urban, industrial, agricultural and other installations and activities. The information is to be sourced from databases generated under source specific legislation. However, for both legislative and technical reasons, it is unlikely that river basin management plans will include any data on the types and volumes of nanomaterials entering water bodies. Firstly, no EU legislation setting controls on water effluent specifically requires the collection of data on the presence of nanoforms in effluents. Secondly, current monitoring methods for the detection and quantification of nanomaterials in effluents are limited[189], making it technically very challenging to generate this data.

According to Annex V point 1.2.6, Member States must establish environmental quality standards for river basin specific pollutants and shall take action to meet those quality standards by 2015 as an

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[185] Li, Q, Mahendra, S, Lyon, D. Y, Liga, M. V, Li D, Alvarez, P, Antimicrobial Nanomaterials for Water Disinfection and Microbial Control: Potential Applications and Implications.Water Res., 2008, 42, 4591–4602

[186] Nano Iron website "Technical Data Sheet. NANOFER 25S" Rajhrad, Czech Republic, http://www.nanoiron.cz/en/?f¼technical_data, 2009

[187] Li, X.-Q., Elliott, D.W., Zhang, W.-X "Zero-valent iron nanoparticles for abatement of environmental pollutants: materials and engineering aspects" (2006) Critical Review of Solid State Material Science 31, 111–122

188 Baun, A., Hartman, N.B., Grieger, K.D, Hansen, S.F. "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11, 1774-1781

[189] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11 p1774-1781

element of achieving good ecological status (Annex V point 1.3). To date, it is thought that no Member State has identified nanomaterials as specific pollutants of river basins and as such, the methodologies for establishing EQS have not been applied to nanomaterials.

11.6 Monitoring water status

The detection of any nanomaterial as pollutant of water bodies is a critical first step towards identifying potential adverse impacts and taking action to reduce its concentration if necessary. Data from monitoring will provide a picture of environmental exposures, as well as informing our understanding of the environmental fate and behaviour of nanomaterials. In their discussion of the application of the Water Framework Directive to nanomaterials, Baun *et al* (2009) identify the need for techniques that measure nanomaterials in surface waters, both qualitatively and quantitatively by mass, concentration, or by other metrics based on physical, chemical or biological monitoring tools[190]. Should an investigation of the source of nanomaterial pollutants be required (as under Article 16 for priority substances), then techniques would be required to measure nanomaterials in industrial and urban waterwater effluent, stormwaters, leachate from landfills and run-off from agricultural land.

Article 8 establishes requirements for the monitoring of surface water status, groundwater status and protected areas. Member States must establish programmes for the monitoring of water status that ensure a comprehensive and coherent view of water status within each river basin, including *inter alia* the ecological and chemical status for surface waters and the chemical status for groundwater.

More detailed requirements are spelled out in Annex V and elements relevant to nanomaterials can be summarised as follows. For surface waters, Member States must carry out surveillance monitoring and operational monitoring programmes and where relevant, investigative monitoring.

Surveillance monitoring is carried out over one year of the period covered by each river basin management plan (unless good status has been achieved in which case every third plan) and involves, amongst others, testing the quality elements: priority list pollutants every month; and other pollutants discharged in significant quantities every three months. Should Member States in the process of developing river basin plans identify nanomaterials as pollutants of relevant surface water bodies under surveillance monitoring, these nanomaterials should then be subject of operational monitoring.

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[190] Baun A, Hartman NB, Grieger KD and Hansen SF “Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?” (2009) Journal of Environmental Monitoring 11 p1774-1781

Feedback from the Stakeholder Workshop

The issue of monitoring nanomaterials in water was discussed by workshop participants, with Member State representatives providing the following overview:

In Denmark, there is no monitoring of nanomaterials in water and it is not currently prioritized by the authorities.

French authorities are concentrating on gathering data on the presence of nanomaterials on the market, and are not monitoring nanomaterials in water.

In the Netherlands, there is no legislation that requires the monitoring of nanomaterials in water.

German authorities do not monitor nanomaterials in water and do not have access to monitoring techniques that would detect the presence of nanomaterials in water.

In Italy, the focus of monitoring efforts for water is on measuring pesticide concentrations. Even if nanomaterials were to be a priority, the authorities do not have appropriate techniques.

Operational monitoring is conducted at frequencies determined by the Member State in order to establish water status and assess changes resulting for the programme of measures. Again, quality elements to monitor include all priority substances discharged and other pollutants discharged in significant quantities.

Investigative monitoring seeks to establish the cause of an exceedance of EQS or the magnitude and impacts of accidental pollution, with the aim of informing a programme of measures designed to remedy the effects of accidental pollution. Additional monitoring requirements are set for protected areas, in particular for drinking water abstraction points, whereby the frequency of monitoring of priority substances and other pollutants discharged in significant quantities is set relative to the community served.

In follow up to Article 8 on monitoring, Directive 2009/90/EC on technical specifications for chemical analysis and monitoring of water status[191] was adopted. The Directive establishes minimum performance criteria for methods of analysis to by applied by Member States when monitoring water, sediment and biota, as well as rule for demonstrating the quality of analytical results, with the aim of ensuring the comparability of chemical monitoring results. Methods of analysis should reflect EN ISO/IEC-17025 standard or other equivalent standards accepted at international level. No such accepted standards have yet been established for nanomaterials at international level, although work proceeds at the OECD. The Directive states that where there are no methods that comply with the minimum performance

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[191] Directive 2009/90/EC on technical specifications for chemical analysis and monitoring of water status, OJ L201 1.8.2009 p36-38

criteria, monitoring should be based on best available techniques not entailing excessive cost (BATNEC). This can therefore be assumed to apply to nanomaterials.

A list of standardised methods for the analysis of priority substances in water[192] is under consideration for inclusion in Annex V 1.3.6 of the Water Framework Directive. The methods do not specifically mention nanomaterials, implying that there are no specific monitoring requirements designed to capture the presence of nanomaterials.

From a technical perspective, monitoring nanomaterials in natural waters is a challenging task[193]. It is worth discussing the current status of analytical techniques in quantitatively determining nanoparticles in environmental waters. It is known that natural nanoparticles in the colloidal state are easily disturbed in water, groundwater, soil and sediment during sampling[194]. For that reason, *in situ* techniques that eliminate the separation between the sampling and the analysis stage are preferable; however, there are almost none that can provide more than very basic information currently. Light scattering methods (e.g. dynamic light scattering (DLS), turbidimetry and laser diffraction) have been found to be useful and can be used to determine size related properties and also concentrations. Dynamic light scattering has particular advantages including rapid analysis time, simple operation and is particularly useful in monitoring agglomeration. However, it has limitations when samples contain a non-homogenous composition of particles of varying sizes. Microscopic methods (e.g. electron microscopy and atomic force microscopy) enable the investigation of properties at the level of individual particles as well as aggregates. Wet Scanning Electron Microscopy (WetSEM) is a method that addresses some of the shortcomings of DLS[195]. The technique uses capsules that comprise an electron transparent membrane enabling the imaging and analysis of liquid samples. Other available methods include fractionation techniques and, finally, spectroscopic techniques that can be used to probe chemical entities on whole samples and on the nanoparticle ensembles in fractionated samples. Methods for the subsequent analysis of nanoparticles include AFM, SEM and TEM. Hydrodynamic chromatography provides size separation ranges of 5-300nm or 20-1200nm and, combined with inductively coupled plasma mass spectrometry (ICP-MS), can be used to detect multiple elements and isotopes. Only very few university laboratories currently possess the relevant equipment for the

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[192] http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/chemical_monitoring/monitoring_2007-10-16pdf/_EN_1.0_&a=d

[193] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11 p1774-1781; Hassellöv M, Readman JW, Ranville JF and Tiede K "Nanoparticle Analysis and Characterization Methodologies in Environmental Risk Assessment of Engineered Nanoparticles" (2008) Ecotoxicology 17(5) p344-361

[194] Hassellöv, M., and Kaegi, R: Analysis and characterisation of manufactured nanoparticles in aquatic environments, chapter in Environmental and Human Health Impacts of Nanotechnology (Lead JR and Smith E (Eds), Blackwell, 2009.

[195] Tiede, K., Tear, S.P, David, H., Boxall, A.B.A (2009) Imaging of engineered nanoparticles and their aggregates under fully liquid conditions in environmental matrices, *Water Research,* 43(13):3335-3343

analyses described above[196].In his review of available techniques for measuring nanomaterials in water at the laboratory scale, Afsset identified problems relating to the presence of naturally occurring nanomaterials, the low concentrations of nanomaterials and difficulties in isolating the nanomaterials fraction in water[197].

Reliable methods are not yet available to determine nanoparticle identity, concentrations and characteristics in complex environmental matrices. Baun et al (2009) identify two major hurdles that exist in monitoring engineered nanoparticles in environmental samples. Firstly, detection limits for most methods are not sufficiently low to detect environmentally-relevant concentrations of nanoparticles. Secondly, environmental samples often contain a high background of natural and incidental nanoparticles and it is important to distinguish between these.

It is likely that the extent to which these techniques are already employed to detect nanomaterials in the aquatic environment within the Member States – in a regulatory context at least – will be very limited. As such, reliable and relatively low cost methods for the monitoring of nanomaterials in waters still need to be developed. A number of outstanding questions require attention, including the choice of sample materials, pre-concentration/fractionation methods, and analytical methods to characterize and quantify collected particles[198]. Given the diverse range of intrinsic properties exhibited by nanomaterials, environmental monitoring techniques will need to be targeted towards specific nanomaterials[199]. While the further development and refinement of specialised monitoring techniques for nanomaterials may be technically feasible, the economic feasibility of their wide application to European river basins remains a key barrier to gathering data on the presence of nanomaterial pollutants in European waters.

11.7 Triggers for action to reduce pollution

Once a pollutant has entered into the aquatic environment and been detected, strategies should be applied to reduce pollution through the implementation of specific measures (outlined under Article 10, Article 11 and Article 16 of the WFD). The requirements of each of these Articles are discussed in turn.

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[196] Agence Française de sécurité sanitaire des aliments (AFSSA) « Les nanoparticules manufacturées dans l'éau » (2008) AFSSA, France

[197] Afsset « Les nanomatériaus – Effets sur la santé de l'homme et sur l'environnement » (2006) France, 248

[198] Hassellöv M, Readman JW, Ranville JF and Tiede K "Nanoparticle Analysis and Characterization Methodologies in Environmental Risk Assessment of Engineered Nanoparticles" (2008) Ecotoxicology 17(5) p344-361

[199] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11 p1774-1781

Following Article 10, a combined approach shall be applied to the reduction of all discharges into surface waters from point and diffuse sources. This involves the application of Best Available Technique (BAT) or relevant emission limit values to point sources, as well as the application of Best Environmental Practice to diffuse sources in order to reduce overall emissions. In this respect, the control measures already established at the EU level should be taken into consideration such as the Directive 75/2010/EC on Industrial Emissions (IED)[200], the Urban Waste Water Treatment Directive 91/272/EEC[201], the Nitrates Directive 91/676/EEC[202] and the "daughter" directives of the Dangerous substances Directive 76/464/EEC (repeal of these latter Directives is foreseen for 22 December 2012). Should the achievement of an EQS established pursuant to the Water Framework Directive or to other Community legislation require stricter conditions than those set out in Article 10(2), more stringent emission controls shall be set.

Regarding the applicability of these measures to nanomaterials, the BAT listed in the BAT Reference Documents (BREF) published to inform operators of IED installations do not, as of yet, specifically address emissions of nanomaterials, nor were the associated emission limit values established with consideration of the nanoform. Overall, the current level of coverage of nanomaterials and ultra-fine particles within the BREFs is limited, although there is some mention of the effectiveness of techniques in reducing sub-micron size particles in relation to emissions to air. However, this is perhaps not surprising given that there has been little regulatory focus in contrast to the broader size fractions (PM2.5, PM10).

In general, there is limited information available on the types of techniques available to control emissions of nanomaterials to water. There is, however, evidence to suggest that the presence of nanomaterials such as silver may, because they act as bactericides, potentially have adverse effects on the microbial communities employed in waste water treatment. Other nanomaterials with anti-microbial properties (such as zinc oxides and titanium dioxides) might also have similar effects.

Furthermore, according to Article 11, Member States shall establish a programme of measures for each river basin district in order to achieve the objectives under Article 4, including good water status. This includes the requirement for point sources to have a specific authorization or a registration based on general binding rules laying down emission controls for pollutants. Diffuse sources must also be regulated by authorization or registration, with controls periodically reviewed and updated. Thus the legislation provides for the establishment of measures to control emissions of nanomaterials into river basin districts, should they be detected as pollutants by existing monitoring regimes.

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[200] Directive 75/2010/EC on Industrial Emissions, OJ L 334, 17.12.2010, 17-119

[201] Urban Waste Water Treatment Directive 91/272/EEC, OJ L 135, 30.05.1995, 40

[202] Directive 91/676/EEC on pollution caused by nitrates from agricultural sources, OJ L 375, 131.12.1991, 1

Requirements for the establishment of control measures for emissions, losses and discharges of priority substances are found in Article 16(1), (6), (8) and (10). Following Article 16(1), (6) and (8), measures shall be adopted aimed at the progressive reduction, and for priority hazardous substances, at the cessation or phasing out of discharges, emissions and losses. Article 16(6) states that the Commission shall identify the appropriate cost-effective and proportionate combination of product and process controls for point and diffuse sources. Where appropriate, process controls may be established on a sector-by-sector basis. Article 16(8) calls on the Commission to submit proposals for emission controls for point sources for priority substances two years following their categorization as priority substances. In the absence of agreement after six years (2014), the Member States shall establish controls. Hence, should nanomaterials be added to the list of priority substances, key point sources could be targeted for point source emission reductions. Proposals for point source controls should be based on a consideration of all technical reduction options, which in the case of nanomaterials may be limited and costly. It is of note that many of the techniques typically employed to capture releases of particulates to air from industrial installations (such as fabric filters, electrostatic precipitators and wet scrubbing) are also effective in abating the nano-scale fraction, although the efficiency is typically less than for coarser particles. There are, however, more advanced techniques that are capable of achieving similar abatement efficiencies for sub-micron particles. There is therefore some scope for achieving additional controls on emissions, particularly as concerns nanomaterials emitted to air and may subsequently be deposited in the aquatic environment.

The Commission has published an informal background document that provides guidance on the control of emissions, discharges and losses of priority substances and priority hazardous substances in the framework of Article 16[203]. It described the technical preparatory process for the development of pollution control measures, including:

- Establishing an inventory of all generic sources that result in releases and their pathways (source screening);
- Identifying existing control measures at EU level; and
- Identifying relevant sources where measures could be taken under the Water Framework Directive, and possible under other EU legislation.

In terms of source screening, it is uncertain as to whether nanomaterial pollutants will be identified as pollutants in specific river basins. This depends upon the sophistication of the monitoring techniques

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[203] European Commission "Informal background document related to the Commission documents on priority substances" (2006) COM (2006) 396 FINAL and COM (2006) 398 FINAL

employed to check the water quality of surface waters. Issues related to monitoring are discussed below.

With regards to identifying control measures, there are currently no specific requirements for controlling the release of nanomaterials through the various pathways identified in the introduction. The options for controlling releases of nanomaterials through these pathways include both end-of-pipe techniques (for example for sedimentation and filtration of industrial effluent, and wastewater emissions from urban waste water treatment plants) and up-stream legislation to eliminate the sources. These exposure pathways are subject to up-stream control under other pieces of legislation, as specified in table 13 below.

Feedback from the Stakeholder Workshop

It was pointed out at the workshop that the utilization of end-of-pipe techniques to filter nanomaterials out of effluent then generates the problem of how to dispose of filters contaminated with nanomaterials.

Table 13: An overview of exposure pathways for sources of nanomaterials entering water, relevant legislation and possible options for control

Exposure Pathway	**Examples of sources of nanomaterials**	**Relevant legislation**	**Possible options for control**
Surface run-off from roads	Spilt lubricants, paints	REACH	Eliminate nanomaterials of concern from lubricants and paints
Wastewater from urban treatment plants	Cosmetics, textiles, detergents, washing machines using nanosilver as antibacterial coating, nanomaterials used to disinfect water	UWWT Directive	End-of-pipe controls on effluent, e.g. existing WWT techniques[204]
		Biocides Directive, Cosmetics Directive, REACH	Eliminate nanomaterials of concern from cosmetics, textiles and detergents
Leachate from landfills	Nanoproducts that have been discarded and disposed of as municipal waste and released nanomaterials in landfills	Waste Framework Directive	Separate nanoproducts from the municipal wastestream
		REACH	Eliminate nanomaterials of concern from products
Run-off from agricultural land	Pesticides that contain nanomaterials	Plant Protection Products Directive	Eliminate nanomaterials of concern from pesticides
	Nanomaterials leaching out of sewage sludge	Sludge Directive	Controls on the spreading of sewage sludge on agricultural lands
Run-off from remediated soils	Iron nanomaterials used to remediate soils		
Industrial point source emissions	Facilities producing or using nanomaterials	Industrial Emissions Directive REACH	Review BAT to consider nanomaterials and apply (nanomaterials are not being specifically addressed under the current BREF reviews)
Atmospheric deposition of nanomaterials released in flue gas emissions from incinerators	Nanoproducts in municipal waste channeled to incinerators	Industrial Emissions Directive REACH	Review BAT to consider nanomaterials and apply (nanomaterials are not being specifically addressed under the current BREF reviews)

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204 Information on controlling releases of nanomaterials through effluent treatment is limited. Limbach et al (2008) found that a model WWTP was effective in removing at least 94% of an engineered nanomaterial (cerium oxide) within sludge, with up to 6% found in the exit stream. This is comparable to levels of controls for various other pollutants in WWTP. Limbach LK, Bereiter R, Muller E, Krebs R, Galli R and Stark WJ “Removal of Oxide Nanoparticles in a Model Wastewater Treatment Plant: Influence of Agglomeration and Surfactants on Clearing Efficiency” (2008) Environmental Science and Technology 42, 5828–5833

11.8 The coverage of nanomaterials under the Water Framework Directive

In principle, the Water Framework Directive provides coverage of nanomaterials, should they be detected as pollutants of European waters. Detected pollutants may be dealt with either as priority substances, or as Annex VIII pollutants and for both triggers exist for control measures, should relevant EQS be transgressed.

However, in practice there exist a number of problems with the current approach stemming principally from major limitations in current capacities to detect and then perform ongoing monitoring of nanomaterials pollutants of waters. This creates a catch 22, whereby nanomaterials will not be detected as pollutants of surface waters, will not be monitored and as a result there is no body of data to justify their inclusions are either priority substances or Annex VIII pollutants. Were nanomaterials to be detected, current end-of-pipe techniques may not be adequate to control point source emissions, while the most effective means of controlling diffuse sources would likely be through up-stream controls on the applications of nanomaterials. This represents a gap in implementation due to a lack a technical capacity.

Given that the literature identifies releases of waste water effluent as a key source of exposure of the aqueous environment to nanomaterials, the inability of current tools under the Water Framework Directive to identify and control these releases represents significant gap. The gap relates firstly to the inapplicability to nanomaterials of the methodology for ranking substances with a view of categorising them as priority substances (e.g. COMMPS procedure), and secondly to questions regarding the applicability of an approach based on environmental quality standards to nanomaterials as pollutants of surface waters.

