Support for 3rd regulatory review on nanomaterials – environmental legislation

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Support for 3rd regulatory review on nanomaterials – environmental legislation

Ricardo Energy & Environment, Milieu Consulting and
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Support for 3rd regulatory review on nanomaterials – environmental legislation

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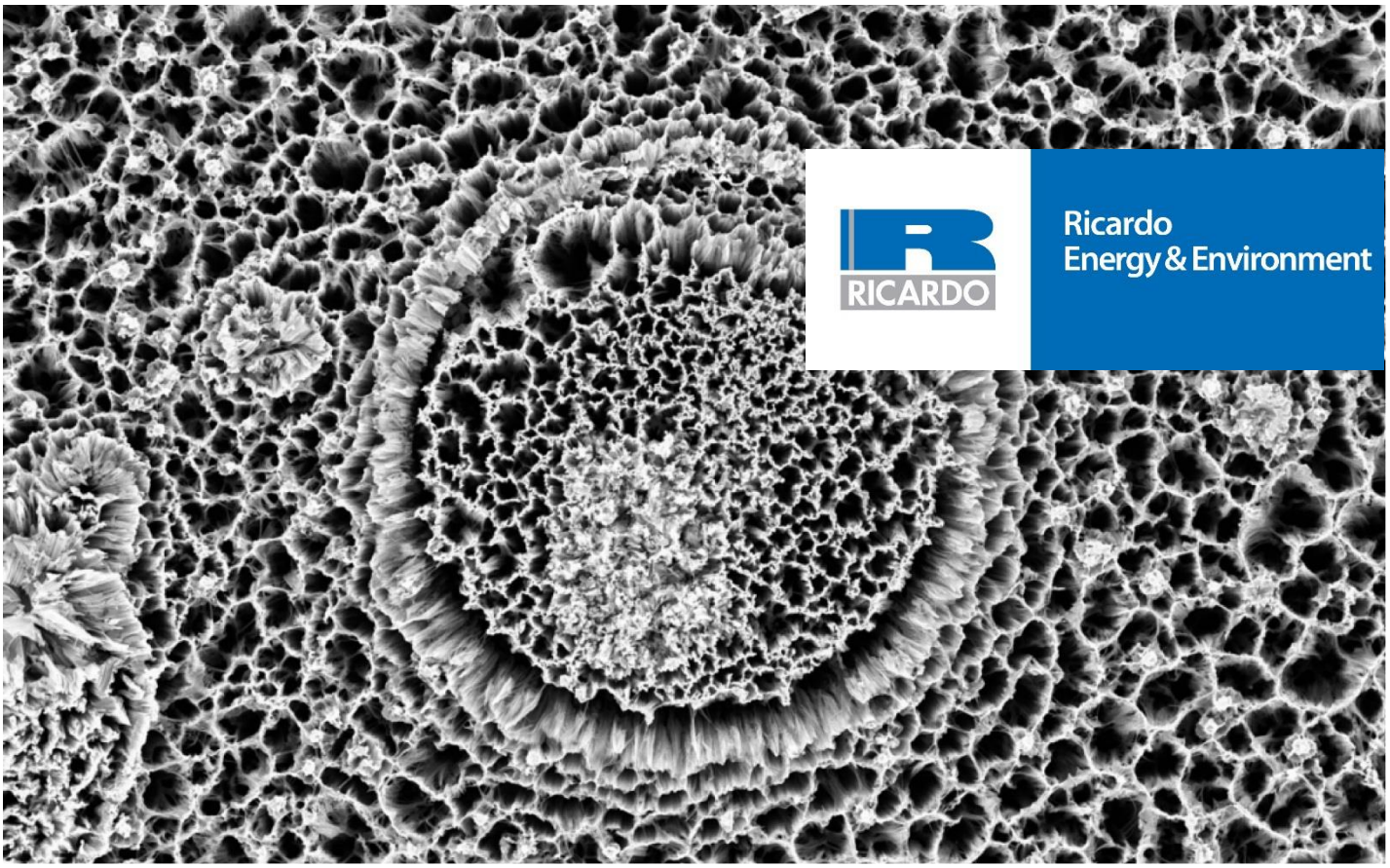

Ricardo Energy & Environment

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Project Report

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Executive summary

This report

Ricardo Energy & Environment, in partnership with subcontractors Milieu Consulting and the Technical University of Denmark (DTU), was commissioned by the European Commission to carry out a project entitled "*The preparation of the third regulatory review on nanomaterials - environmental legislation*", specific contract number 070201/ENV/2015/SI2.716613/ENV.A3, Commission reference ENV.C.3/ETU/2015/0030. The study objective was to compile and develop information on nanomaterials and advanced materials in the environment and explore further the regulatory implementation challenges. The study had three main components:

- A preliminary evaluation of releases of nanomaterials to different media (air, water, land, recycling and waste disposal).
- A review of progress on the application of environmental and other key legislation to nanomaterials.
- A prospective view on future developments in advanced materials, and challenges for environmental legislation.

Consultation with stakeholders was carried out by email and telephone, and a stakeholder workshop was held on 21 June 2016. At the workshop, the interim findings were presented, and stakeholder feedback and views were discussed. Following the workshop, stakeholders provided feedback in writing. This feedback has been taken into account for the finalisation of the report.

Nanomaterials release inventory

A prioritised qualitative release inventory for nanomaterials was developed. This was based principally on data from the French registry of nanomaterial production and importation.

The first step was to develop indicative production profiles for nanomaterials for the period 2000 to 2035. The profiles were designed to represent the evolution in production of manufactured nanomaterials over time. The uses of each material in the French registry with a quantified production and import quantity were then analysed – a total of 188 materials. Uses of each nanomaterial were classified into 10 separate categories. The next step was to estimate indicative profiles for release of nanomaterials to the environment during manufacture, use and disposal. These indicative release profiles were based on published emission factors or other relevant data where available. In cases where there were no published emission factors, emission factors were estimated using the project team's best judgment. Applying the manufacturing and usage release factors over the product lifetimes enabled estimates to be made of the quantities of each of the 188 materials released to each of the five media (air, land, water, recycling, waste disposal) in 2015, 2025 and 2035 across Europe.

The numerical release estimates were considered to be highly uncertain in view of the number of assumptions used to reach the indicative inventory. Consequently, the releases to each medium were described qualitatively as "high", "medium", "low" and "zero." This initial evaluation makes no reference to the potential toxicity of the nanomaterials listed in the French registry.

The following nanomaterials listed in the French registry were identified as having a potentially "high" release to one or more medium.

Substances listed as nanomaterials in French registry	CAS Number	EC Number
Aluminium oxide	1344-28-1	215-691-6
Boehmite (Al(OH)O)	1318-23-6	215-284-3
Calcium carbonate	471-34-1	207-439-9
Mixture of ceria and zirconia	53169-24-7	
Silicon dioxide, or variations of	7631-86-9	231-545-4
Titanium dioxide	13463-67-7	236-675-5
Zinc oxide	1314-13-2	215-222-5
Carbon black	1333-86-4	215-609-9

Substances listed as nanomaterials in French registry	CAS Number	EC Number
Copolymer of vinylidene chloride	9002-86-2	
Polyvinyl chloride	9002-86-2	
Fuller's earth	8031-18-3	
Kaolin	1332-58-7	8031-18-3
Silicic acid, aluminium sodium salt	1344-00-9	215-684-8
Silicic acid, magnesium salt	1343-88-0	215-681-1
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	5102-83-0	225-822-9
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	5567-15-7	226-939-8
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	413-920-6	
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	54660-00-3	601-713-5
Calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	7023-61-2	230-303-5
Clindamycin hydrochloride	21462-39-5	244-398-6
Cerium oxide isostearate		
Cerium and iron oxide isostearate		
Iron oxide isostearate		
Lactose	63-42-3	200-559-2

The substances identified as having a potentially “high” release for one or more pathways were prioritised primarily by consideration of evidence for their potential effects on health, in the absence of systematic information in relation to the potential environmental effects of nanomaterials. The available evidence is insufficient to support the view that the toxicity of a given material increases from larger scale particles to smaller scale particles. There is insufficient evidence in practice to support the view that the toxicity of a given material increases from larger scale particles to smaller scale particles. Nano scale particles of any poorly soluble material could potentially pose a health hazard: however, the nature and scale of any such hazard is likely to depend on the extent of any such exposure and the exposure pathway (e.g. inhalation; dermal contact; dietary exposure).

For a subset of 12 nanomaterials from the French registry, further assessment was undertaken and a preliminary estimate of production and release quantities for 2015, 2025 and 2035 was developed. These estimates are subject to an indicative uncertainty factor of 7, due to the assumptions inherent in carrying out generic calculations based on a limited dataset. The preliminary estimate of production and release quantities of prioritised nanomaterials in Europe for 2015 is as follows:

Chemical name	Estimated quantity produced/ imported (Europe 2015), tonnes	Preliminary release inventory (2015), tonnes (estimated uncertainty factor of 7)				
		Air	Land	Water	Recycling	Waste
Aluminium oxide	16,000	9.0	4.8	19	3522	5921
Mixture of ceria and zirconia	2,300	1.2	0.32	1.3	381	658
Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films	22,000	119	128	27	3312	6254
Titanium dioxide	92,000	183	340	140	17814	30868
Zinc oxide	200	6.5	21	33	16	50
Carbon black	1,480,000	881	290	1077	348354	578525
Clindamycin hydrochloride	340	0.31	17	5.2	0	105
Cerium oxide isostearate	41	5.9	0.515	0.10	5.7	12

Chemical name	Estimated quantity produced/ imported (Europe 2015), tonnes	Preliminary release inventory (2015), tonnes (estimated uncertainty factor of 7)				
		Air	Land	Water	Recycling	Waste
Cerium and iron oxide isostearate	200	29	2.50	0.5	28	60
Silver	100	0.099	6.4	0.34	11	26
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite	1,200	0.64	0.17	0.70	199	343
Piroxicam	4.0	0.0036	0.20	0.061	0	1.2

Regulatory review

The review of environmental legislation, which was carried out for the second regulatory review, was updated with the current report, in order to investigate whether the gaps and challenges identified in the 2012 review have been addressed and whether new gaps have emerged. Four case studies were developed to illustrate the application of EU legislation to nanomaterials, covering a diverse range of nanomaterials (nano-iron oxide, nanosilver, nanosilica and quantum dots).

The review of legislation identified a number of potential legislative and implementation gaps. Most of these gaps had already been identified in the 2012 review. Particular attention was paid to cases where nanomaterials are covered in principle due to assumptions about them being similar to bulk or size-unspecified substances This is particularly important in relation to legislation which covers nanomaterials in principle, but does not effectively address the specific characteristics of nanomaterials due to issues of measurement method, monitoring criteria, etc.

The compiled information was then evaluated with a view of assessing progress toward addressing the action points and conclusions from the second regulatory review. The information was assessed as follows:

- Whether existing legislation has effectively dealt with nanomaterials;
- Whether a regulatory change has happened and if it was effective;
- Whether scientific progress has removed obstacles in implementation and enforcement;
- Whether a specific development can be consistently applied across all legislation on nanomaterials;
- Whether the information is only relevant and applicable to one specific piece of legislation or one specific substance/material/product.

The findings of the legislative review are summarised in the following table.

EU legislation	Conclusions
Waste Framework Directive 2008/98/EC	Categorisation of hazardous waste based on the CLP Regulation. State-of-the-art waste treatment technologies remain inadequate to capture nanomaterials, leading to implementation gaps of the Waste Framework Directive There are knowledge gaps on nanomaterial in waste streams
Decision 2000/532/EC (European Waste Catalogue)	The challenge to determine hazardous properties of nanomaterials in waste/nanowaste based on concentration limits and based on the CLP Regulation Knowledge gaps to assess whether or not it would be relevant to add a specific category of nanomaterials in waste or nano waste category in this Decision
Directive 2000/53/EC on end-of life vehicles (EoLV Directive)	Reliance on CLP to identify 'hazardous nanomaterials' Car dismantlers' difficulties in identifying nanomaterials
Directive 1999/31/EC on the Landfill of Waste (Landfill Directive)	Reliance on the CLP Regulation to categorise hazardous waste Knowledge gaps on nanomaterials behaviour in landfills and the health and environmental risks they may entail.

EU legislation	Conclusions
Directive 2011/65/EU (RoHS Directive)	Article 6 specifically mentions that when reviewing the list of restricted substances, the Commission must take into account several criteria (e.g. negative impacts during EEE waste management operations, uncontrolled or diffuse release into the environment) for substances including substances of very small size or with a very small internal or surface structure. This key provision of the ROHS Directive is considered to be an adequate tool to restrict hazardous nanomaterials in EEE. Such periodic review procedure may lead to the generation of new information on nanomaterials in EEE and their related potential environmental risks.
Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) (recast)	This Directive invites the Commission to evaluate whether amendments to Annex VII are necessary to adequately control nanomaterials. To date, no evaluation assessing amendment needs with regard to treatment requirements under Annex VII has been carried out nor has any delegated act been adopted.
Directive 94/62/EC on packaging and packaging waste (Packaging Directive)	Effective implementation of the Packaging Directive provisions to packaging containing nanomaterials is hampered by poor knowledge on nanomaterials characteristics, releases to the environment and behaviour. The current provisions of the Packaging Directive would be adequate to cover nanomaterials if there were no such knowledge gaps.
Directive 86/278/EEC (Sewage Sludge Directive)	The Sewage Sludge Directive does not currently seem to be an adequate tool to detect, monitor and control the use of hazardous nanomaterials in the treatment of sewage sludge.
The Water Framework Directive 2000/60/EC	The creation of a 'watch list' mechanism introduced by Directive 2013/39/EU which includes reference to considering particle size under the EQS Directive (see next row) has the potential to facilitate the inclusion of substances in nanoform in the list of priority substances and the implementation of related monitoring and control measures under the Water Framework Directive. This addresses potential concerns in relation to the adequacy of the Water Framework Directive..
The Environmental Quality Standards Directive	The changes brought by the inclusion of the new Article 8 in the EQSD open the door to the possible inclusion of nanomaterials in the list of priority substances, despite the lack of monitoring data. This would then have a ripple effect on the other water-related pieces of legislation.
The Groundwater Directive	Nanomaterials are in principle captured under Annex II, Point 2 of the Directive, which refers to man-made synthetic substances. Should specific nanomaterials be identified as pollutants of groundwater in a Member State then threshold values should be established for those nanomaterials against which maximum concentration in ground water is allowed. The list of threshold values is to be updated in response to information on new pollutants, groups of pollutants or indicators of pollutants. However, issues related to the coverage of nanomaterials under the Directive are tightly linked with those for the Water Framework Directive and the EQSD, relating to the absence of techniques for the detection and monitoring of nanomaterials and problems with establishing quality standards.
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.
The Urban Waste Water Treatment Directive	The technical requirements of the Urban Waste Water Directive do not specifically consider the presence of nanomaterials in urban wastewater 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, there is no strong case for focusing on nanomaterials when other hazardous substances are not specifically considered.

EU legislation	Conclusions
Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive – MSFD)	Member States should take into account the substances and threshold values defined under the Water Framework Directive and the EQSD for the definition of GES in the marine environment. More specifically, the minimum requirements used to assess the adequacy of Member States' GES definitions included coverage of all priority substances of the EQS Directive. Thus, considering the strong linkages between the Water Framework Directive, the EQSD and the MSFD, were some nanomaterials designated as 'priority substances' under the Water Framework Directive, they would, in theory, also need to be regulated in the marine environment. All the limitations previously mentioned in relation to the lack of ecotoxicological data and difficulties with monitoring of nanomaterials in water are valid for the marine environment as well.
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso Directive)	The Directive relies on CLP classification to set risk management measures. The current quantity thresholds under the Seveso Directive may not be adequate to reflect the potential specific properties of nanomaterials. Finally, the Seveso Directive does not contain an adequate mechanism to adapt in a rapid manner Annex I if there were evidence of potential major-accident hazard of specific hazardous substances (including hazardous nanomaterials) in industrial facilities.
Ambient Air Quality Directive 2008/50/EC	The Ambient Air Quality Directive does not contain specific control measures and monitoring requirements related to ultrafine particles and air-borne nanomaterials.
Regulation (EC) No 66/2010 on the EU Ecolabel	There is no consistent approach in the coverage of nanomaterials under the different Ecolabel criteria decisions. The older criteria that were not amended since 2012 do not contain any criteria on nanomaterials, nanoforms or forms of substances. The criteria decisions to exclude hazardous substance under EU ecolabel products mainly rely on the CLP classification of hazardous substances. The criteria also exclude substances of very high concern under REACH.
Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)	Limited number of classified nanomaterials under the CLP Regulation. Limited available nanospecific information to classify nanomaterials under the CLP Regulation. Generation of new information on environmental hazards of chemical substances not compulsory Challenges in the determination of environmental hazards of nanomaterials in view of the CLP classification
Regulation (EC) No 1907/2006 (REACH)	Difficulties to identify and/or characterise nanomaterials under REACH. Knowledge gaps to generate information on environment fate and behaviour and ecotoxicology of nanomaterials Information gaps on nanomaterials in the supply chain
Directive 2010/75/EU on industrial emission (IED)	The majority of the BREFs provide information on abatement techniques targeting nano- or ultrafine particles. However, the recent BAT conclusions covering important industrial emitters of ultrafine/nano particles (e.g. refining of mineral oil and gas, production of cement, lime and magnesium oxide) do not contain any specific emission limit values for these particles Reliance on the CLP classification to trigger certain control measures (e.g. monitoring or site closure requirements)
Regulation (EC) No 166/2006 of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register (PRTR Regulation)	No specific entry points for nanomaterials or the nanoforms of these chemical substances (e.g. cadmium) and for ultrafine particles. Knowledge gaps in the monitoring of the releases of nanomaterials in the environment. This is may be one of the reasons why nanomaterials and ultrafine particles are not covered or planned to be covered in the PRTR Regulation.

EU legislation	Conclusions
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)	The BPR is the most advanced and comprehensive EU legislation with regard to the regulation of nanomaterials. However, potential issues remain: • The current lack of adequate methods to test the ecotoxicology and fate and behaviour of nanomaterials in the environment. • The lack of guidance accompanying the BPR on how to provide nano-specific test results, or how to justify the scientific appropriateness of the current test methods for the testing of nanomaterials • The five-year timeframe for Member States reports which might be too long to address any issues which might emerge during the course of the monitoring programme. • The BPR does not contain a mandatory obligation for manufacturers to report on the quantities of nanomaterials in biocidal products placed on the EU market.
Cosmetics Products Regulation (EC) No 1223/2009 (Cosmetic Regulation)	The Cosmetic Regulation contains very comprehensive and stringent control measures on the health impacts of nanomaterials used in cosmetics. There are no measures or information requirements on the potential environmental impacts of nanomaterials used in cosmetics under the Cosmetic Regulation. Such environmental assessment is covered by the REACH Regulation, which is currently not fully adequate to generate information on ecotoxicology, environmental fate and behaviour of nanomaterials.
Regulation (EC) No 1107/2009 on plant protection products (PPP)	The PPP does not contain specific information and assessment requirements for nanomaterials. This is considered as a potential legal gap considering that much effort from economic operators is currently placed on research and development on nanomaterials in plant protection products which may soon be ready to be placed on the market. There are also lot of knowledge gaps on the potential (eco)toxicity of certain plant protection products nanomaterials used on plants, animals and the environment. The PPP Regulation relies in part on the CLP Regulation to implement the active substance approval procedures. However, CLP is currently generating limited information on nanomaterials.
Regulation (EU) 2015/2283 on novel foods (novel food Regulation)	Definition of engineered nanomaterials. In case of food or vitamins, minerals and other substances consisting of nanomaterials used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, applicants for authorisation must provide an explanation of the test method's scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.
Regulation (EC) No 450/2009 on active and intelligent materials intended to be in contact with food	Substances used in components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier may be used in components of active and intelligent materials and articles without being included in the Community list. However, such exemption does not apply to substances deliberately engineered to particle sizes, which exhibit functional physical and chemical properties that significantly differ from those at a larger scale.

EU legislation	Conclusions
Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	Several nanomaterials have been authorised to be used in plastic materials and articles intended to come into contact with food (e.g. titanium nitride, butadiene, ethyl acrylate, methyl methacrylate, styrene copolymer cross-linked with divinylbenzene, in nanoform). The reference to the nanoform of substances must be explicitly mentioned in the Annex I authorisation list. Information on Environmental aspects such as persistence in the environment, ecological impact of their constituents and their fate after the food contact material has been submitted to waste disposal treatment are not required under the authorisation procedure. Under the Regulation, only the potential human health effects of the use of specific nano substances in plastic food contact materials is evaluated. A plastic layer which is not in direct contact with food and is separated from the food by a functional barrier may be manufactured with substances not listed in the Union list or in the provisional list. However, this derogation does not apply to substances in nanoforms.
Regulation (EU) No 1169/2011 on the provision of food information to consumers	All ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word 'nano' in brackets**.** This Regulation defines 'engineered nanomaterial'.
Regulation No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	Nanomaterials are defined according to Regulation (EU) No 1169/2011. This food must not contain any substance in such quantity as to endanger the health of the persons for whom it is intended. For substances, which are engineered nanomaterials, compliance with this requirement must be demonstrated on the basis of adequate test methods, where appropriate.

Advanced Materials

Terms such as "materials" and "advanced materials" are very broad and inclusive terms. Advanced engineering materials or just advanced materials is one of six technologies that have been identified as "Key Enabling Technologies" (KETs) by the European Commission. Advanced materials are used in most manufacturing industries.

It is often claimed that advanced materials offer major improvements in a wide variety of different fields, e.g. in aerospace, transport, building and health care and that they facilitate recycling, the reduction of environmental waste and hazards, lower carbon footprint and energy demand as well as limiting the need for scarce raw materials. Areas with major potential are believed to be energy €19bn (e.g. catalysts and batteries), environment €12bn (e.g. polymers and smart packaging), health (e.g. tissue engineering), transport (e.g. lightweight materials) and information and computer technology (e.g. optical fibres and semiconductors).

This task represents one of the first efforts to systematically categorise and define advanced materials at the EU level in the context of reviewing their coverage by environmental legislation and the extent to which they are relevant to the incorporation of nanomaterials. In order to identify examples of emerging nanotechnologies and advanced materials, governmental and non-governmental reports and reviews were scanned, and a literature search carried out. The technologies and advanced materials identified were classified using the nomenclature and definitions and conventions cited above in order to test workability.

Our experience with using the different definitions of advanced materials was used to propose a classification of advanced materials and develop the associated methodology for regulatory review.

Most of the categorisation schemes suggested for advanced materials provide a clear classification of the advanced material categories that they include in their scheme although they differ substantially in

regard to the number of advanced material categories that they include. For the majority of the schemes, sufficient information is provided on the key characteristics of the different categories of advanced materials. A few schemes entail advanced material categories that are not defined or explained in detail and some schemes which also seem to include unique categories of materials not widely recognized as an advanced material category. All the schemes are flexible enough to accommodate new developments and inventions in the advanced materials science. The categorization developed on the basis of the DAMADEI classification was adopted for this analysis.

The types of advanced material identified in the DAMADEI classification and the preliminary regulatory analysis is as follows:

Category	Classification and coverage under EU legislation	Potential legal issues
Active materials	Articles under REACH Regulation RoHS Directive and WEEE Directive if used in Electronic and Electric Equipment Active food contact material under Regulation (EC) No 450/2009 on active and intelligent materials intended to be in contact with food	None
Advanced composites	Mixtures under REACH Regulation	None
Advanced manufacturing	Electronic and Electric equipment subject to RoHS Directive and WEEE Directive Article under REACH Products under the product safety regulation	None
Advanced textiles and fibres	Regulation (EU) No 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products	None
Coatings	Substance and mixtures under REACH Biocidal product under Regulation (EU) No 528/2012 Coating falling under Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes	None
Nanotechnology	Substance under REACH and CLP Regulation	The legal issues mentioned in the previous table.
Gels and foams	Substances and mixtures under REACH Construction Product under Regulation on construction products Products under the product safety regulation	None
High-performance polymers	Substance under REACH with specific derogations to the REACH obligations. According to Article 2(9) of REACH polymers do not have to be registered, but according to Article 6(3) of REACH, the monomer substance(s) and other substances of the polymers that have not already been registered by an actor up the supply chain, are to be registered if both the following conditions are met: - the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) (i.e. free or unbound monomers shall not be considered when checking this condition); - the total quantity of such monomer substance(s) or	The European Commission may according to Article 138(2) of the REACH Regulation present legislative proposals with requirements for the registration of polymers once a practicable and cost-effective way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established. Such criteria have not yet been established. Furthermore, the definition of

Category	Classification and coverage under EU legislation	Potential legal issues
	other substance(s) makes up 1 tonne or more per year (the total quantity in this context is the total quantity of monomer or other substance ending up in the final polymer unbound or chemically bound to the polymer)	polymers under REACH may not be adequate for high-performance polymers
Light alloys	Alloys are considered as special mixtures under REACH (Annex I(0.11)), they are not subject to registration as such but the alloying elements are. Components not important for the properties of alloys can be considered as impurities and do not need a separate registration dossier	None

Conclusions

It has been possible to develop a preliminary qualitative inventory of nanomaterial releases to five media: air, land, water, recycling and waste disposal for 188 engineered nanomaterials. Building on this analysis, a preliminary quantitative inventory was developed for 12 priority nanomaterials.

Overall, the majority of EU pieces of legislation analysed under this study do not currently adequately address the nanoscale properties of nanomaterials, and any potential hazards which could be associated with these nanoscale properties. One of the main reasons is that the REACH and CLP Regulations do not effectively identify and generate information on nanomaterials, whereas a great deal of downstream environmental legislation (e.g. waste, water, air emissions) relies on these two instruments to trigger their risk management measures for hazardous chemical substances.

Furthermore, at the time of writing this report there are still scientific knowledge gaps on nanomaterial toxicity and behaviour in environmental media which impedes an effective implementation of the EU environmental acquis for such chemical substances. Some pieces of EU legislation have recently been amended to address potential risks from nanomaterials (e.g. ROHS Directive, EU ecolabel criteria decisions, Biocidal Products Regulation, a number of EU food laws, the Cosmetics Regulation). As yet, however, there is no apparent consistent approach across the all EU acquis on the regulation of nanomaterials.

For example, the EU “Recommendation on the definition of a nanomaterial” (2011/696/EU) is a useful reference point for defining nanomaterials, although it presents some practical issues. However, despite the existence of this definition, there is no consistency in the definitions and terms used across the EU legislation to characterise nanomaterials (e.g. nanoforms, substances of very small size or with a very small internal or surface structure, particle size), in part because the recommendation is not legally binding and in part because some of the legally binding definitions were introduced prior to the recommendation. This leads to potential legal uncertainties and different interpretations at the implementation phase.

A second objective of this report was to compile and develop information on advanced materials. Advanced materials can be categorized in a number of different ways e.g. by industry, by application or by a material sub-group and there is no agreed single categorisation system for advanced materials. The DAMADEI system appears to be the most useful means of addressing advanced materials.

In the context of regulatory coverage of advanced materials, it is particularly important to understand whether advanced materials or a specific category of advanced materials e.g. nanomaterials and high-performance polymers would be covered by existing EU legislation definitions. For instance, the definition of polymers under REACH may not be adequate for high-performance polymers that have been modified and reinforced with bio-fibres and/or nanocharges that result in materials with very advanced properties. A substantial effort is needed in order to ensure that existing definitions cover relevant categories of advanced materials. Limited or no regulatory coverage issues are foreseen if they do fall under existing definitions, whereas it might be unclear how advanced materials are regulated, if they do not. A preliminary analysis identified some regulatory issues with Advanced Materials which would need to be resolved in due course.

Recommendations

The inventory developed as part of this project relied on the French database of nanomaterial manufacture and imports. The development of a Europe-wide database would bring advantages for future inventory and environmental risk studies. It is recommended that consideration should be given to the development of such a database. It would be helpful for any such database to provide quantitative data on the end-use of nanomaterials covered in the database.

It is recommended that attention is given to addressing the gaps identified in the regulatory review to ensure appropriate regulation of nanomaterials in the environment.

Test methods are fundamental to identifying the nano-aspects of the materials as well as any hazards or risks resulting from the nanoscale material structure. Available test methods should be reviewed and, where relevant, updated as soon as possible, and new methods should be developed addressing gaps in the test methods.

A better overview is needed of the current annual manufacturing, production and commercialization of advanced materials in general and the different categories of advanced materials. This could be included in, for instance, the Key Enabling Technology Observatory's annual reporting. Except for nanomaterials, it is not at this point in time possible to identify any risks that might be associated with specific categories of advanced materials. Further expert consultation and stakeholder engagement is needed in order to understand what the risks might be and how they might best be explored and handled.

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Appendices

Abbreviations

Abbreviation	Meaning
AM	Advanced Material
BAT	Best Available Techniques
BPR	Biocidal Products Regulation
BREF	Best Available Techniques (BAT) Reference Document
CLP	Classification, Labelling and Packaging
COMAH	Control of Major Accident Hazards
COMMPS	Combined Monitoring-based and Modelling-based Priority Settings
DNA	Deoxyribose nucleic acid
DTU	Technical University of Denmark
DWCNT	Double walled carbon nanotubes
ECHA	European Chemicals Agency
ELV	Emission Limit Value
ENM	Engineered Nano Material
EoLV	End of Life Vehicles
EQS	Environmental Quality Standard
EMEP/EEA	European Monitoring and Evaluation Programme/European Environment Agency
EU	European Union
EWC	European Waste Catalogue
IED	Industrial Emissions Directive
IDIS	International Dismantling Information System
IPPC	Integrated Pollution Prevention and Control
JRC	Joint Research Centre
KET	Key Enabling Technology
MSF	Marine Strategy Framework
MWCNT	Multi walled carbon nanotubes
NIL	Nanoparticle information library
NIOSH	National Institute for Occupational Safety and Health
NM	Nanomaterial
NEMS	Nanoelectromechanical Systems
PHS	Priority Hazardous Substances
PRTR	Pollutant Release and Transfer Register
OECD	Organisation for Economic Co-operation and Development

Abbreviation	Meaning
PPP	Plant Protection Products
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SAS	Synthetic Amorphous Silica
SCENIHR	Scientific Committee On Emerging And Newly Identified Health Risks
SWCNT	Single walled carbon nanotubes
T	Tonnes
UWWTD	Urban Waste Water Treatment Directive
WEEE	Waste Electrical and Electronic Equipment

Key definitions

Term	Meaning
Bulk material	The term "bulk" is used to refer to all non-nano species of a substance which is also encountered as a nanomaterial.[1] See also "size unspecified material"
Engineered nanomaterial	Engineered nanomaterial: An engineered nanomaterial is an intentionally manufactured material, containing particles, in an unbound state or as an aggregate or as an agglomerate, which conforms with the definition of a nanomaterial. "Intentionally manufactured" means that the material is manufactured to perform or fulfil a specific function or purpose.
Environmental nanomaterial	A nanomaterial which has been formed in, or passed into, an environmental medium, including discharge to the atmosphere, on land or in soils, or in waters.
Nanoform	Nanoforms are subgroups of a given nanomaterial, sharing a common size, shape and/or surface chemistry
Nanoparticle	A particle is a small object that behaves as a whole unit with respect to its transport and properties. A nanoparticle is a particle which conforms with the EU definition of a nanomaterial
Nanotechnology	Those areas of science and engineering where phenomena that take place at dimensions in the nanometre scale are utilised in the design, characterisation, production and application of materials, structures, devices and systems
Size-unspecified material	A material for which the size-related properties are unspecified. Such a material may or may not contain or comprise nanomaterials. See also "bulk material".

[1] Taken from: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_030.pdf

1 Introduction

1.1 This document

Ricardo Energy & Environment, in partnership with subcontractors Milieu Consulting and the Technical University of Denmark (DTU) was commissioned by the European Commission to carry out a project entitled "*The preparation of the third regulatory review on nanomaterials - environmental legislation*", specific contract number 070201/ENV/2015/SI2.716613/ENV.A3, Commission reference ENV.C.3/ETU/2015/0030. This document is the Draft Final Report for this contract.

We acknowledge the funding, support and guidance received from the project steering group led by DG Environment (DG ENV). We are also grateful for the input from a wide range of stakeholders to this project both during the consultation phase, and as participants in the Expert Workshop held in June 2016.

1.2 Study context

1.2.1 Introduction

1.2.1.1 What are nanomaterials?

The EU definition of nanomaterials is set out in Recommendation 2011/696/EU, as follows:[2]

> *"A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.*
>
> *"In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.*
>
> *"By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."*

The Commission definition recognises three general types of nanomaterials: naturally occurring particles, incidental nanoparticles and engineered nanomaterials (ENM).[2] The latter type – engineered nanomaterials, or man-made nanomaterials are the key focus of this study. ENMs find use in multiple applications such as advanced materials, display technologies, electronics, nutrition, cosmetics and medical drug design.

Nanomaterials can be in the form of particles at the nanoscale, or their agglomerates or aggregates. Nano-scale properties of the surface or internal structures of bigger particles or materials can also affect material properties, although these would lie outside the EU definition of nanomaterials and are therefore not covered in this report.

Since its adoption, this definition has been used in EU legislation including the Biocidal Products Regulation, in proposals for new legislation such as the Medical Devices Regulation and as part of the ongoing process of amending legislation in force in 2011 or prior to this. The 2011 Recommendation envisaged a review process of the above definition by 2014. The JRC has collected and analysed feedback from stakeholders on experiences working with the above definition, with the final report in the series published earlier in June 2015. The JRC findings suggested that some modifications could be introduced to the definition, accompanied by guidelines on its implementation.

Nanomaterials are subject to the same environmental and health protection regulations as any substance/material. Nanomaterials are not intrinsically more or less hazardous than other chemicals. However, some nanoparticles may have different environmental effects or interact with living organisms in a specific way, reaching different cells and organs to those accessed by a corresponding bulk material. They may also have different properties than bigger particles of the same material. Therefore, there may be a need for specific provisions in regulations to ensure that

[2] European Union, "Recommendation on the definition of a nanomaterial" (2011/696/EU)

those differences are properly addressed when generating relevant hazard or exposure information, carrying out risk assessment and management, or when providing information to consumers.

Some key terms are defined as follows:

- Nanoform: a subgroup of nanomaterials, sharing chemical identity, common size, shape and/or surface chemistry.
- Bulk material: The term “bulk” is used to refer to all non-nano species of a substance which is also encountered as a nanomaterial.
- Nanoparticle: a particle is widely defined as a small object that behaves as a whole unit with respect to its transport and properties. A nanoparticle is a particle which is in a size range of 1nm-100nm, consistent with the EU definition set out above.[2]
- Engineered nanomaterial: An engineered nanomaterial is an intentionally manufactured material, containing particles, in an unbound state or as an aggregate or as an agglomerate, which conforms with the definition of a nanomaterial as set out above.[3] “Intentionally manufactured” means that the material is manufactured to perform or fulfil a specific function or purpose.
- Environmental nanomaterial: a nanomaterial which has been formed in, or passed into, an environmental medium, including discharge to the atmosphere, on land or in soils, or in waters.
- Size-unspecified material: a material for which the size-related properties are unspecified. Such a material may or may not contain or comprise nanomaterials.

1.2.1.2 What are advanced materials?

Advanced materials do not yet have a formal definition similar to that developed for nanomaterials. The term “advanced materials” can be interpreted to refer to all new materials and modifications to existing materials to obtain superior performance in one or more critical characteristics.[4] The use of nano-scale properties to enhance functionality is an important aspect of many advanced materials.

Advanced materials can be broadly described as novel materials engineered to offer high technical performance and added value compared to conventional materials. Some of the key classes of advanced materials are advanced ceramics, polymers, metals and composites. Since the initial developments in the field of advanced materials, there has been an immense progress in the development of new materials applicable to almost any technology sector. They are now being integrated into components and systems, enabling new designs and improved performance of products. In addition to highly desirable properties, advanced materials may offer environmental benefits through the life cycle – for example, lower use of raw materials and energy in their production, longer lifetime, and better recycling opportunities.

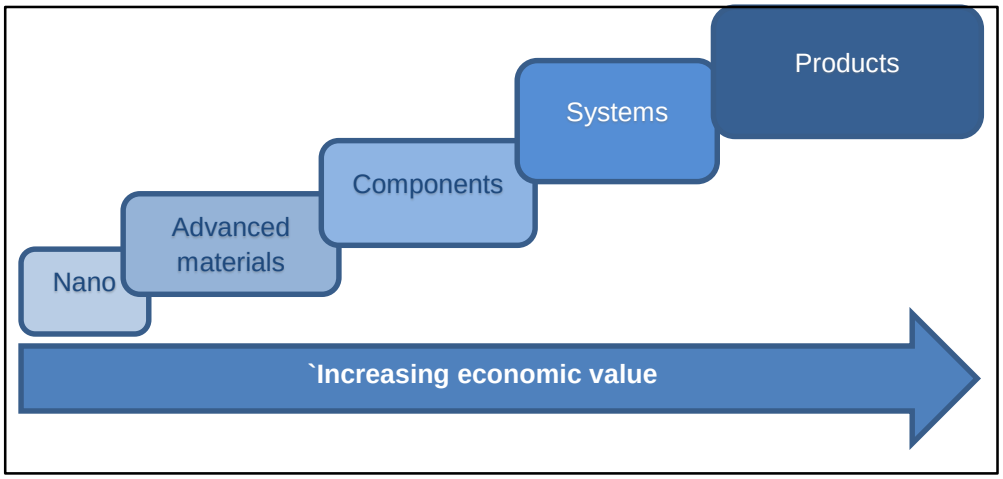
1.2.1.3 What is nanotechnology?

Nanotechnology is the term given to those areas of science and engineering where phenomena that take place at dimensions in the nanometre scale are utilised in the design, characterisation, production and application of materials, structures, devices and systems.[5] Nanotechnology is a key enabling technology (KET), providing the basis for further innovation and new products;[6] see Figure 1. The development of new nanomaterials and advanced materials are both highly innovative areas, providing opportunities for economic growth by revolutionising current manufacturing techniques, across a wide range of industrial areas such as energy, transport and health.

Nanomaterials and advanced materials are essential elements of the high value added products and manufacturing processes. However, not all advanced materials require nanoscale engineering. The key focus of this study is on those utilising nanoscale technologies.

[3] Commission Delegated Regulation (EU) No 1363/2013 of 12 December 2013
[4] Advanced Materials Research Trends, Ed. Levan V. Basbanes, Nova Publishers, 2007
[5] http://ec.europa.eu/health/scientific_committees/opinions_layman/en/nanotechnologies/l-3/1-introduction.htm
[6] See https://ec.europa.eu/programmes/horizon2020/en/area/key-enabling-technologies

Figure 1: Nanomaterials and advanced materials as key enabling technologies (adopted from Hynes A. 2015[7])



The progression shown in Figure 1 suggests that increasing numbers of components and systems can be expected to be engineered at nano-scale in the future. This is discussed further in Section 1.2.3. However, product-based legislation and environmental legislation in relation to hazardous substances is typically focused on the macro-scale properties of size-unspecified material – for example, by consideration of bulk concentrations. One of the key focuses of this study was to analyse the effectiveness of regulation in dealing with potential issues associated with nano-scale characteristics of substances, materials, components, systems and products.

1.2.1.4 Market context

The global market for nanomaterials has been estimated at 11 million tonnes per year, with an estimated market value of Euro €20bn.[8] The European Commission has estimated that around 300,000-400,000 people were directly employed in the nanotechnology sector as of 2014. Globally, the nanotechnology industry is forecast to reach US$76 billion (Euro €68 billion) by 2020.[9] The table below presents a summary of key markets impacted by nanoscale technologies (including but not limited to nanomaterials), demonstrating both the broad spectrum of industries affected and their economic potential.

Table 1 Markets impacted by nanoscale technology – predicted value in 2015 (Source: Materials KTN, 2010[10])

Sector	Predicted nanoscale technology impact in 2015 ($M)
Information and communications technology	41,402
Automotive	7,134
Shipbuilding	4,295
Aerospace and defence	3,768
Food and drink	3,210
Consumer goods	6,225
Life sciences	5,670
Textiles	2,170

[7] Hynes A., 2015, Turning KETs into products through value chain based open innovation: Successes and lessons from Ireland, Presentation at the NanoForum 2015.
[8] http://ec.europa.eu/growth/sectors/chemicals/reach/nanomaterials/index_en.htm
[9] Research and Markets, "Global Nanotechnology Market Outlook 2022," December 2015; see http://www.researchandmarkets.com/reports/3512791/global-nanotechnology-market-outlook-2022
[10] Materials KTN, 2010, Nanotechnology: a UK Industry view, Available online: http://www.matuk.co.uk/docs/Nano_report.pdf

Energy	3,615
Environment and water	3,885
Construction	1,672
Brand and product security	2,650
Total	**85,696**

1.2.1.5 Regulation of nanomaterials

Regulation of man-made nanomaterials is challenging as different nanoforms of the same chemical substance can have different properties. Additionally, transformations such as aggregation (where particles are held together by relatively strong forces) agglomeration (where particles are held together by weaker forces for example electrostatic forces or surface tension) and formation of surface layers on nanomaterials may further influence properties including potential hazard and risk.

EU legislation such as Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), has been driving innovation through the requirements to replace materials which pose significant risks of harm to human health or the environment. Together with their improved technical and functional performance, reduced environmental hazards can also be seen as one of the drivers for development of Advanced Materials.

However, most of the existing regulations were designed to deal with the risks of conventional materials. For the new advanced materials being developed and entering commercial markets, it is often unknown how these will behave once released to the environment. It is important to ensure that regulatory regimes are fit for purpose to deal with potential risks posed by the ongoing development and use of nanomaterials, and future development of advanced materials.

1.2.2 Nanomaterials lifecycles and potential environmental releases

When evaluating potential human and environmental exposure to nanomaterials and their fate in the environment it is important to understand the physicochemical properties of the substance but also what transformation it undergoes once released to the environment. The physical properties affecting the environmental fate of nanomaterials in the environment are size, shape, specific surface area (surface area per unit of mass), tendency to agglomerate, number size distribution, surface characteristics (e.g. how smooth it is), structure (e.g. presence of crystals or crystal defects), and the rate of dissolution. Chemical properties affecting fate of nanomaterials in the environment are molecular structure, purity (also presence of additives), whether it is held in a solid, liquid or gas, its surface chemistry and solubility (whether the molecules are polar, hydro or lipophobic).

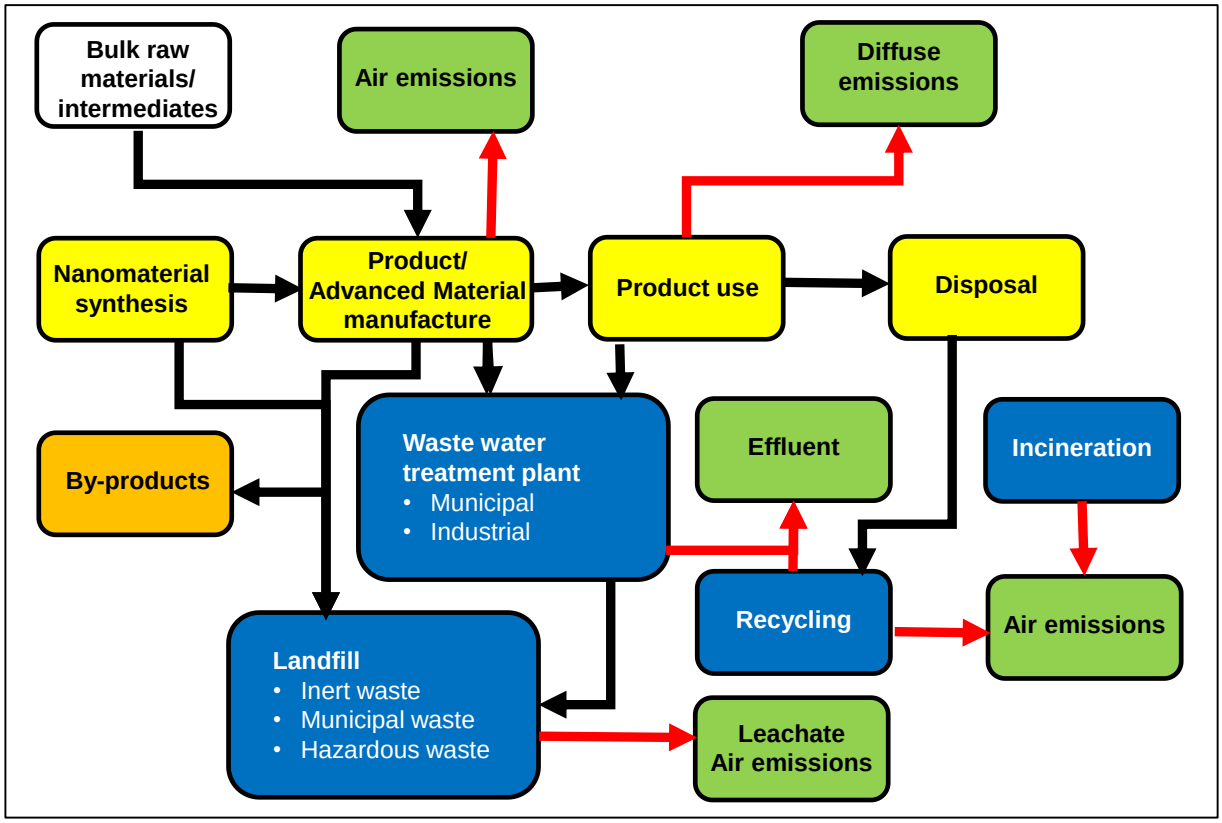
The reactivity of nanomaterials is enhanced compared to the bulk materials due to the higher surface area to volume ratios and higher rates of dissolution. Because of their unique properties, standard environmental fate and transport models are typically not applicable. The heterogeneous nature of nanomaterials means that there is significant variation in fate and behaviour between nanoforms and bulk forms of the same substance, and between different nanoforms of a single substance. Hence it is difficult and inappropriate to generalise on the environmental fate of the nanomaterial based on the properties of bulk or size-unspecified materials. This has particular relevance for the risk-based regulation of nanomaterials (e.g. under REACH), as it is important to ensure that the specific properties of nanomaterials are taken into account during the regulatory processes.

The report informing the secondary regulatory review of environmental legislation in relation to nanomaterials summarised different stages of product lifecycle at which nanomaterials could enter the environment. Nanomaterials can enter the environment during their synthesis, production, product use or disposal. At synthesis and production stage the main pathway for environmental exposure is via the waste stream. At production and product use stage nanomaterials can enter the environment through direct emissions to air, or via wastewater. At the end of the product life, exposure pathway depends on whether it is disposed or recycled.

During product use and disposal, the level of environmental releases will depend on the mobility of the nanoparticles within the product or waste. If the nanoparticles are within a solid matrix, the releases are expected to be lower than from, for example, liquids. The risks levels associated with presence of nanomaterials in the environment will be higher for liquid or gaseous state nanomaterials,

which would be more readily released to airborne or waterborne exposure pathways, and have relatively high contamination potential.

Figure 2: Environmental exposure pathways for nanomaterials (Adapted from Milieu, 2011[11])



Understanding of the toxicity and ecotoxicity of nanomaterials is still an area of ongoing research. Ensuring the applicability of OECD test guidelines, which are the global regulatory test guidelines for chemicals, have repeatedly been highlighted as a priority to enable regulatory safety testing of nanomaterials. The OECD Working Party on Manufactured Nanomaterials has recently finalised a testing programme to clarify how far the OECD Test Guidelines are applicable, which modifications would be relevant, and needs for nano-specific test guidelines. The testing programme included the following nanomaterials: Fullerenes (C60); Single-walled carbon nanotubes (SWCNTs); Multi-walled carbon nanotubes (MWCNTs); Silver nanoparticles; Titanium dioxide; Cerium oxide; Zinc oxide; Silicon dioxide; Dendrimers; Nanoclays and Gold nanoparticles. The dossiers are available at Ref. 12.

1.2.3 Emerging trends in nanotechnology

According to Roco,[13] the development of nanomaterials and nanotechnologies can be divided into five generations i.e. passive structures, active nanostructures, integrated nanosystems, heterogeneous molecular nanosystems and finally the convergence of various types of technologies into nanotechnology. The Staff Working Paper that accompanied the second Regulatory Review found that 2-4 generations of nanomaterials were either at research and development (R&D) stage or at an early stage of market development and did not consider these further due to limited information being available.

[11] Milieu, 2011, Review of Environmental Legislation for the Regulatory Control of Nanomaterials
[12] http://www.oecd.org/chemicalsafety/nanosafety/dossiers-and-endpoints-testing-programme-manufactured-nanomaterials.htm
[13] Roco, M.C. 2015. Nanotechnology Path to Sustainable Society. SUN-SNO-GUIDENANO Sustainable Nanotechnology Conference March 9, 2015. Available online on: http://www.susnano.org/images/SNO-SUN15/Plenary1_NNI_15-0309_NanoPathToSustanability_Roco%20@SNO_65sl.pdf. [Accessed August 10, 2016].

Based on the review of the scientific and non-scientific literature as well as the stakeholder consultations that we have performed as part of preparing this report, it seems clear that discussing generations of nanotechnology is no longer as meaningful as it once was, as emerging trends in nanotechnology are not so much focus on novel nanomaterials, but rather integrated systems and solutions[14]. Three overall trends have been identified by Wohlleben et al.[14] The first trend relates to the fact that one cannot add a given novel nanomaterials and then expect to enhance the mechanical, optical, electrical and barrier properties of the products. Rather the size, shape and interaction of the nanomaterial have to be designed to interact with the surrounding matrix into an integrated material system in order to be functional and achieve the desired properties. The second trend is moving away from nanoparticles and instead focusing on developing nanostructures such as nanopores and surfaces with nanothick patterns to achieve superior material properties. Finally, a third trends seems to be that nano-enabled products have to perform well in regard to not only superior performance, but also in regard to costs, safety and sustainability in order to make it beyond niche applications as traditional – and less novel – materials can be obtain at much lower costs and are associated with less regulatory uncertainty.[14]

1.3 Aims and objectives of the study

The second regulatory review was prompted by the European Council to review whether legislation is fit for purpose for regulation of nanomaterials. This work concluded that the legislation is generally fit for purpose, and that there is no reason why the existing legislation cannot be used to address environmental discharges of nanomaterials, and associated risks, if any. The second review identified that some adjustments may be required, and identified REACH as the major piece of legislation which would need to be adjusted, along with downstream waste regulation.

For REACH, the Commission has undertaken a review of the technical annexes and is considering modifications to ensure their applicability to nanomaterials (amongst other revisions). That process is not yet complete, but it is anticipated that a vote for adoption may take place in early 2017. It was already indicated by the Commission that the changes will not take mandatory effect prior to the REACH 2018 registration deadline for existing (phase-in) substances in low tonnages.

The present study objective as set out in the Terms of Reference is as follows:

> *"The study aims to compile and develop information on nanomaterials in the environment and explore further the implementation challenges identified in 2012, for the restricted scope of environmental legislation. Within this scope, the emerging challenges of a wider family of advanced materials and speciality chemicals that exploits nanoscale should be identified, e.g. nanostructured materials, catalysts and photocatalysts, bio-materials, nano-bio complexes and next generation nanomaterials.*
>
> *The underlying objective is to provide information that will:*
>
> - *Compile information supporting the third regulatory review on nanomaterials. As the content of the review has not yet been prepared and agreed between the services, the tasks below are prepared in the anticipation of likely themes;*
> - *Directly support development and effective implementation of environmental legislation."*

At present, existing work programmes and commitments are subject to review and to date no agreement has been reached on the scope of the Third Review. Nevertheless, DG ENV expects to use information resulting from this contract in the Third Regulatory Review, although at this stage, it is not possible to say when that will be.

Hence, the study aims and objectives were as follows:

1. To review the conclusions of the second regulatory review in the light of ongoing developments, as they relate to relevant EU regulations.

[14] Wohlleben, W. et al. 2016. Nano-Enabled Products. In: Metrology and Standardization of Nanomaterials: Protocols and Industrial Innovations. Eds.: Mansfield, E., Kaiser, D., Fujita, D., Van de Voorde, M. Heidelberg: Wiley

2. To provide information that will support the third regulatory review on nanomaterials by reviewing environmental legislation,.
3. To support the development and effective implementation of environmental policy and legislation in respect of nanomaterials.