The COMMPS procedure is an implementation tool that was developed to identify the substances of highest concern at community level, and responds to the requirement for a methodology under Article 16 of the Water Framework Directive. The increasing number of applications of nanomaterials suggests that nanomaterials will be entering surface waters, in particular through treated waste waters. Increasing concentrations of nanomaterials in surface waters will not be captured by the procedure established to identify pollutants of European surface waters. Firstly, there is a lack of EU wide monitoring data for nanomaterials in surface waters to feed into the COMMPS procedure, with the generation of such data not possible in the foreseeable future due to a lack of cost-effective available techniques. Secondly, limitations in existing ecotoxicology data for specific nanomaterials mean that it is virtually impossible to conduct risk assessments, were specific nanomaterials to be identified as pollutants. As such, the inapplicability of the COMMPS procedures to nanomaterials represents an implementation gap. The Commission is currently working to improve the methodology for the prioritisation of substances based on the most recent information available.

Problems with the application to nanomaterials of an EQS-based approach to controlling pollutants result from uncertainties in establishing relevant mass-based thresholds for nanomaterials. The specific properties of nanomaterials mean that concentrations given in mass terms and subsequently used to establish mass-based thresholds may not be appropriate for nanomaterials, since toxicology studies indicate that generally toxicity increases with decreased dimensions for nanomaterials which would imply that different thresholds would be required for different size distributions. This is considered to represent a potential legislative gap, since the legal approach adopted to limit the risk associated with specific pollutants under the Water Framework Directive may not be relevant for nanomaterials. Finding a solution depends on an increased understanding of the (eco)toxicology of specific nanomaterials at different concentrations in the aqueous environment. Initial studies suggest that results can vary significantly depending upon multiple variables (both related to the specific nanomaterials and the environmental conditions), questioning the applicability of traditional approaches to building a body of robust monitoring data. In practice, this is made even less likely by the lack of specific techniques that allow for the monitoring of nanomaterials in surface waters.

Given that the literature identifies releases of waste water effluent as a key source of exposure of the aqueous environment to nanomaterials, the inability of current tools under the Water Framework Directive to identify and control these releases represents significant gap. The limitations in scientific understanding suggest that the application of the precautionary principle is relevant to regulating the potential risks of nanomaterials in surface waters. Table 14 provides a summary of gaps in coverage under the Water Framework Directive.

Table 14: Issues related to the coverage of nanomaterials under the Water Framework Directive

Issues	**Article**	**Type of gap, implications and uncertainties**
The current methodology for raking substances with a view of categorising them as priority substances (e.g. COMMPS procedure), is not applicable to nanomaterials due to a lack of monitoring and ecotoxicology data for specific nanomaterials	Article 16	Implementation gap: Nanomaterials will not be identified as priority substances under the current COMMPS procedure
Questions regarding the application of an approach based on EQS to nanomaterials	Article 16	Legislative gap: Uncertain whether it will be possible to set EQS for nanomaterials in the near future
End-of-pipe measures to control discharges of nanomaterial pollutants from point sources are not developed, not listed as BAT in the BREF	Article 16	Implementation gap: Process control options are very limited
Identification of nanomaterials as specific pollutants of river basins difficult due to lack of monitoring techniques	Annex VIII, Annex V	Implementation gap: Nanomaterial pollutants may go undetected

12. Directive 2008/105/EC on Environmental Quality Standards in the Field of Water Pollution

12.1 Introduction

Directive 2008/105/EC of lays down environmental quality standards (EQS) for priority substances and certain other pollutants as required under Article 16 of the Water Framework Directive.

Currently, no nanomaterial has specifically been included as a priority substance in Annex I of Directive 2008/105/EC, although the EQS set for Cadmium and Nickel would also apply for the nanoform. A key question in regard to Directive 2008/105/EC and Directive 2000/60/EC is whether nanomaterials are possible candidates as priority substances. In favour of their inclusion is the widespread and diffuse use of nanomaterials in a range of consumer products, along with the hazard characteristics of some nanomaterials such as functionalized carbon nanotubes, nano-scale silver and zinc oxide. Some applications of nanomaterials furthermore involve direct contact with the water cycle, e.g. in relation to their use for disinfection and wastewater treatment as well as in regard to the direct use to treat soil and groundwater contamination. For now however, the inclusion of some nanomaterials as priority substances under the Water Framework Directive remains a theoretical scenario. As discussed under section 11 on the Water Framework Directive, this is because the application of the Combined Monitoring-based and Modelling-based Priority Setting (COMMPS) scheme with which priority substance are established to nanomaterials is hampered by a lack of data of the (eco)toxicology of nanomaterials, the unlikelihood of nanomaterials being detected by current monitoring techniques, and the lack of prior reference to nanomaterials as hazardous under other EU and international legislation.

Feedback from the Stakeholder Workshop

Representatives from the Water Unit of DG Environment clarified at the workshop that the COMMPS Scheme is currently under review. However, they noted that the revised methodology is unlikely to be applicable to nanomaterials as it stands. The four year review cycle for priority substances will provide an opportunity to consider how the methods could be adapted to consider nanomaterials. However, there is no monitoring data of nanomaterials in EU surface waters that would currently support the inclusion of any nanomaterials as a priority substance.

Should a nanomaterials nevertheless be included on the list of priority substances, the establishment of the EQS for a given nanomaterial is hampered by the lack of ecotoxicological data on toxicity, persistency and bioaccumulation even for the most tested nanomaterials such as fullerenes, carbon nanotubes, titanium dioxide, zinc oxide, and silver. This makes it virtually impossible to set an EQS for nanoparticles. Besides these issues, mainly related to the lack of relevant data, it is also questionable whether the principles for deriving EQS for chemicals can be directly transferred to nanomaterials. These issues are discussed in more detail below.

Finally, monitoring is required for priority substances. Monitoring of the concentrations of nanomaterials in the aqueous environment is currently not possible as it holds a number of technical challenges such as insufficiently low detection limits for most methods, high background of natural and unintentionally produced nanoparticles in environmental samples.

12.2 Establishing EQS for nanomaterials

If a nanomaterial were to be included in the list of priority substances based on environmental occurrence or PTB hazard information, an EQS would have to be defined. To derive an EQS for a priority substance, the Water Framework Directive outlines that test results from both acute and chronic ecotoxicological standard tests should be used for the ‘‘base set’’ organisms, i.e. algae and/or macrophytes, crustacean, and fish. The starting point for setting an EQS for surface water (defined as a maximum annual average concentration) is the lowest available effect concentration obtained using base-set organisms. This concentration is divided by an assessment factor taking into account the nature and quality of the available data, as described in the EU Technical Guidance Document for risk assessment of chemicals[205]. The concentration derived in this way is referred to as the Predicted No-Effect Concentration (PNEC). Furthermore, taking into account the risk of secondary poisoning, additional considerations of a substance’s degradability and bioaccumulation may lead to an EQS lower than the PNEC. This may in practice be done by dividing the PNEC with an additional assessment factor, as suggested by the Danish Environmental Protection Agency in their 2004 guidance on setting EQS for surface water[206]. As an alternative to deriving PNEC using a “safety factor procedure” (also known as the deterministic approach), the Technical Guidance Document also

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[205] European Commission “Technical Guidance Document on Risk Assessment. Part II” (2003) European Commission, Brussels, Belgium

[206] Danish Environmental Protection Agency “Vejledning fra Miljøstyrelsen” Nr. 4 (2004) Danish Environmental Protection Agency, Copenhagen, Denmark (in Danish)

allows the use of field studies/mesocosm data and probabilistic approaches involving species sensitivity distribution modeling[207]. Using the latter approach, at least ten NOECs/EC10-values from different species covering eight taxonomic groups are needed. However, in both cases not only will the available number of ecotoxicological studies highly influence the value of PNEC but the relevance and quality of these will also play a key role[208].

As with determining the PTB-profile of nanoparticles, estimating EQS for nanoparticles is currently hampered by lack of ecotocicological data even for the most tested nanoparticles such as fullerenes, carbon nanotubes, titanium dioxide, zinc oxide, and silver. For instance, the degradability of C_{60} and carbon nanotubes and their ability to bioaccumulate in the aquatic environment remains to be studied making it virtually impossible to set an EQS for these two nanoparticles. Not only are the number of studies very limited but the number of tested taxa is also too few to be used in the context of setting an EQS. The reliability and interpretation of the available ecotoxicity data is furthermore impeded as a result of factors such as: particle impurities, suspension preparation methods, release of free metal ions, and particle aggregation [209].

Besides these issues, mainly related to the lack of relevant data, it is also questionable whether the principles for deriving EQSs for chemicals can be directly transferred to nanomaterials. The setting of EQS is, as shown above, based on the Technical Guidance for risk assessment of chemicals, for which the European Commission's Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) have pointed out that amendments have to be made "*due to the physico-chemical properties of nanoparticles, their behaviour and their potential adverse effects are not solely dependent on exposure in terms of the mass concentration*"[210]. Nanoparticles have heterogeneous distributions in e.g. size, shape, surface charge, composition, and degree of aggregation or dispersion, and hence differ from most conventional dissolved chemicals for which a concentration can be

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[207] European Commission "Technical Guidance Document on Risk Assessment. Part II"(2003) European Commission, Brussels, Belgium

[208] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11, 1774-1781

[209] Baun A, Hartman NB, Grieger KD and Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11, 1774-1781; Hartmann NB, Von der Kammer F, Hofmann T, Baalousha M, Ottofuelling S and Baun A "Algal testing of titanium dioxide nanoparticles—Testing considerations, inhibitory effects and modification of cadmium bioavailability"(2010) Toxicology 269, 190–197; Stone V, Hankin S, Aitken R, Aschberger K, Baun A, Christensen F, Fernandes T, Hansen SF, Hartmann NB, Hutchinson G, Johnston H, Micheletti G, Peters S, Ross B, Sokull-Kluettgen B, Stark D and Tran L "Engineered Nanoparticles: Review of Health and Environmental Safety" (2010) (ENRHES) last accessed 1/2/10 at: http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report

[210] Scientific Committee for Emerging and Newly-Identified Health Risks, The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials, European Commission, Brussels, Belgium, 2007

unequivocally determined[211]. Aggregated particles are often considered to be less bioavailable, although the aggregation behaviour of nanomaterials in environmental matrices and its biological implications are hardly described in the scientific literature today. In the laboratory, aggregation is found to be concentration-dependent and it has also been found that smaller aggregates are formed at lower initial concentrations. Higher concentrations of nanomaterials may therefore not necessarily result in higher effects – a fact that challenges the traditional concentration–response testing used in standardized ecotoxicity. As described above, the current procedure for setting EQSs for chemicals is based on extrapolations from well-defined ecotoxicological endpoints originating from standardized tests to a protection level for aquatic life. For nanomaterials, not only is the starting point of the extrapolation uncertain and sometimes ill-defined, it is also unknown whether the principle of 'moving down the concentration scale' will in fact be protective[212].

12.3 Environmental monitoring of nanomaterials

Besides laying down the EQS that Member States have to apply for water bodies, Directive 2008/105/EC also requires Member States to arrange for the long-term trend analysis of concentrations of those priority substances that tend to accumulate in sediment and/or biota. The frequency of monitoring should provide sufficient data for a reliable long-term trend analysis and should as a guideline take place every three years. Arrangement of long-term monitoring furthermore entails a responsibility on Member States to take measures that such concentrations do not significantly increase in sediment and/or relevant biota.

As mentioned previously, monitoring in natural waters represents some profound challenges when it comes to nanomaterials[213]. It is known that colloidal nanoparticle dispersions are unstable and hence it may be argued that *in situ* analyses of samples in natural media are preferred, although these methods are rarely available[214]. While applicable methods for *in situ* monitoring remain to be developed and refined, it is also challenging to set up a reliable monitoring program for nanomaterials since a number of issues still remain to be resolved, e.g. choice of suitable sampling materials, pre-

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[211] Hassellöv M, Readman JW, Ranville JF, Tiede K "Nanoparticle analysis and characterization methodology in environmental risk assessment of engineered nanoparticles" (2008) Ecotoxicology 17, 344–361

[212] Baun A, Hartman NB, Grieger KD, Hansen SF "Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?" (2009) Journal of Environmental Monitoring 11, 1774-1781

[213] Tiede K "Detection and fate of engineered nanoparticles in aquatic systems" (2008) PhD Thesis, University of York, Environment Department & Central Science Laboratory; Hassellöv M, Readman JW, Ranville JF, Tiede K "Nanoparticle analysis and characterization methodology in environmental risk assessment of engineered nanoparticles" (2008) Ecotoxicology 17, 344–361

[214] Lead JR, Wilkinson KJ "Aquatic colloids and nanoparticles: current knowledge and future trends" (2006) Environmental Chemistry 3, 159–171

concentration/fractionation methods, and analytical methods to characterize and quantify collected particles[215]. In this respect, it important to recognize that nanomaterials exhibit as much, if not more, diversity than the present variety of different bulk-scale chemicals. Therefore, all attempts to establish environmental monitoring programs must be targeted towards specific nanomaterials, although this is extremely challenging to date, since there is extensive uncertainty in not only the detection of nanomaterials but also in terms of characterization and environmental fate and behaviour. Despite significant progress in recent years, reliable methods are not yet available to determine nanomaterial identity, concentrations, and characteristics in complex environmental matrices, such as water, soil, sediment, sewage sludge, and biological specimens. Two fundamental challenges currently exist in regard to developing a feasible and effective monitoring methodology of nanomaterials in environmental samples. First, the detection limits for most methods are not sufficiently low to detect environmentally relevant concentrations of nanomaterials in the range of $\mu g\ L^{-1}$–$pg\ L^{-1}$. Second, environmental samples often contain a high background of natural and unintentionally produced nanoparticles, and it is vital that we are able to distinguish between the two since they may have different toxicological profiles. Coping with these challenges is not expected to be easy and a long-term strategy is required that combines both existing and new methodologies [216].

12.4 The coverage of nanomaterials under the EQS Directive

Gaps in the coverage of nanomaterials under the EQS Directive relate to the signficiant technical challenges in setting EQS for nanomaterials. Limitations in the availability of data mean that it is virtually impossible to set EQS for a given nanomaterial. In addition, due to the lack of detection and monitoring equipment, long-term trend analysis is not possible. The technical challeneges involved in developing EQS for nanomaterials are summarized in table 15 below. Relevant limitations in knowledge and technical capacities are summarized in box 12.

In addition, as mentioned in section 11 above, there are questions regarding the relevance of mass-based thresholds to nanomaterials, where potential adverse effects are not solely dependent on exposure in terms of the mass concentration. Regarding those priority substances for which nanoforms

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[215] Hassellöv M, Readman JW, Ranville JF, Tiede K ”Nanoparticle analysis and characterization methodology in environmental risk assessment of engineered nanoparticles” (2008) Ecotoxicology 17, 344–361

[216] Hassellöv, M., Readman, J. W., Ranville, J. F., Tiede, K. 2008. Nanoparticle analysis and characterization methodology in environmental risk assessment of engineered nanoparticles. Ecotoxicology, 2008, 17, 344–361; Handy RD, von der Kammer F, Lead JR, Hassellöv M, Owen R and Crane M “” (2008) Ecotoxicology 17, 287–314

exist (i.e. cadmium and nickel) it is not know whether the EQS are adequate to mitigate risks from the nanoforms of these substances.

While limitations in available data and technical capacity for monitoring represent an implementation gap, questions regarding the applicability of mass-based thresholds to nanomaterials highlight a possible legislative gap.

Table 15: Summary of issues relating to the coverage of nanomaterials under the EQS Directive

Issues	**Article**	**Type of gap, implications and uncertainties**
Currently not feasible to set EQS for a given nanomaterial due to lack of data e.g. on ecotoxicology and widespread environmental contamination	Article 3(2)	Legislative gap: No scientifically valid EQS can be set
Detection and monitoring of nanomaterials in the environment is currently not technical possible and hence long-term trend analysis is not possible	Article 3(3)	Implementation gap: Impossible to say anything about the short- and long-term outlet and accumulation of nanomaterials in the environment

Box 12: Summary of limitations in knowledge and technical capacities relating to establishing EQS for nanomaterials

Knowledge gaps:

- It is unclear whether the criteria for identifying priority substances are applicable for nanomaterials
- Lack of data hampers determination of the PTB-profile and hence the categorization of a nanomaterial as a priority hazardous substance
- In general, information on PTB is not available for most nanomaterials and it is not clear whether terms such as "persistency" makes much sense for nanomaterials due to the propensity of inorganic nanomaterials to undergo chemical transformations in the environment.
- Should a nanomaterial be identified as a priority substance, there is a lack of data to establish EQS
- The reliability and interpretation of the available ecotoxicity data impeded by issues such as: particle impurities, suspension preparation methods, release of free metal ions, and particle aggregation
- It is unclear that the guiding principles used to establish EQS apply as these all assume that the dose-makes-the-poison. Establishing dose characteristics involves significant challenges for nanomaterials due to variations in surface area, surface activation etc.
- It is unknown what the environmental background level is of natural and unintentionally produced nanoparticles, which hampers trend analysis

Limitations in technical capacities:

- Test methods are currently not available that specifically address the hazard properties of nanomaterials such as surface area, surface reactivity, etc.
- Methods used to establish EQS are based on the Technical Guidance Document. This guidance was however not developed for discrete and dispersed nanoparticles, but for soluble chemical substances and hence these might give misleading results and need to be validated for nanomaterials
- A number of limitations exist in the capacity to do monitoring of nanoparticles in the environment, including:
    1. First, the detection limits for most methods are not sufficiently low to detect environmentally relevant concentrations of nanomaterials in the range of ng L^{-1}–pg L^{-1}
    2. Second, environmental samples often contain a high background of natural and unintentionally produced nanoparticles, and
    3. Third, there are currently no technical measures by which we can distinguish between natural and unintentionally produced nanoparticles, which are vital as they may have different toxicological profiles.

13. Directive 2006/118/EC on the protection of groundwater against pollution and deterioration

13.1 Introduction

The Directive on the protection of groundwater against pollution and deterioration (the Groundwater Directive)[217] responds to Article 17 of the Water Framework Directive, which calls for strategies to prevent and control the pollution of groundwater. As such, the Groundwater Directive establishes common monitoring methodologies, including criteria for assessing good groundwater chemical status and criteria for the identification of significant and sustained upwards trends and for the definition of starting points for trend reversals. Furthermore, the Groundwater Directive establishes measures for preventing or limiting the inputs of pollutants to groundwater, in addition to those laid down under the Water Framework Directive.

13.2 Criteria for assessing groundwater chemical status

According to the Water Framework Directive, good groundwater status must also be achieved by 2015, whereby both the quantitative status and chemical status of the groundwater are at least "good". Good groundwater chemical status means that criteria set out in the Groundwater Directive are met. Member States shall implement the measures required to reverse any significant and sustained upward trend in the concentration of any pollutant in groundwater resulting from human activity. The objective for groundwater to reverse upward trends in any pollutant would theoretically capture nanomaterials (those that are identified as relevant pollutants), depending upon the technical capacity of the groundwater monitoring network established under Articles 7 and 8 of the Water Framework Directive to detect nanomaterials in groundwater.