1.4 Contents of this report

This report is structured as follows:

- The overall study approach and context is set out in Appendix 1.
- Chapter 2 provides a preliminary evaluation of emissions of nanomaterials to different media (air, water, land, recycling and waste disposal). Qualitative emissions estimates are then prioritised by reference to information on human health hazards.
- Chapter 3 provides a review of progress on the application of environmental and other key legislation to nanomaterials.
- Chapter 4 sets out a prospective view on future developments in advanced materials, and challenges for environmental legislation.
- Chapter 5 sets out the study conclusions.
- Chapter 6 provides the study recommendations.

2 Compilation of information on emissions of man-made nanomaterials

2.1 Introduction

The EU spending on research and development in nanotechnology has increased in the last decade, from the EUR 1.3bn under the Sixth Framework Programme (2002-2006) to EUR3.5bn under the Seventh Framework Programme (2007-2013). Under the existing Horizon 2020 EUR 3.85bn have been allocated to 'nanotechnologies, advanced materials and advanced manufacturing and processing' (running up to 2020). Nanotechnology is additionally supported in the EU by governments of individual Member State governments, but also globally by both public and private sector investment. Advanced research and development in the area of nanomaterials will result in changes to the types of nanomaterials used, their properties and their future uses. This in turn may create a changes in the quantity, nanoform and composition of environmental releases, human exposure and the overall risks related to the presence of manufactured nanomaterials in the environment.

Following release to the environment, nanomaterials may undergo a range of transformations which may affect their transport properties, reactivity, and toxicity. Such transformations may include acquisition of organic coatings in the environment (e.g., natural organic matter), aggregation, weathering (including redox reactions), and biological transformations.[15] Evaluation of environmental transformations did not form part of this study, but any such transformations would be expected to materially affect the environmental and health risks associated with nanomaterials released to the environment.

Task 1 of this study was targeted at capturing the existing knowledge on the current use of nanomaterials and their presence in the environment, and predicting how these could change in the next 5 to 15 years. Information was collected on over 100 man-made nanomaterials to estimate potential future trends of releases to the environment. More detailed assessment was then undertaken for a subset of these nanomaterials.

Methods for developing environmental release inventories are well established and widely used in support of European policy and legislation. The European Pollutant Release and Transfer Registry is an example of an established inventory, which contains robust data on releases of individual substances to a range of environmental media (air, land, water), as well as data on waste transfers. Transparent application of robust inventory techniques is a key component of critical European and international instruments, including the National Emissions Ceiling Directive, the Convention on Long-Range Transboundary Air Pollution and the Kyoto Protocol. In recognition of the importance of these initiatives in securing ongoing improvements in the local, regional and global environment, the European Commission continues to support the development and application of state-of-the-art inventory methodologies,[16] although to date these have not addressed manufactured nanomaterials.

Our approach was therefore to use current methodologies to create an inventory of 100 priority man-made nanomaterials. This was designed to draw on information on key properties, current presence on the EU market and the most important uses of the substance that can lead to environmental releases and subsequently human exposure via the environment. The study is not designed to evaluate human exposure, for which other pathways such as via the food chain or use of pharmaceuticals or cosmetics may be important, as well as environmental exposure pathways. Similarly, the study does not evaluate environmental exposure. However, the information developed in this study may be useful to inform human and environmental exposure analyses.

Once the base year data on the nanomaterials was collated, an estimate was made of how releases of the materials to the environment are likely to evolve moving forward.

[15] Gregory V. Lowry, Ernest M. Hotze, Emily S. Bernhardt, Dionysios D. Dionysiou, Joel A. Pedersen, Mark R. Wiesner and Baoshan Xing “Environmental Occurrences, Behavior, Fate, and Ecological Effects of Nanomaterials: An Introduction to the Special Series,” J. Environ. Qual. 39:1867–1874 (2010)

[16] For example, update to the EMEP/EEA Guidebook on Emission Inventory Compilation, recently completed by a team led by Ricardo Energy & Environment, as part of a targeted project funded by the European Commission

For a subset of 10-20 nanomaterials, a more quantitative estimate of future releases was developed, providing supporting evidence and additional observations used to characterise anticipated future trends. This will provide the Commission with evidence to support the prioritisation of any actions as part of ongoing and future legislative developments.

2.2 Methodology

2.2.1 Semi-quantitative inventory

The French reporting scheme on nanomaterials was used as the starting point for developing a prioritised qualitative release inventory.[17] The French registry provided the most robust basis for a nanomaterials inventory, for the following reasons.

(a) The French registry is supported by legislation and enforcement and is therefore considered to comprise a reasonably complete profile of nanomaterial production in France. It is the only such registry in Europe

(b) The inventory provides quantitative information on nanomaterial manufacture, and also provides an indication of the uses to which these materials were put. Both these aspects are important for developing a qualitative inventory

(c) As a relatively large country in Western Europe, France can be considered as reasonably representative of the European Union as a whole, at least for the purpose of development of a qualitative inventory.

The French registry has been in force since 2013. In the first two years, it was found to be subject to over-declaration as declarers were concerned to avoid under-declaration. This has improved since the commencement of the registry, but it is possible that over-declaration has continued into the 2015 registrations. The French registry provides for reporting of intentionally produced nanomaterials only. Summary data from the French registry for 2015 on the quantities of nanomaterials produced in France, and imported into France in 2015 was used for this assessment.

The first step was to develop indicative production profiles for nanomaterials. Once the list was prepared based on FR registry, the first step of the assessment was to develop indicative profiles for “Inherent”, “Established” and “Novel” materials, defined as follows:

- “Inherent” nanomaterials are those which have been developed prior to understanding or regulation of nanomaterials. While the nano-scale properties may be important in the properties of such materials and products, they are not novel materials and were not specifically developed as nanomaterials. Examples include some pigments which rely on the nano-scale properties of the pigment to achieve the required colour characteristics.[18]
- “Established” nanomaterials are those which have been developed specifically for their nanoscale properties, but which are now well established. Usage can be expected to grow relatively slowly in future. Examples include nano-silver.
- “Novel” nanomaterials are those which have been recently developed or which are under development, and for which usage may be expected to grow more rapidly in the future. Examples include nanoscale drug delivery systems

The profiles were designed to represent the evolution in production of manufactured nanomaterials over time, referenced to a baseline of 100 in 2015. This enabled nanomaterial production and use activity for years other than 2015 to be estimated. “Inherent” nanomaterials were assumed to follow past trends in GDP for the EU.[19] Future production and use of inherent nanomaterials was assumed to grow at the average annual growth in EU GDP over the period 2000 to 2015, an increase of 1.43% per year.

No independent data on past production trends for Established or Novel nanomaterials was identified. An evaluation of market trends suggested that nanomaterial production across a range of different

[17] Ministère de l'Environnement, de l'Énergie et de la Mer (2015), “Éléments issus des déclarations des substances à l’état nanoparticulaire: Rapport d’etude 2015”, available from www.r-nano.fr
[18] Communication from BASF, review of Material Safety Data Sheets for 15 pigments, 2016
[19] http://databank.worldbank.org/data/reports.aspx?source=2&country=EUU

sectors over the period c.2014 to c.2020 would increase in the range of 9% to 29% per year.[20] This was combined with the project team's understanding of likely trends in nanomaterial production to give an assumed profile for nanomaterial manufacture over the period 2000 to 2035. This stage in the process was subject to significant uncertainty. Three separate profiles were produced to represent likely growth of "Inherent", "Established" and "Novel" nanomaterials. These profiles are shown in Table 2.

Table 2: Indicative nanomaterial production profiles (quantity manufactured per year relative to 2015 = 100 for each nanomaterial)

Year	Inherent	Established	Novel	Year	Inherent	Established	Novel
2000	83	5	0	2018	104	130	160
2001	85	10	0	**2019**	106	140	200
2002	86	20	0	**2020**	107	150	250
2003	87	30	0	**2021**	109	160	300
2004	89	40	0	**2022**	110	170	400
2005	91	50	0	**2023**	112	180	500
2006	94	55	0	**2024**	114	190	700
2007	97	60	0	**2025**	115	200	1000
2008	98	65	10	**2026**	117	210	1200
2009	93	70	20	**2027**	119	220	1400
2010	95	75	50	**2028**	120	230	1500
2011	97	80	60	**2029**	122	240	1500
2012	97	85	70	**2030**	124	250	1500
2013	97	90	80	**2031**	126	260	1500
2014	98	95	90	**2032**	127	270	1500
2015	100	100	100	**2033**	129	280	1500
2016	101	110	120	**2034**	131	290	1500
2017	103	120	140	**2035**	133	300	133

The French registry was then analysed to categorise the use(s) of each manufactured nanomaterial. The majority of entries in the database are provided with a description of the use(s) of the materials. Where no usage description was provided, an internet search was carried out to characterise typical uses of each material. This enabled manufactured nanomaterial uses to be classified into the following categories:

a) Durable material – e.g. vehicle component. Nanomaterials encapsulated in a durable material can be expected to have limited release pathways over a relatively long product lifetime.

b) Short lifetime material – e.g. ink or toner. Nanomaterials used in such materials are expected to be released into the environment during consumer use.

c) Fuel additive. Similarly, nanomaterials used as a fuel additive are expected to be released into the atmosphere in exhaust fumes during use.

d) Cosmetic. Nanomaterials used in cosmetics will be released to the environment immediately after use, typically through washing (resulting in a transfer to water treatment) or wiping (typically resulting in the production of waste materials which are handled as household waste)

[20] German Federal Ministry of Education and Research, "nano.DE-Report 2013: Nanotechnology in Germany today," October 2014

e) Textile. Nanomaterials used in textiles are released to the environment over the lifetime of the product, e.g. during wearing and washing of clothes. Nanomaterials not used in this way will enter a recycling or waste treatment/disposal pathway.

f) Construction material. Nanomaterials encapsulated in a construction material can be expected to have very limited release pathways over a long product lifetime which may typically extend over decades.

g) Food additive. Nanomaterials used as food additives are expected to be released into the environment during consumer use, typically into wastewater treatment or solid waste management pathways.

h) Research and Development material. Nanomaterials used for research and development are likely to be utilised and disposed of soon after production. Waste management procedures can be expected to be effective in this sector.

i) Pharmaceutical. Nanomaterials used in pharmaceutical products are expected to be released into the environment during consumer use, typically into wastewater treatment or solid waste management pathways.

j) Biocides and Plant Protection Products (PPP). Nanomaterials used in biocides and PPP are expected to be released into the environment during consumer use, resulting in a release to land. Subsequent wash-out into watercourses is also likely to occur.

Where a substance had more than one application, it was necessary to make an estimate of the likely breakdown in use across the different applications. This was based on the project team's expertise, as there were no other data sources to enable this breakdown to be evaluated in more detail for the full range of substances under consideration at this stage.

The development of usage profiles enabled the nanomaterials under consideration in this study to be characterised in terms of both their chemical composition, and their likely use. While it was not possible to determine the nanoforms for each nanomaterial under consideration, this was investigated in more detail for the selected priority substances (see Section 2.4). Three examples of usage profiles developed at this semi-quantitative assessment stage are given below, with the full profiles for all substances provided in Appendix 2.

Table 3: Example usage profiles

Chemical substance name	Nano form	Usage category	Estimated %
Kaolin	Hyper-platy crystals, i.e. with ratio of effective diameter of plates to thickness of 20:1 or greater. Lateral dimension typically >= 200 nm. Generally used without further surface treatment	Paper Products: Short lifetime	53%
		Ceramics: Durable material	30%
		Refractories: Construction material	7%
		Paints & Coatings: Durable material	5%
		Rubber Products: Durable material	5%
Calcium silicate	Typically platelets about 5-10 nm thick and about 50-500 nm wide. Other nanoforms involve the formation of nanosheets from individual nanofibers with a width of c.10 nm, or spherical particles with diameter of a few 10s of nm. May be functionalised with reactants such as iodine	Elastomers, carriers, polymers, plastics: Durable material	82%
		Detergents & cosmetics: Cosmetic	9%
		Sealants: Durable material	5%
		Paints & Coatings: Durable material	2%
		Inks & toners: Short lifetime	2%
Iron oxide isostearate	Rods with short dimensions of the order of 1 nm, or spheroids in the c.80 nm size range. Isostearate used as a penetration enhancer in cosmetics	Vehicles, Machines and electronics: Durable material	20%
		Cosmetics: Cosmetic	15%
		Leather: Textile - Type 1	5%
		Fuels: Fuel additive	15%
		Lubricants & greases: Short lifetime	15%

Chemical substance name	Nano form	Usage category	Estimated %
		Dye, Food Dye, Pigment: Durable material	15%
		General Manufacturing: Durable material	15%

Having allocated the produced materials to the relevant usage categories, the next step was to estimate indicative profiles for release of nanomaterials to the environment during manufacture, use and disposal. These indicative release profiles were based on published emission factors or other relevant data where available. In cases where there were no published emission factors, emissions were estimated using the project team's best judgment. A sensitivity analysis was carried out to highlight critical assumptions for the semi-quantitative release inventory.

Emission factors were identified for manufacturing and for product use and for release to air, land, water, recycling, and waste disposal – typically either incineration or landfill. Additionally, the proportion of nanomaterial released which retains nanomaterial characteristics was estimated, as in some cases the relevant nano-scale properties of the material will be altered during use or disposal.

Emissions during manufacturing are set out in Table 4. Where a figure for the % emitted during manufacture is provided, the figures for the five release media represent how the released material is allocated to each medium. Where a figure for the % emitted during manufacture is not provided, the figures for the five release media apply directly to the manufactured quantity.

Data for textiles and biocides were estimated from the BREF note for polymer manufacturing,[21] which included data on the fraction of material released during production associated with the use of Best Available Techniques (BAT). If BAT is not applied, release rates during production could be higher than the proportions assumed for this study. An additional allocation of emissions to waste disposal from textiles manufacturing was made to reflect a proportion of approximately 10% which is not retained in the material and would be discharged to wastewater treatment.[22] Data for emissions to water and waste disposal for short lifetime materials, fuel additives, cosmetics, food additives, R&D and pharmaceuticals were taken from indicative mass balance calculations for specialty chemical production.[23] Data for emissions to air for these products were taken from the OECD Emission Scenario Document for the chemical industry.[24] Data for construction materials were estimated from the BREF note for ceramic manufacturing, which included data on product release rates associated with the use of Best Available Techniques.[25] Data for durable materials were taken from the OECD Emission Scenario Document for paints and coatings.[26]

As discussed in Section 3.4.3, the BREF notes and OECD Emission Scenario Documents do not provide data specific to nanomaterials. This introduces some additional uncertainty in the application of BREF note data to nanomaterial emissions, although it is not possible to quantify this uncertainty. ECHA provides guidance on developing emissions scenarios which was taken into account in developing generic emission factors where available.[27]

All other values were project team estimates.

[21] Polymer BREF
[22] OECD Series on Emission Scenario Documents Number 7, "Emission Scenario Document on Textile Finishing Industry," ENV/JM/MONO(2004)12
[23] Fine Chemicals Manufacture: Technology and Engineering, A. Cybulski, M.M. Sharma, R.A. Sheldon, J.A. Moulijn, 2001
[24] OECD "Emission Scenario Document on the Chemical Industry," Environment, Health and Safety Publications, No. 30 Series on Emission Scenario Documents, 2011, ENV/JM/MONO(2011)49
[25] Ceramics BREF
[26] OECD Series on Emission Scenario Documents Number 22, "Emission Scenario Documents on Coating Industry (Paints, Laquers and Varnishes) , 2009 ENV/JM/MONO(2009)24
[27] http://www.oecd.org/chemicalsafety/risk-assessment/introductiontoemissionscenariodocuments.htm

Table 4: Assumed emissions during manufacturing

Manufacturing emissions	% emitted during manufacture	Medium				
		Air	Land	Water	Recycling	Waste disposal
Durable material	n/a	0.044%	0%	0.26%	0%	4.2%
Short lifetime	1.6%	6%	0%	30%	0%	64%
Fuel additive	1.6%	6%	0%	30%	0%	64%
Cosmetic	1.6%	6%	0%	30%	0%	64%
Textiles	n/a	0.0017%	0%	0.0025%	0%	10.3%
Construction material	0.7%	0%	0%	5%	50%	45%
Food additive	1.6%	6%	0%	30%	0%	64%
R&D	1.6%	6%	0%	30%	0%	64%
Pharmaceutical materials	1.6%	6%	0%	30%	0%	64%
Biocide	n/a	0.0017%	0%	0.0025%	0%	0.29%
% of emitted material in nanoform		100%	n/a	10%	100%	100%

Table 5 and Table 6 sets out the estimated emissions during product use and at end of life. The values given represent the proportion of material remaining in use which is released to each medium per year. The emission factor for cosmetics to air was taken from the EMEP EEA guidebook,[28] Chapter 2.D.3.i (use of chemical products) Table 3-16. As for the BREF note data, this reference does not provide data specific to nanomaterials, which introduces some additional uncertainty to the evaluation. The washout factors (i.e. proportion of nanomaterial removed by washing per year) for textiles containing nanosilver and nano-titanium dioxide were derived from Ref. 29. It was assumed that 95% of nanomaterials released during washing of textiles would be captured during sewage treatment, and would result in an emission to land. Similarly, it was assumed that nanomaterials released from cosmetic use would enter the wastewater treatment system, with 95% of released material captured and discharged to land.

All other parameters were estimated values. Emissions of food additives were estimated on the basis that food would either be ingested or enter the waste and recycling system. Following ingestion, nanomaterials would be transferred to the sewage system, followed by discharge to water, or capture in sewage sludge. Sewage sludge would be dried and digested, resulting ultimately in spreading of digested sludge to land with a small fraction possibly being discharged to the air as a component of biogas. A similar profile was assumed for pharmaceuticals, but with a higher proportion being disposed as waste rather than being consumed to reflect expected somewhat lower usage of pharmaceutical products compared to foods.

Table 5: Assumed emissions during product use and at end of life

	Air	Land	Water	Recycling	Waste disposal	Calculated Product life
Durable material	0.01%	0.02%	0.05%	2.4%	3.6%	11 years
Short lifetime	0%	2%	8%	30%	60%	Immediate use
Fuel additive	90%	0%	0%	5%	5%	Immediate use
Cosmetic	7%	60%	3%	0%	30%	Immediate use

[28] EMEP-EEA Guidebook (2013)
[29] Aiga Mackevica & Steffen Foss Hansen (2015): Release of nanomaterials from solid nanocomposites and consumer exposure assessment – A forward-looking review, Nanotoxicology, DOI: 10.3109/17435390.2015.1132346

	Air	Land	Water	Recycling	Waste disposal	Calculated Product life
Textile (silver)	0.05%	33%	1.7%	5.6%	8.4%	5 years
Textile (titanium dioxide)	0.05%	2.0%	0.1%	5.6%	8.4%	5 years
Textile (other)	0.05%	33%	1.7%	5.6%	8.4%	5 years
Construction material	0.01%	0.02%	0.05%	1.0%	1.5%	27 years
Food additive	5%	65%	20%	0%	10%	Immediate use
R&D	2%	0%	0%	0%	98%	Immediate use
Pharmaceutical	5%	50%	15%	0%	30%	Immediate use
Biocide	5%	30%	55%	0%	10%	Immediate use

Table 6: Estimated proportion of each product type and pathway emitted in nano form

Manufacturing emissions	Air	Land	Water	Recycling	Waste disposal
Durable material	20%	10%	10%	100%	100%
Short lifetime	N/a	12%	12%	100%	100%
Fuel additive	100%	n/a	n/a	100%	100%
Cosmetic	100%	10%	10%	n/a	100%
Textile	100%	10%	10%	100%	100%
Construction material	20%	10%	10%	100%	100%
Food additive	0%	10%	10%	100%	100%
R&D	100%	n/a	n/a	n/a	100%
Pharmaceutical	0%	10%	10%	100%	100%
Biocide	100%	100%	100%	n/a	100%

Having set up release parameters, each nanomaterial in the French registry was categorised into the above material types, and categorised as “established” or “novel” for the purpose of characterising likely past and future release profiles. The quantities of nanomaterials produced in France in 2015 were taken from the French database, with breakdown across different usage categories estimated as described above. The quantities of nanomaterials used in France in 2015 were assumed as a first estimate to be the same as the quantities manufactured. Quantities produced and used in other years were estimated on the basis of the usage profiles set out in Appendix 2. Applying the manufacturing and usage release factors over the product lifetimes enabled estimates to be made of the quantities of each material released to each of the five media (air, land, water, recycling, waste disposal) in 2015, 2025 and 2035.

Based on this evaluation, the annual release of each nanomaterial to each medium was estimated. A figure for Europe was estimated on the basis of the proportion of the European chemical industry in France for production releases, and on the basis of population for in-use releases. The numerical release estimates are considered to be highly uncertain in view of the number of assumptions used to reach the indicative inventory. Consequently, the specific release quantities are not listed here, but instead releases to each medium were banded as “high”, “medium”, “low” and “zero,” based on the inventory mass estimates for 2015, using the following arbitrary banding. This banding does not provide any indication of potential risk, but is used as a means to focus attention in the subsequent stages of inventory development.

- High: 98th to 100th percentile for releases to each medium
- Medium: 90th to 98th percentile for releases to each medium
- Low: Below 90th percentile for releases to each medium
- Zero release to each medium

It was found that the 98th percentile quantities were 20 to 100 times higher than the 90th percentile values, and the 100th percentile values were 20 to 40 times higher than the 98th percentile values.

2.2.2 Prioritisation

The next step was to identify typical nanoforms for each of the "high" priority materials. Relevant nanoforms were identified from databases including:

- Nanowerk database.[30] This was described as "the most comprehensive online database" in a recent review.[31]
- The DaNa2.0 database.[32]
- Manufacturer and commercial agent product descriptions.

The study terms of reference specified that 10 to 20 nanomaterials should be prioritised for more detailed assessment based on the benchmarking of the risks and the identification of nanospecific aspects in assessment or regulatory management. Release data for the key nanoforms identified from the semi-quantitative inventory was combined with information on hazards and risks to enable substance prioritisation to be carried out.

The EU has set out principles for risk profiling of nanomaterials.[33] This document considers that:

> "*The development of a widely accepted and robust methodology that would be used at the R&D stages to identify and mitigate potential human health (including occupational health) and environmental risks, associated with individual nanomaterials should be given high priority. For this purpose it is vital to develop a data bank of case histories to assess its validity.*"

However, at present, no such methodology or data bank of case histories exist. A range of alternative sources were evaluated to identify potentially valuable reference points for the evaluation of risks posed by nanomaterials.

- Nanoparticle information library (NIL)[34]
  - This provides reference information on nanoparticles which may be useful for classifying risks
- Nanomaterial registry https://www.nanomaterialregistry.org/
  - This comprises an archive of research data on nanomaterials and their biological and environmental implications, which may be useful for classifying risks
- OECD information on Safety of Manufactured Nanomaterials http://www.oecd.org/science/nanosafety/
  - This site contains useful information on the outcomes and the on-going work on manufactured nanomaterials regarding, e.g., the testing programme, applicability of OECD test guidelines, as well as reports from expert meeting on physical/chemical properties, categorization, genotoxicity, inhalatory testing, and environmental end-points.
  - Information on specific nanomaterials is available via: http://www.oecd.org/chemicalsafety/nanosafety/dossiers-and-endpoints-testing-programme-manufactured-nanomaterials.htm
- eNanoMapper database[35]
  - This is a database solution which provides diverse data on nanomaterials. While it would potentially be useful for a study such as this, it is at present at pilot stage only.

[30] http://www.nanowerk.com/nanomaterial-database.php
[31] Wendel Wohlleben, Christian Punckt. Jasmin Aghassi-Hagmann, Friedrich Siebers, Frank Menzel, Dr. Daniel Esken, Claus-Peter Drexel, Dr. Henning Zoz, Dr. Andreas Weier, Martin Hitzler, Andrea Ines Schäfer, Luisa De Cola, Eko Adi Prasetyanto, "Nano-Enabled Products", in "Metrology and Standardization of Nanomaterials: Protocols and Industrial Innovations", Wiley Heidelberg, 2016
[32] DeChema BV / Karlsruhe Institute of Technology, DaNa2.0 (Data and knowledge on Nanomaterials) www.nanopartikel.info
[33] http://ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterials/en/l-3/7.htm
[34] http://nanoparticlelibrary.net/
[35] http://www.beilstein-journals.org/bjnano/single/articleFullText.htm?publicId=2190-4286-6-165

- The DaNa 2.0 database
    - This is a reference point for a wide range of third party information on nanomaterials.

Additional information on the health risks of the nanomaterials identified in the “high” potential release category was sourced from the literature review. Based on this information, 12 nanomaterials were identified as being the highest priority for development of a more quantitative release inventory.

2.3 Semi-quantitative release inventory

The semi-quantitative release inventory developed for this project is set out in Appendix 3. Each substance identified in the French registry is classified as high, medium, low or zero release to each of the five media, for 2015, 2025 and 2035.

The following nanomaterials were identified as having a potentially “high” release to one or more medium. These substances were taken forward for more quantitative evaluation.

Table 7: Nanomaterials identified as having a potentially "high" release to one or more medium

Chemical name	Nanoform	Uses
Aluminium oxide	Plate-like, powder, spherical or pseudo-spherical particles with size typically in the range 10 – 50 nm[30,36]	Aluminium oxides are used as catalyst carriers in the petro-chemical industry. In the colour and polymer industries, they are applied as thickening agent, polishing agent and filler material and to enhance colour. They are also used in the ceramic industry, the paper industry, and as artificial gemstones and carriers for luminescent substances.
Boehmite (Al(OH)O)	Plate-like or rod-like particles in the range 2 to 250 nm[30,36]	As aluminium oxide.
Calcium carbonate	Rod-like, spherical, pseudo-spherical, cubic or hexagonal particles of size typically 10 - 80 nm[30,37]	Approximately 90% of use in Europe is in paper manufacturing as anti-compaction and bulking agent, with approximately 3% used in each of paints & coatings; adhesives & sealants; and plastics. The remaining c.1% is used in cosmetics and as a food additive.
Mixture of ceria and zirconia	Average ceria particle size is between 5 and 105 nm, with most registrations in the 10-20 nm range. Zirconia particle size may be between 20 nm and 150 nm particle size. [30] Nano active cerium oxide in dry powder form has a high specific surface area, and can be dispersed in various carrier fluids to reduce the particle size.	Mainly used in vehicle three-way catalytic convertors
Silicon dioxide, or variations of	May consist of spherical or pseudo-spherical nanoparticles; nanotubes, films, powder or rodlike nanoforms. Most particles in 10 – 30 nm size range[30, 36]	Nano-silica has many diverse uses. The majority (approximately 80%) of precipitated silica in Europe is used in elastomers. Smaller quantities are used in detergents, cosmetics, polymers, plastics, sealants, paints, coatings and as carrier material, sealant, water absorbent, flow agent or bulking agent.
Titanium dioxide	Most particles in 30 – 50 nm size range	Titanium dioxide is used to impart whiteness and opacity (including UV opacity) to products including paints, printing inks, plastics, textiles, ceramics, construction materials, cosmetics, food, and pharmaceuticals. It is produced primarily as a pigment which contains a small proportion of particles < 100 nm. Additionally, about 1-2% of titanium dioxide is manufactured as a nanomaterial for use in sunscreen and catalyst supports.
Zinc oxide	Rodlike, spherical, powder or star-shaped nanoforms. Most particles in 30 – 50 nm size range[30, 36]	Zinc oxide nanoparticles are used in the manufacture of paints, rubber and ceramics, and as an additive in concrete manufacture. It is used as a support material, as a filter in cigarettes and as a UV filter in a wide range of skin creams and ointments.
Carbon black	Carbon black nanoparticles are normally only present during the manufacturing process. Carbon black consists of more than 96% amorphous carbon and of small quantities of oxygen, hydrogen, nitrogen, and sulphur. Most of these elements are concentrated on the surface. It is produced from small spherical particles with sizes in the range of 15–300 nm. These particles melt into aggregates of 85–500 nm in aerodynamic diameter. On the basis of their primary particle size, all Carbon Black	Carbon black is used as a bulking agent, dye, elastomer booster, and as a semi-conductor. 67% of carbon black is used in tyre manufacture, with a further 24% used in other rubber products. Plastics and pigments each account for 4% of use in Europe.

[36] Bureau des Produits Chimiques, Ministere de l'Environnement, del'Energie et de la Mer, France, communication to DG Environment, November 2016

[37] Data taken from https://www.americanelements.com/calcium-carbonate-nanoparticles-471-34-1

Chemical name	Nanoform	Uses
	materials are considered as nano-structured materials.	
Copolymer of vinylidene chloride	Rodlike, spherical, star or kidney-shaped nanoforms. Most particles in 10 – 30 nm size range[30, 36]	PVC is an established durable plastic material. Nanoscale particles are incorporated in the structure to modify the material's physical properties
Polyvinyl chloride	No data found	PVC is an established durable plastic material. Nanoscale particles are incorporated in the structure for seeding and to modify the material's physical properties
Fuller's earth	Carbon black nanoparticles are normally only present during the manufacturing process. Carbon black consists of more than 96% amorphous carbon and of small quantities of oxygen, hydrogen, nitrogen, and sulphur. Most of these elements are concentrated on the surface. It is produced from small spherical particles with sizes in the range of 15–300 nm, typically spherical, pseudo-spherical or star-shaped nanoforms.[36] These particles melt into aggregates of 85–500 nm in aerodynamic diameter.[32] On the basis of their primary particle size, all Carbon Black materials are considered as nano-structured materials.[44]	Fuller's earth is used as an adsorbent for organic material and as a thickener. This term is a generic description of a range of materials used for this application in textiles, cosmetics, pharmaceuticals and paper manufacturing
Kaolin	Hyper-platy, nano-dimensional thickness crystals	Kaolin is used in manufacturing paper, ceramics, rubber, paints and refractory materials.
Silicic acid, aluminum sodium salt	Likely to be composite with e.g. nano CaCO3, so PVC not in nano form	Assumed to be similar to silicon dioxide
Silicic acid, magnesium salt	Likely to be composite with e.g. nano CaCO3, so PVC not in nano form	Assumed to be similar to silicon dioxide
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	Irregularly shaped particles with diameter distributed from c. 1000 nm to c. 20 nm. Particles are normally embedded in the ink polymer or product matrix.	Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione		Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione		Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)
Calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate		Organic pigments mainly used in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)
Clindamycin hydrochloride	No data found	Clindamycin is a widely used antibacterial agent
Cerium oxide isostearate	Most cerium oxide particles in 10 – 20 nm size range, spherical or pseudo-spherical.[30, 36]	Nano functionality used to enhance colouring in cosmetics, and as a fuel additive
Cerium and iron oxide isostearate	Most cerium oxide particles in 10 – 20 nm size range. Most iron oxide particles in 5 to 50 nm size range[30]	Nano functionality used to enhance colouring in cosmetics, and as a fuel additive
Iron oxide isostearate	Most iron oxide particles in 5 to 50 nm size range, spherical, pseudo-spherical or star-shaped.[30, 36]	Iron oxides are the largest-volume inorganic pigments due to their low cost, high opacity, good lightfastness and stability. They lack brightness compared with other inorganic pigments. Nano functionality is used to enhance colour, and as a fuel additive

Chemical name	Nanoform	Uses
Lactose	No data found	Lactose is used as a supplement to assist in digesting milk and other dairy products

Additionally, the following nanomaterials were identified as being of interest despite not being identified as having a potentially "high" release. Nanoscale silver is widely used, and emissions are likely to be under-estimated from the use of data in the French database. The relatively low manufacture quantities in the French database may reflect differences between manufacturing activities in France, and manufacture/use throughout Europe as a whole.

Some carbon nanotubes are potentially of interest in relation to their widespread potential application, and concerns about their potential health risks by analogy to other fibrous materials. Nano-piroxicam is of interest in view of the use of nanotechnology for drug delivery in this case, with potential subsequent release into wastewater and waste management systems. These substances were also taken forward for quantitative evaluation.

Table 8: Additional nanomaterials identified as being of interest

Chemical name	Nanoform	Uses
Silver	Most silver particles in <50 nm size range; typically spherical.	An evaluation by number of products indicates that nanosilver is mainly used in cosmetics, appliance manufacture and clothing. There are less extensive uses in food and drink, and in garden products.[38]
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite	Carbon nanotubes are cylindrical in form, typically 1 – 3 microns in length with other dimensions falling in the nanoscale range. 75% of MWCNT registrations are in the <50 nm size range.	CNTs have very high electrical and thermal conductivity, strength, stiffness, and toughness. These properties open a wide range of potential applications, including batteries and accumulators; metal articles; laboratory chemicals; polymer composites; chemical process intermediate; rubber products; fine chemical manufacture; R&D
Piroxicam	No data found	Piroxicam is used to relieve pain, tenderness, swelling, and stiffness caused by arthritis. There is interest in using nano-piroxicam to assist in delivery to the active site.

[38] University of Milano, "Silver Nanoparticles: Situation and Perspective for Industrial Application in the Lombardia Region (an overview)," 2014

2.4 Prioritisation criteria related to identified health risks

The substances identified as having a potentially "high" release for one or more pathway were prioritised primarily by consideration of evidence for their potential effects on health. Consideration of environmental hazards would have been an alternative approach for this prioritisation. However, it was judged that there was insufficient systematic data on environmental impacts to enable a comparative prioritisation to be carried out.

2.4.1 Summary of health risks of manufactured nanomaterials

The health risks of nanomaterials were summarised on behalf of DG Enterprise and Industry in 2014.[39] This study reported that:

> "*The reason why manufactured nanomaterials are of such interest and offer such potentially significant benefits to society is that they often have very different properties to the same substances on the macro scale – they may be more reactive, have increased strength, etc. However, these same differences also mean that they may also be more readily absorbed into biological systems and that their hazards may be different from those of their larger forms. Nevertheless, as stated by Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): "the hypothesis that smaller means more reactive, and thus more toxic, cannot be substantiated by the published data." The increasingly growing body of literature on health and safety aspects of nanomaterials is focusing on those insoluble or with very low solubility: "From a toxicological point of view, nanomaterials of poor solubility in biological fluids are of special importance, because they maintain their nanostructure after contact with the human body. Nanomaterials that are enclosed in an insoluble matrix are of minor importance, but may become relevant as soon as they are released by e.g. mechanical forces". It should be noted that "most of currently relevant nanomaterials occur in a solid aggregate state and have a (very) low solubility*"."

The 2014 study went on to quote EU-OSHA (2009): "*The smallness of nanomaterials can lead to an increased potential to cross barriers in living organisms which increases the number of organs that can be affected,*" and the UK Health and Safety Executive: "*Not all nanomaterials are hazardous, not all nanomaterials are equally hazardous and there can be considerable variation in toxicity between nanomaterials with a similar chemical composition, because of their physicochemical characteristics*."

Suggested exposure benchmarks were highlighted for carbon nanotubes, fullerenes, silver (18-19 nm) and titanium dioxide (10-100 nm). A generic "nano reference value" has also been proposed as a warning or concern level. In the US, a more demanding exposure guideline has been set for nano-titanium dioxide than micro-scale titanium dioxide, principally because of the greater surface area of nano-scale particles for a given mass compared to micro-scale particles. The small size of nano particles affects absorption, distribution, metabolism and excretion, because it influences the ability of the particles to penetrate biological barriers and reach different organs and cells.[40] Other metrics such as aspect ratio in the case of fibrous materials including carbon nanotubes may also be important. In a study of titanium dioxide, the US NIOSH concluded that: "*the adverse effects of inhaling TiO_2 may not be material-specific but appear to be due to a generic effect of poorly soluble low-toxicity (PSLT) particles in the lungs at sufficiently high exposure*."

The 2014 study cites a review by the Health Effects Institute,[41] which concluded that "*the evidence of adverse effects from short-term exposure to ambient UFPs on acute mortality and morbidity from respiratory and cardiovascular diseases is suggestive rather than conclusive. Due to underlying deficiencies in exposure data, it is not possible to conclude (or exclude) that UFPs alone account*

[39] RPA et al (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Building Blocks report for DG Enterprise and Industry, October 2014, Loddon, Norfolk, UK

[40] Harri Alenius, Julia Catalán, Hanna Lindberg, Hannu Norppa, Jaana Palomäki, Kai Savolainen, "Handbook of Nanosafety: Measurement, Exposure and Toxicology, Chapter 3 – Nanomaterials and Human Health " 2014, Pages 59–133

[41] HEI (2013): "Understanding the Health Effects of Ambient Ultrafine Particles, HEI Review Panel on Ultrafine Particles," HEI Perspective 3, Health Effects Institute, Boston, Massachusetts

substantially for the adverse effects associated with other ambient pollutants such as PM2.5. No epidemiological studies of long-term exposures to UFPs have been conducted so far."

Hougaard et al. (2015)[42] studied potential developmental toxicity of inhaled nanoparticles, but could only conclude that "*the potential for hazard remains to be characterized. Considering the increased production and application of nanomaterials and related consumer products a testing strategy for NP should be established.*"

On the basis of this information,[39,40,41,42] it is concluded that:

(a) There is insufficient evidence to support the view that the toxicity of a given material increases from larger scale particles to smaller scale particles

(b) Nano scale particles of any poorly soluble material could potentially pose a health hazard. The nature and scale of any such hazard is likely to depend on the extent of any such exposure (expressed as mass, number of particles and/or surface area), and the exposure pathway (e.g. inhalation; dermal contact; dietary exposure).

It is important to distinguish between health issues which are associated with the general chemical characteristics of the material in question, and those which are associated with or affected by the nano-scale properties of nanomaterials. Much published information on the health effects of nanomaterials is derived from observations on bulk or size-unspecific materials. While this is relevant to understanding potential health effects, the key issue for the prioritisation process was to identify any evidence for health effects specifically associated with the nano-scale properties of the nanomaterials classified as having a potentially "high" release potential.

2.4.2 Prioritisation and selection for detailed assessment

The health risks of nanomaterials classified as having a potentially "high" release potential were characterised as set out in Appendix 4. On this basis, 12 substances were selected for further assessment, as set out in Table 9.

Table 9: Selection of nanomaterials for detailed assessment

Chemical name and nanoform	Main uses	Reason for consideration	Evaluation	Included?
Aluminium oxide Plate-like or spherical particles with size typically in the range 10 – 50 nm	Aluminium oxides are used as catalyst carriers in the petro-chemical industry. In the colour and polymer industries, they are applied as thickening agent, polishing agent and filler material and to enhance colour. They are also used in the ceramic industry, the paper industry, and as artificial gemstones and carriers for luminescent substances.	High release	High production quantity. Pulmonary inflammation hazard if respired[32]	Yes
Boehmite (Al(OH)O) May comprise plate-like or spherical particles with size typically in the range 10 – 50 nm	As aluminium oxide.	High release	Possible pulmonary inflammation hazard if respired, but nano-clays unlikely to be toxic	No
Calcium carbonate Cubic or hexagonal particles of size typically 10 - 80 nm	Approximately 90% of use in Europe is in paper manufacturing as anti-compaction and bulking agent, with approximately 3% used in each of paints & coatings; adhesives & sealants; and plastics. The remaining c.1% is used in cosmetics and as a food additive.	High release	Indication of potential for cell stress, but only at very high exposures which are not likely in an environmental context[32]	No

[42] Karin S. Hougaard, Luisa Campagnolo, Pascale Chavatte-Palmer, Anne Tarrade, Delphine Rousseau-Ralliard, Sarah Valentino, Margriet V. D. Z. Park, Wim H. de Jong, Gerrit Wolterink, Albert H. Piersma, Bryony L. Ross, Gary R. Hutchison, Jitka S. Hansen, Ulla Vogel, Petra Jackson, Rémy Slama, Antonio Pietroiusti, Flemming R. Cassee, "A perspective on the developmental toxicity of inhaled nanoparticles" 43rd Annual Conference of the European Teratology Society, 2015

Chemical name and nanoform	Main uses	Reason for consideration	Evaluation	Included?
Mixture of ceria and zirconia Ceria particle size is between 5 and 105 nm, mostly in the 10-20 nm range. Zirconia particle size may be between 20 nm and 150 nm	Mainly used in vehicle three-way catalytic convertors	High release	IARC indicates that ceramic nanofibres could potentially pose a carcinogenic hazard, although there is no evidence for such effects from titanium dioxide fibres.[319]	Yes
Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films. Most particles in 10 – 30 nm size range	Nano-silica has many diverse uses. The majority (approximately 80%) of precipitated silica in Europe is used in elastomers. Smaller quantities are used in detergents, cosmetics, polymers, plastics, sealants, paints, coatings and as carrier material, sealant, water absorbent, flow agent or bulking agent.	High release	High production quantity. Higher risks of ultrafine silica compared to larger particles. Well known potential risks from crystalline silica not relevant to amorphous silica.[32,34] Found to cause pulmonary inflammation in rats[43]	Yes
Titanium dioxide Most particles in 30 – 50 nm size range	Titanium dioxide is used to impart whiteness and opacity (including UV opacity) to products including paints, printing inks, plastics, textiles, ceramics, construction materials, cosmetics, food, and pharmaceuticals. It is produced primarily as a pigment which contains a small proportion of particles < 100 nm. Additionally, about 1-2% of titanium dioxide is manufactured as a nanomaterial for use in sunscreen and catalyst supports.	High release	Use in cosmetic products and wide prevalence of other uses; however, no evidence of crossing skin barrier. Antibacterial; risk of pulmonary inflammation if respired.[32,34,43, 319] More demanding exposure guideline set in the US for nano-scale titanium dioxide in view of potential carcinogenic activity.	Yes
Zinc oxide Most particles in 10 – 30 nm size range	Zinc oxide nanoparticles are used in the manufacture of paints, rubber and ceramics, and as an additive in concrete manufacture. It is used as a support material, as a filter in cigarettes and as a UV filter in a wide range of skin creams and ointments.	High release	Use in cosmetic products, and some evidence of potential health hazards. Antibacterial; risk of pulmonary inflammation if respired[32,34,43]	Yes
Carbon black Produced from spherical particles with sizes in the range of 15–300 nm. These particles melt into aggregates of 85–500 nm in aerodynamic diameter. On the basis of their primary particle size, all Carbon Black materials are considered as nano-structured materials	Carbon black is used as a bulking agent, dye, elastomer booster, and as a semi-conductor. 67% of carbon black is used in tyre manufacture, with a further 24% used in other rubber products. Plastics and pigments each account for 4% of use in Europe.	High release	Wide range of uses and high production quantity. No significant risks associated with use of particles >20 nm on the skin. Risks are associated with inhalation pathway, and potential trace contaminants.[44,32]	Yes
Copolymer of vinylidene chloride	PVC is an established durable plastic material. Nanoscale particles are incorporated in the structure to modify the material's physical properties	High release	No information on health impacts specific to nano form of this substance. Substance may not be in nano form	No
Polyvinyl chloride	PVC is an established durable plastic material. Nanoscale particles are incorporated in the structure for seeding and to modify the material's physical properties	High release	No information on health impacts specific to nano form of this substance. It is unclear why only a marginal share of PVC production was reported to the French registry. The only PVC form in sub-micron particles are	No

[43] Wiesner, Lowry, Alvarez, Dionysiu, Biswas, "Assessing the Risks of Manufactured nanomaterials," Environmental Science and Technology 2006, 4337-4346
[44] Scientific Committee on Consumer Safety, "Opinion on Carbon Black (nano-form)," December 2015

Chemical name and nanoform	Main uses	Reason for consideration	Evaluation	Included?
			"plastisols", but nanoparticles would not be generated by this route. Advances in metrology may enable PVC to be eliminated from the list.	
Fuller's earth May consist of c.1 nm thick layers surface-substituted with metal cations and stacked in c.10 µm-sized multilayer stacks	Fuller's earth is used as an adsorbent for organic material and as a thickener. This term is a generic description of a range of materials used for this application in textiles, cosmetics, pharmaceuticals and paper manufacturing	High release	No information on health impacts specific to nano form of this substance. No significant health risks associated with nanoclays	No
Kaolin Hyper-platy, nano-dimensional thickness crystals	Kaolin is used in manufacturing paper, ceramics, rubber, paints and refractory materials.	High release	No information on health impacts specific to nano form of this substance. No significant health risks associated with nanoclays It is understood that there was some uncertainty regarding conformance of kaolins with the French definition. Consequently, a marginal share of production volume was reported.	No
Silicic acid, aluminum sodium salt Nanoform likely to be similar to silicon dioxide	Assumed to be similar to silicon dioxide	High release	Likely to be similar to silicon dioxide	No
Silicic acid, magnesium salt Nanoform likely to be similar to silicon dioxide	Assumed to be similar to silicon dioxide	High release	Likely to be similar to silicon dioxide	No
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)	High release	No significant acute effects. No evidence for specific toxicity of nano form.	No
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)	High release		
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)	High release		
Calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	Organic pigments with high colour fastness, used since the 1980s mainly in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%) Organic pigments mainly used in printing inks (45%), paints & coatings (28%), plastics (21%) and textiles (6%)	High release		
Clindamycin hydrochloride	Clindamycin is a widely used antibacterial agent	High release	Pharmacologically active material making use of nano characteristics. No evidence for specific toxicity of nano form.	Yes
Cerium oxide isostearate Most cerium oxide particles in 10 – 20 nm size range	Nano functionality used to enhance colouring in cosmetics, and as a fuel additive	High release	No data on health or eco toxicology specific to nano form. Possibly analogous to cerium dioxide	Yes
Cerium and iron oxide isostearate Most cerium oxide particles in 10 – 20 nm size range. Most iron oxide particles in 5 to 50 nm size range	Nano functionality used to enhance colouring in cosmetics, and as a fuel additive	High release	No data on health or eco toxicology specific to nano form. Possibly analogous to cerium dioxide	Yes
Iron oxide isostearate	Iron oxides are the largest-volume	High release	Some evidence for cell	No

Chemical name and nanoform	Main uses	Reason for consideration	Evaluation	Included?
Most iron oxide particles in 5 to 50 nm size range	inorganic pigments due to their low cost, high opacity, good lightfastness and stability. They lack brightness compared with other inorganic pigments. Nano functionality is used to enhance colour, and as a fuel additive		tolerance to superparamagnetic iron oxide nanoparticles	
Lactose	Lactose is used as a supplement to assist in digesting milk and other dairy products	High release	No evidence for specific toxicity of nano form.	No
Silver Most silver particles in <50 nm size range	Nanosilver is mainly used in cosmetics, appliance manufacture and clothing. There are less extensive uses in food and drink, and in garden products.	Widely used	Lack of data to enable health risks to be fully characterized. Hazards may include dissemination of resistance mechanism.[45]	Yes
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite 75% of MWCNT registrations are in the <50 nm size range	CNTs have very high electrical and thermal conductivity, strength, stiffness, and toughness. These properties open a wide range of potential applications, including batteries and accumulators; metal articles; laboratory chemicals; polymer composites; chemical process intermediate; rubber products; fine chemical manufacture; R&D	Widely used; fibrous structure	Rigid, needle-like MWCNTs with a diameter of >50 nm pose a hazard of causing asthma-like inflammation and DNA damage in the lungs. Thinner (diameter ~ 8-15 nm), tangled MWCNTs do not have such effects.[46] Conflicting evidence on the relative potency of nanomaterials compared to micro-sized particles.[39]	Yes
Piroxicam	Piroxicam is used to relieve pain, tenderness, swelling, and stiffness caused by arthritis. There is interest in using nano-piroxicam to assist in delivery to the active site.	Pharma-ceutical use	Pharmacologically active material making use of nano characteristics. No evidence for specific toxicity of nano form.	Yes

2.5 Quantitative release inventory for priority materials

2.5.1 Introduction

For the subset of 12 nanomaterials identified in the previous step, further assessment was undertaken, specifically concentrating on the quantitative aspects and any additional observations that will be relevant for the legislative review in Task 2.

The data in this step was collected by literature research and expert liaison targeted at specific nanomaterials, as described in Section 2.2.2.

In addition to completing any gaps present in the qualitative inventory for these substances, our efforts concentrated on gathering information of most relevance to the case studies to be evaluated in task 2, specifically:

- Better, more detailed characterisation and quantification of the environmental releases (which environmental media, at which point in the life cycle of the nanomaterial).
- What regulation-related information is available, e.g. any hazard classification of the nanoform, any nanomaterial-specific SDS.
- Whether the substance can be identified and monitored via available measuring techniques, if any such monitoring is being carried out in practice, and what monitoring data is available.
- Identifying key risk hotspots across the nanomaterial lifecycle and applicable regulatory provisions.

[45] Scientific Committee on Emerging and Newly Identified Health Risks, "Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance," 2014

[46] Finnish Institute of Occupational Health, "Evaluation of the health effects of carbon nanotubes," Project No. 109137, 2013

2.5.2 Additional data

The nanomaterials prioritised were as follows:

Aluminium oxide

There are 51 registrations on the Nanowerk database, of which 11 are for European producers, indicate that average particle size is between 10 and 150 nm. The majority of products are in the 10 - 50 nm range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of aluminium oxide ENM production estimates for Europe between 0.1 and 15,000 tonnes per year. The upper end of this range is consistent with the production and importation estimate of 16,000 tonnes per year derived from the French registry. In view of this reasonable agreement between published data and this updated analysis, the value derived from the French registry was retained for the quantitative inventory.

Mixture of ceria and zirconia

There are 21 registrations for ceria on the Nanowerk database, of which three are for European producers, together with one EU registration for zirconia. Average ceria particle size is between 5 and 105 nm, with most registrations in the 10-20 nm range. The single zirconia registration offers 20 nm and 150 nm particle size. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of cerium oxide ENM production estimates for Europe between 40 and 2,300 tonnes per year. This range is lower than the production and importation estimate of 11,000 tonnes per year derived from the French registry. In view of the lower values provided from four separate studies, and the possibility of over-declaration in the French registry, the upper range value from Nowack et al. was used to develop the quantitative inventory.

Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films

There are 30 registrations for silica on the Nanowerk database, of which three are for European producers. Average particle size is between 10 and 200 nm, with most registrations in the 10-30 nm range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of silicon dioxide ENM production estimates for Europe between 2,000 and 22,000 tonnes per year, with a further value of 990,000 tonnes per year derived from an earlier analysis of the French registry. The value of 990,000 tonnes per year is close to the production and importation estimate of 1,110,000 tonnes per year derived from the French registry. However, these figures seem high in the context of overall silica usage in manufacturing: the European consumption of precipitated silica in 2010 was separately reported to be 262,000 tonnes,[48] and nanoparticles would only make up a proportion of this quantity. In view of this, and the possibility of over-declaration in the French registry, the upper range value from Nowack et al. excluding data derived from the French registry was used to develop the quantitative inventory.

Titanium dioxide

There are eight registrations for titanium dioxide on the Nanowerk database, none of which are for European producers. Average particle size is between 7 and 250 nm, with most registrations in the 30-50 nm range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of titanium oxide ENM production estimates for Europe between 550 and 92,000 tonnes per year. The upper end of this range is lower than the production and importation estimate of 188,000 tonnes per year derived from the French registry. In view of the lower values provided from four separate studies, and the possibility of over-declaration in the French registry, the upper range value from Nowack et al. was used to develop the quantitative inventory.

Zinc oxide

[47] Bernd Nowack, Nikolaus Bornhoft, Yaobo Ding, Michael Riediker, Araceli Sanchez Jimenez, Tianyin Sun, Martie van Tongeren and Wendel Wohlleben, "*The Flows of Engineered Nanomaterials from Production, Use, and Disposal to the Environment*," 2015

[48] Chemical Economics Handbook, excerpt

There are 36 registrations for zinc oxide on the Nanowerk database, of which two are for European producers. Average particle size is between 10 and 200 nm, with most registrations in the 10-30 nm range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of zinc oxide ENM production estimates for Europe between 55 and 7,900 tonnes per year. The production and importation estimate of 200 tonnes per year derived from the French registry is within this range. In view of this reasonable agreement between published data and this updated analysis, the value derived from the French registry was retained for the quantitative inventory.

Carbon black

There are no registrations for carbon black on the Nanowerk database.