In assessing the chemical status of groundwater according to Article 3, Member States shall use two criteria, namely:

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[217] Directive 2006/118/EC on the protection of groundwater, OJ L 372, 27.12.2006, p19-31

- groundwater quality standards set out in Annex I for nitrates (50 mg/l) and active substances in pesticides, including their relevant metabolites, degradation and reaction products (0.1 µg/l or 0.5µg/l (total) (^{2}); and
- threshold values established by Member States for pollutants, groups of pollutants and indicators of pollution that have been identified as contributing to the characterisation of groundwater as being at risk (under Article 5 and Annexes II and III of the Water Framework Directive), as a minimum, pollutants listed under Annex II, Part B.

Nanomaterials are in principle captured under Annex II, Point 2, which refers to man-made synthetic substances. In addition, should specific nanomaterials be identified as pollutants of groundwater in a Member State then threshold values should be established for those nanomaterials against which chemical status can be assessed. The list of threshold values is to be updated in response to information on new pollutants, groups of pollutants or indicators of pollutants.

Here two challenges are encountered with regards to nanomaterials. Firstly, in order to be identified as pollutants the nanomaterials must have been detected by groundwater monitoring techniques. This is unlikely given both the lack of availability of *in situ* detection methods for nanomaterials in natural media[218] and technical limitations of currently available methods (see discussion on monitoring techniques in the analysis of the Water Framework Directive).

Secondly, the establishment of threshold values for pollutants requires specific knowledge on the environmental fate and behaviour of the pollutants. In particular, Annex II, Part A, Point 3 requires that determination of threshold values take account of the toxicology and dispersion tendency of the pollutants, their persistence and potential for bioaccumulation. Furthermore, Article 3 requires that knowledge of human toxicology and ecotoxicology be taken into account. While the number of scientific studies on the ecotoxicology of nanomaterials is rapidly increasing, current data sets remain inconsistent and insufficiently systematic. Baun *et al* (2009) provide a review of available ecotoxicological literature on the aquatic toxicity of the most frequently tested nanomaterials, namely fullerenes, carbon nanotubes, titanium dioxide, zinc oxide and silver, with the aim of assessing the basis for establishing EQS. They conclude that available ecotoxicity data is not reliable and that the lack of knowledge on the ecotoxicity, degradability and bioaccumulation of nanomaterials makes it virtually impossible to set EQS for nanomaterials now and in the foreseeable future. This is supported by Greiger *et al* (2009), who conclude that understanding of the basic ecotoxicological parameters of nanomaterials is very low and flag the need for improved testing procedures and equipment, human

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[218] Baun, A., Hartmann, N.B, Grieger, K.D and Hansen, S.F. (2009) Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?, *Journal of Environmental Monitoring,* 11:1774-1781

and environmental effect and exposure assessments and full characterisation of nanomaterials[219]. In particular, they suggest that attention should be paid to those ENPs that are used to directly treat groundwater contamination, such as zero-valent iron nanoparticles that are injected into contaminated area for remediation[220].

As such, nanomaterial pollutants are, in theory, included in the range of pollutants that require assessment against a quality standard when assessing chemical status. However, in practice, the methodological tools for detecting their presence are not currently available or used in a regulatory context and data are not available to support the establishment of EQS.

13.3 Procedure for assessing groundwater chemical status

Article 4(2) sets out the procedures that Member States must follow when assessing groundwater status and provides three options for achieving good chemical status. These are set out in table 16 below together with an assessment of their application to nanomaterial pollutants in groundwater. The table identifies a number of issues which suggest that the presence of nanomaterials in groundwater may not be identified when undertaking the assessment. To summarise, these relate to: difficulties in identifying nanomaterial pollutants due to limitations in monitoring techniques; the inapplicability of current quality standards under other Community legislation and threshold values established at Member State level to nanoforms of pollutants; and limited knowledge on the environmental fate and behaviour of nanomaterials in the aquatic environment.

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[219] Grieger KD, Hansen SF, Baun A "The known unknowns of nanomaterials: describing and characterizing uncertainty within environmental, health and safety risks" (2009) Nanotoxicology 3 p222-233

[220] Li, X., Elliott, D.W., Zhang, W.X, (2006) Zero-Valent Iron Nanoparticles for Abatement of Environmental Pollutants: Materials and Engineering Aspects, Critical Reviews in *Solid State and Materials Sciences,* 31:111-122

Table 16: Procedures for assessing groundwater chemical status and their application to nanomaterials

Procedure for assessing groundwater chemical status	**Application to assessing nanomaterials in groundwater**
(a) the relevant monitoring demonstrates that the conditions set out in Table 2.3.2 of Annex V to Directive 2000/60/EC are being met: or i.e. • Quality standards under other relevant Community legislation are not exceeded • Article 4 objectives met for associated surface waters • No significant damage to dependent terrestrial ecosystems	• Detection of nanomaterials in groundwater is unlikely due to technical limitations and high cost of currently available monitoring techniques (their actual application in a regulatory context is limited or non-existent) • Existing quality standards for groundwater do not take the nanoform into consideration • Nanomaterials unlikely to be identified as additional pollutants under Annex VIII of the Water Framework Directive due to limitations in monitoring techniques
(b) the values for the groundwater quality standards listed in Annex I and the relevant threshold values established in accordance with Article 3 and Annex II are not exceeded at any monitoring point in that body or group of bodies of groundwater; or	• Nanomaterials unlikely to be identified as Annex II pollutants due to limitations in monitoring techniques and lack of evidence that they constitute significant groundwater pollutants • Existing threshold values under Article 3 will not consider the nanoform • Detection of nanomaterials in groundwater is unlikely due to technical limitations and high cost of currently available monitoring techniques
(c) the value for a groundwater quality standard or threshold value is exceeded at one or more monitoring points but an appropriate investigation in accordance with Annex III confirms that: *(i) on the basis of the assessment referred to in paragraph 3 of Annex III, the concentrations of pollutants exceeding the groundwater quality standards or threshold values are not considered to present a significant environmental risk, taking into account, where appropriate, the extent of the body of groundwater which is affected;* *(ii) the other conditions for good groundwater chemical status set out in Table 2.3.2 in Annex V to Directive 2000/60/EC are being met, in accordance with paragraph 4 of Annex III to this Directive;* *(iii) for bodies of groundwater identified in accordance with Article 7(1) of Directive 2000/60/EC, the requirements of Article 7(3) of that Directive are being met, in accordance with paragraph 4 of Annex III to this Directive;* *(iv) the ability of the body of groundwater or of any of the bodies in the group of bodies of groundwater to support human uses has not been significantly impaired by pollution.*	• Same considerations apply as for procedures (a) and (b) • (iii) refers to water abstracted for drinking water, whereby deterioration shall be avoided and the required level of purification reduced. Annex III Point 4 then requires the assessment of a range of elements related to the behaviour of the pollutants in the aquatic environment, as well as risks relating to the quality of water for human consumption. Knowledge on the behaviour of nanomaterials in the aquatic environment, their impact on water purification systems, and risks to human health is currently limited, impeding such an assessment.

13.4 Identification of significant and sustained upward trends and the definition of starting points for trend reversals

Article 5 sets out the requirement regarding the identification of significant and sustained upward trends in concentrations of pollutants, groups of pollutants or indicators of pollutants, stating that trends that present a significant risk of harm to the quality of aquatic ecosystems or terrestrial ecosystems, to human health or to actual or potential legitimate uses of the water environment shall be reversed. Limitations in the data sets on the ecotoxicity of nanomaterials present challenges to undertaking a thorough risk assessment for specific nanomaterials.

Trend reversal shall be achieved through the programme of measures provided for under Article 11 of the Water Framework Directive. End-of-pipe controls on point sources of nanomaterials would be subject to the technical limitations discussed under the Water Framework Directive.

Starting points for trend reversals are to be defined as a percentage of the level of groundwater quality standards set out in Annex I and the threshold values established by Member States, on the basis of the identified trend and the environmental risk associated therewith. It is clear that there is a significant way to go before the evidence on any risks of nanomaterials for groundwater is sufficient to provide a basis against which trend reversal should take place.

13.5 Monitoring requirements

Monitoring requirements for groundwater are laid down in Annex II of the Water Framework Directive. Annex II point 2.4 sets out the requirements for establishing a groundwater monitoring network, with the aim of meeting the objectives of Article 7 on waters used for the abstraction of drinking waters and Article 8 on monitoring. The network should provide a coherent and comprehensive overview of groundwater chemical status and detect the presence of long term anthropogenically induced upward trends in pollutants. In theory therefore, any sustained increase in nanomaterial pollutants in European groundwater should be detected.

Surveillance monitoring aims at assessing long term trends, including those resulting from anthropogenic activities. Where bodies of groundwater have been identified as being at risk of failing to achieve good status, they shall be monitored for those parameters that are problematic. Operational monitoring shall be undertaken, at a minimum, once per year in the periods between surveillance monitoring and shall establish the chemical status of those groundwater bodies determined as being of risk, as well as establishing any long term anthropogenically induced upward trends in pollutants. Member States are to provide colour-coded maps of groundwater chemical status, with good status marked in green and poor in red. Upward trends in pollution are to be marked by a black dot, with trend reversal marked by a blue dot.

As such, for monitoring of a nanomaterial pollutant to be required, it must first have been identified as a pollutant of the groundwater body under initial characterisation. Given that the detection of nanomaterials in water requires the use of specialised techniques and that use of these techniques is currently not common, it is unlikely that nanomaterial pollutants will be detected in groundwater.

13.6 Measures to prevent or limit inputs of pollutants into groundwater

Should nanomaterial pollutants be detected in groundwater, measures should be put in place to limit their input to groundwater. Article 6 calls on Member States to ensure that the programme of measures established under Article 11 of the Water Framework Directive includes all measures necessary to prevent inputs of any hazardous substances, with particular reference to hazardous substances belonging to the groups of pollutants listed in Annex VIII of the Water Framework Directive. Given that Annex VIII covers nanomaterials under Point 10 *Materials in suspension*, this establishes a legal requirement to prevent the entry of hazardous nanomaterials into groundwater. The critical step lies in specific nanomaterials being categorised as hazardous.

For pollutants that are not categorised as hazardous, inputs should be limited through measures that take into account best practice, Best Environmental Practice and Best Available Techniques specified in Community legislation. While such practices are the subject of repeated revisions to adapt them to technical and scientific progress, current technical standards were not developed with the aim of specifically reducing the concentrations of nanomaterials from diffuse or point sources.

Following Article 11 of the Water Framework Directive, direct discharges of pollutants into groundwater are prohibited, with a number of exceptions. One of these exceptions is the injection of waters resulting from mining activities (Article 11(3)(j)). Some nanomaterials are used in the detoxification of mining wastewaters, while some nanomaterials are sourced through mining[221]. It will

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[221] Azonano "Atlas mining in discussion with nanotechnology companies" Last accessed 11/5/11 at: http://www.azonano.com/article.aspx?ArticleID=821

be necessary to monitor the emergence and application of these practices in order to determine whether they pose any risk through the contamination of groundwater with nanomaterials.

13.7 The coverage of nanomaterials under the Groundwater Directive

Issues related to the coverage of nanomaterials under the Groundwater Directive are tightly linked with those for the Water Framework Directive and the EQS Directive, relating to the absence of techniques for the detection and monitoring of nanomaterials and problems with establishing quality standards.

Firstly, the criteria for assessing groundwater chemical status may fail to capture nanomaterial pollutants as monitoring techniques not sufficiently developed to allow for reliable, low-cost monitoring of nanomaterials in groundwater. Secondly, were nanomaterials to be detected as pollutants, there is insufficient data on ecotoxicity of nanomaterials in the aquatic environment to establish threshold values for specific nanomaterials. Thirdly, knowledge is too limited to allow for an assessment of the risk from nanomaterial pollutants in groundwater to be abstracted for drinking water. Finally, the reliability of technical measures to prevent or reduce inputs of nanomaterial pollutants into groundwater from point and diffuse sources is uncertain. In addition, there is no basis for establishing starting points for trend reversal in concentrations, should nanomaterials be detected in groundwater. These issues, summarised in table 17, arise from limitations in available data on nanomaterials and a lack of technical capacity and as such represent implementation gaps. In terms of a potential legislative gap, questions regarding the applicability of mass-based threshold values to nanomaterials are again relevant.

Table 17: Summary of issues related to the coverage of nanomaterials under the Groundwater Directive

Issue	Article	Type of gap, implications and uncertainties
Criteria for assessing groundwater chemical status may fail to capture nanomaterial pollutants as monitoring techniques not sufficiently developed to allow for reliable, low-cost monitoring of nanomaterials in groundwater	Article 3	Implementation gap: Nanomaterial pollutants may not be detected and may not be included as an element of chemical status
Insufficient data on ecotoxicity of nanomaterials in the aquatic environment to establish threshold values for specific nanomaterials. Mass-based threshold values may not be relevant for nanomaterials.	Article 3	Legislative gap: No threshold values for nanomaterial pollutants of groundwater, no means for control
Knowledge is too limited to allow for an assessment of the risk from nanomaterial pollutants in groundwater to be abstracted for drinking water	Article 4(2)(c)	Implementation gap: Difficult to undertake an assessment of the risks to drinking water
The reliability of technical measures to prevent or reduce inputs of nanomaterial pollutants into groundwater from point and diffuse sources is uncertain	Article 6	Implementation gap: The programme of measures under Article 11 of the WFD is unlikely to include specific measures to control releases of nanomaterials at point source. Upstream controls are required in the absence of technical measures at point source.
No basis for trend reversal should nanomaterials be detected	Article 11	Implementation gap

14. Urban Waste Water Directive 91/271/EEC

14.1 Introduction

The Directive concerning urban waste water[222] regulates the collection, treatment and discharge of urban waste water and the treatment and discharge of waste water from certain industrial sectors. It defines urban waste water as domestic waste water or the mixture of domestic waste water with industrial waste water and/or run-off rain water.

14.2 Exposure pathways for nanomaterials into waste water

As already mentioned in the review of the Sewage Sludge Directive possible sources of nanomaterials into waste water include the following:

- Cosmetics entering domestic waste waters during washing or split during application;
- Detergents and other domestic, commercial and institutional products that are disposed of down the drain during use;[223]
- Nanomaterials released from fabrics during washing;
- Surface run-off of spilled lubricants, oils, catalysts from cars;
- Nanomaterials released from paints used for indoor and outdoor applications;

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[222] Directive 91/271//EEC concerning urban waste-water treatment, OJ L 135, 30.5.1991, p. 40–52

[223] For example, Kim et al (2010) recovered nanosized silver sulphide (α-Ag_2S) particles from the final stage sewage sludge materials of a full-scale municipal wastewater treatment plant that they interpreted as reaction products formed from Ag NPs in waste water during wastewater treatment.

Box 13: Overview of environmental risks and possible legislative issues for nano-scale zinc oxide

Properties and applications

Nanosized zinc oxide (ZnO) has the flexibility to form different nanostructures and exhibits multi-functionality. Properties such as thermal stability, irradiation resistance, antibacterial, antifungal, anticorrosive and catalytic together with their status as semiconductors provide for applications of ZnO nanomaterials in UV protection (both personal and industrial scale), electronic devices, industrial catalysts and in medicine. Structures like ZnO nanowires, nanobelts, quantum dots and nanorings are of great interest in photonics research, optoelectronics and biomedicine (nanowerk 2006). ZnO can be synthesised to be soluble in a range of aqueous or organic solvents, allowing for their incorporation into most material processing (Z-MITE, 2005). ZnO nanomaterials are available as dry powders for coatings, or as dispersion in water or organic solvents designed to be compatible with a range of resins for incorporation into solid matrices (Umicore). A number of applications for which product information was found are listed below:

Emerging applications for ZnO quantum dots • Opotoelectronic applications • Quantum computing • Spintronics • Photocatalysts • Luminescence labelling	Electronics • Semi-conductor properties in plastics • Transparent conductive layers • Permanent anti-static properties • nano-piezotronic electronic components such as diodes • Use of zinc oxide nanofibres on a gallium arsenide, sapphire or flexible polymer substrate to create energy generator	Industrial applications • functional coating formulations to protect wood, plastics and textiles from UV, bacterial and fungal action • Rubber emulsions • Industrial catalyst in methanol synthesis
Medicinal applications • Biosensors • Bactericide	Cosmetics (personal UV protection + bacteriostatic and fungistatic properties) • Sunscreen & sunblock • Lipsticks • Anti-bacterial lotions	Vehicles • Improves colour fastness of exterior and interior automotive parts
Animal husbandry • Anti-inflammatory in dairy production		

Sources: Understanding nano.com, Z-MITE, nanophase, umicore

According to the inventory of the Woodrow Wilson International Centre for Scholars, ZnO nanomaterials are referenced in 31 consumer products, including; 27 cosmetic products; 1 air sanitizer; 2 vitamin supplements; and 1 industrial coating (note that since labelling is not mandatory, this does not reflect the true number of consumer products containing ZnO).

Production volumes and projected growth

Data is not available on current production volumes for nano ZnO.

Pathways for environmental exposure

In terms of releases of ZnO during industrial applications, industrial wastes may include powder forms of nano ZnO, excess solvents and resins, and materials contaminated with nano ZnO. Such wastes will be treated as hazardous wastes under the Waste Framework Directive due to the classification of the bulk powder forms of zinc oxide (both standard and low grade) as hazardous under the CLP Regulation. Such industrial wastes would therefore be channelled into landfills for hazardous waste and It can be expected that zinc oxides in cosmetics and personal care products will enter the environment by being washed off of users' skin and passing into sewage waters. A study by Limbach et al (2008) suggests that current biological wastewater treatment processes are limited in removing oxide-based nanomaterials. While a majority of the nanomaterials could be captured through adherence to sludge, a significant fraction escaped the clearance system and exited in wastewaters. Musee (2011) argues that low concentrations of nano ZnO will disfavour agglomeration, suggesting that zinc oxides will enter the environment through wastewaters. Gottschalk et al found nano ZnO to enter soils through the spreading of sewage sludge. These studies suggest that both effluent and sludge from wastewater treatment plants will be significant sources of nano ZnO to the environment. It can be expected that containers of liquid products containing nano ZnO (i.e. sunscreen) will be disposed of in municipal waste streams and channelled for municipal landfills or incineration. There is no data on the behaviour of nano ZnO in landfill or incinerators. Bulk forms of zinc are found as contaminants in landfill leachate. With regards to nano ZnO in electrical and electronic equipment, there are no specific requirements for the treatment of nanomaterials in such waste. While Directive 2002/96/EC aims to promote the reuse, recycling and recovery of electrical and electronic equipment, two thirds of such waste is not collected and is potentially going to landfill or to sub-standard treatment sites in or outside the EU (European Commission).

The behaviour of nano ZnO in relevant recovery processes for electrical and electronic equipment is not known. Given that bulk zinc oxide is classified as hazardous under the CLP Regulation, applications of nano ZnO in vehicles should be limited following Article 4(1)(a) of Directive 2000/53/EC on end-of-life vehicles, so reducing the possibilities for environmental exposure.

Environmental fate and behaviour

In their modelling of environmental exposure to nanomaterials, Gottschalk et al estimated concentrations of nano-ZnO to be 10µg/l in surface waters and 432µg/l in treated wastewaters in the EU. They found that risks to aquatic organisms may currently emanate from nano-ZnO released into the environment in sewage treatment effluents. Boxall et al predicted UK exposure levels for ZnO of 76µg/l in water and 3,194µg/kg in soil. Nano ZnO tends to aggregate and settle into sediment in the aqueous medium.

(Eco)toxicity

The solubility of ZnO in water and antimicrobial properties make ZnO nanomaterials toxic to aquatic organisms. Nano ZnO undergoes speciation and releases free metal ions in water, with toxicity party attributable to the release of dissolved metal ions (Baun et al 2009). Nano ZnO aggregates cause toxicity to zebrafish embryos and larvae, including malformations in the cardiovascular system, blocked hatching and embryo mortality (Zhu et al, 2009). Further studies have found evidence of aquatic toxicity to bacteria (Brayner et al, 2006), vertebrates (Heinlaan et al, 2008) and nematodes (Wanga et al, 2008). Adams et al (2006) found the toxicity of nano ZnO to bacteria to increase with the presence of light. Li et al (1999) found that metal nanomaterials induced more severe lung toxicity in mice that the equivalent bulk materials. Humans exposed to 5mg/m^{-3} zinc nanomaterials for 2hrs experienced sore throats, chest tightness, headaches, fever and chills (Gordon et al 20). A repeat of the test at lower concentrations (i.e. 500µg/cm^{-3}) found no indication of adverse effects (Beckett et al 2005), suggesting that toxicity is concentration dependent with the respiratory system serving as the uptake path (Hristozov and Malsch 2009). Sayes et al (2007) observed indicators of inflammation in rat lung epithelial cells in vitro after 1hr of exposure to zinc nanomaterials at 520µg/cm^{-2}. Gastrointestinal administration of zinc nanomaterials can cause severe symptoms of lethargy, anorexia, vomiting, diarrhea, loss of body weight and death in mice (Wang et al 2006). In his characterization of the degree of hazard associated with different nanomaterials, Musee (2011) ranked zinc oxides as posing a medium degree of hazard.

Monitoring Options

Monitoring options for naturally occurring inorganic nanomaterials include transmission electron microscopy and scanning probe microscopy, although results are limited to the minute fraction of the material analysed making it extremely difficult to ensure that a representative sample of examined. Very little has been published on the analysis of engineered inorganic nanomaterials (Norwark and Bucheli, 2007). FFF was used to study the stability of nano-ZnO in soil suspension (Gimbert et al., 2007)

Existing legislative coverage and possible future approaches:

The likely exposure pathways into water and soil and the aquatic toxicity of nano ZnO suggest that measuring and possibly controlling the presence of nano ZnO in the aquatic and soil media is most important. A number of issues related to the coverage of ZnO under environmental legislation have been identified and are listed below:

- The limit values for zinc in soil (150-300mg/kg), sewage sludge for use in agriculture (2,400-4,000mg/kg) and average volumes that can be added to soil over 10yrs (15kg/ha/yr) established under Directive 86/278/EEC are not relevant for nano ZnO. The limit values are based on volume thresholds for the bulk form, while adverse effects from nano ZnO are not solely based on exposure in terms of mass concentration. Although, the requirements for the analysis and sampling of sewage sludge include zinc as a parameter, techniques for measuring concentrations of nano ZnO are not developed.
- Directive 91/271/EEC on urban wastewater treatment does not include any treatment or monitoring requirements for nano ZnO, or for the bulk form of zinc oxide.
- Nano ZnO are not captured under the chemical parameters listed under Annex I Part B of the Drinking Water Directive 98/83/EC, implying that testing for nano ZnO in water destined for human consumption is not required.
- Nano ZnO will not be detected in water bodies using currently available monitoring equipment and hence will not be identified as a pollutant under the Water Framework Directive, were they to be present. As such, threshold values are unlikely to be established for nano ZnO in groundwater by Member States under Directive 2006/118/EC.
- Given the classification of bulk forms of zinc oxide as hazardous under CLP, industrial facilities producing the powder form of nano ZnO would fall under the SEVESO-II Directive 96/82/EC, were the production volume thresholds to be reached.

The paucity of (eco)toxicology data on nano ZnO means that their individual classification under CLP is uncertain as conducting risk assessments is currently difficult, if not impossible. However, bulk forms of zinc oxide are classified under CLP as follows. The standard powder form of zinc oxide is classified as hazards to the environment; specifically very toxic to aquatic life with long lasting effects on the aquatic environment (H410). Lower grade zinc oxide powder is classified for health hazards as exhibiting acute toxicity 4 (H302 & H332), as a reprotoxin 1A (H360) and for specific target organ toxicity through repeat exposure (STOT Rep. Exp. 2) (H373), as well as for the environmental hazard aquatic chronic 1 (H410). As such, Material Safety Data Sheets are required for zinc oxide powder in the bulk form, as well as in the nano form. For example, nano-scale ZnO in the powder form (such as production industrial waste) will be subject to hazardous waste management procedures under the Waste Framework Directive.

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Box 13 provides further details on the specific exposure pathways for nano-scale zinc oxide for the aqueous environment, as well as other concerns relating to this specific nanomaterial.

The main question regarding coverage afforded by the Urban Waste Water Directive is whether the treatment requirements under this Directive are adequate to address nanomaterials in urban waste water. Regarding implementation, it is then relevant to consider whether there are technological tools to monitor nanomaterials in urban waste water and to remove them before this water is being discharged in the environment media.

14.3 Treatment requirement

Pursuant to this Directive agglomeration of more than 2,000 people must have collecting systems for urban waste water and agglomerations of more than 10,000 people must provide for secondary treatment or an equivalent treatment to their urban waste water.

Secondary treatment is defined under this Directive as a process generally involving biological treatment with a secondary settlement or other process that must respect the requirements listed in table 18.

Waste water treatment plants in agglomeration of more than 10 000 people in sensitive areas (e.g. water bodies such as natural freshwater lakes), which are subject to eutrophication, must in addition satisfy the requirements set out in table 19.

Table 18: Requirements for secondary treatment of urban wastewaters

Parameters	Concentration	Minimum percentage of reduction	Reference method of measurement
Biochemical oxygen demand (BOD5 at 20 °C) without nitrification (2)	25 mg/l O2	70-90 40 under Article 4 (2)	Homogenized, unfiltered, undecanted sample. Determination of dissolved oxygen before and after fiveday incubation at 20 °C ± 1 °C, in complete darkness. Addition of a nitrification inhibitor
Chemical oxygen demand (COD)	125 mg/l O2	75	Homogenized, unfiltered, undecanted sample Potassium dichromate
Total suspended solids	35 mg/l 35 under Article 4 (2) (more than 10 000 p.e.) 60 under Article 4 (2) (2 000-10 000 p.e.)	90 90 under Article 4 (2) (more than 10 000 p.e.) 70 under Article 4 (2) (2 000-10 000 p.e.)	— Filtering of a representative sample through a 0,45 μm filter membrane. Drying at 105 °C and weighing — Centrifuging of a Representative sample (for at least five mins with mean acceleration of 2 800 to 3 200 g), drying at 105 °C and Weighing

Table 19: Requirements for treatment of waste waters in agglomerations of <10,000 in sensitive areas

Parameters	Concentration	Minimum percentage of reduction	Reference method of measurement
Total phosphorus	2 mg/l (10 000 — 100 000 p.e.) 1 mg/l (more than 100 000 p.e.)	80	Molecular absorption spectrophotometry
Total nitrogen	15 mg/l (10 000-100 000 p.e.) 10 mg/l (more than 100 000 p.e.)	70-80	Molecular absorption spectrophotometry

Some commentators have stated that the available physical chemical and biological methods of wastewater treatments cannot be adapted to remove nanomaterials from waste water effluents due to their size and their specific properties (Moore, 2006; Reijnders, 2006). However, there is however no clear consensus in the scientific community on this issue. For instance Limbach et al (2008) found that a model wastewater treatment plant was effective in removing at least 94% of an engineered nanomaterial (cerium oxide) within sludge, with up to 6% found in the exit stream. This is comparable to levels of controls for various other pollutants in waste water treatment plants.[224] In their analysis of the efficiency of waste water treatment plants in removing nanomaterials from effluent, Kiser *et al* found that different types of nanomaterials are removed from water to different extents. With 400 mg/L total suspended solids of biomass, about 97% of silver nanoparticles were removed due to aggregation and settling, while 88% of fullerenes, 39% of nanosilver, 23% of titanium dioxide, and 13% of fullerol suspension (*n*C60(OH)x) sorbed to biomass[225]. A recent UK report measured the

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[224] Limbach LK, Bereiter R, Muller E, Krebs R, Galli R and Stark WJ "Removal of Oxide Nanoparticles in a Model Wastewater Treatment Plant: Influence of Agglomeration and Surfactants on Clearing Efficiency" (2008) Environmental Science and Technolology 42, 5828–5833

[225] Kiser MA, Westerhoff P, Benn T, Wang Y and Ryu Hodon (2010) "Release of Nanomaterials from Wastewater Treatment Plants" last accessed 6/6/11 at: http://rivm.nl/rvs/Images/Kiser%20et%20al%202010-abstract_tcm35-69097.pdf

presence of nano silver in both the influent and effluent from nine sewage treatment plants and found removal rates of approximately 50% and 97% for colloidal and particulate silver respectively[226].

Research is on-going to find specific treatments to remove nanomaterials from waste water streams[227]. The following include a number of examples of possible techniques:

- The use of magnetic filters to capture nanomaterials with permanent magnetic moments;[228]
- The use of synthesized magnetite nanoparticles to aggregate target nanoparticles by the electrostatic attraction between the two oppositely charged particles;
- Separation and analysis of nanoparticles by capillary electrophoresis;[229]
- The capture of nanoparticles by clearing sludge through the addition of dispersion stabilizing surfactants;[230]
- Coagulation and/or flotation processes used in the treatment of chemical and mechanical polishing (CMP) wastewater, which contains nanosized particles such as SiO2,[231]

Technologies that are specifically designed to remove nanomaterial from waste waters are not yet available for large scale wastewater treatment plants.

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[226] Centre for Ecology and Hydrology (CEH) “Exposure assessment for engineered silver nanoparticles throughout the rivers of England and Wales” (2011) CEH, UK

[227] Information taken from Liu Y, “élimination de nanoparticules d'effluents liquids” PHD thesis presented in November 2010 available at:http://eprint.insa-toulouse.fr/archive/00000375/01/2010_LIU.pdf

[228] Zarutskaya T and Shapiro M “Capture of nanoparticles by magnetic filters” (2000) Journal of Aerosol Science 31(8) 907–921

[229] Michael, A. R. and Armstrong, D. W. (2004). Separation and analysis of colloidal/nanoparticles including microorganisms by capillary electrophoresis: a fundamental review. Journal of Chromatography B, 800:7–25.

[230] Limbach LK, Bereiter R, Müller E, Krebs R, Gälli R and Stark WJ “Removal of oxide nanoparticles in a model wastewater treatment plant: influence of agglomeration and surfactants on clearing efficiency” (2008) Environmental Science and Technology 42, 5828–5833

[231] Tourbin, M., Liu, Y., Lachaize, S., and Guiraud, P. (2008). Removal of nanoparticles from liquids wastes: a review on coagulation and flotation processes and the development of characterization techniques. In Industrial Water Treatment Systems, Amsterdam, the Netherlands. IWA Conference.

14.4 Prior regulations and authorisations for the discharge of industrial waste water

According to Article 11 read in conjunction with Annex I section C of the Directive, the discharge of industrial water into collecting systems and urban waste water treatment plants are subject to prior regulations or authorisations that must satisfy the following requirements:

Industrial waste water must be pre-treated in order to:

- protect the health of staff working in collecting systems and treatment plants,
- ensure that collecting systems, waste water treatment plants and associated equipment are not damaged,
- ensure that the operation of the waste water treatment plant and the treatment of sludge are not impeded,
- ensure that discharges from the treatment plants do not adversely affect the environment, or prevent receiving water from complying with other Community Directives,
- ensure that sludge can be disposed of safety in an environmentally acceptable manner.

The requirement that industrial wastewater must be pre-treated in order to ensure that discharges from the treatment plants do not adversely affect the environment and that sludge can be disposed of safely in an environmentally acceptable manner could be interpreted as covering the removal during this pre-treatment of potentially hazardous nanomaterials for the environment in industrial waste water.

It is noteworthy that were other EU legislation on water (e.g. groundwater directive, Water Framework Directive) to set concentration limits for specific nanomaterials in surface waters this may then directly impact the pre-treatment requirements for industrial waste water.

Finally, according to Article 11(2) of the Directive, the Commission may amend these authorisation requirements through comitology. Therefore these requirements could be amended to specifically mention that the pre-treatment of industrial waste water should cover the removal of potentially ‘hazardous nanomaterials’.

14.5 The re-use of sludge

Article 14 states that sludge arising from waste water treatment must be re-used whenever appropriate and that disposal routes shall minimize the adverse effects on the environment. Nanomaterials may end-up on sludge and the re-use of sludge and their disposal should take into account their potential impact on health and the environment (See section 10 on the Sewage Sludge Directive)

14.6 Monitoring requirements

Section D of Annex I of the Directive sets some monitoring requirements that apply for the verification of the following parameters: biochemical oxygen demand without nitrification, chemical oxygen demand, total suspended solids, total phosphorus, total nitrogen) such as minimum annual number of samples. The Directive does not require the monitoring of the concentration levels of any nanomaterial in treated urban waste water.

As already mentioned in the review of the Water Framework Directive, monitoring techniques that are able to capture nanomaterials include the use of WetSEM imaging of liquid samples as contained within a QuantomiX capsule, followed by the EDX analysis of WetSEM images. Hydrodynamic chromatography provides size separation ranges of 5-300nm or 20-1200nm and, combined with inductively coupled plasma mass spectrometry (ICP-MS), can be used to detect multiple elements and isotopes. While these monitoring techniques make the monitoring of nanomaterials technically feasible at the laboratory scale (with limitations), the economic feasibility of their application across waste water treatment plants and their efficiency and reliability *in situ* remain key barriers to gathering data on the presence of nanomaterial pollutants in treated waste waters.

All Member State authorities that responded to our request for information mentioned that they were not using monitoring tools to control the concentration of nanomaterials in water.

14.7 The coverage of nanomaterials under the Urban Waste Water Directive

The technical requirements of the Urban Waste Water Directive do not specifically consider the presence of nanomaterials in urban waste water and do not provide for the monitoring of nanomaterials in wastewater effluent. Since the monitoring requirements do not include any other specific hazardous chemicals, but rather chemical oxygen demand in general, it would seem to be lending an undeserved focus to nanomaterials to include them before other hazardous substances for which evidence on hazard and exposure scenarios is considerably more robust. It is not, therefore, considered reasonable to identify this as a legislative gap, despite the identification of waste water as a major release path for nanomaterials into the environment (together with sewage sludge).

Given that studies suggest that the efficiency of the removal of nanomaterials from wastewater is dependent upon the specific nanomaterials, it may be relevant to conduct further research to determine which specific nanomaterials are being released into the environment from waste water treatment plants in order to inform decision making.

15. Drinking Water Directive 98/83/EC

15.1 Introduction

Directive 98/83/EC on the quality of water intended for human consumption[232] sets out quality standards for drinking water, as well as specifying the parameters that must be monitored to ensure that quality is maintained. The Directive does not specify the techniques that should be used to clarify water for the purpose of human consumption, but rather leaves this technical choice to the Member State and focuses on quality standards.

15.2 Nanomaterials in drinking water

With the entry of nanomaterials into the aquatic environment comes the concern that drinking water sources will become contaminated with nanomaterials and possibly lead to risks for human health. In addition, there are a number of specific applications of nanomaterials in the field of water purification that may involve the release of nanomaterials into the water, including the use of nano-filters, nanomaterials as absorbents, titanium dioxide photocatalysts and nanotechnology based sensors[233].

Feedback from the Stakeholder Workshop

At the workshop, participants highlighted the lack of knowledge regarding the potential presence of nanomaterials in drinking water, in a context where a very limited number of studies address the issue. Studies identified within the context of this review involved laboratory experimentation to test removal efficiencies rather than testing actual drinking waters.

Although the toxicity of nanomaterials to humans remains a matter for investigation,

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[232] Directive 98/83/EC on the quality of water intended for human consumption, OJ L 330, 5.12.1998, p. 32–54

[233] Tuccillo ME, Boyd G, Dionysios D and Shatkin JA “Challenges and opportunities of nanomaterials in drinking water” (2011) Web Report No. 4311, Water Research Foundation, USA, available at: http://collab.waterrf.org/Workshops/nanowksp/Document%20Library/Nanomaterials%20White%20Paper.pdf

in recent years a number of experimental studies have found that exposure to nanomaterials can lead to adverse health effects in living organisms[234]. In 2007, Hansen *et al.* reviewed 428 studies on the toxicity of nanomaterials which collectively identified adverse health effects for 965 nanomaterials of varying chemical composition[235]. It is beyond the scope of this report to review the literature on the toxicity of nanomaterials to living organisms and the reader is referred to Hristozov and Malsch (2009) for a summary.

In response to the growing awareness of the release of nanomaterials into the environment, some researchers have undertaken studies on the fate and behaviour of nanomaterials in drinking water and their potential removal. While most drinking water treatment processes have not been designed to remove nanomaterials, some removal may occur. In particular, reverse osmosis and nanofiltration are expected to remove nanomaterials and aggregated nanomaterials are likely to be removed by microfiltration[236]. Experiments have been conducted at laboratory scale that simulate the removal of nanomaterials from water through drinking water treatment processes, including coagulation, flocculation, sedimentation, and filtration. Overall, coagulation and sedimentation alone were found to remove 40-60% of these nanoparticles, and filtration removed an additional 50-80%. However, 10-30% of the nanoparticles remained in the water[237]. Research is ongoing at Arizona State University into the removal efficiency of nanomaterials by drinking water unit processes and the toxicity of nanomaterials in drinking water. In simulated drinking water treatment processes, 30-80% of nano metal oxides were removed through coagulation and sedimentation[238]. As such, further research is required before techniques are available that can guarantee the removal of nanomaterials from drinking water.

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[234] Hristozov, D. And Malsch, I. "Hazards and risks of engineered nanoparticles for the environment and human health" (2009) Sustainability 1, 1161-1194

[235] Hansen, S. Larsen, B. Olsen, S. And Baun, A. "Categorization framework to aid hazard identification of nanomaterials" (2007) Nanotoxicology 11, 243-250

[236] Tuccillo ME, Boyd G, Dionysios D and Shatkin JA "Challenges and opportunities of nanomaterials in drinking water" (2011) Web Report No. 4311, Water Research Foundation, USA, available at: http://collab.waterrf.org/Workshops/nanowksp/Document%20Library/Nanomaterials%20White%20Paper.pdf

[237] Westerhoff, P. Capco, D. Zhang, Y. Crittenden, J. Koeneman, B. and Chen, Y. "Removal and toxicity of nanomaterials in drinking water" (2006) American Water Works Association, 1 June 2006

[238] US Environmental Protection Website, Presentation Abstract for "The fate, transport, transformation and toxicity of manufactured nanomaterials in drinking water" Westerhoff, P, last accessed 01.07.11 at: http://www.epa.gov/ncer/publications/workshop/10_26_05/abstracts/westerhoff.html

15.3 Quality standards

The quality standards for drinking water are laid down for a range of parameters in Annex I. Article 4 requires that Member States set values for water intended for human consumption that are not less stringent than those set out in Annex I. Chemical parameters are listed under Annex I Part B and include several substances for which nanoforms are currently in use (nickel, cadmium, copper). However, the associated parametric values have not been established with consideration of the intrinsic properties of the nanoforms. In addition, a large number of nanomaterials are not captured by the parameters under Annex I Part B, including some of the most commonly used such as carbon nanotubes, C_{60} fullerenes and a range of other metal and metal oxides.