The quantity of carbon black derived from the French registry data is approximately 12% of total global consumption of carbon black. This value can therefore be considered to refer to both nano-scale materials, and agglomerated materials which are no longer at nano-scale.

Clindamycin hydrochloride

There are no registrations for clindamycin hydrochloride on the Nanowerk database.

No new information on manufacture quantities was identified.

Cerium oxide isostearate

As noted above, there are 21 registrations for ceria on the Nanowerk database, of which three are for European producers. Average particle size is between 5 and 105 nm, with most registrations in the 10-20 nm range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of cerium oxide ENM production estimates for Europe between 40 and 2,300 tonnes per year. The production and importation estimate of 41 tonnes per year for the stearate material derived from the French registry is within this range. In view of this reasonable agreement between published data and this updated analysis, the value derived from the French registry was retained for the quantitative inventory.

Cerium and iron oxide isostearate

Cerium oxide registrations are described above. There are 57 registrations for iron oxide on the Nanowerk database, of which 15 are for European producers. Average particle size is between 5 and 50 nm, with registrations throughout this size range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of cerium oxide ENM production estimates for Europe between 40 and 2,300 tonnes per year. For iron oxide, the production estimates were between 550 and 9,700 tonnes per year. The production and importation estimate of 200 tonnes per year for the stearate material derived from the French registry is below the range of iron oxide ENM given by Nowack et al. As the French inventory refers to a specific isostearate product, it would comprise only a proportion of the total cerium and iron oxide production. Consequently, the value derived from the French registry was retained for the quantitative inventory.

Silver

There are 90 registrations for silver on the Nanowerk database, of which 20 are for European producers. Average particle size is between 3.5 and 150 nm, with most registrations in the <50 nm size range. No further information was provided on nanoforms.

Nowack et al.[47] identified a range of silver ENM production estimates for Europe between 0.006 and 100 tonnes per year. The lower end of this range was derived from an earlier analysis of the French registry. The production and importation estimate of 0.003 tonnes per year derived from the French registry lies outside the range identified by Nowack et al. An audit of the French registry has independently highlighted the desirability of further investigation of potential under-reporting of nano-silver production and importation. This may possibly be due to reporting thresholds, or may be related to awareness of nano-silver content of imported materials. In view of the higher values provided from five separate studies reported by Nowack et al., the upper range value from Nowack et al. was used to develop the quantitative inventory.

Carbon nanofibers, Carbon nanotubes multi-walled, Graphite

On the Nanowerk database, there are 144 registrations for Single-walled carbon nanotubes (SWCNT), 36 registrations for Double-walled carbon nanotubes (DWCNT) and 566 registrations for Multi-walled carbon nanotubes (MWCNT). 75% of MWCNT registrations are in the <50 nm size range. There are also seven registrations for carbon nanofibres, and one registration for graphite nanopowder.

Nowack et al.[47] identified a range of carbon nanotube production estimates for Europe between 26 and 1,200 tonnes per year. The production and importation estimate of 24 tonnes per year derived from the French registry lies outside this range. In view of the higher values provided from five separate studies, the upper range value from Nowack et al. was used to develop the quantitative inventory.

Piroxicam

There are no registrations for piroxicam on the Nanowerk database.

2.5.3 Results

The production and preliminary estimated release quantities for these priority materials are set out in Table 10.

Table 10: Preliminary estimate of production and release quantities in Europe of prioritised nanomaterials (T)

Chemical name	Estimated quantity produced/ imported (Europe 2015), T	Preliminary release inventory (2015), T				
		Air	Land	Water	Recycling	Waste
	Data for 2015					
Aluminium oxide	16000	9.0	4.8	19	3522	5921
Mixture of ceria and zirconia	2300	1.2	0.32	1.3	381	658
Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films	22000	119	128	27	3312	6254
Titanium dioxide	92000	183	340	140	17814	30868
Zinc oxide	200	6.5	21	33	16	50
Carbon black	1480000	881	290	1077	348354	578525
Clindamycin hydrochloride	340	0.31	17	5.2	0	105
Cerium oxide isostearate	41	5.9	0.515	0.10	5.7	12
Cerium and iron oxide isostearate	200	29	2.50	0.5	28	60
Silver	100	0.099	6.4	0.34	11	26
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite	1200	0.64	0.17	0.70	199	343
Piroxicam	4.0	0.0036	0.20	0.061	0	1.2
	Data for 2025					
Aluminium oxide		11.7	6.6	24	5090	8394
Mixture of ceria and zirconia		2.6	0.73	2.9	881	1495
Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films		239	256	56	7663	14068
Titanium dioxide		341	677	254	27845	48140
Zinc oxide		13	42	66	36	106
Carbon black		1082	402	1410	482254	787925
Clindamycin hydrochloride		3.1	170	52	0	1050
Cerium oxide isostearate		12	1.030	0.2	13	26
Cerium and iron oxide isostearate		58	5.01	1.0	61	127
Silver		0.20	12.8	0.67	22	52
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite		1.3	0.38	1.5	460	780

Chemical name	Estimated quantity produced/ imported (Europe 2015), T	Preliminary release inventory (2015), T				
		Air	Land	Water	Recycling	Waste
Piroxicam		0.007	0.40	0.12	0	2.4
	Data for 2035					
Aluminium oxide		14.7	8.6	30	6679	10912
Mixture of ceria and zirconia		4.1	1.3	4.9	1571	2618
Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films		360	386	89	13668	24362
Titanium dioxide		504	1026	374	38698	66698
Zinc oxide		19	62	99	63	172
Carbon black		1284	499	1715	598996	972895
Clindamycin hydrochloride		4.7	255	79	0	1574
Cerium oxide isostearate		18	1.6	0.32	21	43
Cerium and iron oxide isostearate		87	7.6	1.5	102	207
Silver		0.30	20	1.03	33	78
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite		2.1	0.7	2.6	820	1366
Piroxicam		0.011	0.59	0.18	0	3.7

The release data in these tables are subject to significant uncertainty due to the assumptions inherent in carrying out generic calculations based on a limited dataset. It is considered likely that the emissions estimates are reliable to within an order of magnitude (i.e. a factor of 10), reflecting uncertainty in the quantity of nanomaterials manufactured (factor of 3), usage of nanomaterials (factor of 3), and release rate during manufacture and use (factor of 5). Combining these uncertainties on a root-mean-square basis gives an indicative uncertainty factor of 7.

3 Progress review on implementation of environmental legislation to nanomaterials

3.1 Introduction

3.1.1 Second regulatory review

The second regulatory review for nanomaterials published by the European Commission in 2012[49] identified a number of challenges in the regulation of nanomaterials but it concluded that limited regulatory changes would be needed and that the REACH regulation is the best regulatory framework for the regulation of nanomaterials. The findings of the 2012 review may be summarised as follows:

- Nanomaterials are similar to bulk chemicals/substances in that some may be toxic and some may be not;
- Nanomaterials require a risk assessment, which should be performed on a case-by-case basis. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required;
- The definition of nanomaterials will be integrated in EU legislation, where appropriate;
- Important challenges relate primarily to establishing validated methods and instrumentation for detection, characterization, and analysis, completing information on hazards of nanomaterials and developing methods to assess exposure to nanomaterials. The Commission is currently working on detection, measurement and monitoring methods for nanomaterials and their validation to ensure the proper implementation of the definition;
- Overall the Commission remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures;
- More specific requirements for nanomaterials within the REACH framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes;
- The Commission encourages ECHA to further develop guidance for registrations after 2013.

3.1.2 Scope of this study

This study provides an update to the review of environmental legislation which was carried out for the second regulatory review, and is designed to investigate whether the gaps and challenges identified in the 2012 review have been addressed. It verifies whether new gaps have emerged and provide recommendations for addressing them.

The approach to this analysis is set out in Section 4.2. The legislative evaluation is then broken down into three sections:

- An update to the review of legislation which was covered in the 2011 study commissioned by DG ENV on the review of environmental legislation for the control of nanomaterials[50] (2011 study) and led by Milieu.
- An evaluation of additional EU environmental legislation.
- An evaluation of other potentially relevant EU legislation.

At appropriate points in the text, we have added stakeholder opinions on the relevant regulatory measures which were provided by delegates following the Stakeholder Workshop. This is followed by a gap analysis, and four case studies illustrating the application of EU legislation to nanomaterials.

[49] European Commission, 2012, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE Second Regulatory Review on Nanomaterials COM(2012) 572 final

[50] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011 available at: http://ec.europa.eu/environment/chemicals/nanotech/pdf/review_legislation.pdf http://ec.europa.eu/environment/chemicals/nanotech/pdf/review_legislation.pdf

3.2 Approach and methodology

3.2.1 Legislative review

The methodology for reviewing implementation of environmental legislation with respect to specific nanomaterials used a consistent and coherent approach. It drew on scientific insights as well as the practical experience gained since the second review. Differences among the individual legal acts were taken into account: for example, methods for implementing the waste management legislation with respect to nanomaterials might not capture all of the important aspects that would need to be considered for a review of implementation of water quality requirements. The review assessed the extent to which the safe use of nanomaterials is covered by the relevant legislation and through the implementation of other activities as foreseen by the second regulatory review.

The evaluation of legislation covering nanomaterials 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 – for example, EQS, ELVs? Are they also effective for nanomaterials?
4. Can sources of nanomaterials be identified?
5. Are there examples of any nanomaterials that are potentially relevant to those sources?
6. Are relevant exposure pathways controlled?
7. Are thresholds/limits applicable to nanomaterials in terms of volume and associated risks?
8. Are monitoring requirements (criteria, measurements, thresholds, regularity, monitoring – e.g. by an authority of self-monitoring) applicable to nanomaterials in terms of volume and associated risks? Are they feasible for nanomaterials?
9. Enforcement – is there a need for specific elements covering nanomaterials?
10. What are the penalties for noncompliance and are these relative to the risks posed by nanomaterials?
11. How is the legislation being implemented, are there gaps that throw up concerns regarding application to nanomaterials?

The review of legislation identified a number of potential legislative and implementation gaps which were analysed in detail to confirm whether a gap exists, and to analyse the reasons for the gap. Gaps could potentially be characterised as follows:

- Nanomaterials not covered by the general objective of the legislation;
- Nanomaterials covered by the general objectives but explicitly excluded from the scope;
- Nanomaterials covered in principle but not effectively addressed; and
- Nanomaterials ineffectively covered due to implementation or regulatory gaps or critical dependence on other legislation.

Particular attention was paid to cases where nanomaterials are covered in principle due to assumptions about them being similar to bulk or size-unspecified substances. This will be particularly important in relation to legislation, which covers nanomaterials in principle, but does not effectively address the specific characteristics of nanomaterials due to issues of measurement method, monitoring criteria, etc.

The compiled information was then evaluated with a view of assessing progress toward addressing the action points and conclusions from the second regulatory review. The information was assessed as follows:

- Whether existing legislation has effectively dealt with nanomaterials;
- Whether a regulatory change has happened and if it was effective;
- Whether scientific progress has removed obstacles in implementation and enforcement;
- Whether a specific development can be consistently applied across all legislation on nanomaterials;

- Whether the information is only relevant and applicable to one specific piece of legislation or one specific substance/material/product.

3.2.2 Case studies

Four case studies were evaluated to demonstrate how environmental legislation has been implemented with respect to specific nanomaterials.

The selection of the case studies was based on the relative importance of the nanomaterial and its use and possible releases to the environment and data availability. Four substances were identified as representing nanomaterials at a range of stages of development, with a diverse range of uses and environmental characteristics and risk profiles. The materials listed below are first generation and second generation nanomaterials.

- **Iron oxide** was selected as a case study due to its widespread use, as identified in the inventory. Iron oxide has been used as a pigment for many decades and the regulation of this substance has evolved as understanding of the role of nanomaterials in the properties of iron oxide pigments has developed.
- **Nanosilver** was selected as a case study due to widespread consumer use of products that are claimed to entail this form of nanomaterial (see for instance, The Nanodatabase available at www.nanodb.dk) combined with research findings that many of these uses entail a great environmental exposure potential. Prior to its development as a nanomaterial, silver had very limited uses: however, the development of nanosilver has resulted in very widespread applications. This case study enables a range of different uses and environmental exposure pathways to be considered
- **Synthetic amorphous silica** (SAS) was selected as a case study due to its widespread consumer use, including food uses, and its relevance to most legislation dealing with nanomaterials. SAS has been approved as an active substance under the BPR, and under REACH a substance evaluation decision has been adopted, including a request for a significant quantity of information from the registrant.[51]
- **Cadmium Selenide (CSE) quantum dots** are used as light emitting diodes (LEDs) for electronic and medical applications. CSE quantum dots was selected as a case study in view of these uses, and in view of their anticipated increasingly widespread use in consumer products, due to their use in high resolution computer and TV screens, and increasingly in mobile devices. Cadmium selenide in size-unspecified form is restricted under REACH, as a member of the substance group “cadmium and its compounds”. This case study enables potentially significant health risks to be evaluated.

The approach to this task was to verify, for each substance selected, whether all known uses are covered by the relevant legislation and that the risks are properly addressed during the life cycle. For each selected case, the use and possible releases to the environment were investigated. The case studies considered:

- challenges in the identification of nanomaterials across legislative domains;
- availability of nano specific information throughout the relevant applicable legislation and associated requirements (e.g. CLP, safety data sheets) or from more generic sources of information;
- implementation of waste legislation with respect to specific nanomaterials;
- control of exposure pathways during the entire life cycle of the selected nanomaterial;
- availability of adequate tools for monitoring and enforcement, including whether monitoring of environmental media is in fact being carried out for the selected case study nanomaterial.

The existence of gaps in legal coverage (legislative gap) or inadequate implementation or lack of technical capacity (implementation gap) were investigated.

3.2.3 Identification of gaps and provision of recommendations

The study has identified, as far as possible, any remaining or new gaps in legislation, and provided recommendations as to how these could potentially be addressed.

51 Note: this decision is currently subject to an appeal

3.3 Legislation covered in the 2011 regulatory review

3.3.1 Waste Framework Directive 2008/98/EC

3.3.1.1 Summary of requirements

The Directive establishes the legal framework for the treatment of waste within the EU. It lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use (Article 1).

It applies to waste other than gaseous effluents, radioactive elements, decommissioned explosives, faecal matter, waste waters, animal by-products, carcasses of animals that have died other than by being slaughtered, and elements resulting from mineral resources (Article 2).

Article 3 of the Directive sets out the main concepts and definitions related to waste management, including the definitions of waste, hazardous waste and waste management. Articles 5 and 6 explain when waste ceases to be waste and becomes a secondary raw material (so called end-of-waste criteria), and how to distinguish between waste and by-products.

The Directive sets out the following waste hierarchy that Member States shall apply as a priority order in their waste management legislation and policy: prevention, preparing for re-use, recycling, recovery and disposal (Article 4).

In line with Article 15 of the Directive, any original waste producer or holder of waste must carry out the treatment of waste themselves or must have the treatment handled by a dealer, or an establishment, or undertaking. Member States may cooperate, if necessary, to establish a network of waste disposal installations.

Dangerous waste must be stored and treated in conditions that ensure the protection of health and the environment (Article 17). They must not, in any case be mixed with other dangerous waste and must be packaged or labelled in line with international or Community regulations (Articles 18 and 19).

Establishments or undertakings intending to carry out waste treatment must obtain a permit from the competent authorities. Authorities determine the quantity and type of waste to be treated, the methods used as well as the monitoring and controlling operations. Any incineration or co-incineration method aimed at energy recovery must only be carried out if this recovery takes place with a high level of energy efficiency (Article 23).

The competent authorities must establish one or more management plans to cover the whole territory of the Member State concerned. These plans contain, in particular, the type, quantity and source of waste, existing collection systems and location criteria (Article 28).

Prevention programmes must also be drawn up, with a view to breaking the link between economic growth and the environmental impacts associated with the generation of waste. These programmes are to be communicated by Member States to the European Commission (Article 29).

The competent authorities of the Member States shall carry our periodic inspections of waste treatment installations, professional waste collectors or transporters, brokers and dealers and at hazardous waste producers. Member States shall take the appropriate measures to prohibit the abandonment, dumping or uncontrolled management of waste and lay down provisions on penalties applicable to infringements (Articles 34 and 36).

The Directive also contains some criteria to classify waste as ‘hazardous waste’ which are based to a large extent on the hazardous classification of substances under the CLP Regulation (Annex III).

The directive does not explicitly mention nanomaterials or nanowastes, but they are de facto covered under the Waste Framework Directive since Article 3(1) defines ‘waste’ as “any substance or object which the holder discards”. Therefore the Directive applies to discarded materials that contain nanomaterials. No specific treatment measures have been set for nanomaterials; the directive treats them as any other waste. Finally, there is no obligation to label products containing nanomaterials or programmes to separate and collect end-of-life products containing them either.

3.3.1.2 Conclusions of the 2011 study[50]

Several gaps concerning the coverage of nanomaterials by the Waste Framework Directive were identified by the 2011 study:

- The classification of hazardous waste based on the CLP Regulation classification criteria leading to inadequate control measures (e.g. hazardous nanowaste exempted from hazardous waste management measures) due to the difficulties to classify hazardous nanomaterials under the CLP regulation.
- No specific provisions for waste oils containing nanomaterials
- No specific definition of nanowaste and no mechanism to generate information on the nanowaste content in different waste streams
- Permits waste management facilities do not consider any specific practice for the management of nanowaste
- No requirements regarding the management of nanowaste in waste management plans
- Lack of information on nanomaterials in waste (e.g. products involved, life cycle analysis, behaviour of nanomaterials , information on impact on recycling processes on their re-use)
- Lack of technical capacity and knowledge to implement Waste Framework Directive control measures for nanomaterials (e.g. test methods, identification of waste containing nanomaterials)

3.3.1.3 Changes since the 2011 study

Since the 2011 study, there have been no legislative changes that would address categorisation or regulation of nanomaterials under the Waste Framework Directive. A Commission proposal for its update was published in 2015:[52] however, this proposal does not address issues relevant to nanomaterials. The only changes that could be relevant to nanomaterials in waste under the Commission Proposal are the new definition of “non-hazardous waste” and improved record keeping through electronic registries for hazardous waste. Furthermore, the proposal envisages that electronic data collection should be extended beyond hazardous waste, where appropriate.[53]

New amendments proposed to the Waste Framework Directive:

Article 3 ‘Definitions’ to add point 2a:

'2a. "non-hazardous waste" means waste which displays none of the hazardous properties listed in Annex III;'[54]

Article 35 ‘Record Keeping’ to add electronic record keeping:

'1. […] the producers of hazardous waste […], shall keep a chronological record of the quantity, nature and origin of that waste, and, where relevant, the destination, frequency of collection, mode of transport and treatment method foreseen in respect of the waste. They shall make that data available to the competent authorities through the electronic registry or registries to be established pursuant to paragraph 4';

'4. Member States shall set up an electronic registry or coordinated registries to record the data on hazardous waste […] covering the entire geographical territory of the Member State concerned. Member States may establish such registries for other waste streams, in particular those waste streams for which targets are set in Union legislation. Member States shall use the data on waste reported by industrial operators in the European Pollutant Release and Transfer Register set up under Regulation (EC) No 166/2006 of the European Parliament and of the Council […]'.[55]

Representatives from the waste sector interviewed as part of this study have expressed their concern regarding legal and knowledge gaps relating to nanowaste. For example, they stress that the Waste Framework Directive breakdown of reducing −recycling −recovering waste does not cope well with a multitude of nano-polymers with different attributes. They also flagged that the waste treatment technologies used in state of the art waste treatment systems are not able to capture or retain all

[52] Proposal for a directive of the European Parliament and of the Council amending Directive 2008/98/EC on waste (Text with EEA relevance) [SWD(2015) 259 final} [SWD(2015) 260 final] Brussels, 2.12.2015COM(2015) 595 final 2015/0275 (COD).
[53] Ibid., p. 10.
[54] Ibid., p. 13.
[55] Ibid. p.22.

nanomaterials releases. This is further confirmed by a recent 2016 OECD study[56] which stressed that while state of the art waste treatment processes may be able to retain a large share of nanomaterials, significant amounts of emissions are still likely to pass through them. This study also identifies that there is a lack of information on the type and quantities of nanomaterials in waste streams. It flags that nanomaterials can have negative effects on certain waste treatment processes. Finally this study recommends that there should be further research on the identification and quantification of nanomaterials in waste flows, on behaviour and fate of nanomaterials. One interviewee of the waste sector anticipates that such gaps will become significant issues with the increase of production of nanomaterials in the near future. Note also that NGOs signed a declaration which calls for a better regulation of waste containing nanomaterials in April 2016 requiring policy makers to adopt a precautionary approach and to aim at minimising human and environmental exposure to waste containing nanomaterials[57].

3.3.1.4 Conclusion

As a conclusion the legal, technological and knowledge gaps identified under the 2011 study still remain. The categorisation of hazardous waste still relies on the CLP Regulation. However, there are still some issues with identification and classification of hazardous nanomaterials under CLP. The Waste Framework Directive has not been amended to set specific requirements on nanowaste and the 2015 Commission Proposal does not include any 'nano' specific requirements (information requirements). Furthermore, the state of the art waste treatment technologies remain not adequate to capture nanomaterials leading to implementation gaps of the Directive. Finally there are still a lot of knowledge gaps on nanomaterial in waste streams (e.g. identification and quantification of nanomaterials in waste streams), as outlined by a 2016 OECD study.

3.3.2 Decision 2000/532/EC (European Waste Catalogue)

3.3.2.1 Summary of requirements

Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1 (a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1 (4) of Council Directive 91/689/EEC on hazardous waste, provides for a harmonised Union list of hazardous wastes which is common encoding of waste characteristics, including the classification of hazardous wastes. It also sets definitions among others on hazardous substance according to the CLP Regulation and heavy metal. The classification of hazardous waste triggers specific control measures under the different EU pieces of legislation on waste.

For example, according to Article 17 (1) of the Waste Framework Directive, traceability and control of substances that qualify as hazardous waste must be ensured. According to Article 18 (1) of the Waste Framework Directive, whenever substances qualify as hazardous waste they shall not be mixed. An authorisation must be obtained in order to treat substances that qualify as waste (Article 23 (1) of Directive 2008/98/EC) and the substances that qualify as hazardous waste are subject to international and EU law requirements on labelling (Article 19 (1) of Directive 2008/98/EC). However, uncertainties remain as to the classification of nanomaterials as hazardous waste[58].

3.3.2.2 Summary of findings under 2011 study

The 2011 study found that the list of waste annexed to Decision 2000/532/EC does not mention wastes that contain nanomaterials in any form. When establishing the properties that lead to the classification of a waste as hazardous, Decision 2000/532/EC includes concentration thresholds for all properties other than thermal flash point. However, due to the properties that are specific to nanomaterials, concentrations given in mass terms and used to establish thresholds may not be best

[56] OECD (2016), *Nanomaterials in Waste Streams. Current knowledge on risks and impacts* available at: https://www.oecd.org/env/nanomaterials-in-waste-streams-9789264249752-en.htm
[57] http://www.eeb.org/index.cfm/library/nanomaterials-in-waste-declaration/
[58] For example, "*a nanoproduct, such as sunscreen, may not present a risk to the consumer, but may present varying hazards upon disposal (Musee, 2011) due to potential degradation of the product or potential interactions with other materials in the waste stream or the landfil environment. This is an area that requires further research and consideration*": OECD (2016), *Nanomaterials in Waste Streams. Current knowledge on risks and impacts,* p. 66.

suited for nanomaterials. For example, toxicology studies indicate that toxicity of some nanomaterials increases with decreased dimensions of particles[59].

Two issues arose from the study: Firstly, nanowastes have no categorisation and are not "recognised" by waste managers. Secondly, a hazardous nanowaste may still involve risk at concentration below the thresholds established in the list of waste[60].

3.3.2.3 Changes since the 2011 study

Since the 2011 study, Decision 2000/532/EC has been amended by Decision 2014/955/EU in order to align it with the terminology used in Regulation (EC) 1272/2008 (CLP Regulation). The annexed list of waste was replaced by 1 June 2015. No nanomaterial is specifically mentioned. They may be considered to be covered by Chapter 16 (Wastes not otherwise specified in the list). In this chapter, code 16 01 99 refers to "wastes not otherwise specified". However, as Decision 2000/532/EC does not specifically mention nanomaterials it is questionable whether they can be considered to be covered by Chapter 16 and subject to the regime of Directive 2008/98/EC (to the extent that they have a holder and that the holder discards or intends or is required to discard them)[61]. Indeed, a German study of 2015 establishes that '*whereas the content of hazardous nanomaterials in wastes may be a reason to classify a waste as hazardous, it is not sufficient as such. In order to classify waste as hazardous, concentration limits of the substances which have the same hazardous properties have to be exceeded*'[62]. However, as recently reaffirmed by the 2016 OECD study, data and knowledge gaps continue to make difficult the determination of nanomaterials' concentration limits[63]. Finally, the definition of hazardous waste relies on the classification of hazardous substances under the CLP Regulation. However, there are still some issues with regard the identification and classification of hazardous nanomaterials under CLP.

3.3.2.4 Conclusion

As stated above, two major issues seem to be the causes impeding adequate coverage of nanomaterials by the list of wastes: the absence of a specific category of nanomaterial-containing waste and the challenge posed by determining hazardous properties of nanomaterials based on concentration limits and based on the CLP Regulation.