Should the protection of human health require it, Member States must set values for additional parameters not included in Annex I. As such, theoretically Member States could set values for specific nanomaterials found to pose a danger to human health, although they would encounter significant challenges in applying the relevant methodology to nanomaterials due to limitations in data (see discussions of the EQS Directive under section 12). In addition, monitoring and enforcing those values is practically impossible, given the limitations in techniques for monitoring nanomaterials and for their effective removal from water.

15.4 Monitoring

Monitoring requirements for a range of parameters are set out in Article 7, with minimum requirements for monitoring programmes specified in Annex II and methods for analysis in Annex III. The requirements do not specifically mention nanomaterials, although again some nanomaterials would be captured under certain substances (cadmium, nickel, copper, iron). However, the parametric limits were not established with consideration of the nanoform and are therefore unlikely to bear relevance to the risks associated with particular concentrations of nanomaterials of these substances.

Article 7(6) states that additional monitoring should be carried out for substances for which no parametric value has been set if there is reason to suspect that they are present in volumes that constitute a potential danger to human health. This affords a theoretical possibility for Member States to include nanomaterials.

However, as discussed in the sections above, techniques for accurately monitoring nanomaterials in water remain in the early stages of development, and so even if monitoring of all or specific nanomaterials in drinking waters were to be required, it is not technically feasible at this stage.

15.5 Remedial action and restrictions in use

Article 8 requires that any failure to meet the quality standards set for drinking water must be immediately investigated and remedial action taken to restore quality. Should nanomaterials in general or specific nanomaterials be included as parameters for which quality standards are set and should those standards be transgressed, this would then serve to require action to redress the concentrations to below acceptable thresholds. This discussion remains rather academic in the absence of methodologies to set standards and techniques to monitor concentrations of nanomaterials.

In addition, Article 8(3) requires that Member States ensure that any supply of drinking water that constitutes a danger to human health is prohibited or its use restricted until action is taken to protect human health. Should nanomaterials, or a specific nanomaterial, be found to pose a significant threat to human health **and be detected** in drinking water, this provision would then requires that action be taken. Given current limitations in technical capacities to effectively remove nanomaterials from drinking water, it would seem that upstream controls of point and diffuse sources would be required. Such measures could be enacted under Article 7 of the Water Framework Directive, where Member States are required to ensure the necessary protection of bodies of water used for the abstraction of drinking water. Given the importance of protecting human populations from potential risks, it is relevant to apply the precautionary principle to the enactment of measures to control the entry of specific nanomaterials into drinking water. The precautionary principle applies to potential risks, i.e. risks that cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data. The Commission Communication on the precautionary principle, issued in 2000,[239] provides general guidance on the application of the precautionary principle.

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[239] Commission Communication on the precautionary principle, COM(2000)1

15.6 The of coverage of nanomaterials under the Drinking Water Directive

The Drinking Water Directive provides legal mechanisms by which the presence of specific nanomaterials in drinking water could be controlled, including establishing quality standards and remedial action and restrictions in use. However, both mechanisms would require that the nanomaterials are first detected in drinking water, which is considered unlikely given the absence of specific monitoring requirements and the lack of technical capacity. In addition, the applicability to nanomaterials of an approach based on quality standards is again called into question, in a context where data with which to establish threshold concentrations at which nanomaterials pose no threat to human health is lacking. These issues are summarised in table 18 below.

Although the review serves to flag potential areas of concern, there is currently no evidence to suggest that drinking water is contaminated with nanomaterials. As such, a first step would be to conduct testing using standardised approaches in order to provide a coherent body of evidence for decision making.

Table 18: Summary of issues relating to the coverage of nanomaterials under the Drinking Water Directive

Issue	**Article**	**Type of gap, implications and uncertainties**
Quality standards were not set with consideration of the nanoform (nickel, cadmium, copper)	Article 4, Annex I	Legislative gap: The nanoform of these substances may have effects of human health at concentrations below the threshold values set for the bulk from
Monitoring requirements do not consider the nanoform	Article 7, Annex II	Potential limitation: Techniques for monitoring nanomaterials in water are still under development

16. Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (Seveso II Directive)

16.1 Introduction

The safety of chemical facilities at EU level is directly addressed by Council Directive 96/82/EC on the control of major-accident hazards, the so-called SEVESO-II Directive[240]. The Directive aims at the prevention of major-accident hazards involving dangerous substances. However, as accidents do continue to occur, the Directive aims at the limitation of the consequences of such accidents for man and the environment. A review of the SEVESO-II Directive has recently been concluded and, on 21 December 2010, the Commission adopted a proposal for a new Directive that would repeal and replace the current Directive by 1 June 2015.

The SEVESO-II Directive takes a tiered approach to requiring safety measures at facilities based on the volumes of dangerous substances present at facilities. As such, dangerous substances are defined in Annex I, together with the thresholds for each substance that trigger requirements. SEVESO sites are categorized as lower-tier SEVESO establishments or upper-tier SEVESO establishments. Operators of lower-tier SEVESO establishments have to notify the competent authority, design a major-accident prevention policy (MAPP), draw up accident reports and take into account land-use planning. In addition to these requirements, operators of upper-tier SEVESO establishment must establish a safety report, implement a safety management system, define an internal emergency plan and provide the competent authorities with all necessary information.

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[240] Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (OJ L 10, 14.1.1997, p. 13)

Box 14: Overview of environmental risks and possible legislative issues for carbon nanotubes

Properties and applications:

Carbon nanotubes (CNT) can be visualised as a rolled-up graphene sheet. Single-walled carbon nanotubes (SWCNT) have a single layer of carbon atoms, while multi-walled carbon nanotubes (MWCNT) are created by placing one carbon nanotube inside the other, typically as unconnected sliding layers. Depending up on the synthesis method, the technique used for separation from by-products, cleaning steps and functionalizations, a variety of different CNT can be generated that exhibit very different properties (Nowack and Bucheli, 2007). CNT can behave as metallic or semiconducting solids depending on their structure, and exhibit unique physical properties. CNT have the highest tensile strength of any know material, and hence scientists are exploring applications in ultra-strong, ultra-light materials. The electro-magnetic properties of CNT make them the subject of research for use in batteries and capacitors, with use in electric motor brushes in vehicle widespread. The hollow shape of CNT suggests possible applications in drug delivery, or in filtration techniques. Some current and possible future applications are listed below.

- Electric motor brushes in vehicles
- Sports equipment
- Tear-free fabrics
- Drug delivery
- Air and water filters
- Re-enforced resins
- Batteries
- Capacitors
- Ropes
- Body armour
- Re-enforced concrete

The Woodrow Wilson Inventory found carbon nanotubes to be referenced in 22 consumer products most of which were sporting goods, with 2 products from electronics and computers and 1 product from the aviation sector (note that since labelling is not mandatory, this does not reflect the true number of products containing carbon-based nanomaterials).

Production volumes and projected market growth:

In 2004, global production estimates for CNT stood at 65 tons (Cientifica, 2005). The compound annual growth rate in production was well over 60% (Mindbranch, 2005). In 2007, production capacity estimates for multiwalled CNTs were 74 ton/year for the US, 170 ton/year for Asia and 27 ton/year for Europe. Equivalent figures for single walled CNT were 1.5 ton/yr for North America, 5.3 ton/yr for Asia and 0.1 ton/yr for Europe (nanotechweb.org, 2007). The current global market for carbon nanotubes has been measured at approximately $247 million. It is predicted that new functionalised nanotubes applications will come onto the market in the next few years that will greatly increase global revenues to $2.7 billion plus by 2015; driven mainly by the needs of the electronics and data storage, defence, energy, aerospace and automotive industries (Nanoposts.com, 2008).

Pathways for environmental exposure:

Pathways for exposure may arise from industrial waste and production by-products, or releases from products that contain CNT over the lifecycle of those products. Industrial production of CNT results in the generation of a waste soot containing a number of impurities, including graphite sheets, amorphous carbon, and carbon nanofibres. Where CNT are incorporated into a solid matrix they are first introduced into a resin, resulting in a resin waste stream. Qualitative and quantitative information on the characteristics of these industrial wastes as well as on their ultimate fate is not available, inhibiting an assessment of impacts (Franco *et al* 2007). Regarding CNT that are contained within a solid matrix in a product, the release of CNT during the use phase of a product lifecycle is considered unlikely (Franco *et al* 2007). Consumer products containing CNT are likely to be disposed of in household waste and will enter municipal waste streams and hence be channelled either for landfill or incinerations. Again, CNT in a solid matrix are not thought to pose considerable concern in landfill since their particle mobility is low, although it is unknown whether mobility may be increased by pre-lanfil treatments such as crushing or exposure to chemicals in landfill. The permeability of current landfill linings to nanomaterials has not been investigated. CNT in liquids that enter waste water treatment plants (e.g. lubricants or cosmetics) are more likely to be released and enter surface waters. Gottschalk *et al.* (2009) estimated the concentration of CNT in European waters to be 0.0008 µg/L under a high emission scenario. Regarding incineration, CNT have been found to exhibit very low reactivity in incinerators, similar to diamonds, making them unlikely to degrade (Catalo 2002). This suggests that the CNT may be released in gaseous emissions to the atmosphere.

Environmental fate and behaviour:

CNT are not dispersible in water (Chen *et al,* 2004) and act as powerful adsorbents for a wide variety of organic compounds from water, including a number of persistent organic pollutants, as well as metals, including lead and cadmium (Nowark and Bucheli, 2007).

(Eco)toxicity:

It is important to note that different forms of CNT have been found to exhibit very different levels of toxicity, making generalisation about CNT as a group not possible. Several acute toxicity studies with rodents suggest that certain types of single- and multiwalled CNTs pose hazards to the lung or mesothelial surfaces under experimental exposure conditions (Lam et al. 2004; Liu 2007; Mercer et al. 2008; Porter et al. 2010; Shvedova et al. 2005), with effects for exposure to multi-walled CNTs likened to those caused by asbestos (Poland et al. 2008). In his characterization of the degree of hazard associated with different nanomaterials, Musee (2011) ranked SWCNT and MWCNT as posing a high degree of hazard.

Monitoring Options:
No method has yet been developed to allow for the quantification of CNT in natural media (Nowark and Bucheli, 2007). UV-vis spectrometry has been used to analyse CNT in the laboratory (Jiang *et al,* 2003).

Existing legislative coverage and possible future approaches:

- The paucity of (eco)toxicology data on CNT means that their classification under CLP is uncertain as conducting risk assessments is currently difficult if not impossible. In addition, mass based thresholds are not appropriate. Their classification under the CLP Regulation determines how they are managed under other pieces of environmental legislation, such as the Waste Framework Directive.
- CNT do no not have a nomenclature under the list of wastes, implying that if they are not classified as hazardous under the CLP Regulation, they will not be subject to specific waste management procedures.
- Carbon nanotubes are not captured under the chemical parameters listed under Annex I Part B of the Drinking Water Directive, implying that testing for these substances in water destined for human consumption is not required.
- CNT will not be detected in water bodies using currently available monitoring equipment and hence will not be identified as a pollutant, were they to be present.
- The Best Available Technique Reference Documents do not currently address the production of CNT implying that there are no BAT for reducing releases to the environment during production. The production of CNT is not specifically included under Annex I of Directive 61/1996 on the Integrated Pollution Prevention and Control, although it may be considered as the synthesis of chemicals.

References:

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Hendren CO, Mesnard X, Dröge J, and Wiesner MR “Estimating Production Data for Five Engineered Nanomaterials As a Basis for Exposure Assessment” (2011) Environmental Science and Technology 45 (7) 2562–2569
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Nanoposts.com “The Global Market for Carbon Nanotubes to 2015: A realistic assessment - 2nd Edition” (2008) Executive summary last accessed 24.05.11 at: http://www.nanoposts.com/upload/nanotubes_exec.pdf
Nanotechweb.org “Carbon nanotube production – the big picture” Last accessed 31.5.11 at: http://nanotechweb.org/blog/2007/05/carbon_nanotube_production_the.html
Nowack B and Bucheli TD “Occurence, behaviour and effects of nanoparticles in the environment” (2007) Environmental Pollution 150, 5-22
Poland CA, Duffin R, Kinloch I, Maynard A, Wallace WAH, Seaton A, Stone V, Brown S, MacNee W and Donaldson K “Carbon nanotubes introduced into the abdominal cavity display asbestos-like pathogenic behaviour in a pilot study” (2008) Nature Nanotechnology 3, 423-428
Woodrow Wilson International Centre for Scholars “Online Inventory of nano-based consumer products” 2011, last accessed 23.05.11 at: http://www.nanotechproject.org/inventories/consumer/analysis_draft

16.2 Nanomaterials in industrial facilities

In a context where demand for nanomaterials continues to grow, the industrial production of nanomaterials is also expanding. As of March 2011, the Woodrow Wilson international Centre for Scholars' inventory of nanotechnology-based consumer products included 1317 products, 367 of which were produced in the EU (namely UK, France, Germany, Finland, Switzerland, Italy, Sweden, Denmark, and the Netherlands)[241]. The EU nanomaterials industry grew by 22% in 2010, with major companies investing in new industrial installations producing nanomaterials. For example, Bayer opened a large carbon nanotube pilot facility in Leverkusen with an annual capacity of 200 tonnes. Bayer's future investment plans include a €22 million new facility producing carbon nanotubes in Leverkusen[242]. Box 14 above, provides a summary of the environmental risks and possible legislative issues associated with carbon nanotubes. The ongoing expansion of industrial capacity for the production of nanomaterials raises questions regarding the possible consequences for man and the environment of accidents in facilities producing, using or storing nanomaterials. It is therefore relevant to ask at whether Seveso II Directive adequately covers these facilities. However, it should also be noted that there is currently little, if any, evidence to suggest that nanomaterials could lead to the types of major industrial accidents that the SEVESO-II Directive is intended to address (at least in terms of additional risks compared to materials in the bulk form).

There are two relevant issues with regards to the application of SEVESO II to facilities where nanomaterials are produced, used and/or stored. Firstly, it is possible that nanomaterials that exhibit dangerous properties may not be captured by the definition of dangerous substances. Secondly, the volume thresholds for dangerous substances may not be applicable to nanomaterials due to their small scale. These issues are addressed in turn.

16.3 Defining dangerous substances

Annex I includes both a list of specified dangerous substances (part 1), and a set of criteria against which substances can be categorised as dangerous. The list of dangerous substances under Annex I

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[241] Woodrow Wilson international Centre for Scholars, Inventory of nanotechnology-based consumer products, last accessed on 22.04.11 at: http://www.nanotechproject.org/inventories/consumer/analysis_draft/

[242] Lucintel, Global Nanomaterials Opportunity and Emerging Trends , Lucintel Brief, published March 2011 available at: http://www.lucintel.com/LucintelBrief/GlobalNanomaterialsopportunity-Final.pdf

Part 1 of the Directive does not include any nanomaterials specifically and does not make any reference to possible nanoforms of these dangerous substances. However, there are some examples of substances that may also be present in nano-form or which may themselves contain nanomaterials and, in theory, could pose different risks to those of the bulk form. Examples include:

- Nickel compounds in inhalable powder form (nickel monoxide, nickel dioxide, nickel sulphide, trinickel disulphide, dinickel trioxide).
- Petroleum products (e.g. gasoline and oils may contain nanomaterial additives).
- 4,4-Methylenebis (2-chloraniline) and/or salts, in powder form (e.g. if the powder form contains significant ultrafine fraction).

Annex I Part 2 sets out categories of dangerous substances (e.g. very toxic, toxic, oxidizing, explosive, etc.) with their corresponding qualifying tonnage quantities. Substances are currently classified according to Directive 67/548/EC[243] and Directive 1999/45/EC[244]. These Directives will be repealed in 2015 by the CLP Regulation and the Commission has therefore adopted a proposal for a Directive to align the Seveso II requirements with the new categorisation of dangerous substances under the CLP Regulation[245].

Theoretically, nanomaterials that exhibit hazardous properties should be captured under Annex I Part 2. However, it is possible that nanomaterials exhibiting hazardous properties not seen in the bulk form may slip through the net and not be classified as hazardous under CLP. It is therefore possible that the Seveso II Directive would not be applied to establishments where nanomaterials that exhibit hazardous properties are produced, used, handled or stored.

The categories of dangerous substances included in Annex I, Part II appear to provide a suitable basis for picking up nanomaterials that may pose a potential for major accident hazards (e.g. due to their toxic or ecotoxic properties). However, the extent to which these categories and the relevant thresholds will apply to nanomaterials specifically is dependent upon form-specific hazards being identified in the classification and labelling regime (e.g. differences in hazards compared to the bulk form).

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[243] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances OJ 196, 16.8.1967, p. 1–98.

[244] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations OJ L 200, 30.7.1999, p. 1–68.

[245] Proposal for a Directive of the European Parliament and of the Council on control of major-accident hazards involving dangerous substances, COM(2010) 781 final.

16.4 Volume thresholds

Annex I sets out substance-specific volume thresholds both for substances listed under Part 1 and for the categories of dangerous substances set out under Part 2. Given the elevated reactivity of some nanomaterials and their small scale, it is – in theory at least – possible that these thresholds may not be appropriate for the nanoform in terms of recognising their potential risk. It may therefore be relevant to consider the development of lower thresholds for nanomaterials, were specific nanomaterials to be categorised as hazardous under CLP.

However, there seems to be insufficient evidence at the current time to consider developing lower thresholds for any specific nanomaterials. If evidence becomes available that lower thresholds would be appropriate for specific nanomaterials (or groups/types thereof), it would presumably be possible to amend the Seveso-II Directive accordingly. The practical provisions of the Directive, such as assessments of risks to health, safety and the environment from potential major accident hazards and management of those risks appear to provide a suitable basis for addressing any such risks that may occur for nanomaterials. As with other legislation, the extent to which the Directive is able to do this is dependent on the generation of information on any differences in the specific hazards/risks of nanomaterials as compared with the bulk form, or on the identification of any specific nanomaterials that may merit inclusion in Annex I in the future.

The Trojan horse effect of nanomaterials, whereby some nanomaterials have been found to pick up and transport other more hazardous substances[246], presents an additional concern, since this could exacerbate the possible consequences for the environment and human health of an accident.