3.3.3 Directive 2000/53/EC on end-of life vehicles (EoLV Directive)

3.3.3.1 Summary of requirements

The two main objectives of Directive 2000/53/EC (the EoLV Directive) consist of minimising the impact of end-of life vehicles on the environment, and to ensure the smooth operation of the internal market[64]. These objectives must be reached by taking into account the principles of subsidiarity, of precaution and prevention and the polluter-pays principle[65]. In the management of waste, priority should be given to reuse and recycling[66]. The use of some heavy metals in particular should be restricted to certain applications according to a list regularly reviewed by the Commission[67]. The Directive furthermore lays down requirements for storage and treatment operations. It invites

[59] European Commission, Health and Consumer Protection Directorate General, 2004, "Nanotechnologies: a preliminary risk assessment on the basis of a workshop", European Commission, Brussels, Belgium, quoted by Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 53.
[60] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 54.
[61] This question was asked by Andreas Herrmann and Dr. Andreas R.Köhler of the ECOS, CIEL, Öko-Institut in the presentation they gave on Nanomaterial-waste in the Production Phase and in Post-consumer Waste at the Nano-project Conference on 9 December 2015 in Brussels, http://ecostandard.org/wp-content/uploads/Hermann-Köhler_Nanomaterial-waste.pdf, slide 11.
[62] Ökopol (2015), *Nanodialogue of the German Government, Nanotechnologies and Waste.* Report by the Federal German Ministry of the Environment, pp. 6-7.
[63] See in particular the summary of knowledge gaps and áreas of further research: OECD (2016), *Nanomaterials in Waste Streams. Current knowledge on risks and impacts,* p. 68.
[64] Preamble, first recital of Directive 2000/53/EC.
[65] Preamble, recitals 2 and 4 of Directive 2000/53/EC.
[66] Preamble, recital 5 of Directive 2000/53/EC.
[67] Preamble, recital 11 of Directive 2000/53/EC.

manufacturers and producers to use component and material coding standards to be established by the Commission, duly taking into account the ongoing work in international forums[68].

The Directive covers vehicles and end-of life vehicles, including their components and materials[69]. It follows from this wording that even though the Directive does not explicitly refer to nanomaterials they can be considered to be covered implicitly[70]. More specifically, Article 4 (2)(a) of the Directive prohibits the distribution, after 1 July 2003, of materials and components of vehicles that contain lead, mercury, cadmium or hexavalent chromium. Annex II lists a limited number of derogations from this provision[71]. Annex II must be amended regularly by the Commission, according to technical and scientific progress in order to establish maximum tolerated concentration values, exempt certain materials and components if their use is unavoidable, delete from the list those materials and components the use of which is avoidable, designate materials and components that can be stripped before further treatment and make sure that they are labelled or made identifiable by other appropriate means[72].

3.3.3.2 Summary of findings of the 2011 study

The EoLV Directive aims at reducing the quantity of waste arising from vehicles through prevention of waste and promotion of the reuse, recycling and other forms of recovery of EoLV and their components and materials in accordance with the requirements of the Waste Framework Directive. It encourages limiting the use of hazardous substances in new vehicles and to avoid the need to dispose of hazardous waste, to facilitate re-use and recycling and integrate recycled materials in vehicles. It provides for establishment of collection systems, transferral to authorised treatment facilities, issuing of a certificate of destruction. Furthermore, 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. In practice however, the 2011 study found that identification of nanomaterials present in vehicles is problematic at the end-of-life for two reasons: firstly, managing a wealth of data, as typical vehicle manufacturers deal with many thousands of suppliers[73]. Secondly, the automotive industry´s 'International Material Data System' or the 'Global Automotive Declarable Substance List' that could be used to communicate information on nanomaterials present in vehicles does not include appropriate data elements.[73]

Examples of nanomaterials used in vehicles at the time of the 2011 study included polymer nanocomposite, nanocrystalline structures, nanocoating applications, nanotechnology-based solid lubricants, nano iron-based particles and carbon black.[70]

3.3.3.3 Conclusion of the 2011 study

The 2011 study found that in theory, the EoLV Directive covers nanomaterials despite not specifically mentioning them, based on Article 3 according to which the Directive shall cover vehicles and end-of-life vehicles including their components and materials.[70] Practical barriers such as knowledge gaps and insufficient disclosure and combination of data hinder effective implementation of the Directive.

3.3.3.4 Changes since the 2011 study

The most obvious success in terms of effectiveness regarding implementation of this Directive is the reduction of hazardous substances in EoLV.[74]

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[68] Preamble, recital 25 of Directive 2000/53/EC.
[69] Article 3 (1) of Directive 2000/53/EC.
[70] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 57.
[71] Article 4 (2)(a) of Directive 2000/53/EC.
[72] Article 4 (2)(b) of Directive 2000/53/EC.
[73] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 56.
[74] Commission Staff Working Document Ex-post evaluation of Five Waste Stream Directives Accompanying the document Proposal for a Directive of the European Parliament and of the Council reviewing the targets in Directives 2008/98/EC on waste, 94/62/EC on packaging and packaging waste, and 1999/31/EC on the landfill of waste, amending Directives 2000/53/EC on end-of-life vehicles, 2006/66/EC on batteries and accumulators and waste batteries and accumulators, and 2012/19/EC on waste electrical and electronic equipment /* SWD/2014/0209 final.

Since the 2011 study the EoLV Directive was amended by Commission Directive 2013/28/EU of 17 May 2013 updating and replacing Annex II of Directive 2000/53/EC in accordance with technical and scientific progress. This updated list of components and materials still does not mention nanomaterials or nanoforms of these substances. Therefore, we cannot observe any regulatory changes related to nanomaterials in EoLV. The main challenge concerning coverage of nanomaterials by the EoLV Directive relates to the definition of 'hazardous substance' under the CLP Regulation. Indeed, there are some issues with regard to the identification and classification of hazardous nanomaterials under CLP (See section 3.4.1). Additionally, nanomaterials cannot always be easily identified by car dismantlers (Ref. 74 para 6.1b). One step to remedy this has been the creation of an International Dismantling Information System (IDIS) by manufacturers to communicate data on vehicle composition to treatment facilities[75]. IDIS provides user friendly navigation to an extensive database with practical information on pre-treatment, safety related issues like airbag deployment and handling of high voltage batteries, on potentially recyclable parts and other safety related elements mentioned in the EoLV directive[76]. The data contained in IDIS is compiled by the vehicle manufacturer and is not reviewed or controlled by any other institution. Access to IDIS is provided free of charge but limited to commercial enterprises in the EoLV business.[76] Therefore, it was not possible to investigate how it addresses nanomaterials.

Further shortcomings concerning effective application of the EoLV Directive to nanomaterials are reported to be related to insufficient reliability and comparability of statistics across Member States, notably because of the use of different reporting systems and calculation methods (Ref. 74 para 6.1b). For example, the use of plastic streams obtained by post-shredder treatment in a blast furnace is counted as recycling by some Member States and "thermal recovery" by others. Member States do not systematically report on recycling and other recovery or the quality of such operations.[76] The two major challenges that remain concern on the one hand, collection and treatment of EoLVs by illegal operators and the illegal shipment of EoLVs and, on the other hand, absence of uniform practice in all Member States as to the follow up of deregistered and exported vehicles.[76]

The problem of distinguishing between EoLVs and used cars due to the absence of definition of "EoLV" is a known issue with this Directive[77]. Therefore, private exports, illegal shipments, disposal or long term garaging and a high volume of EoLVs treated in non-legal or unauthorized treatment facilities in the EU also impede fully effective implementation of the Directive (Ref. 74 para. 6.1b)

3.3.3.5 Conclusion

It follows from a 2014 Commission Staff Working Document that the removal from vehicles of four hazardous substances identified in the EoLV Directive with the exception of lead can be considered a success of effective application of the Directive. Also, more sophisticated post-shredder technology has been developed with the aim to recycle more non-ferrous EoLV parts (Ref. 74 para. 6.1b). However, despite regular updates of the EoLV Directive, the main conclusions of the 2011 study remain valid. A systematic barrier to effective application of the EoLV Directive to nanomaterials remains the current difficulties in classifying hazardous nanomaterials as hazardous substances under CLP (See Section 3.4.1).

Furthermore, car dismantlers' difficulties in identifying nanomaterials, statistically missing EoLVs due to illegal shipments and collection and treatment of EoLVs by illegal operators contribute to impede effective application of the EoLV Directive to nanomaterials. There is potential for improving cooperation and coordination between Member States regarding the follow up of deregistered and exported vehicles including issuing a certificate of destruction in case of a final deregistration of a car (Ref. 74 para. 6.1b).

[75] http://idis2.com
[76] http://idis2.com/index.php?action=rmi&language=english
[77] Christa Friedl and Ulrich Leunig (BDSV), Recycling Magazine 08/2012, p. 35, quoted in Ref. 74, para. 6.1b.

Last but not least, further harmonisation may remedy the lack of reliability and comparability of statistics across Member States due to different reporting systems and calculation methods. In order to improve coherence among waste legislation, it is suggested to use the same definitions (this is currently not systematically the case[78], e.g. the definition of "recycling" in Art. 2 (7) EoLV Directive differs from the Waste Framework Directive which excludes from recycling "reprocessing into materials that are to be used as fuels or for backfilling operations", contrary to the EoLV Directive) (Ref. 74 para. 6.4b)..

3.3.4 Directive 1999/31/EC on the Landfill of Waste (Landfill Directive)

3.3.4.1 Summary of requirements

The Landfill Directive[79] sets out 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. It applies to all landfills defined as waste disposal sites for the deposit of waste onto and into lands. It divides landfills in three classes (landfills for hazardous waste, for non-hazardous waste and for inert waste with specific legal requirements for each landfill that must be subject to a permitting procedure before being in operation. It sets a list of waste that may not be accepted in a landfill. It also contains waste acceptance criteria and procedures and monitoring requirements in landfill in operation and closed.

The Landfill Directive does not contain specific requirements related to nanomaterials but nanomaterials in waste or nanowaste due to the definition of waste are de facto covered by the Landfill Directive. Furthermore the Landfill Directive is relevant for the control of nanomaterials in waste since landfills are an important waste stream for nanomaterials in consumer products at the end of their useful life, for nanowaste from manufacturing and from remediation as well as for nanowaste from waste treatment systems (e.g. ash or slag as a result of incineration)[80].

3.3.4.2 Conclusion of the 2011 study

Concerning the coverage of nanomaterials under the Landfill Directive the 2011 study pointed out several legislative and knowledge gaps:

- Some hazardous nanowastes may not be categorised as hazardous under CLP Regulation and may be treated as non-hazardous and be dumped into landfill for inert waste or municipal waste;
- The difficulty to apply the waste acceptance procedure for nanowaste due to the lack of available information to characterise such waste (e.g. composition, leachability, long-term behaviour and characteristic properties);
- Leaching limit values unlikely to be appropriate for nanomaterials.

3.3.4.3 Changes since the 2011 study

Since the 2011 study, the Landfill Directive has not been amended and no specific initiatives have been taken by the European Union on the disposal of nanomaterials in landfills. According to a recent 2016 OECD study on nanomaterials in waste streams, there are still a lot of knowledge gaps concerning landfilling of waste containing nanomaterials which may limit the effective application of existing regulatory management controls as already identified in the 2011 study.

This OECD study stresses that further research is needed in the following areas:

- Development of analytical chemistry test methods to identify nanomaterials in environmental media and distinguish them from normal scale chemicals they may contain;

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[78] "*European waste law looks however rather kaleidoscopic. Perhaps the most striking feature is the co-existence between framework legislation and waste stream specific legislation. In recent years, and as shown by this evaluation, it has become more and more apparent that a parallel development of framework legislation and waste stream legislation can create tensions. Such tensions relate to the relatively static elements of legislation, such as definitions, concepts of EPR, life cycle thinking and resource efficiency as well as calculation methods for targets. Such static elements and principles should be developed coherently across all the Directives of a certain sector and not in parallel following different speeds of development*", Ref. 74 , para 7.1.

[79] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.

[80] OECD (2016), *Nanomaterials in Waste Streams. Current knowledge on risks and impacts*

- Characterisation and quantification of nanowaste in landfills and understanding of the chemical and environmental processes in landfills;
- Understanding of the effectiveness and constraints of current landfill methods and technologies;
- Understanding of the applicability of a future nanomaterial classification system for waste management in order to classify, label, and segregate hazardous nanowaste and waste containing hazardous nanomaterials.

The study concludes that landfills will increasingly receive nanomaterials alongside the growth of nanotechnology industry and the broad use of materials and this is why it is urgent to close these knowledge gaps in order to adequately control the potential risks of nanomaterials in landfills.

3.3.4.4 Conclusion

As already identified in the 2011 study, there are still several gaps hindering the adequate application of the requirements of the Landfill Directive to nanomaterials and nanowaste (e.g. reliance on the CLP Regulation to categorise hazardous waste). Despite the potential increase of nanowaste in landfills in a near future, the current knowledge gaps on their behaviour in landfills, the health and environmental risks they may entail, the Directive has not been amended and there have been no EU initiative to foster research on this field to ensure that these risks are controlled.

3.3.5 Directive 2011/65/EU (RoHS Directive)

3.3.5.1 Summary of requirements

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) 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). Directive 2011/65/EU is a recast of Directive 2002/95/EC. It was published in the Official Journal on 1 July 2011 and had to be transposed by 2 January 2013. Certain hazardous substances (listed in Annex II[81]) must not be contained in EEE placed on the market above the maximum concentration limits.

There are however exemptions to these prohibitions[82]. In particular, exemption 39 of the Directive is relevant for this study since it allows for the use of Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm2 of light-emitting area) for use in solid state illumination or display systems. The colour converting component in LEDs consists of cadmium containing quantum dots nanomaterials. In January 2015 the Commission proposed extending the exemption until 2017 and adding a new exemption (39b) relating to Cadmium in downshifting cadmium based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0.2 µg Cd per mm2 of display screen area).[83]

However, the European Parliament objected to the Commission Delegated Directive,[84] therefore triggering a new assessment.[85] Recital 16 of the recast Directive provides that the list of restricted hazardous substances of Annex II be extended and their substitution by more environmentally friendly alternatives be examined "*as soon as scientific evidence is available, and taking into account the precautionary principle*". Article 6 provides that "*in order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure or a group of similar substances […] (a) could*

[81] Lead (0,1%), Mercury (0,1%), Cadmium (0,01%), Hexavalent chromium (0,1%), Polybrominated biphenyls (PBB) (0,1%), Polybrominated diphenyl ethers (PBDE) (0,1%)

[82] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 88.

[83] Proposal for Commission delegated Directive of 30.1.2015 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applications, C(2015) 383 final.

[84] European Parliament resolution on the Commission delegated directive ../.../EU amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applications (2015/2542(DEA)), B8-0464/2015, 13.5.2015.

[85] Details relating to the new assessment are available at: http://rohs.exemptions.oeko.info/index.php?id=261

have a negative impact […]; (b) could give rise […] to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products […]; (c) could lead to unacceptable exposure of workers; (d) could be replaced by substitutes or alternative technologies which have less negative impacts". Clearly, the Directive here refers to nanomaterials (*"substances of very small size or with a very small internal or surface structure").*

Periodical reviews, based on thorough assessment, must be considered by the Commission according to Article 6 (3), 1st paragraph. They must refer to publicly available knowledge obtained from the application of such legislation[86]. However, the practical barrier consists in obtaining scientific evidence from publicly available data. At the time of the 2011 study "*data on the risks of specific nanomaterials [was] limited*[87]", which explains the difficulties to provide any information on nanomaterials to be potentially included in Annex II of the RoHS Directive.

3.3.5.2 Summary of findings of the 2011 study

The key issue identified in the 2011 report concerning coverage of nanomaterials under the RoHS Directive was related to the applicability of the maximum concentration values determined in Annex II to nanomaterials, namely cadmium-based quantum dots[88]. At the time of the 2011 study, no nanomaterials were included under Annex II as restricted substances[89].

3.3.5.3 Conclusion of the 2011 study

As mentioned above, the 2011 study concluded that the lack of scientific evidence as to the hazardous character of nanomaterials in EEE can lead to possible releases of nanomaterials into the environment during recycling processes[90].

3.3.5.4 Changes since the 2011 study

Since the 2011 study, between 10 October 2012 and 31 March 2015 the RoHS Directive underwent a recast[91] and has been amended by 29 Commission delegated Directives. These update the Annex II list of restricted substances in accordance with Article 6(1) and Annex III related exemptions. Following thorough assessments, where available evidence indicates that the identified substances, when used in EEE, can have a negative impact on recycling and on human health and the environment during EEE waste management operations and when substitutes that have less negative impacts are available for those substances, then these Commission delegated Directives include them in Annex II. Lately, for example, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP), which are substances of very high concern (SVHC) were integrated in Annex II to comply with the principle of coherence of Union legislation, as DEHP, BBP and DBP are already restricted through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[92]. Whereas Annex II has been constantly updated extending the list of restricted substances to substances for which scientific evidence jointly with the principle of precaution justify the restriction, this Annex does not currently contain any restricted substances that are nanomaterials.

Concerning exemptions to the Annex II prohibitions, it is important to mention the Commission proposal to extend the exemption on cadmium quantum dots in illumination and display lighting applications was objected to by the European Parliament and is now under assessment.

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[86] Article 6(1) second sentence.
[87] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 89.
[88] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 89.
[89] Idem.
[90] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 90.
[91] Directive 2011/65/EU repealed Directive 2002/95/EC
[92] Commission delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances, OJEU of 4 June 2016, nº L137, pp. 10-12, recitals 4-6.

3.3.5.5 Conclusion

Nanomaterials are regulated under this text via restriction of certain hazardous substances in EEE. Article 6 specifically mentions that when reviewing the list of restricted substances, the Commission must take into account several criteria (e.g. negative impacts during EEE waste management operations, uncontrolled or diffuse release into the environment) for substances including substances of very small size or with a very small internal or surface structure. Therefore this key provision of the ROHS Directive is considered to be an adequate tool to restrict hazardous nanomaterials in EEE. Such periodic review procedure may lead to the generation of new information on nanomaterials in EEE and their related potential environmental risks.

3.3.6 Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) (recast)

3.3.6.1 Summary of requirements

The WEEE Directive[93], which has since the 2011 study, undergone a recast process, lays down requirements for the prevention of waste from 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 (EEE).

Nanomaterials are increasingly found in EEE, being a key component in the new generation of computers and new compact energy sources such as lithiumion batteries (carbon nanotubes CNT, fullerene, nano Iron oxides, nano phosphate). Nanosilver coating in domestic appliances to limit bacterial growth is another key area.

The old 2002/96/EC WEEE Directive treatment requirements did not address nanomaterials, nor was the removal of nanomaterials from WEEE specifically required, but number or provisions were applicable to WEEE containing nanomaterials as briefly described below in chapter 3.2. The new 2012 directive contains some requirements related to nanomaterials.

3.3.6.2 Summary of findings of the 2011 study

Although the Directive 2002/96 EC did not explicitly address nanomaterials, it provided a number of options to manage them. As for proper treatment of collected WEEE, the then article 6(1) on the 'proper treatment of waste of electronic and electrical equipment' provided a possibility for the Member States to set up minimum quality standards for the treatment of collected WEEE. Under such standards it was possible to require for example that certain kinds of nanomaterials should be removed from WEEE during treatment due to their potential impact on the environment. The study confirmed however that none of the Member States had by then identified specific nanomaterials or set up regulation requiring their removal.

In addition, it was also foreseen that the Article 13 on adaption to scientific and technical knowledge could enable the Commission to review at any time the applicable treatment requirements, including regarding nanomaterials.

The old Directive further contained information obligations vis-à-vis users and facilities. For example, Article 10 (1) required that users were given the necessary information on potential effects on the environment and human health as a result of the presence of hazardous substances in EEE. Under Article 3(1) the producers were required to provide reuse centres, treatment and recycling facilities reuse and treatment information to identify the different EEE components and materials, as well as the location and mixtures of in EEE. The study stressed that a fully effective application of both obligations would have nevertheless required improved scientific information on the hazard qualities of them and most likely assessing hazard criteria under a specific nanomaterial category different from the then applicable size-unspecified form assessment.

3.3.6.3 Changes since the 2011 study

Since the 2011 study, the WEEE Directive has undergone a recast process and Directive 2012/19/EU now contains a provision related to nanomaterials. Article 8 (4) point 2 requires the Commission to

[93] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast).

evaluate whether Annex VII listing the substances, mixtures and components that have to be removed from any separately collected WEEE need to be amended to address nanomaterials . Recital 18 of the WEEE Directive underlines 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. Other relevant provisions to control health and environmental risks of nanomaterials in WEEE are Article 8 (4) point 1 which empowers the Commission to adopt delegated acts concerning the amendment of Annex VII in order to introduce other treatment technologies that ensure at least the same level of protection for human health and the environment and Article 8(5) which requests the European standardisation organisations to develop European standards for the treatment, including recovery, recycling and preparing for re-use, of WEEE that reflect the state of the art.

3.3.6.4 Conclusion

The WEEE 2012/19/EU Directive (recast) invites the Commission to evaluate whether amendments to Annex VII are necessary to adequately control nanomaterials. However to date, no evaluation assessing amendment needs with regard to treatment requirements under Annex VII have been carried out nor any delegated acts adopted. The Commission has nevertheless requested the European Standardization Organization to develop European standards for the treatment of WEEE. Although the Commission request to the European Standardisation Organisation does not specifically address nanomaterials, the set of new standards may in the long run turn out to be relevant in terms of nanomaterial treatment in WEEE. The new standards include the following: EN 50419 on the marking of electrical and electronic equipment; EN 50574 on the collection, logistics & treatment requirements for end-of-life household appliances containing volatile fluorocarbons or volatile hydrocarbons; and EN 50625-1: Collection, logistics & treatment requirements for WEEE - Part 1: General treatment requirements.[94]

3.3.7 Directive 94/62/EC on packaging and packaging waste (Packaging Directive)

3.3.7.1 Summary of requirements

Directive 1994/62/EC on packaging and packaging waste (Packaging Directive)[95] lays down measures aimed at preventing the production of packaging waste. It set targets for the recovery and recycling of packaging waste to reduce the disposal of such waste. Annex II on essential requirements, requires that packaging must be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimized with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled. Article 11 also sets out maximum concentration levels of lead, cadmium, mercury and hexavalent chromium which can be present in packaging.

The definition of ‘packaging “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 ‘ applies to packaging containing nanomaterials.

Nanomaterials are increasingly used in packaging, especially in food packaging which accounts for 30% of the packaging market. According to a 2014 study, research is on-going to use nanomaterials in food packaging for different applications such as oxygen scavengers, antimicrobial nanomaterials, and nanobiosensors[96].

3.3.7.2 Conclusion of the 2011 study

The 2011 study pointed out that in seeking to prevent the harmful effects of materials and substances used in packaging, evidence of harm has to be brought forward under the Packaging Directive. This was illustrated by the essential requirement for packaging under Annex II on the minimisation of

[94] See more in detail European Commission, Waste Electrical and Electronic Equipment (WEEE) Standards on WEEE treatment available at http://ec.europa.eu/environment/waste/weee/standards_en.htm

[95] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

[96] Packaging technology and Science International Journal, Nanomaterials: A map for their selection in food packaging applications, June 2014 available at: http://onlinelibrary.wiley.com/doi/10.1002/pts.2076/abstract;jsessionid=9CCD43CDAADCE4248F4E9BEDDA9380B6.f02t04

noxious and other hazardous substances in emissions, ash or leachate from processing of waste packaging, and the CEN standard on packing waste prevention (EN 13428:2004), which mentions that 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 and evaluate their possible release into the environment and related risks. The 2011 study however concluded that 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.

3.3.7.3 Changes since the 2011 study

The Packaging Directive has been amended since 2011 but the amendments do not affect provisions applying to nanomaterials. The latest revision of the Packaging Directive occurred on April 2015 with the adoption of Directive (EU) 2015/720 of the European Parliament and of the Council amending Directive 94/62/EC as regards the consumption of lightweight plastic carrier bags.

The CEN standard on packing waste prevention (EN 13428:2004) mentioned in the 2011 study is still in effect. No new CEN standard has been yet adopted. Since the 2011 study, there is more evidence on the increased use of nanomaterials in packaging and mainly in food packaging.

3.3.7.4 Conclusion

As with regard to Waste Framework, Landfill and WEEE directives, effective implementation of the Packaging Directive provisions to packaging containing nanomaterials is hampered by poor knowledge on nanomaterials characteristics, releases to the environment and behaviour. The current provisions of the Packaging Directive would be adequate to cover nanomaterials if there were no such knowledge gaps which were already identified in the 2011 study.

3.3.8 Directive 86/278/EEC (Sewage Sludge Directive)

3.3.8.1 Summary of requirements

Directive 86/278/EEC of the Council of the European Communities on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (Sewage sludge Directive) lays down rules 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 humans. The Directive establishes limit values for concentrations of heavy metals (cadmium, copper, nickel, lead, zinc, mercury and chromium) in soil, in sludge for use in agriculture, and for concentrations of amounts of heavy metals which may be added annually to agriculture land based on a 10-year average. It does not contain any literal reference to nanomaterials. It does not fix specific limit values for the nano-form of these heavy metals, or any other specific nanomaterials. However, some nanomaterials present in waste water, when treated, will be captured in sewage sludge[97].

3.3.8.2 Summary of findings of the 2011 study

The 2011 study pointed to the absence of an evidence base to establish thresholds below which nanomaterials concentrations do not cause any harm to human health or the environment. It stressed that mass-based limit values may not be adequate to ensure that nanomaterials' toxicity effects be rendered negligible. Furthermore, it emphasized that given the heterogenous distributions of nanomaterials, concentration determination within a given sample is difficult (in 2011 monitoring nanomaterials' concentrations in sludge was not technically feasible)[98]. It was observed concerning the example of titanium dioxide that as the bulk forms do not meet the criteria for classification as hazardous under the CLP regulation, it is uncertain whether nano-TiO_2 are to be classified as hazardous[99].

[97] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 37.
[98] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. xix.
[99] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 107.

3.3.8.3 Conclusion of the 2011 study

The 2011 study concluded that on the one hand, limit values for heavy metals may not be low enough to ensure that the toxicity effects of nanoforms are rendered negligible. Establishing limit values for nanomaterials remains subject to challenges due to limited data[100]. On the other hand, in the absence of adequate monitoring the uncertainty regarding the presence of nanomaterials in sewage sludge will persist[101]. Indeed, some nanomaterials such as nano-TiO_2 are unlikely to be detected in water bodies using existing monitoring equipment[102].

3.3.8.4 Changes since the 2011 study

A 2015 study on exposure to nanomaterials in Denmark from the Danish Environment underlines that application of sewage sludge to (agricultural) soil is considered to be the main direct source of nanomaterials to the soil environment[103].

Another 2015 study of the Federal German Ministry of the Environment establishes that nanomaterials in sewage sludge such as for example nanosilver are firmly bound in a sludge-soil mixture and can hence accumulate in soils, inhibiting the activity of microorganisms and are therefore likely to disturb natural processes in soils[104]. The Sewage Sludge Directive has not been amended since the 2011 study. According to a 2012 study, "*detecting engineered nanomaterials is one of the greatest challenges in quantifying their risks*". Therefore, it is "*imperative to develop techniques capable of measuring and characterizing exposures, while dealing with the innate difficulties of nanomaterial detection in environmental samples*"[105]. Both, a 2013 study and the 2016 OECD study underline the need of more realistic experimental designs with improved quantification of nanomaterials properties in order to better understand their fate and effect associated with wastewater treatment plants[106].

3.3.8.5 Conclusion

The main conclusions of the 2011 study concerning coverage of nanomaterials by the Sewage Sludge Directive remain valid. As of today, major knowledge gaps remain (e.g. on nanomaterials production, application and release) that affect modelling of nanomaterials' environmental concentrations[107]. Furthermore, as mentioned above, it is not sure whether concentration limits are an adequate factor to assess the hazard criterion, given that their size and structure may need to be taken into account as well. The Sewage Sludge Directive therefore does currently not seem to be an adequate tool to detect monitor and control the use of hazardous nanomaterials in the treatment of sewage sludge. Whereas the 2015 Danish study establishes that concentration of nanomaterials in agricultural soil even with sewage sludge applications would remain very low according to measured and modelled concentrations[108], it follows from the 2015 German study that nanosilver and iron oxide particles can disturb natural processes in soil partly already in very low concentrations[109].

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[100] Review of Environmental Legislation for the Regulatory Control of Nanomaterials – Contract Nº 070307/2010/580540/SER/D – Final Report – September, 2011, p. 110.
[101] Idem.
[102] Idem.
[103] The Danish Environmental Protection Agency, exposure to nanomaterials from the Danish environment (2015) available at:http://www2.mst.dk/Udgiv/publications/2015/01/978-87-93283-54-1.pdf
[104] Ökopol (2015), *Nanodialogue of the German Government, Nanotechnologies and Waste.* Report by the Federal German Ministry of the Environment, p. 13.
[105] Mitrano, D.M. et al., Detecting nanoparticulate silver using single-particle inductively coupled plasma–mass spectrometry, *Environ. Toxicol. Chem.* 2012;31:115–121.
[106] Neale, Peta A et al., A review of the detection, fate and effects of engineered nanomaterials in wastewater treatment plants, *Water Science & Technology*. 2013, Vol. 68 Issue 7, pp. 1440-1453; OECD (2016), *Nanomaterials in Waste Streams. Current knowledge on risks and impacts,* p. 86.
[107] Gottschalk F., Yin Sun T., Nowack B., Environmental concentrations of engineered nanomaterials: Review of modeling and analytical studies, *Environmental Pollution,* Volume 181, October 2013, Pages 287–300.
[108]The Danish Environmental Protection Agency, exposure to nanomaterials from the Danish environment (2015) available at:http://www2.mst.dk/Udgiv/publications/2015/01/978-87-93283-54-1.pdf. This study was performed for Denmark and does not necessary represent the whole EU
[109] Ökopol (2015), *Nanodialogue of the German Government, Nanotechnologies and Waste.* Report by the Federal German Ministry of the Environment, p. 13.

Stakeholder views on EU waste legislation

The comments in this box are relevant to waste legislation discussed in Sections 3.3.1to 3.3.8 above.

Representative of German Federal Environmental Agency on Sewage Sludge Directive

Adapted limit values for such substances with increasing amounts of their nano-forms (Ag, ZnO) are urgently needed. Even though monitoring of nano-forms is challenging, our knowledge on their fate in the environment (accumulation in soil and sludge) and harmful effects (soil tox) is sufficient to act, e.g. in a first step by installing limit values for the chemical substance in general. Furthermore, from the point of view of environmental protection, the use of sewage sludge for agriculture is questionable in general. The increasing amounts of potentially environmentally harmful substances resulting from increasing use, release and environmental exposure of their nano-scale forms is a further argument not to use sewage sludge for agricultural soil fertilization.

NIA on nanomaterials and EU waste legislation

Nanomaterials are already targeted by specific provisions in waste legislation under RoHS and WEEE. They are already covered under the definition of 'substance' by the CLP regulation. Nanotechnology industries consider that there is no ground for a specific treatment of nanomaterials in waste. Where dossiers and testing demonstrate the similarity of nanoforms of a substance to their non-nano counterparts there should be no need for additional specific provisions for nanomaterials in waste. NIA considers that nanomaterials in waste area already covered by European legislation and that adding further complexity to the legal framework, with more stringent, not easily applicable nanomaterial-specific provisions, would not participate in improving the situation of waste management with regards to waste export and mishandling. The term 'nanowaste' should not be used, for it is misleading.

Leitat representative on nanomaterials and EU waste legislation

Requirements for waste management are related to classification of the waste material, so it may not be necessary to include additional considerations for the fact of being 'nano', unless the nano-size would lead to differential release/exposure patterns. In those cases, it should be recommended establishing notification/label requirements.

3.3.9 Directive 2000/60/EC (Water Framework Directive)

3.3.9.1 Summary of requirements

Directive 2000/60/EC establishing a framework for Community action in the field of water policy (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. This sub-section focuses on the requirements related to surface waters; any requirements related to groundwater and drinking water being treated in separate sub-sections below.

According to Article 4 of the Water Framework Directive, surface waters should have achieved good water status by December 2015, meaning that both the chemical status and ecological status of the surface water are at least "good". This entails that:

- Concentrations of priority substances (as identified in Annex X of the Directive) are below the Environmental Quality Standards (EQS – see next sub-section) set at EU level;
- Pollution from priority substances is gradually reduced; and
- Emissions, discharges and losses of priority hazardous substances are phased-out.

3.3.9.2 Conclusions of the 2011 study

Based on Art 16(2), the Commission has developed a Combined Monitoring-based and Modelling-based Priority Settings (COMMPS) scheme for the identification of priority substances and priority hazardous substances (PHS), which are selected among priority substances for their persistency, toxicity and liability to bioaccumulate.

The scheme is based on a risk-based assessment methodology which 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.

The study concluded that it is unlikely that the increasing concentrations of nanomaterials in surface waters would be captured by the COMMPS procedure, for a number of reasons. 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 and thus determine whether any nanomaterials give rise to an equivalent concern as PTB substances (i.e. persistent, toxic and able to bioaccumulate). Thirdly, at the time of the study, no nanomaterials had been included in any international agreements or EU legislation on hazardous substances, which could have been taken into account in the identification of PHS, as per Article 16(3) of the Directive. As such, the study concludes that the inapplicability of the COMMPS procedures to nanomaterials represents an implementation gap.

Two additional implementation gaps were identified in 2011:

- The lack of appropriate end-of-pipe measures to control discharges of nanomaterial pollutants from point sources;
- The impossibility to categorise nanomaterials as specific pollutants of river basins (as per Annex VIII) because of the absence of appropriate monitoring techniques.

Finally, the Water Framework Directive requires the establishment of environmental quality standards (EQS) for priority substances (Article 16(8)). For nanomaterials, this is hampered by uncertainties related to the use of mass-based thresholds for establishing EQS and was identified as a legislative gap in 2011 (see next section on the EQS Directive).

3.3.9.3 Changes since the 2011 study

The main direct legislative change that has occurred since 2011 has been the amendment of Annex X of the Water Framework Directive listing the priority substances, on the basis of the newly adopted Directive 2013/39/EU amending Directive 2008/105/EC on environmental quality standards in the field of water policy.

The review of Annex X of the Water Framework Directive has been undertaken in accordance with Article 16(4), which requires the Commission to regularly review its Annex X, and with Article 8 of the EQSD, which requires the Commission to take into account the substances listed in its Annex III to amend Annex X of the Water Framework Directive. Thus, in 2011-2012, the Commission supported by Member State experts worked on a revised list of priority substances and appropriate EQS for these new substances, as well as revised EQS for existing priority substances.[110] This was done using a revised methodology for COMMPS scheme. However, although now able to do so, none of the new substances identified with the new methodology are nanomaterials, due to the lack of monitoring data of nanomaterials in EU surface waters.[111]

One of the changes to the EQS Directive is the inclusion of Article 8 on the creation of a 'watch list' mechanism (more details about the mechanism and its effects are provided in the next section). This mechanism has the potential to facilitate the identification of nanomaterials as 'priority substances', which would trigger the implementation of a number of control measures under the Water Framework Directive, as described above. Other changes that could have the potential to impact on the coverage of nanomaterials in the water legislation include any mention in other EU legislation or international agreement of nanomaterials as hazardous substances, as per Article 16(3) of the Water Framework Directive. While there are still some issues with regard the identification and classification of hazardous nanomaterials under CLP (see section 3.4.1), recent changes to the Biocides Directive

[110] Report from the Commission to the European Parliament and the Council on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy, COM(2011) 875 final, 31 January 2012.
[111] 2011 study, p135

means that nanomaterials in biocides considered hazardous (see section 3.4.1) could start getting phased-out in the near future.

3.3.9.4 Conclusions

The creation of a 'watch list' mechanism under the EQS Directive (see next section) has the potential to facilitate the inclusion of substances in nano form in the list of priority substances and the implementation of related monitoring and control measures under the Water Framework Directive.

3.3.10 Directive 2008/105/EC (Environmental Quality Standards Directive)

3.3.10.1 Summary of requirements

Directive 2008/105/EC lays down environmental quality standards (EQS) for priority substances and certain other pollutants as required under Article 16 of the Water Framework Directive.

The first step for nanomaterials to be considered under the EQS Directive is their inclusion in the list of 'priority substances' in Annex X of the Water Framework Directive. Then, the EQS Directive sets the environmental quality standards for those priority substances in various matrices (water, sediment, biota) and the conditions for their use and for their review. Finally, the EQS Directive 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.

3.3.10.2 Conclusions of the 2011 study

Beyond the fact that the classification of nanomaterials as 'priority substances' is unlikely, the 2011 study concluded that:

1. The lack of ecotoxicological data and the low reliability of existing data hampers the establishment of EQS.
2. The methods to derive the EQS for a priority substance are not adapted to nanomaterials. The setting of EQS is based on the Technical Guidance for risk assessment of chemicals. In 2007 the SCENIHR has acknowledged that this guidance is not adapted to nanomaterials, which behaviour and effects do not depend only on their mass concentrations.[112] Thus, lowering the concentrations of nanomaterials in various matrices (which is the basic principle of the EQS) may not be effective.
3. The requirement to arrange long-term monitoring presents challenges when it comes to nanomaterials, considering the lack of appropriate monitoring techniques and tools and thus the difficulty to set up a comprehensive monitoring programme for nanomaterials – even targeted ones – in aquatic ecosystems.

The study concluded that 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.

3.3.10.3 Changes since the 2011 study

Since 2011, the EQS Directive has been amended. One of the new elements of Directive 2013/39/EU is Article 8(b) putting in place a mechanism to create a 'watch list' of substances to gather monitoring data in view of future reviews of the list of priority substances. The watch list shall contain up to 14 substances, selected among those 'for which the information available indicates that they may pose a significant risk at Union level to, or via, the aquatic environment, and for which monitoring data are insufficient.' The selection of the substances for the watch list should take into account certain types of information including:

- The outcomes of the reviews of Annex X of the Water Framework Directive;
- Research and stakeholder recommendations;
- The outcomes of MS monitoring programmes; and
- Production volumes, use patterns, intrinsic properties (including, where relevant, particle size).

[112] 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.

Article 8(b) provides a list of the type of information that may be used to constitute the watch list, including information on 'intrinsic properties (including, where relevant, particle size)'. The mention of particle size could be an indirect reference to nanomaterials, even if the term itself is not used. This provision therefore gives the possibility to the European Commission to include certain substances on the watch list based on information regarding their intrinsic properties and production volumes, in cases where monitoring data are insufficient to demonstrate the risk they pose to the aquatic environment. This is a significant step as monitoring data on the bioavailability and toxicity of nanomaterials in the aquatic environment is still very limited and a historical dataset is not available.[113]

It is worth noting that the first watch list developed by the JRC in 2015 does not make any reference to specific nanomaterials or to the nano form of other substances.

3.3.10.4 Conclusions

The changes brought by the inclusion of the new Article 8 in the EQSD open the door to the possible inclusion of nanomaterials in the list of priority substances, despite the lack of monitoring data. This would then have a ripple effect on the other water-related pieces of legislation.

3.3.11 Directive 2006/118/EC (Groundwater Directive)

3.3.11.1 Summary of requirements

Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (the Groundwater Directive) 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' (i.e. in relation to the maximum allowed concentration of chemicals in groundwater) 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.

3.3.11.2 Conclusions of the 2011 study

Nanomaterials are in principle captured under Annex II, Point 2 of the Directive, which refers to man-made synthetic substances. Should specific nanomaterials be identified as pollutants of groundwater in a Member State then threshold values should be established for those nanomaterials against which maximum concentration in ground water is allowed. The list of threshold values is to be updated in response to information on new pollutants, groups of pollutants or indicators of pollutants.

However, issues related to the coverage of nanomaterials under the Directive are tightly linked with those for the Water Framework Directive and the EQSD, 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. These issues 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.

3.3.11.3 Changes since the 2011 study

Annexes I and II of the Groundwater Directive 2006/118/EC were reviewed in 2013 in order to ensure that the provisions of the Directive were still in consensus with the technical/scientific developments

[113] Ganzleben, C., Foss Hansen, S., 'Nanomaterials as priority substances under the Water Framework Directive', *Elni Review*, No2/2012, 2012.

and in line with the Water Framework Directive. A public consultation was carried out prior to the review. The background document developed for the public consultation mentions the gaps in the Directive in relation to a number of emerging pollutants for which monitoring data is lacking. However, the list of emerging pollutants mentioned in the document does not include nanomaterials, and neither does the amended Directive.

Another important change since 2011 is the creation of the 'watch list' mechanism under the EQS Directive, allowing for the possible inclusion of nanomaterials in the list of priority substances, as explained in the previous section.

In addition, since 2014, a number of 'volunteer' Member States and the Commission are working on the creation of a similar 'watch list' mechanism for the Groundwater Directive, which would identify the risk posed by emerging substances for which monitoring or modelling data is not available. In background documents related to this mechanism, no mention of particle size is made, however.

3.3.11.4 Conclusions

The conclusions of the 2011 study are still valid as recent changes in the legislation do not have any impact on the coverage of nanomaterials. As with other water-related legislation, any changes to the Water Framework Directive or EQSD in relation to nanomaterials would also have an impact on the Groundwater Directive.

3.3.12 The Drinking Water Directive

3.3.12.1 Summary of requirements

Directive 98/83/EC on the quality of water intended for human consumption (the Drinking Water Directive) sets out quality standards for drinking water and specifies 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 leaves this technical choice to the Member State and focuses on quality standards.

In relation to nanomaterials, there are two main issues:

- The risk of drinking water sources becoming contaminated by nanomaterials, with possible consequences for human health, increases as the production and use of nanomaterials – and thus their release into the aquatic environment – increase.
- Nanomaterials are specifically used in the field of water purification, including through the use of nano-filters, nanomaterials as absorbents, titanium dioxide photocatalysts and nanotechnology-based sensors, which may involve a more direct release of nanomaterials into the water.

3.3.12.2 Conclusions of the 2011 study

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.

The study concluded that, at the time, there was no evidence to suggest that drinking water was contaminated with nanomaterials and recommended to conduct testing using standardised approaches in order to provide a coherent body of evidence for decision making.

3.3.12.3 Changes since the 2011 study

In 2015, Annexes II and III of the Drinking Water Directive, which regulate the monitoring of drinking water, were amended to allow Member States to choose parameters and frequencies for monitoring based on a risk assessment procedure.

3.3.12.4 Conclusions

The conclusions of the 2011 study are still valid.

3.3.13 The Urban Waste Water Treatment Directive

3.3.13.1 Summary of requirements

Directive 91/271/EEC concerning urban waste water treatment (the Urban Waste Water Treatment Directive, UWWTD) 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. The main issue is whether the treatment requirements under this Directive are adequate to address nanomaterials in urban waste water.

3.3.13.2 Conclusions of the 2011 study

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, there is no strong case for focusing on nanomaterials when other hazardous substances (for which evidence on hazard and exposure scenarios is considerably more robust) are not specifically considered. 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.

3.3.13.3 Changes since the 2011 study

There have not been any amendments to this Directive since 2011.

3.3.13.4 Conclusions

The legislative and implementation gaps identified in 2011 still remain.

3.3.14 The Marine Strategy Framework Directive

3.3.14.1 Summary of requirements

Directive 2008/56/EC stablishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive – MSFD) establishes a framework within which Member States must take the necessary measures to achieve or maintain good environmental status in the marine environment by the year 2020 at the latest.

3.3.14.2 Conclusions of the 2011 study and further evaluation

Most of the contamination of the marine environment comes from land-based sources. While the second regulatory review did not investigate the potential for regulating nanomaterials in the marine environment, it is relevant to explore what are the conditions for the MSFD to take into account contamination by nanomaterials.

Good environmental status (GES) is defined in the Directive through 11 qualitative descriptors, two of which are directly related to contamination by hazardous substances of the marine environment (descriptor 8) and of fish and other seafood for human consumption (descriptor 9). Commission Decision 2010/477/EU, which further specifies the criteria for good environmental status, states that Member States should take into account the substances and threshold values defined under the Water Framework Directive and the EQSD for the definition of GES in the marine environment. More specifically, the minimum requirements used to assess the adequacy of Member States' GES definitions included coverage of all priority substances of the EQS Directive. Thus, considering the strong linkages between the Water Framework Directive, the EQSD and the MSFD, were some nanomaterials designated as 'priority substances' under the Water Framework Directive, they would, in theory, also need to be regulated in the marine environment.

The issue of nanomaterials is also relevant for Descriptor 10 on marine litter, which focuses on macro- and micro-litter on the beach and seafloor and in the water column as well as its impacts on marine species and habitats. While nano-size plastic is not mentioned in the Commission Decision on GES criteria, its absorption by marine animals and its presence in the food chain are a potential risk to

the marine environment. The European Food Safety Authority has recently recalled that the lack of ecotoxicological data for nanoplastics makes human risk assessments difficult and has recommended the development of analytical methods to assess the presence, identity (including shape) and quantity of nanoplastics in food[114]

3.3.14.3 Changes since the 2011 study

There have not been any amendments to this Directive since 2011. However, the Commission Decision is currently under review. One of the objectives of the review is to create even stronger links between the MSFD and the Water Framework Directive /EQSD as regard the chemical status of marine waters.

3.3.14.4 Conclusions

All the limitations previously mentioned in relation to the lack of ecotoxicological data and difficulties with monitoring are valid for the marine environment as well.

3.3.15 Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III Directive)

3.3.15.1 Summary of requirements

The aim of the Seveso Directive[115] is to prevent and, in case they occur, limit major accidents involving dangerous substances. It applies to establishments where dangerous substances may be present in quantities above a certain threshold. Certain industrial activities covered by other EU legislation are excluded from the Seveso Directive (e.g. nuclear establishments or the transport of dangerous substances).

The Seveso Directive takes a tiered approach to requiring safety measures at facilities based on the volumes of dangerous substances present at facilities. 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.

Dangerous substances are defined in Annex I together with the thresholds for each substance that trigger requirements. Annex I part I includes hazard categories in accordance with the CLP Regulation.

There is no specific reference to nanomaterials nor related obligations under the Seveso Directive.

3.3.15.2 Conclusion of the 2011 study

The 2011 study identified two relevant issues with regards to the application of Directive 96/82/EC (previous version of the Seveso Directive) to facilities where nanomaterials are produced, used and/or stored. It outlined that it was possible that nanomaterials that exhibit dangerous properties may not be captured by the definition of dangerous substances. It then mentioned that the volume thresholds for dangerous substances may not be applicable to nanomaterials due to their small scale.

3.3.15.3 Changes since the 2011 study

Since the 2011 study, Directive 96/82/EC, as a result of a legislative review, was repealed and replaced by Directive 2012/18/EU. The new version of the Seveso Directive brought the following changes:

- It updated and aligned the list of substances covered by the Directive to the CLP Regulation hazard classes and categories.

[114] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2016. Statement on the presence of microplastics and nanoplastics in food, with particular focus on seafood. EFSA Journal 2016;14(6):4501, 30 pp.

[115] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC

- It set a safeguard clause for substances not list in Annex I but that present a major-accident hazard.
- It enhanced citizens' rights on access to information, justice and on participation in decision-making;
- It improved the way information is collected, managed, made available and shared;
- It set inspection requirements

The changes that are relevant for the coverage of nanomaterials by the Seveso Directive are the new criteria on Annex I dangerous substances.

Under Part A of Annex I the dangerous substances are now defined based on the hazard categories set under the CLP Regulation (health hazards, physical hazards, environmental hazards, other hazards). In other words, if nanomaterials present in a facility fall under the different CLP hazardous categories set under Annex I and above a related quantity threshold (lower tier or upper tier) then certain safety measures must be applied. Part B of Annex I set an updated list of specific substances and their related thresholds (e.g. Anhydrous Ammonia, boron trifluoride, hydrogen sulphide, and piperidine are new substances). There is no mention of nanomaterials or nanoforms of these substances in this updated list of substances.

It is also noteworthy that the Seveso Commission proposal[116] both contained a safeguard procedure, allowing the Commission based on Member States requests to propose new substances to be covered under Annex I and a similar derogation procedure to remove substances under Annex I. The Seveso Directive only contains the derogation procedure to exclude substances under Annex I. This safeguard procedure could have however been an adequate mechanism to adapt Annex I if there were evidence of potential major-accident hazard of specific nanomaterials in industrial facilities.

3.3.15.4 Conclusion

Despite the adoption of a new version of the Seveso Directive, the main conclusions of the 2011 study remain valid. As mentioned in the analysis of the CLP Regulation, there are still some issues with regard the identification and classification of hazardous nanomaterials under CLP. Furthermore, the current quantity thresholds under the Seveso Directive may not be adequate to reflect the potential specific properties of nanomaterials. Finally, unlike in the original Commission proposal for a revised Directive, the adopted Seveso Directive does not contain an adequate mechanism to adapt in a rapid manner Annex I if there were evidence of potential major-accident hazard of specific hazardous substances (including hazardous nanomaterials) in industrial facilities.

3.3.16 Ambient Air Quality Directive 2008/50/EC

3.3.16.1 Summary of requirements

Directive 2008/50/EC defines and establishes objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment. This Directive is a consolidation of a number of pollutant specific air quality directives. 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 measures (i.e. limit values, target values, long-term objectives, air quality plans, alert and information thresholds) 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 $PM_{2.5}$). The measures (e.g. limit and target values) concerning particulate matter (PM_{10} and $PM_{2.5}$) are the focus of this review because both airborne nanomaterials and ultrafine particles[117] may constitute part of the PM_{10} and $PM_{2.5}$ size fraction.

[116] Proposal for a Directive on control of major-accident hazards involving dangerous substances/* COM/2010/0781 final - COD 2010/0377 */ available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2010:0781:FIN

[117] 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

3.3.16.2 Conclusions of the 2011 study

The 2011 study stressed that 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 and that they may be affected by a range of processes in the air, including evaporation, condensation, coagulation, chemical reaction and deposition. It identified that road and other transport; residential/commercial combustion; industrial combustion and industrial process emissions; power generation; and agriculture were significant sources of nanomaterials and ultrafine particles. It highlighted the lack of data on their health impacts in view of defining ambient air limit values for nanomaterials and ultrafine particles.

The 2011 study suggested that other metrics (e.g. particle number at surface rather than mass concentration) should be used to set these limit values. It also flagged that the sampling and measurement methods for PM_{10} and $PM_{2.5}$ were not adequate for nanomaterials and ultrafine particles. It however considered that control measures such as the set-up of air quality plans and short-term action plans could easily apply to airborne nanomaterials and ultrafine particles.

3.3.16.3 Changes since the 2011 study

Since the 2011 study the Ambient Air Quality Directive has been amended by Directive 2015/1480/EC[118]. This Directive updates part of the Annexes to the Ambient Air Directive and provides new reference methods for the sampling and analysis of arsenic, cadmium, nickel, polycyclic aromatic hydrocarbons, mercury in ambient air, and their deposition. It also sets new reference methods for the assessment of concentrations of sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter (PM_{10} and $PM_{2.5}$), lead, benzene, carbon monoxide and ozone. The reference method for the sampling and measurement for PM_{10} $PM_{2.5}$ is now the one described in EN12341:2014 "*Ambient Air — standard gravimetric measurement method for the determination of the PM_{10} or $PM_{2,5}$ mass concentration of suspended particulate matter*'.

New research confirms the view of the 2011 study that control technology applied to waste incineration, such as fabric filters, electrostatic precipitators, and wet electrostatic scrubbers, are expected to be at least partially effective at removing nanomaterials from incinerator flue gas.[119]

3.3.16.4 Conclusion

Since the 2011 study several scientific papers have been published on the potential health and environmental hazards of ultrafine particles and airborne nanomaterials confirming that this ambient air pollution is an area of growing health concern[120]. Furthermore in recent years there has been some scientific progress in the monitoring of these particles and in the understanding of their atmospheric formation, dispersion, physical and chemical transformation[121]. However the Ambient Air Quality Directive does not contain specific control measures (e.g. limit values) and monitoring requirements related to ultrafine particles and air-borne nanomaterials. There are indeed still many regulatory challenges with regard to the implementation of control and monitoring measures for ultrafine particles and airborne nanomaterials. According to a 2014 study[122] on ultrafine particles in cities these challenges are as follows:

- Safe levels of ultrafine particles and airborne nanomaterials exposure and the biological mechanisms through which they affect human health are still uncertain
- Even though a number of monitoring instruments exist, their lack of robustness for long-term unattended operations, their high cost for field deployment in sufficient number, the limited

[118] Commission Directive (EU) 2015/1480 of 28 August 2015 amending several annexes to Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality

[119] Amara L. Holder, Eric P. Vejerano, Xinzhe Zhou and Linsey C. Marr, "Nanomaterial disposal by incineration," Environ. Sci.: Processes Impacts, 2013, 15, 1652-1664

[120] See Klara Slezakova, Simone Morais and Maria do Carmo Pereira, *atmospheric nanoparticles and their impacts on public health*, Intech 2014 available at: http://www.intechopen.com/books/current-topics-in-public-health/atmospheric-nanoparticles-and-their-impacts-on-public-health

[121] See Prashant Kumara, Lidia Morawskac, Wolfram Birmilid, Pauli Paasonene, f, Min Hug, Markku Kulmalae, Roy M. Harrisonh, i, Leslie Norfordj, Rex Britterk, Ultrafine particles in cities, Environment International, volume 66 May 2014 page 1-10 available at: http://www.sciencedirect.com/science/article/pii/S016041201400018X

[122] Ibid.

reproducibility of data by different instruments, the lack of monitoring standards methods are main constraints for the setting of binding monitoring requirements.