16.5 Article 4: Derogation and safeguard clauses

Article 4 of the Commission proposal includes a corrective mechanism to allow for the future adaptation of Annex I to either include or exclude substances that do or do not present a major-accident hazard. Article 4 (5) allows a Member State to take appropriate measures and notify the

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[246] Baun, A Sørensen, S.N. Rasmussen, R.F. Hartmann, N. Bloch I, Koch, CB "Toxicity and bioaccumulation of xenobiotic organic compounds in the presence of aqueous suspensions of aggregates of nano-C60" (2008) Aquatic Toxicology 86 (3) 379-387; Hartmann N, Bloch I and Baun A "The nano cocktail – ecotoxicological effects of engineered nanoparticles in chemical mixtures" (2010) Integrated Environmental Assessment and Management 6, 311-313, 2010; Baun A, Hartmann NB, Grieger K, Kusk KO. "Ecotoxicity of engineered nanoparticles to aquatic invertebrates: a brief review and recommendations for future toxicity testing" (2008) Ecotoxicology 17(5) 387-95

Commission should that Member State consider that a dangerous substance not listed under Parts 1 or 2 of Annex I presents a major-accident hazard. The Commission shall then inform the forum of competent authorities, and, where appropriate, may list the substance in Part 1 or 2 of Annex I by a delegated act. This provides a channel through which Member States could flag concerns regarding the potential major-accident hazard of specific nanomaterials in industrial facilities, should evidence be found to support such concerns.

16.6 The coverage of nanomaterials under SEVESO II

In general, the provisions of the SEVESO II Directive provide coverage of nanomaterials. The application of SEVESO II to dangerous nanomaterials depends upon their being effectively classified as hazardous under the CLP Regulation, this being subject to some constraints as discussed previously. Article 4 of the Commission Proposal provides a channel for introducing nanomaterials under Annex I, should a Member State identify major-accident risks associated with specific nanomaterials. It would then be necessary to develop thresholds for these nanomaterials.

A potential concern comes with the application of the volume thresholds for categorising sites as upper or lower tier, since as stated by the SCENIHR "*due to the physico-chemical properties of nanoparticles, their behaviour and potential adverse effects are not solely dependent on exposure in terms of mass concentration*"[247]. However, at this stage, there is insufficient data available to define appropriate thresholds for nanoforms of substances categorised under Annex I Part 1 or Part 2, representing an implementation gap.

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[247] SCENIHR "The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials"(2007) European Commission, Brussels, Belgium

17. Air Quality Directive 2008/50/EC

17.1 Introduction

Directive 2008/50/EC[248] defines and establishes objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment. It sets common methods and criteria for assessing the ambient air quality in Member States. It establishes requirements for obtaining information on ambient air quality in order to help combat air pollution and nuisance and to monitor long-term trends and improvements.

The risk management measures on ambient air quality under this Directive apply to specific targeted pollutants which are sulphur dioxide, nitrogen dioxide and oxides of nitrogen, lead, benzene, carbon monoxide and particulate matter (PM_{10} and $PM_{2.5}$). This review will particularly look at the risk management measures that apply to particulate matter - specifically PM_{10} and $PM_{2.5}$ and whether these measures are adequate for nanomaterials.

Feedback from the Stakeholder Workshop

As part of the review of the Thematic Strategy on air quality in 2013, the Commission is planning to look at specific components smaller than those already covered by the Air Quality Directive (such as black carbon). The World Health Organisation has also been questioned as to whether there is any new evidence available on specific substances that are relevant for air quality, and this may include the smaller size fraction.

17.2 Nanomaterials in air

Definitions of PM_{10} and $PM_{2.5}$under this Directive read as follows:

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[248] Directive 2008/50/EC on ambient air quality and cleaner air for Europe, OJ L 152, 11.6.2008, p. 1-44

- PM_{10} shall mean particulate matter which passes through a size-selective inlet as defined in the reference method for the sampling and measurement of PM_{10}, EN 12341, with a 50 % efficiency cut-off at 10 µm aerodynamic diameter;

- $PM_{2.5}$ shall mean particulate matter which passes through a size-selective inlet as defined in the reference method for the sampling and measurement of $PM_{2.5}$, EN 14907, with a 50 % efficiency cut-off at 2.5 µm aerodynamic diameter.

The following definitions of nanomaterials and ultrafine particles have been applied in a related study on industrial emissions of nanomaterials and ultrafine particles[249]:

- Nanomaterial means a material in which one or more properties are determined to a significant degree by the presence of nanoscale[250] structural features.

Feedback from the Stakeholder Workshop

At the workshop, participants discussed the interchangeability of the terms nanomaterial, ultrafine particle and engineered nanomaterials and identified difficulties in distinguishing between them when monitoring emissions and presence in ambient air.

- Ultrafine particles are defined as particles that have at least one dimension between 1 and 100 nm or have an aerodynamic diameter between 1 and 100 nm. Structures of larger dimensions such as aggregated nanomaterials[251] are included provided that they have retained properties and/or functionalities. Nanomaterials of biological origin and capable of replication such as viruses are outside the scope of that study.

For the purposes of the review of the Air Quality Directive, reference is made herein to nanomaterials and ultrafine particles, both of which may constitute part of the PM_{10}/ $PM_{2.5}$ size fraction, based on the definitions above. Where a distinction specifically needs to be made for 'engineered' nanomaterials, this is made clear in the following text.

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[249] Industrial emissions of nano- and ultrafine particles. Tender reference no : ENV.C.4/SER/2010/006

[250] Nanoscale means a scale at which the surface or interfacial properties of a material become significant compared with those of the bulk material. The term nanoscale is generally used to refer to the dimensions of the order of 1 nm to 100 nm.

[251] NMs have specific properties and/or functionalities and can be nano-objects (sheets, tubes or particles) that may have respective one, two or three dimensions at the nanoscale, or nano-structured materials which have an internal or a surface structure at the nanoscale both of which lead to these specific functionalities. The definition of NMs therefore explicitly also covers in nanostructured materials, agglomerates or aggregates of parts which have internal or surface structures at the nanoscale, but which are larger than nanoscale and retain properties and/or functionalities that lead to specific properties that are characteristic to the nanoscale.

Nanomaterials and ultrafine particles only represent a small fraction of the ambient $PM_{2.5}$ or PM_{10} mass but may make up a large proportion of airborne particles by number. They may be affected by a range of processes in the air, including evaporation, condensation, coagulation, chemical reaction and deposition. The relative importance of these processes will depend on the properties of the individual nanomaterials and the environmental conditions. There is, however, a lack of comprehensive information in this area. There is perhaps even greater uncertainty with regard to fate and behaviour of engineered nanomaterials.

Feedback from the Stakeholder Workshop

Participants noted that emissions for sources such as industrial plants, non-road mobile machinery, small heating installations and others have been identified as important contributorsto air quality and are therefore addressed systematically and in parallel in the Thematic Strategy on Air.

The main significant sources of ultrafine particles (as $PM_{0.1}$) have been estimated in an initial inventory in the related project on industrial emissions of nanomaterials and ultrafine particles. Significant sources include: road and other transport; residential/commercial combustion; industrial combustion and industrial process emissions; power generation; and agriculture. The relative importance of each source type in terms of contribution to total emissions is likely to be different to that for coarser particles (such as PM_{10}) because there are differences in particle size distributions amongst sources.

The toxicity of particles generally increases with decreased particle size, when dose is expressed in terms of mass. Content of leachable metals within ultrafine particles may be an important factor in toxicity. There is limited information on the toxicity of engineered nanomaterials, however. There is also limited information on impacts upon ecosystems.

17.3 Limit values and alert thresholds for the protection of human health

According to Article 13 read in conjunction with Annex XI, levels of PM10 in the zones and agglomerations defined by Member States shall not exceed the limit values set out in table 19 for the protection of human health.

Table 19: Limit values for PM10

Averaging period	Limit value	Margin of tolerance
One day	50 µg/m^3, not to be exceeded more than 35 times a calendar year	50 %
Calendar year	40 µg/m^3	20 %

According to Article 16 read in conjunction with Annex XIV Member States shall take all necessary measures not entailing disproportionate cost to ensure that concentration of PM 2.5 in ambient air do not exceed the targets for the protection of human health set out in table 20 below.

Table 20: Limit and target values for $PM_{2.5}$

Averaging period	Value	Margin of tolerance	Date by which limit value is to be met
Calendar year	Limit value: 25 µg/m^3	Decreasing from 20% in June 2008 to 0% in 2015.	1 January 2015
Calendar year	Limit value: 20 µg/m^3 (indicative, to be reviewed by the Commission)		1 January 2020
Calendar year	Target value: 25 µg/m^3		1 January 2010

The Directive also includes a national exposure reduction target and an exposure concentration obligation for $PM_{2.5}$.

There is probably insufficient reliable information at present to define comparable limit values for the protection of human health for nanomaterials or ultrafine particles, due to a lack of data. It may be that other metrics (rather than mass concentration which is used for PM_{10} and $PM_{2.5}$) would be more appropriate. For example, particle number of surface area may be better indicators of the level of potential harm.

Furthermore, it is likely that factors such as chemical composition become increasingly important at the nano-scale, meaning that a limit based purely on size/mass may not be appropriate.

17.4 Assessment regime

Article 5 read in conjunction with Annex II sets upper and lower assessment thresholds that apply to particulate matter (PM 10 and PM 2.5). It requires that each zone and agglomeration shall be classified in relation to the assessment thresholds set out in table 21 below.

Feedback from the Stakeholder Workshop

In addition to a number of typographical issues, it was also highlighted that, in setting any limit, it would be important to define exactly what nanomaterials are covered.

Table 21: Assessment thresholds for PM_{10} and $PM_{2.5}$

	24-hour average PM_{10}	Annual average PM_{10}	Annual average $PM_{2.5}$ (1)
Upper assessment threshold	70 % of limit value (35 µg/m^3, not to be exceeded more than 35 times in any calendar year)	70 % of limit value (28 µg/m^3)	70 % of limit value (17 µg/m^3)
Lower assessment threshold	50 % of limit value (25 µg/m^3, not to be exceeded more than 35 times in any calendar year)	50 % of limit value (20 µg/m^3)	50 % of limit value (12 µg/m^3)

As with limit values, there is probably insufficient information available at present to set similar assessment thresholds for nanomaterials and ultrafine particles.

17.5 Reference measurement methods

Article 8 read in conjunction with Annex VI of the Directive provides for the reference measurement methods for PM_{10} and $PM_{2.5}$, as set out in table 22 below.

Table 22: Reference methods for PM_{10} and $PM_{2.5}$

Reference method for the sampling and measurement of PM_{10}	EN 12341:1999 'Air Quality —Determination of the PM10 fraction of suspended particulate matter — Reference method and field test procedure to demonstrate reference equivalence of measurement methods'
Reference method for the sampling and measurement of $PM_{2.5}$	EN 14907:2005 'Standard gravimetric measurement method for the determination of the $PM_{2.5}$mass fraction of suspended particulate matter'

These methods are unlikely to be sufficient for nanomaterials and ultrafine particles. There are a number of techniques that can be used for monitoring various parameters of these species, including measurement of:

- Surface area (TEM, SED, diffusion charger, ELPI, MOUDI).
- Size (AFM, DMA, photon correlation spectroscopy, X-ray diffraction).
- Number (CPC, OPC, SEM/TEM, SMPS).
- Mass (size-selective static sampler, TEOM, filter collection with elemental analysis).

It is of note that the technical standards report ISO/TR 27628[252], whilst indicating that "with only limited toxicity data and negligible exposure data, it is currently unclear how exposure to nanoaerosols should be most appropriately monitored and regulated", does include guidelines on measuring occupational nanoaerosol exposure against a range of metrics. It includes methods to measure mass

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[252] Workplace atmospheres — Ultrafine, nanoparticle and nano-structured aerosols — Inhalation exposure characterization and assessment, 2007.

concentration, surface-area concentration, number concentration, size-resolved characterisation, on-line chemical analysis and single particle analysis (e.g. electron microscopy and scanning force microscopy).

This demonstrates that it is possible to identify standard approaches for measuring these types of particles, but also shows there is currently significant uncertainty around this issue. Similar approaches could also presumably be adopted for measuring environmental concentrations. However, it is of note that no formal standard has been drawn up for workplace atmospheres (only a technical standards report), which is probably indicative that there is insufficient information to do so.

17.6 Sampling points

Article 7 read in conjunction with Annex III set a number of requirements on sampling points (e.g. macroscale siting of sampling points and microscale siting of sampling points).

If nanomaterials and/or ultrafine particles were added to the Directive, there would presumably be a need for defining sampling points for these materials. These may or may not be the same as those for coarser particulate matter (PM_{10}, $PM_{2.5}$).

17.7 Contributions from natural sources

According to Article 20 of the Directive Member States must transmit to the Commission, for a given year, lists of zones and agglomerations where exceedances of limit values for a given pollutant are attributable to natural sources. They shall provide information on concentrations and sources and the evidence demonstrating that the exceedances are attributable to natural sources.

It is thought that the proportion of total ultrafine particle ($PM_{0.1}$) emissions from natural sources is much lower than that for coarser particulates (PM_{10}), though it is not clear whether this is also true for concentrations in the environment. Potential sources of $PM_{0.1}$ emissions include, for example, fires and volcanoes.

Techniques such as elemental analysis of composition might be options for attributing nanomaterials to natural sources, though it is currently unclear how feasible it would be to apply such techniques in practice.

17.8 Exceedance attributable to winter-sanding or salting of roads

Member States may designate zones or agglomerations within which limit values for PM_{10} are exceeded in ambient air due to the re-suspension of particulates following winter-sanding or -salting of roads.

Winter-sanding or salting of roads could be sources of nanomaterials in suspension, though there is a lack of data in this area. It is possible that, as with other non-combustion sources, the proportion of the total emissions from such sources could be less than for coarser particles such as PM_{10}. This is, however, rather speculative.

17.9 Air quality plans

According to Article 23, air quality plans are to be established for those zones and agglomeration in order to achieve the limit value or target for PM_{10}/ $PM_{2.5}$. These air quality plans must contain information on the pollutant (e.g. nature and assessment of pollution; origin of pollution; and analysis of the situation) and must list the measures or projects adopted with a view to reducing pollution following the entry into force of the Directive (i.e. listing and describing all the measures; a timetable for implementation; an estimate of the improvement of air quality planned; and of the expected time required to attain the objective) and the measures or projects planned or being researched for the long term.

Measures that could be adopted to reduce levels of nanomaterials and/or ultrafine particles in the environment in relation to possible future air quality plans/programmes for these substances (should they be included on the Directive in the future) could be similar to those for coarser particles.

For example, industrial emissions abatement techniques such as fabric filters, cyclones and wet scrubbers can all abate ultrafine particles, though sometimes not as effectively as for coarser particles. There are several other techniques that are at a developmental stage and which could have higher abatement efficiencies for ultrafine particles. In relation to transport emissions – which are likely to be a large contributor to ambient concentrations – techniques might include fuel switching, changing driving use/behaviour and use of abatement such as diesel particulate filters, amongst others.

17.10 Short-term action plans

When alert thresholds are exceeded, Member States must draw-up action plans indicating the measures to be taken in the short term in order to reduce the risk or duration of such an exceedance. Those action plans may include measures in relation to motor-vehicle traffic, construction works, ships at berth and the use of industrial plants or products and domestic heating. These action plans may also contain action aiming at the protection of sensitive population groups including children.

Something similar could be done for nanomaterials and/or ultrafine particles, but further work would be needed to refine, for example, inventories on sources and levels of concern for health and the environment in order to address such sources.

17.11 Transboundary air pollution

There is a provision in the Directive related to transboundary air pollution. Long-range transport may also be important for certain nanomaterials and/or ultrafine particles. The extent to which it is relevant will depend greatly on the type of species in question, and on factors such as their chemical composition.

17.12 The coverage of nanomaterials under the Air Quality Directive

A lack of information on the toxicity of nanomaterials to human health when inhaled through ambient air makes it difficult to assess the coverage provided by the Air Quality Directive. While it may seem desirable to have limit values and assessment thresholds, the data required to allow for their establishment is not available. In addition, the current reference measurement methods are not applicable and no appropriate standards exist. These limitations represent implementation gaps.

Whilst the existing Directive does not specifically cover nanomaterials or ultrafine particles and the test methods used do not specifically identify the nano-fraction, a portion of the PM10 and PM2.5 fractions will be ultrafine particles and hence subject to indirect control/coverage by the Directive.

The Directive includes a review Article to trigger periodic re-assessment of the coverage of the Directive and may, through co-decision procedure, also lead to introduction of new pollutants. The Directive through its revision therefore provides a potential legal mechanism for reducing pollution to levels which minimise harmful effects on human health in relation to nanomaterials and/or ultrafine particles.

Given the level of data currently available, it is assumed that further work would be required to develop, for example, appropriate limit values or target values, as well as appropriate metrics for dose and monitoring/characterisation strategies. There would also need to be further work related to determining appropriate sampling locations; approaches for dealing with contributions from natural sources; and the techniques that would need to be used within Member States in developing plans and programmes to achieve reductions in ambient concentrations.

18. Regulation (EC) No 66/2010 on the EU Ecolabel

18.1 Introduction

This Regulation[253] lays down rules for the establishment and application of the voluntary EU Ecolabel award scheme. It applies to any goods or services that are supplied for distribution, consumption or use on the Union internal market whether in return for payment or free of charge. The EU Ecolabel criteria shall be based on the environmental performance of products, taking into account the latest strategic objectives of the Community in the field of the environment. They shall be determined on a scientific basis considering the whole life cycle of products. The Regulation lists a set of general requirements that shall be taken into account when granting the EU Ecolabel to products (e.g. substitution of hazardous substances by safer substances; reducing animal testing).

The more specific EU Ecolabel criteria for each group of products are developed and adopted through a procedure that involves the Commission, Member States competent bodies and other stakeholders (See Article 8 and Annex I of the Regulation on EU Ecolabel). The revision of EU eco-label criteria of groups of products involves the following procedure. After consulting the European Union Eco-labelling Board (EUEB), the Commission drafts a proposed Decision setting the EU eco-label criteria. Following a number of revisions, in which changes are tracked, the final proposal is adopted according to the comitology procedure through a vote of Member State representatives' parties to the Eco-label Regulatory Committee. A common approach has been adopted to the consideration of nanomaterials under the review of criteria for specific product categories and this is discussed in section 18.3.

Feedback from the Stakeholder Workshop

Participants at the workshop noted that the EU Ecolabel scheme is intended to promote products with a reduced environmental impact throughout their life cycle. The lack of data regarding environmental exposure over the product life cycle makes any such assessment challenging for products containing nanomaterials.

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[253] Regulation (EC) No 66/2010 on the EU Ecolabel, OJ L 27, 30.1.2010, p. 1–19

18.2 Nanomaterials under the EU Ecolabel

The issue here is whether products containing nanomaterials for which initial evidence suggests that they pose potential risks to the environment (e.g. detergents containing nanosilver) could still be granted an EU Ecolabel. It should be noted that existing EU Ecolabel criteria, as set out in Commission Decisions, are already able to require that specific substances be excluded from products in order for the EU Ecolabel to be granted, either in terms of requiring that the substances not be used or by limiting their concentration. This mechanism could be used to set requirements to exclude specific nanomaterials, were sufficient evidence of risk to be found.

18.3 Common approach to addressing nanomaterials under EU Ecolabel criteria

A common approach to nanomaterials has been consistently applied in the recent revision of EU Ecolabel criteria for three product categories, and will now be consistently applied to the review of criteria for specific product categories. The product groups for which decisions for the EU Ecolabel criteria have been taken include hand dishwashing detergents[254], all-purpose cleaners and sanitary cleaners[255], and lubricants[256].

The approach in reviewing the criteria has been to make specific mention of the nanoform under Criterion 3 - excluded or limited substances and mixtures. Criterion 3(c) prohibits the presence of hazardous substances and mixtures in products awarded the EU Ecolabel in concentrations that exceed 0.010% by weight of the final product. The introductory text for Criterion 3 has been revised to specify that nanoforms intentionally added to the product shall be excluded at any concentration, i.e. nanoforms of hazardous substances are fully excluded. This recognises the fact that the risks associated with nanomaterials may not be linked to mass concentrations. Hazardous substances and mixtures include those categorised as such according to the CLP Regulation, as well as those substances referred to under Article 57 of REACH (i.e. Substances of very High Concern, SVHC).

In demonstrating compliance with criterion 3 (c), the application shall provide the exact formulation of the product to the competent authority. As a minimum the data provided must meet the requirements

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[254] Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents, L 169/40, 29.06.2011

[255] Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners, L 169/52, 29.06.2011

[256] Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants, L 196/27, 29.06.2011

in Annex VII of REACH (e.g. skin irritation, eyes irritation, acute toxicity).[257] Such information must be specific to the particular form of the substance, including nanoforms, used in the product.

The implications of these changes are as follows:

- Products granted the EU Ecolabel under criteria revised following October 2010 will not contain nanomaterials recognised to be hazardous under CLP; and
- Applicants will have to generate and provide information specifically on nanoform substances in products that contain non-hazardous nanomaterials in order to be granted an Ecolabel.

18.4 Substitution of hazardous substances

Pursuant to Article 6(3)(b) the substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible is a criterion to be taken into account when granting an EU Ecolabel to a group of products. This Article refers to hazardous substances but has no explicit reference to hazardous nanomaterials or to the nanoforms of hazardous substances. Nonetheless, it is assumed that it could equally apply to nanomaterials that are classified as hazardous.

18.5 Links with the CLP Regulation and REACH

Article 6(6) provides that the EU EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with the CLP Regulation (1272/2008) nor to goods containing substances referred to in Article 57 of REACH Regulation (i.e. those subject to the authorisation process). As already mentioned in section 3 on the Waste Framework Directive, it is unlikely that nanomaterials would be classified as toxic, hazardous to the environment,

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[257] Annex VII of REACH provides for standard information requirements for substances manufactured or imported in quantities of one tonne or more.

carcinogenic, mutagenic or toxic for reproduction under the CLP Regulation where the bulk form is not already classified as such.

Article 57 of the REACH Regulation sets the categories of substances of very high concern that must be subject to authorisation under REACH. The five categories are:

- (a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;
- (b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;
- (c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008;
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- (f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment […] (commonly referred to substances of equivalent concern).

It is unlikely that nanomaterials would be classified under the following CLP Regulation categories: hazard class carcinogenicity category 1A or 1B, unless the bulk form is classified as carcinogenic. Existing classifications of substances might be transferred to nanomaterials. The European Commission has stated that “it is essential and advisable” that the nano-form be considered by CLP registrants[258]. Any classification of a substance as carcinogenic in Annex VI to the CLP Regulation would also apply to the nanoform.

Experimental evidence for the carcinogenicity of nanomaterials is currently limited, although there are indications that some nanomaterials have carcinogenic potential or higher carcinogenic potential

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[258] EC Doc CA/90/2009 Rev 2. Annex II: Final version of Classification, labelling and packaging of nanomaterials in REACH and CLP

compared to larger particles of the same material. For instance, there is certain evidence that different forms of carbon nanotubes and nanoscale TiO_2 particles may induce tumours in sensitive animal models[259] (with evidence on $nTiO_2$ having led to its categorisation as a potential carcinogen category III by the US National Institute for Occupational Health and Safety). However, of the studies conducted on selected nanomaterials to date, only a handful meet the standardisation and quality criteria necessary to consider them for regulatory assessment (*ibid)*.

It is also unlikely that nanomaterials would be classified under the following CLP Regulation categories: hazard class germ cell mutagenicity category 1A or 1B, reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development, unless the bulk form is classified under these categories.

It will not be possible to predict and extrapolate findings on the toxic potential of nanoparticles until specific adverse effects in biological systems/organisms can be attributed to defined particle characteristics. The OECD Working Party on Manufactured Nanomaterials aims to provide a solid basis for assessing the toxic potential of nanomaterials. Initial results are expected in 2011.

However, nanomaterials that are (very) persistent, (very) bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of the REACH Regulation or having endocrine disrupting properties could potentially be subject to the REACH authorisation and be included in Annex XIV of REACH. Currently there are no nanomaterials included in the list of substances of very high concern under Annex XIV of REACH. It is a long procedure and it is unlikely that there would be any nanomaterials included in Annex XIV to REACH in a near future, at least in terms of those included specifically in relation to properties that arise from the nano-form. The current Candidate List of substances of very high concern for authorisation[260] does not appear to include any substances where there is identified concern regarding nano-form in particular. The number of nanomaterials where there seems to be some evidence of carcinogenic effect is relatively limited (including e.g. TiO2 and CNTs).

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[259] Becker H, Herzberg F, Schulte A and Kolossa-Gehring M "The carcinogenic potential of nanomaterials, their release from products and options for regulating them" (2010) International Journal of Hygiene and Environmental Health

[260] http://www.echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

It should also be noted that the suitability of existing testing methods in determining the toxicity of nanomaterials have been questioned. RIVM (2009) considers that whilst the majority of testing methods are suitable for nanomaterials, certain modifications would be required.[261]

18.6 The coverage of nanomaterials under the EU Ecolabel Regulation

The Commission has taken steps to integrate concerns regarding the potential risks associated with hazardous nanomaterials into the criteria for the granting of Ecolabel. Essentially, the approach recognises that the risks associated with hazardous nanomaterials may not be determined by the concentration by weight of the nanomaterials in the final product. In addition, the requirement to provide data specific to substances in the nanoform should serve to generation information on the applications of nanomaterials, if only within products seeking registration under the EU Ecolabel.

As with most other EU environmental legislation (excluding water legislation) the EU Ecolabel relies on the categorisation of substances under the CLP Regulation as hazardous when excluding hazardous substances from EU Ecolabel products. As discussed previously, some nanomaterials that exhibit hazardous properties not seen in the bulk from may not be captured under the CLP criteria.

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[261] RIVM, National Institute for Public Health and the Environment “Nanomaterial under REACH (nanosilver as a case study)” Report 60178003/2009 (2009) available at http://www.rivm.nl/bibliotheek/rapporten/601780003.pdf

19. Summary of Feedback from Member States on Activities on Nanomaterials

19.1 Introduction

This section provides a brief summary of the information received from Member States in response to an information request sent out during the project, and of information provided at the Stakeholder Workshop. In response to the information request, replies were received from Denmark, Estonia, France, Sweden and Portugal. The Stakeholder Workshop was attended by representatives from Belgium, France, Denmark, Germany, Italy, Latvia, the Netherlands and Poland. As such, the information provided here is not comprehensive regarding all activities in the Member States, but rather provides a snap shot of activities in those Member States who participated in the project either by sending in information or attending the workshop.

Initiatives towards the establishment of national databases for nanomaterials are being undertaken in Italy, Belgium and France. These initiatives sit within the context of a common project “Towards harmonization of national databases for nanomaterials on the market”. France is the only country to have taken legal action to require the declaration of the production, importation or placing on the market of nanoparticles or materials that may emit such substances, although the requirement is not yet in force. In addition, a number of other Member States have initiated discussions regarding possible national nanomaterials databases. Other action taken by Member States to date regarding nanomaterials has mainly involved studies and analyses to determine the legislative coverage of nanomaterials, assess applications on the market and investigate specific technical questions. Details of the various initiatives are briefly summarised below, with the common project first introduced before activities at Member State level are discussed.

19.2 Common project on national nanomaterials databases

France, Belgium and Italy are collaborating on a common project, with expert input from the Netherlands, Sweden, Denmark, Austria and the German REACH Competent Authorities, with the objective of proposing a common framework for nanomaterials databases[262]. The project arose out of an event organised by the Belgian Presidency of the EU entitled "Towards a regulatory framework for the traceability of nanomaterials"[263]. By coordinating on the proposal of a common framework, the project should avoid duplication of efforts, create a level playing field for industry, promote the exchange of good quality information, and in doing so contribute to an improvement of the legislative framework for nanomaterials. Common aims of the participating countries include:

- Gathering data on which nanomaterials are produced or on the market, their quantity, their uses and available information on hazard exposure;
- Maintaining transparency towards consumers and workers along the supply chain by providing access to information on substances, mixtures, articles and consumer products containing manufactured nanomaterials;
- Allowing for the traceability of manufactured nanomaterials on the market (with rapid market recall if needed);
- Allowing for an approximate estimation of the exposure of workers, consumers and the environment to manufactured nanomaterials;
- Establishing tools to help national authorities establish an adequate risk assessment system and to enable risk reduction measures when necessary; and
- Increasing knowledge on nanomaterials for the improvement of the legislative framework and to exchange with other public national authorities, including research institutes and other international bodies.

The proposal covers key elements of possible databases to ensure a certain degree of harmonisation, while allowing Member States the flexibility to add in additional requirements, as required. The proposal focuses upon a number of elements of possible databases, including: aim, scope, definitions, content, data protection and public information, enforcement and IT tools. Regarding the definition, participating countries have agreed to apply the definition finalized in the EC Recommendation (in

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[262] A common project "Towards harmonization of national databases for nanomaterials on the market" Version 17/05/2011, document provided through personal communication with Luc Maurer, Ministère de l'écologie, du développement durable, des transports et du lodgement, France

[263] Belgian Presidency of the Council of the European Union, "Towards a regulatory framework for the traceability of nanomaterials" available at : http://www.eutrio.be/towards-regulatory-framework-traceability-nanomaterials

final phases of preparation, earlier version for public consultation is available[264]), once final agreement is reached. In terms of scope, the reporting requirement will cover substances, mixtures, articles and all consumer products containing manufactured nanomaterials. The inclusion of waste was considered and finally dropped, with some participants considering this step premature.

A modular approach has been taken to setting information requirements, with Module 1 to include core data, with Member States then having the option to request additional information under Module 2. Elements under each module are summarised in table 23 below.

Databases should be linked to other relevant databases (REACH/IUCLID, OECD, JRC NANOhub, ECHA inventory on CLP) and should inform the implementation of other relevant legislation. Regarding the accessibility of information to the public, reports with basic information are to be prepared by the administrator and published, including on the web. Commercially sensitive information will not be disclosed.

Approaches to implementation, enforcement and control are being developed at the Member State level and include such options as starting with a voluntary approach and moving to a compulsory approach, or moving directly to a compulsory approach.

Recognising the links with REACH, the project coordinators note that reporting schemes will complement REACH requirements, serve to improve the application of REACH to nanomaterials, and inform the review of REACH in 2012. Data is expected to cover nanomaterials placed on the market at all volumes (hence broader in scope than REACH which applies only the volumes above1 tonne per year) and to be more readily available and more explicit. Where in place, reporting schemes are expected to raise awareness of industry regarding the need to provide specific information on the uses of nanomaterials in registration dossiers, as well as informing the definition of priorities for evaluation (of both dossiers and substances).

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[264] EC Draft Recommendation on the definition of the term “nanomaterials”, October 2010

Table 23: Proposed data requirements for a possible harmonized reporting scheme for nanomaterials

Module 1: Proposed requirements for core data	**Module 2: Possible additional data requirements**
• Materials identification : For manufactured nanomaterials on its own (substances): Trade name, chemical name, chemical formula physical form and physical-chemical properties For manufactured nanomaterials contained in mixtures, articles, consumer products: Reference to substance(s) identification and physical-chemical properties if possible. • Basic information related to uses : Uses area (food, packaging, cosmetics etc.), specification of whether is a consumer product or not, inclusion (or not) in a matrix (with indication of matrix nature), release intended or not; • Industry identification and economic sector (a proposal is to use SIC, International Standard Classification of industrial activities).[265] • Substance quantity (declarations for quantities above a given threshold lower than 1 ton produced/imported or distributed per year are considered). • Links to regulatory information (REACH registration numbers, EINECS of the bulk material, CLP inventory, etc).	• others physical-chemical properties (including the ones mentioned in ISO TTC229, WG3, PG5, project group); • reference of analytical methods utilized for the nanomaterials characterization; • information on the CLP classification and information about the bulk and nanoform, if possible and relevant, included toxicological and ecotoxicological information; • identification of workplace exposures and risks; • safety measures for workers; • available exposure data (estimations, validated studies) including occupational exposure limits; • detailed description of the products in which the nanomaterial is included; • description of the production process; • industry size (PME,…) • identity of downstream users; • disposal procedures; • wearing tests and/or characterization of the wastes.

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[10]The SIC Code is a four-digit numeric code assigned to each company based on its core business. This classification is an international standard, developed to facilitate the collection, analysis and presentation of uniform statistical data by organizations for economic studies. The classification covers all economic activities through a division of sectors.

19.3 Belgium

In Belgium, the Public Health, Food Safety and Environment Ministry has been tasked with studying the terms, conditions and methods for the establishment of a compulsory nanomaterials database. Completion is anticipated for 2012.

19.4 Denmark

In their response to the request for information, the Danish authorities indicated that awareness of how to address nanomaterials amongst environmental authorities responsible for managing waste and water is low. As such, nanomaterials are either ignored or causing unnecessary concerns. They noted that authorities do not currently have the technical equipment or methods to measure nanomaterials in different environmental compartments, indicating that measurements can only be made in collaboration with research institutes.

Regarding the coverage of nanomaterials provided under EU environmental legislation, they identified specific limitations, including the lack of a consistent definition and the possible deficiencies of test and evaluation methods under chemical legislation. There is no domestic legislation in Denmark that specifically addresses nanomaterials.

The Danish Environmental Protection Agency has conducted targeted surveys on the use of nanomaterials in consumer products and industry, resulting in publications[266]. In 2007, a report examined the potential health risks of nanomaterials and their coverage under health legislation[267]. In addition, the Danish Environmental Protection Agency is currently preparing a number of reports that address the main health and environmental issues for the most common nanomaterials.

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[266] Danish Environmental Protection Agency “Survey of nanotechnological consumer products” Survey of chemicals in consumer products no. 81 (2007) Danish EPA, Denmark; Danish Environmental Protection Agency “nanotechnology in the Danish industry – survey on production and application” Environmental project no. 1206 (2007) Danish EPA, Denmark

[267] Danish Ministry of the Interior and Health “Nanoteknologi og sundhed” (2007) Danish Ministry of the Interior and Health, Denmark

19.5 Estonia

Estonian authorities responded to the request for information, indicating that there is no special monitoring system in place in Estonia and hence no indications that nanomaterials are present in the environment. Laboratories involved in water monitoring programs do not currently monitor nanomaterials. No specific national environmental regulations on the nanomaterials are in place. There are research institutions dealing with research and development of nanomaterials, including their characterisation.

19.6 France

In their response the information request sent out under this study, the French authorities highlighted a lack of knowledge regarding the potential risk of specific nanomaterials amongst competent authorities, and noted that these risks are not adequately addressed under the current implementation of EU environmental legislation. They indicated that measurement techniques are not available on a routine basis to allow for the quantification of nanomaterials in environmental compartments and noted that competent authorities do not know what kinds of nanomaterials are likely to be found in water and waste streams.

As a measure designed directly to address the lack of knowledge regarding which nanomaterials are being used in applications and in what volumes, the French government has established a compulsory reporting scheme for nanomaterials placed on the market by producers, importers or distributers. Information requirements include an annual declaration of the identity, the quantity and the uses of the nanomaterials, as well as the identity of recipients down the supply chain. The first declarations are required in 2013 and will relate to nanomaterials manufactured, imported or distributed in 2012.

The objective to establish a reporting scheme was introduced under Article 42 of Law No. 2009-967 of 3rd August 2009 on the programme relating to the implementation of the Environment Round Table (Grenelle 1), with further details provided under Article 185 of Law No. 2010-778 (Grenelle 2). A

Decree relative to the annual declaration of substances in nanoform[268] is currently being finalised under French law and is due to enter into force on 1st January 2013.

In terms of studies at the national level, French authorities have investigated the use of nanomaterials for drinking water production[269], and have generated recommendations on nanomaterials and safety in the workplace[270].

19.7 Germany

In Germany, competent authorities are working on nanomaterials at a number of levels. German authorities are engaged with the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials. In addition, German authorities have been exploring the coverage of nanomaterials under REACH and other environmental legislation. In doing so, the German government is supported by an advisory body, the NanoKommission. In a recent report on "Responsible Handling of Nanotechnology"[271], the NanoKommission called for a number of changes to REACH, including:

- the inclusion of a definition of nanomaterials;
- adjustment of the data requirements to nano-scale substances;
- provisions for the inclusion of nano-specific information in Safety Data Sheets;
- adjustment of the transitional periods for registration of nanoscale substances;
- review of the tonnage thresholds for a nano-specific test programme allowing for a Chemical Safety Report; and
- the further examination of OECD test methods.

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[268] A draft version from December 2010 is available at : http://www.developpement-durable.gouv.fr/IMG/pdf/DecretNano_consultation.pdf

[269] Agence Française de sécurité sanitaire des aliments (AFSSA) « Les nanoparticules manufacturées dans l'éau » (2008) AFSSA, France, available at : http://www.anses.fr/Documents/EAUX-Ra-Nanoparticules.pdf

[270] Agence Française de sécurité sanitaire de l'environnement et du travail (AFSSET) « Les nanomatériaux : Sécurité au travail » (2008) AFSSET, France, available at : http://www.anses.fr/ET/DocumentsET/afsset-nanomateriaux-2-avis-rapport-annexes-vdef.pdf

[271] NanoKommission "Verantwortliche Umgang mit nanotechnologien" (2011) BMU, Germany, available at: http://www.bmu.de/files/pdfs/allgemein/application/pdf/nano_schlussbericht_2011_bf.pdf

The relevance of these proposed changes to the environmental legislation reviewed within the context of this report is that they could be expected to generate a significant body of nano-specific data under the REACH registration process. Data generated under REACH registrations feeds into the classification of substance under the CLP Regulation. As such, it would substantially increase the body of data used to classify individual nanomaterials under CLP and in doing so address some of the concerns regarding the recognition of specific nanomaterials as hazardous. The report also includes preliminary guidelines for assessing the benefits and potential risks of nano-products.

The Federal Environment Agency and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) supported a legal feasibility study on the introduction of a nano product register in Germany, which found the introduction of such a register to be feasible and workable in practice[272]. In its most recent publication, the NanoKommission notes that its members were unable to reach agreement on the function and possible goals of a legally binding nano product register[273].

19.8 Italy

In Italy, a project to establish a nanomaterials database has been initiated and the exact content of the database is currently under consideration. The Italian database will be established on a voluntary basis, with the possibility that it may evolve into a compulsory reporting system.

19.9 The Netherlands

In September 2010, the Dutch Ministry of Housing, Spatial Planning and Environment published a study on the regulation of nanomaterials, "Regulating uncertain risks of nanomaterials"[274]. The study

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[272] Hermann A and Möller M "Legal feasibility study on the introduction of a nanoproduct register" (2010) Öko-Institute, Germany

[273] NanoKommission "Verantwortliche Umgang mit nanotechnologien" (2011) BMU, Germany, available at: http://www.bmu.de/files/pdfs/allgemein/application/pdf/nano_schlussbericht_2011_bf.pdf

[274] Vogelezang-Stoute EM, Popma JR, Aalders MVC and Gaarthuis JV, "Regulating uncertain risks of nanomaterials" English summary of "Regulering van onzekere risico's van nanomaterialen. Mogelijkheden en knelpunten in de

explores the possibilities and limitation for the regulation of nanomaterials under current legislation to protect the environment, consumers and on occupational health and safety, given current uncertainties regarding the potential risks of nanomaterials. It also evaluates the possibility and suitability of establishing a national database on nanomaterials.

On 21 June 2011, the Netherlands presented an information note to delegations in the Environment Council on the risks associated with nanomaterials[275]. The document highlighted the difference in the risk profiles of nanomaterials versus the bulk parent material, noting that EU chemical legislation is not geared to evaluating the specific hazards of nanomaterials. It stressed the urgency of assessing the safety and risks of nanomaterials in products in a context where the number of product applications for nanomaterials continues to expand. Stating that several assessments to date have found existing coverage of nanomaterials under EU legislation to be inadequate, the note identified three essential steps, including:

- reaching agreement on a broadly applicable definition of nanomaterials that covers as many materials with nanospecific risks as possible;
- ensuring the traceability of specific nanomaterials, possibly through the mandatory registration of nanomaterials and products with nanoscale features; and
- developing an adequate risk assessment system for nanomaterials and for products with nanoscale features, and, where necessary, or risk control measures.

The information note explains that taking such steps at Community level will avoid confronting industry with an unlevel playing field following divergent actions at Member State level, and called upon the European Commission to adopt appropriate measures as soon as possible.

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regelgeving op het gebied van milieu, consumentenbescherming en arbeidsomstandigheden" (2010) STEM, Netherlands

[275] Information Note from the Dutch Delegation, 11626/11, Council of the European Union, Brussels 16 June 2011

19.10 Portugal

The Portuguese authorities reported that no specific activities have been undertaken in Portugal on nanomaterials, but that they are following EU and international developments closely.

19.11 Sweden

In their response to the request for information, Swedish authorities replied that knowledge regarding the presence of nanomaterials in water and waste streams was scarce. They noted that while competent authorities are not technically able to measure nanomaterials in general in environmental compartments, nano silver can be measured.

The Swedish authorities indicated that from their perspective, EU environmental legislation does not provide sufficient coverage of the potential risks posed by specific nanomaterials. There is no domestic legislation in Sweden that specifically addresses nanomaterials.

The Swedish Chemicals Agency, KEMI, has published a number of reports on nanomaterials, including an analysis of which nanomaterials can be found in products on the market in Sweden[276] and a national report on the environmental regulation of nanomaterials[277]. The latter report calls for a number of measures at EU level, including:

- agreement on a definition of nanomaterials;
- a requirement to notify products containing nanomaterials in the EU;
- a review of the application of REACH and CLP to nanomaterials, and if necessary their adaptation; and
- regulation of the use of nanomaterials as additive in biocides.

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[276] KemI “The use of nanomaterials in Sweden 2008 – analysis and prognosis” (2009) KemI PM 1/09, available at: http://www.kemi.se/upload/Trycksaker/Pdf/PM/nano_pm_1_09_sum_en.pdf

[277] KemI “Safe use of nanomaterials – need for regulation and other measures” (2010) KemI Report 1/10, available at: http://www.kemi.se/upload/Trycksaker/Pdf/Rapporter/Rapport_1_10_sum.pdf

20. Conclusions

This report has provided a review of EU environmental legislation on waste, water and three other legislative acts (namely the SEVESO II Directive, the Air Quality Directive and the EU Ecolabel Regulation) for their coverage of nanomaterials. The identification of gaps in the coverage of nanomaterials under EU environmental legislation and its subsequent implementation required an understanding of the potential risks associated with environmental exposure to nanomaterials. This understanding drew on possible environmental exposure pathways for specific nanomaterials and for nanomaterials in general and on data on the possible hazards associated with specific nanomaterials that were identified in the literature. Although a wide range of possible exposure pathways were identified, concrete evidence of releases was only found to support some of these pathways, notably releases of treated waste waters into surface waters and into soil through sewage sludge and treated effluent from sewage plants. For other pathways, either the very limited number of studies or the complete lack of studies made the identification of possible exposure more speculative. Regarding hazards, there is a lack of ecotocicological data even for the most tested nanomaterials such as fullerenes, carbon nanotubes, nano titanium dioxide, nano zinc oxide, and nano silver. The wide range of different nanomaterials and the subsequent diversity of their environmental footprints mean that general statements cannot be made concerning the hazards associated with nanomaterials.

Limitations in both exposure data and hazard data for specific nanomaterials made it extremely difficult to assess the potential risks of nanomaterials. In turn, the lack of a clear and comprehensive overview of the risks posed by nanomaterials made the identification of both implementation and legislative gaps challenging. In assessing each piece of legislation against potential risks, a distinction was made between the kinds of gaps in coverage that were identified, be they gaps in implementation or actual gaps in the legislative framework. Issues relating to limitations in data, a lack of technical capacity, or the inapplicability of implementation tools were considered to be implementation gaps, since these gaps could be addressed through further research and/or technical developments. The identification of a legislative gap required that an environmental risk from nanomaterials that is flagged as high in peer-reviewed scientific articles is not captured by the legislative framework. This could be either because approaches to identifying and controlling emissions employed under specific legislation are considered inappropriate for nanomaterials, or because the legislation does not provide for the control of specific release pathways. Where the discussion of possible pathways for environmental exposure was speculative rather than being based on evidence, the study nevertheless flagged potential issues in the interest of being comprehensive, without going so far as to label these issues as gaps.

In terms of the level of coverage afforded to nanomaterials, all the legislation reviewed could be considered to address nanomaterials in principle. However, most pieces of legislation were found to have some limitations in the coverage of nanomaterials, resulting generally from a lack of knowledge and technical capacity (in particular monitoring and detection techniques) and in some cases from the inapplicability of existing legal mechanisms (such as concentration thresholds to control the presence of pollutants).

In particular, the water legislation is considered limited in providing for the control of nanomaterials as pollutants in surface waters, groundwater and drinking water. Limitations stem from a lack of technical capacity to detect and monitor nanomaterials in aqueous environment and a lack of reliable data on the ecotoxicology of nanomaterials to feed into risk assessments, representing gaps in the capacity for implementation. In addition, there are questions surrounding the applicability of a threshold-based approach to controlling pollutants (as applied under the Water Framework Directive, EQS Directive, Groundwater Directive and Drinking Water Directive), in a context where the potential adverse effects associated with nanomaterials are not solely dependent on exposure in terms of the mass concentration. This represents a potential legislative gap in the coverage of nanomaterials under these Directives. Finally, there is a lack of consensus in the scientific literature regarding reliability of existing end-of-pipe technical controls in reducing the concentrations of specific nanomaterials in effluent from waste water treatment plants (both urban and industrial). This creates uncertainies as to whether end-of-pipe controls can effectively control exposure pathways for nanomaterials into water. Up-stream controls on the inclusion of specific nanomaterials in products may be the most effective control measures, where there to be sufficient evidence of risks from specific nanomaterials.

Concerns regarding the coverage of nanomaterials under waste legislation reflect uncertainties surrounding the classification of specific nanomaterials as hazardous under the CLP Regulation. In common with the water legislation, a number of limitations that fall under the scope of the waste legislation relate to the applicability of threshold-based limit values to nanomaterials, for example under the Lits of Waste, Sewage Sludge Directive, Landfill Directive and RoHS Directive. It should be noted that environmental exposure pathways for nanomaterials in waste have received less attention under scientific studies than those in water, and this made it difficult to assess coverage and identify specific gaps.

A number of cross-cutting issues were identified that serve to limit the effectiveness of environmental legislation in addressing nanomaterials in practice. Firstly, a high proportion of the legislation is depended upon the CLP Regulation for the identification of hazardous substances. Table 23 below provides a summary of the interface between EU environmental legislation and the CLP Regulation and identifies the operative provisions that are triggered when a substance is identified as hazardous.

There are three key concerns with regards to the classification of nanomaterials as hazardous under CLP. The first question is whether substances in the nanoform will receive a separate classification under CLP to those in the bulk form. Secondly, given that hazard classification should be based on available data and considering the existing data limitations for most nanomaterials, classification may be based on available data for the bulk form, rather than an examination of the specific intrinsic properties of the nanoform. Finally, in a case where additional tests are conducted, there are doubts surrounding the applicability of current tests to the nanoform.

Thus it is possible that, in the absence of *available* nano-specific data, nanomaterials will be categorised according to the bulk form and in some cases hazardous properties may not be recognised. This would imply that operative provisions across a range of environmental legislation that serve to control releases of hazardous substances into the environment would not be triggered for specific nanomaterials.

EU water legislation adopts an approach based on monitoring pollutants and setting environmental quality standards. This highlights two other cross-cutting issues, namely limitations in measurement and monitoring techniques (in particular in situ) and questions regarding the applicability of mass-based quality standards to nanomaterials in a context where the potential adverse effects are not solely dependent on exposure in terms of mass concentration.

Limitations in the availability of cost-effective monitoring techniques have significant implications for the detection of pollutants under water legislation. The detection of pollutants in surface waters (under the Water Framework Directive) and groundwater (under the Groundwater Directive) under specific monitoring programmes serves to trigger measures to control these pollutants. Currently avaibale monitoring techniques do not readily provide for the detection of nanomaterials, should they be present in surface or groundwaters. Without the capacity to monitor nanomaterials in water there will be no data, hence measures will not be triggered, even in cases where nanomaterials are present as pollutants.

Table 23: Summary of the interface between EU environmental legislation and the CLP Regulation

Legislative act	**Interface with CLP Regulation**	**Operative effect**
Waste Framework Directive	Under Annex III, Hazard classification of waste	Determines application of specific measures for hazardous waste, Articles 17, 18, 19 and 35
ELV Directive	Under Article 2(11) Identification of hazardous substances based on CLP	Requirements to limit the use of hazardous substances in vehicles under Article 4(1)(a) Article 6(3) – requirement to remove and segregate hazardous materials when undertaking treatment of end-of-life vehicles
Landfill Directive	Definition of hazardous waste refers to Waste Framework Directive, hence to CLP Regulation	Determines which class of landfill non-municipal waste will be channelled to.
WEEE Directive	Article 3(1) defined dangerous substances or mixtures as a substance fulfilling the criteria for the hazard categories under Annex I of the CLP Regulation	Article 10(1)(d) requires that users of EEE are given information regarding the potential environmental and health effects of hazardous substance in WEEE
SEVESO II	Annex I Part 2: dangerous substances are classified according to the CLP Regulation	Facilities with these dangerous substances on site above the threshold volumes provided in Annex I Part 2 are regulated under SEVESO II
EU Ecolabel Regulation	Criterion 3: excluded or limited substances and mixtures	EU Ecolabel good cannot contain nanoforms of substances classified as hazardous under the CLP regulation at any concentration EU Ecolabel goods cannot contain substances classified as CMR under CLP, nor can they contain substances under Article 57 of REACH
Water Framework Directive	Under Article 16(3) the identification of priority hazardous substances shall take into account the the selection of substances of concern undertaken in the relevant Community legislation regarding hazardous substances	Prior identification of hazardous substances under CLP will be taken into account in the identification of priority hazardous substances

In addition, the lack of low cost techniques for monitoring nanomaterials in environmental compartments impacts on the feasibility of possible future options for managing nanomaterials in water, in particular any monitoring requirements for specific nanomaterials in sludge and soils, in landfill leachate, in treated waste waters, or in drinking water. At the same time, the enactment of legislation frequently acts as a trigger for the development and commercialisation of new techniques and pushes the existing technical boundaries. Further research is required to investigate the future feasibility and relevance of monitoring the concentrations of nanomaterials in different environmental compartments.

Another cross-cutting issue relates to questions regarding the applicability of mass-based thresholds to nanomaterials. The specific properties of nanomaterials mean that concentrations given in mass terms and subsequently used to establish mass-based thresholds may not be appropriate for nanomaterials, since toxicology studies indicate that generally toxicity increases with decreased dimensions for nanomaterials which would imply that different thresholds would be required for different size distributions. Mass-based threshold are used throughout environmental legislation with a summary provided in table 24 below.

There are several ways in which threshold values may be used in legislation, including limits on the concentration of specific substances in products, quality standards whose transgression trigger controls (including EQS), and emission limit values that set a cap on the concentrations of a specific substance that can be emitted in effluent or flue gas. Further research is required on the fate and behaviour of nanomaterials in the environment, as well as on their toxicology, to determine whether it will be possible in the future to establish threshold values for specific nanomaterials with confidence. Should this not be the case and in the meantime should further evidence of significant environmental contamination with nanomaterials be found *and* be identified as posing a risk to human health and the environment, it may require a paradigm shift in the approach to controlling pollutants in the environment: one not based solely on mass-based thresholds.

Table 24: The use of mass-based thresholds in EU environmental legislation

Legislative act	**Article**	**Application**
Decisions on the List of Waste	Article 2	Concentrations thresholds that quality waste under specific categories
Sewage Sludge Directive	Annex I	Limit values for heavy metals in sludge and treated soils
RoHS Directive	Article 4	Maximum concentration limits for certain hazardous substances (of relevance to nanomaterials is cadmium, due to presence of cadmium dots in electrical equipment)
Landfill Directive	Annex III	Member States to establish values for specific substances found to enter groundwater from landfill leachate, the transgression of which would trigger action to control sources of those specific substances
Water Framework Directive	Annex V & Annex VIII Article 16 & EQS Directive	EQS set by the Member States for Annex VIII pollutants (river basis specific pollutants) EQS for priority substances (relevant to nanoforms of cadmium and nickel)
EQS Directive	Annex I	EQS for priority substances (relevant to nanoforms of cadmium and nickel)
Groundwater Directive	Annex II, Point 2	Threshold values to be set by Member States for groundwater pollutants
Drinking Water Directive	Annex I	Quality standards for drinking water

This discussion serves to highlight a third cross-cutting issue, the lack of data regarding the intrinsic properties of specific nanomaterials and their behaviour in environmental compartments and limitations in current approaches to testing substances. Table 25 below provides a summary of potential questions regarding the application of current physicochemical, ecotoxicity and toxicity tests to nanomaterials.

Table 25: Potential issues regarding physicochemical, ecotoxicity and toxicity tests

Mass concentration
Mass concentration (in mg/kg or mg/mL) may not be an appropriate metric for dosage of nanomaterials. Instead exposure metrics such as particle number and surface area concentration may be important.

Appropriate route of exposure
For initial *in vivo* toxicity testing methods, normally the oral exposure route is used. However, for testing of nanomaterials, this may not be sufficient and administration via dermal or inhalation routes is likely to be more applicable. Furthermore, the effect of oral administration of nanomaterials on gut flora may show toxic effects which are not investigated and identified during routine toxicity testing (which also counts for bulk materials).

Duration of tests
Sub-chronic or chronic studies are likely to be the most appropriate to study the toxic effects of nanomaterials since the duration of human exposure to small amounts of nanomaterials will be over a longer period of time. Single or short-term exposures are likely to occur with high concentrations of nanomaterials as a result of accidental release. This point also holds for non-nanomaterials.

Detection of nanomaterials
Whereas the potential toxic effects of nanomaterials will be detectable by using light microscopy, their presence, as single particles or in small aggregates, may not be. Therefore, to show the presence of nanomaterials within a histological sample it will be necessary to use EM, which may be overly laborious.

Distinction and identification of nanomaterials
As the standard analytical detection methods may not be suitable to detect the presence of nanomaterials within a sample (see above), and EM techniques only show their presence, additional techniques such as EDX and XPS would be required to provide information at the particle level e.g. structure and shape. This is essential for the identification of nanomaterials (both manufactured and naturally occurring).

Systemic effects of toxicity
The most probable scenario is that a nanomaterial, after entering the body, will relocate in the organism and exert a systemic effect at a target site. This cannot be determined by single cell *in vitro* studies and therefore the need for animal experimentation remains until more developed screening tests are available or the relationship between the physicochemical properties of a nanomaterial and its toxic effect can be determined. Again this concern also holds for bulk materials.

Effect of particulate number
Given the small particle sizes of nanomaterials and the normal dosimetrics in toxicity studies (mass concentration in mg/kg), there is a distinct possibility that due to the large amount of nanomaterial to be administered (which may no longer be representative for the actual exposure situation), toxic effects induced are a consequence of an overload phenomenon, rather than a consequence of exposure to the nanomaterial itself (or a combination of both).

Solution or suspension of (nano)material
The distinction between a solution or suspension of a material, whether in nanoform or in bulk form, for use in sample preparation must be considered. However, it is likely that this will only be a problem with long term administration of the test substance as the suspension may precipitate out over time (sediment).

Use of appropriate solvent
Whilst the test nanomaterial may be soluble and stable in an organic solvent, the effects of the solvent on the test system must also be considered. Conversely, the potential of the nanomaterial to interact with the surrounding media (*e.g.* plastic of syringe, cell culture media) must also be considered in the administration of the nanomaterial. This concern also holds for bulk materials.

These limitations in knowledge and in our ability to test nanomaterials and increase our knowledge base in a systematic fashion imply that both regulators at the EU level and practitioners on the ground are struggling to manage a risk that remains essentially unquantifiable. For example, when seeking to characterise nanowaste (where they need to be informed that the waste was nanowaste), landfill operators do not have access to the data required to make a basis characterisation of the waste. At the EU level, regulators do not have the ecotoxicology data required to assess whether nanomaterials could qualify as priority substances under the Water Framework Directive. Waste managers are not informed as to the behaviour of nanomaterials in recycling processes and producers notifying nanomaterials under CLP do not have data on the intrinsic properties of specific nanomaterials. Operators of waste water treatment plants are not informed as to the efficiency of their treatment techniques in removing nanomaterials.

As already noted, this paucity of information served to inhibit a comprehensive review of the coverage of nanomaterials under EU environmental legislation, since the risks cannot be accurately defined. REACH is one of the main drivers generating data on the risks associated with nanomaterials at all stages of their life cycle, and as such should contribute to the upstream elimination from the exposure pathways controlled under environmental legislation of specific nanomaterials that may be found to pose concerns. However as noted in the report, the requirement for an assessment of all possible environmental impacts of a substance over its life cycle in all foreseen uses form part of the Chemical Safty Report which only required for substances placed on the market at 10 tonnes per year or more, implying that most nanomaterials will be exempt from this requirement.

In conclusion, it is relevant to highlight the relevance of the precautionary principle to the discussion of whether to act to regulate nanomaterials and, if so, how to act. The precautionary principle serves to guide decision makers in cases where preliminary objective scientific evaluation uncovers reasonable grounds for concern regarding potentially dangerous effects on the environment, human, animal or plant health, effects that may be inconsistent with the high level of protection chosen for the EU Community. Given the particular emphasis on managing limitations in scientific knowledge, recourse to the precautionary principle would seem to be extremely relevant to the regulation of nanomaterials.