The focus on the control of potential emission sources should therefore be the priority of decision makers. The EU has for example set in place very stringent requirements on diesel vehicles emissions of ultrafine particles (Euro-5 and Euro-6 vehicle standards) and on such emissions from industrial sources (see section on the Industrial Emissions Directive).

Stakeholder views

Representative of German Federal Environmental Agency:

Even though there is currently a lack of monitoring standard methods related to ultrafine particles and air-borne nanomaterials as described in the conclusions, the set-up of binding monitoring requirements should be in the focus of decision makers when it comes to an update of the Ambient Air Quality Directive. There are two main reasons for that:

First, a binding monitoring requirement will accelerate the development of the required measurement systems.

Second, only a binding monitoring requirement will provide sufficient data to set up potential limit values which require both an epidemiological evidence about health outcomes and knowledge about current spatial-temporal distribution of ambient concentrations of ultrafine particles.

3.3.17 Regulation (EC) No 66/2010 on the EU Ecolabel

3.3.17.1 Summary of requirements

This Regulation 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 EU 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; reuse, recycling etc.).

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).

Several of these product groups which can be certified ‘EU Ecolabel’ may contain nanomaterials such as:

- Rinse-off cosmetics,
- Paints and varnishes
- Dishwashing detergents and detergent for dishwashers
- Laundry detergents
- All-purpose cleaners and sanitary cleaners
- Lubricants
- Industrial and Institutional Laundry detergents
- Textiles
- Footwear
- Paper products
- Bed mattresses

Article 6(3) of the EU Ecolabel Regulation requires that EU Ecolabel criteria must be determined on a scientific basis considering the whole life cycle of products. This Article adds that in determining such criteria, the substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible must be considered. Article 6(6) provides that the 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), under the CLP Regulation nor to goods containing substances referred to in Article 57 of the REACH Regulation.

3.3.17.2 Summary of findings of the 2011 study

The previous Milieu study identified that a common approach to nanomaterials was applied in the revision of EU ecolabel criteria for three product categories that may contain nanomaterials (i.e. hand dishwashing detergents, all-purpose cleaners and sanitary cleaners and lubricants).

The decisions setting the EU ecolabel criteria for these three product categories provided that the presence of certain hazardous substances and mixtures in products awarded the EU Ecolabel in concentrations that exceed 0.010% by weight of the final product were prohibited. They specified that nanoforms of these hazardous substances intentionally added to the products had to be excluded at any concentration.

These decisions also explicitly specified that substances, in any forms including nanoforms, falling under certain CLP Regulation hazard categories, as well as substances referred to under Article 57 of REACH (i.e. Substances of very High Concern, SVHC) could not be used under these EU ecolabels.

3.3.17.3 Conclusion of the 2011 study

The study acknowledged that the EU has in these three decisions taken steps to integrate concerns related to the risks associated with nanomaterials. It however stressed that the EU Ecolabel mainly relied on the categorisation of hazardous substances under CLP which was however not considered as an adequate tool to classify and categorise hazardous nanomaterials.

3.3.17.4 Changes since the 2011 study

Amendments to EU Ecolabel Regulation

Since the 2011 study the EU Ecolabel Regulation has been amended by Commission Regulation (EU) No 782/2013 of 14 August 2013 which replaced Annex III related to application, annual and inspection fees. Such amendment has no impact on the coverage of nanomaterials under the EU Ecolabel Regulation.

New decisions on EU ecolabel criteria for certain product categories

Since the 2011 study several EU ecolabel criteria decisions referring to nanomaterials or 'nanoform' or different 'forms of substances' were adopted.

In respect to nanomaterials Commission services consider that EU Ecolabel criteria shall address nanomaterials similar to other chemical substances and materials and develop criteria in a technology neutral way. This implies also that nanomaterials cannot be banned as such from EU Ecolabel products; but restrict only specific nanomaterials of concern, like nanosilver, as there is solid scientific evidence supporting the ban.

In the provisions of the general Assessment and Verification (see Section 8.5) it is required that the applicant shall list all ingoing substances mentioning (beside the ingoing quantity and the function of the substance) the form of the substance as it is present in the final product formulation.

In the assessment and verification of the criterion on chemicals it is also requested that a declaration of compliance shall be provided that none of the substances present in the product meets the criteria for classification with one or more of hazard statements in the form(s) and physical state(s) they are present in the product. Thus, the verification process compliance needs to be ensured for the specific form of the substance, this includes the nano-form.[123]

In August 2012, the Commission adopted a decision establishing the ecological criteria for the award of the EU Ecolabel for printed paper[124]. This Decision was amended in June 2014 and June 2015. Criterion 2 sets the categories of hazardous substances under CLP and substances of very high concern under REACH that cannot be used under these products. Among other information

[123] JRC, Revision of European Ecolabel Criteria for the six detergent product groups Technical report and draft criteria proposal For the second AHWG meeting (Draft), September 2015, page 170.
[124] 2012/481/EU: Commission Decision of 16 August 2012 establishing the ecological criteria for the award of the EU Ecolabel for printed paper (notified under document C(2012) 5364). Consolidated version available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012D0481-20150606

requirements on substances used in these products, criterion 2 mentions that information provided by applicants must relate to the forms or physical states of the substance or mixtures as used in the final product.

In November 2012, the Commission adopted two decisions establishing respectively the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents[125] and for Industrial and Institutional Laundry Detergents[126]. These Decisions were both amended in May 2014.

The Annex to these Decisions set, among others, the categories of hazardous substances under CLP and substances of very high concern under REACH that must be excluded from these EU ecolabels. Among other information requirements these decisions require that information on substances provided by applicants must relate to the forms or physical states of the substance or mixtures as used in the final product.

In December 2014, the Commission adopted a decision establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products[127]. It applies to rinse-off substance or mixture falling under the scope of Regulation (EC) No 1223/2009 intended to be placed in contact with the epidermis and/or the hair system with a view exclusively or mainly to cleaning them (toilet soaps, shower preparations, shampoos), to improve the condition of the hair (hair conditioning products) or to protect the epidermis and lubricate the hair before shaving (shaving products). The criteria to award the EU ecolabel to these products relevant for nanomaterials are:

- Toxicity to aquatic organisms (critical dilution volume)
- Biodegradability
- Excluded or limited substances and mixtures

Among the list of substances to be excluded from rinse-off cosmetic products, criterion 3 refers to nanosilver. Nanosilver was excluded because silver nanoparticles reveal high ecotoxicity even at very low effect concentrations. Another important aspect with regard to this product groupis that at low concentrations inhibition of nitrifying bacteria can occur and the function of wastewater treatment plants may be affected due to the presence of silver nanoparticles.[128]

This decision also implements Article 6(6) of the EU Ecolabel Regulation by mentioning certain categories of substances classified under CLP and substances of very high concern under REACH cannot be used under these products. Criterion 3 of this Decision explicitly mentions that applicants must provide information on substances in the form(s) and physical state(s) they are present in the product.

In May 2014, the Commission adopted a decision establishing the ecological criteria for indoor and outdoor paints and varnishes[129]. Point 5 of the Annex to this Decision sets the following hazardous substances and mixtures restrictions:

- Overall restrictions that apply to hazard classifications and risk phrases
- Restrictions that apply to substances of very high concern
- Restrictions that apply to specific hazardous substances

On the overall restrictions, Point 5(a) provides that the final product formulation, including all intentionally added ingredients present at a concentration of greater than 0,010 %, must not contain

[125] 2012/720/: Commission Decision of 14 November 2012 establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents**.** Consolidated version available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012D0720-20121201

[126] 2012/721/: Commission Decision of 14 November 2012 establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Laundry Detergents (notified under document C(2012) 8055) Consolidated version available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012D0721-20121201

[127] 2014/893/EU: Commission Decision of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products (notified under document C(2014) 9302)

[128] JRC Technical report including revised draft criteria proposal for the product group of rinse-off cosmetic products, May 2013, page 73.

[129] 2014/312/EU: Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes (notified under document C(2014) 3429) consolidated version available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014D0312-20160318

substances or mixtures classified as toxic, hazardous to the environment, respiratory or skin sensitisers, or carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008. Point 5(a)(i) sets potential derogations to this prohibitions.

Among information that must be provided by applicants to fulfil this criterion, it is interesting to note that this Decision requires that '*Substances and mixtures shall be characterised in accordance with sections 10, 11 and 12 of Annex II to the REACH Regulation (Requirements for the Compilation of Safety Data Sheets). This shall include information on the physical form and state of the ingredients and shall include identification of manufactured nanomaterial ingredients for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm.'*

The EEB[130] and BEUC[131] views on the EU ecolabel criteria for indoor and outdoor paints and varnishes related to nanomaterials were not reflected in the final decision. They called for restricting the use of nanomaterials in EU ecolabel paints and varnishes until a proper toxicological and ecotoxicological assessment framework for nanomaterials is in place and the manufacturer can prove that the substances have been adequately assessed and are safe for the environment and health, considering existing concerns on their potential hazardous properties, methodology gaps to assess their safety and regulatory loopholes[132].

In May 2014, the Commission adopted a decision establishing the ecological criteria for the award of the EU ecolabel for converted paper products[133]. Criterion 3 of the Annex to this decision, excludes substances and/or mixtures falling under certain hazardous CLP categories and substances of very high concern under REACH. Among other information requirements, applicants must provide information that shall relate to the forms or physical states of the substance or mixtures as used in the final product.

In June 2014, the Commission adopted two decisions establishing respectively the ecological criteria for the award of the EU Ecolabel for textile products[134] and for bed mattresses[135].

The Appendix of the textile decision sets an EU label textile restricted substance list. Table (e) includes restrictions applying to finishing processes. It provides that biocides must not be incorporated into fibres, fabrics or the final product in order to impart biocidal properties. It mentions nanosilver as an example of such biocides. Criterion 14 of this Appendix contains categories of hazardous substances under CLP and substances of very high concern under REACH that must be excluded from EU ecolabel textiles. Under the assessment and verification requirements, applicant must provide information on the classification/non-classification of substance used. However, there are no specific information requirements on 'nanoforms' or nanomaterials.

Criterion three of the EU ecolabel criteria decision on mattresses sets two lists of restricted substances, one on substances that cannot be used in latex foam under certain concentration and another that set substances that cannot be emitted above certain limit values. Criterion 10 of this decision contains categories of hazardous substances under CLP and substances of very high concern under REACH that must be excluded from EU ecolabel bed mattresses. Among other information requirements, applicants must provide information that shall relate to the forms or physical states of the substance or mixtures as used in the final product.

In the same vein as for EU Ecolabels on paints, the EEB and BEUC called for restricting the use of nanomaterials in EU ecolabel bed mattresses until a proper toxicological and ecotoxicological assessment framework for nanomaterials is in place and the manufacturer can prove that the substances have been adequately assessed and are safe for the environment and health, considering existing concerns on their potential hazardous properties, methodology gaps to assess their safety and regulatory loopholes.

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[130] European Environmental Bureau
[131] European Consumer Organisation
[132] http://www.beuc.eu/publications/x2013_074_bmo_eeb_and_beuc_comments_on_paints_and_varnishes.pdf
[133] 2014/256/EU: Commission Decision of 2 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for converted paper products
[134] 2014/350/EU: Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (notified under document C(2014) 3677)
[135] 2014/391/EU: Commission Decision of 23 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for bed mattresses (notified under document C(2014) 4083)

In 2013, the Commission adopted two criteria decisions respectively for the award of the EU Ecolabel for sanitary tapware[136] and for flushing toilets and urinals[137]. These decisions set the CLP categories of hazardous substances and substances of very high concern under REACH that must not be included in their products. They require applicants to provide information that must relate to the forms or physical states of the substance or mixtures as used in the final product[138].

In October 2014 the Commission adopted a decision establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products[139]. Point 6.6 of the Annex to this Decision explicitly mentions that nanosilver particles must not be intentionally added to the product or to any homogeneous part or material of it.

Nanosilver was excluded because of the uncertain consequences associated to its widespread use, with some indications suggesting the risk of promoting the antibiotic resistance of bacteria, and the potential hazards associated to the use of silver particles.[140]

Criterion 7 lists the categories of hazardous substances under CLP and substances of very high concern under REACH that must be excluded from EU ecolabel absorbent hygiene products. Among other information requirements, applicants must provide information about *'the forms or physical state'* of the substances or mixtures as used in the final product.

In November 2015, the European Commission adopted a decision establishing the ecological criteria for the award of the EU ecolabel for growing media, soil improvers and mulch[141]**.** Criterion 5.1 sets limits for heavy metals (e.g. Cadmium, Lead). Criterion 5.2 sets limits for Polycyclic Aromatic Hydrocarbons (PAH). Criterion 5.3 contains categories of hazardous substances under CLP that must be excluded from EU ecolabel growing media, soil improvers and mulch. Criterion 5.4 provides that the final product must not contain intentionally added substances of high concern under REACH, present in the final product in concentrations > 0,010 % in terms of wet weight. The only provision relevant for nanomaterials is the applicant obligation to provide information on the forms or physical state of the substances or mixtures as used in the final product.

Amendments to pre-2011 study decisions

Since the 2011 study the Commission criteria decisions on hand dishwashing detergents and all-purpose cleaners and sanitary cleaners were amended.

The Commission criteria decisions on hand dishwashing detergents and on all purpose cleaners and sanitary cleaners were amended in May 2014 and in March 2015. The amended version of the decisions now specify that applicants must demonstrate compliance with this criterion for substances in the products on the basis of information consisting as a minimum of that specified in Annex VII to the Regulation (EC) No 1907/2006. They then add that this information must be specific to the particular form of the substance, including nanoforms, used in the product.

3.3.17.5 Conclusion

The table below provides an overview of how nanomaterials are covered under the different EU ecolabel criteria decisions. It shows that there is no consistent approach in the coverage of nanomaterials (e.g. information requirements on nanoforms or based on definition of nanomaterials or reference to forms and physical state of substances, or no reference at all). It also shows that the older criteria that were not amended since 2012 do not contain any criteria on nanomaterials, nanoforms or forms of substances.

[136] 2013/250/EU: Commission Decision of 21 May 2013 establishing the ecological criteria for the award of the EU Ecolabel for sanitary tapware (notified under document C(2013) 2826)
[137]2013/641/EU: Commission Decision of 7 November 2013 establishing the ecological criteria for the award of the EU Ecolabel for flushing toilets and urinals
[138] The sanitary tapware decision contains criteria on chemical and hygienic characteristics of materials in contact with drinking water. There is however no reference to nanomaterials (e.g. nanosilver as an antimicrobial)
[139] Commission Decision of 24 October 2014 establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products (notified under document C(2014) 7735)
[140] European Commission JRC – IPTS, Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products") Technical Report – Draft v.4 page 49-50.
[141] Commission Decision (EU) 2015/2099 of 18 November 2015 establishing the ecological criteria for the award of the EU Ecolabel for growing media, soil improvers and mulch

Table 11: Coverage of nanomaterials under EU ecolabel criteria decisions

Product categories	Entry into force of latest criteria requirements	Exclusion from concentration exemptions for nanoforms	Specific nanomaterials excluded	Information requirements on forms and physical state	Information requirements on nanoforms	Reference to a specific definition of nanomaterials
Hand Dishwashing Detergents	2015	X			X	
Laundry Detergents	2015					
Detergents for Dishwashers	2015					
growing media, soil improvers and mulch	2015			X		
Printed paper	2014			X		
Rinse-off cosmetic products	2014		X[142]	X		
Absorbent Hygiene Products	2014		X[143]	X		
All-Purpose Cleaners and Sanitary Cleaners	2014	X			X	
Industrial and Institutional Automatic Dishwasher Detergents	2014			X		
Industrial and Institutional Laundry Detergents	2014			X		
Textiles	2014		X[144]			
Paints and varnishes	2014			X		X
Lubricants	2011	X			X	
Bed Mattresses	2014			X		
Converted paper	2014			X		
flushing toilets and urinals	2013			X		
Sanitary tapware	2013			X		
Newsprint paper	2012					
Copying and graphic papers	2009					

[142] Nanosilver
[143] Nanosilver
[144] Biocides such as for example nanosilver must not be incorporated into fibres, fabrics or the final product in order to impart biocidal properties.

Product categories	Entry into force of latest criteria requirements	Exclusion from concentration exemptions for nanoforms	Specific nanomaterials excluded	Information requirements on forms and physical state	Information requirements on nanoforms	Reference to a specific definition of nanomaterials
Tissue paper	2009					
Footwear	2009					
Wooden furniture	2009					
Hard covering	2009					

As mentioned in the text above, the criteria decisions to exclude hazardous substance under EU ecolabel products mainly rely on the CLP classification of hazardous substance. They also exclude substances of very high concern under REACH. The majority of these decisions require the applicants to demonstrate that all forms of substances used are not falling under certain categories of hazardous substances under CLP and are not substances of very high concern under REACH. However as mentioned in the CLP analysis there is a limited number of classified nanomaterials under the CLP Regulation despite that the information on substances must relate to their different forms. Furthermore, there is currently limited available information on nanomaterials to classify them under CLP (e.g. data gaps on nanomaterials under REACH). Finally, there are still considerable knowledge gaps on the determination of environmental hazards of nanomaterials (e.g. toxicity of the substance or mixture, and information on the degradation and bioaccumulation behaviour) for their classification under CLP.

The Nordic Ecolabelling programme, among other Ecolabels, prohibits the use of nanomaterials under certain product categories[145] (e.g. cosmetics, dishwasher, detergents for professional use, cleaning products).

Stakeholder views:

CEFIC

Nanomaterials are per se not hazardous and should not generally be banned. A specific risk assessment should be performed as performed by EFSA, SCCS among others.

NIA

There is no reason to generally exclude 'nanomaterials' from the EU Ecolabel for nanomaterials, similarly to other chemical substances, may or may not be harmful to the environment independently from their size.

Nanomaterials need to be included in the EU Ecolabel for they are designed for their positive ecological impact:

- nanomaterials can be produced from less educt chemistry,
- nanomaterials can be produced with less energy consumption,
- nanomaterials need less material to fulfil the same functionality.

Nanomaterials tick all the boxes of "Green Chemistry". The EU Ecolabel should therefore not consider products incorporating nanomaterials differently from other productions when evaluating their environmental impact, by doing so, it would create an unfair competition which would be detrimental to the final objective of the EU Ecolabel: to promote products which have a reduced environmental impact.

Leitat representative

Ecolabel criteria should be based on CLP rather than on universal criteria for nanomaterials, but presenting all the data needed to demonstrate that these nanomaterials do not have an impact in the environment and on human health. Again, it should be clearly defining the required tests

[145] Information retrieved from the Nordic Ecolabelling website: http://www.nordic-ecolabel.org/criteria/product-groups/

(physico-chemical characteristics and (eco)toxicological data) to ensure no human and environmental impact.

3.4 Additional EU environmental legislation not covered in the 2011 regulatory review

3.4.1 Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)[146]

3.4.1.1 Summary of requirements

The CLP Regulation was adopted to align EU law to the United Nations Globally Harmonised System criteria for classification and labelling of hazards at the global level to ensure high level of protection of human health and the environment and to facilitate trade. It applies to all chemicals placed on the market independently of the tonnage threshold. Title II of CLP Regulation sets the procedures for classification of substances and provides a standard set of criteria (often as threshold values) for the classification. It requires manufacturers, importers and downstream users to identify and examine available information on potential physical, health and environmental hazards of substances and mixtures, and regulates the methods for the generation of new information. The information gathered and generated must then be evaluated by the duty holders for the purpose of classification. Title III provides rules for labelling of substances and mixtures according to any hazard identified. Title IV sets in place requirements for the packaging of hazardous substances or mixtures (design, materials, fastenings). Finally, Title V refers to the harmonised classification and labelling of substances. As further explained below the classification on CLP is mostly based on available information (including scientific literature) and that generation of data specifically for CLP can only be required for some physical hazards. The definition of chemical substances is the same as the one under REACH.

3.4.1.2 Coverage of nanomaterial under CLP

The CLP does not include any specific references to nanomaterials or nanoform(s) of substances. However, Articles 5(1) and 6(1) respectively stipulate that the information on a substance and mixture in view of its classification must relate to the forms or physical state in which the substance or the mixture is placed on the market and in which it can reasonably be expected to be used. Furthermore, when evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users must consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.This would mean that hazard classification should also be based on the tested form or physical state of a substance including its nanoform.

The ECHA's CLP guidance on the application of CLP criteria[147] includes a dedicated section on the significance of the terms 'form of physical state' and 'reasonably expected use' with respect to classification according to CLP. With regard to physical hazards, the guidance provides that

'*the classification of a substance or mixture relates to the tested form and physical state. If the form and/or physical state is changed it has to be evaluated whether this might affect the classification and whether re-testing is necessary*'. For environmental hazards, however, it is stated that *'the system of classification is designed to ensure that a single classification applies to a substance. In general it takes no account of the specific form since this can vary and is not intrinsic to the substance. The form in which the substance is placed on the market is taken into account when deciding what label to apply and various derogations from labelling exist, e.g. the metals in the massive form. In the massive form the hazard may not be present and the substance need not be labelled. The SDS will, however, indicate the classification and intrinsic hazardous properties to warn the user that subsequent transformation of the substance may produce the hazardous form'*.

[146] 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)
[147] Guidance on the Application of the CLP Criteria available at:
http://echa.europa.eu/documents/10162/13562/clp_en.pdf

Furthermore, at the time of writing this report there are only few references to nanomaterials in the Classification and Labelling inventory[148]. Other nanomaterials placed on the market are either not classified or would have the same classification as the size-unspecified substance.

According to Article 5(1) for the classification of substances (with likewise provisions given in Article 6(1) for mixtures, with data referring to the mixture itself or the substances contained in it) relevant available information has to be identified, in particular, the following:

- epidemiological data and experience on the effects on humans for the mixture itself or the substances contained in it, such as occupational data or data from accident databases;
- information generated in accordance with Annex XI of REACH
- any new scientific information
- any other information generated under internationally recognised chemical programmes

In case there is no adequate and reliable available information to classify a substance, Article 8 of the CLP explains the option to generate new information, which is an obligation for physical hazards, whereas the generation of information for health and environmental hazards is not stipulated as an obligation but as a pursuable option. This would mean that, on the one hand, manufacturers are unlikely to have available information to adequately classify nanomaterials in practice (e.g. at present limited information generated under REACH and important knowledge gaps on nanomaterials in general). On the other hand, they are unlikely to generate new information on environmental and health hazards of nanomaterials since it is not compulsory under CLP Regulation. Besides that, there are still many challenges to adequately assess these hazards as outlined in the evaluation of water policy.

There are no specific provisions related to the labelling of nanomaterials under the CLP Regulation. However, nanomaterials classified as hazardous are subject to labelling requirements. As mentioned above the difficulty to classify nanomaterials indirectly impacts the application of the hazard labelling requirements. The UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals the GHS has set-up an informal group on nanomaterials which have been working on the applicability of the United Nations Globally Harmonised System to nanomaterials since 2008[149].

3.4.1.3 Conclusion

Limited number of classified nanomaterials under the CLP Regulation

Article 5(1) and 6(1) and Article 9(5) respectively stipulate that the information on a substance and mixture shall relate to the forms or physical state in which the substance or the mixture is placed on the market and in which it can reasonably be expected to be used. This means that hazard classification should also be based on the tested form or physical state of a substance including its nanoform. However, as the conclusion of a screening of the Classification and Labelling Inventory was that only a limited number of nanomaterials had a specific classification entry, and that means that nanomaterials placed on the market are either not classified as hazardous or have the same classification as the size-unspecified substance. However, Article 41 of the CLP requires, where the notification results in different entries for the same substance, the notifiers and registrants to make every effort to come to an agreed entry to be included in the inventory. This obligation applies to all hazardous substances independently of the quantity of the substance being manufactured or imported.

Limited available information to classify nanomaterials under the CLP Regulation

[148] According to the ECHA website, this database contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonised classifications. The database is refreshed regularly with new and updated notifications. However, updated notifications cannot be specifically flagged because the notifications that are classified in the same way are aggregated for display purposes. The CLH contains the following references to the following nanomaterials: Carbon nanotubes, NanoTether BPA, Nanofin, NanoTether OH, Zinc oxide nano, Carbon Nanotube Dispersion, Graphene nanoplatelets, Amorphous Silica.

[149] This informal group task is to establish whether there is a need to amend the GHS to make clear that nanoforms of a substance are within scope of the GHS, to review the classification and labelling criteria in the GHS to establish whether they are appropriate for nano, as well as bulk forms of a substance and to review the content of safety data sheets set out in the GHS in terms of their applicability to nano-forms of a substance.

The classification of substances and/or mixtures relies on available information, except for some physical hazards. However, at present, there appear to be significant gaps concerning specific information for nanomaterials (e.g. very little nano-specific information available under REACH) which may render difficult their classification based on available information.

Generation of new information on environmental hazards not compulsory

The generation of new information on physical hazards referred to in Part 2 of Annex I is compulsory unless there is adequate and reliable information available. However, for health and environmental hazards, the generation of new information is not an obligation but a pursuable option. This would mean that in practice manufacturers are unlikely to generate new information on environmental and health hazards of nanomaterials since it is not compulsory under CLP. This is to some extent reflected in the Classification and Labelling Inventory where for most of the nanomaterials listed it is mentioned that there is no available information on environmental hazards.

Challenges in the determination of environmental hazards of nanomaterials in view of the CLP classification

The environmental hazard classification is principally concerned with the aquatic environment and the basis of the identification of hazard is the aquatic toxicity of the substance or mixture, and information on the fate, i.e. degradation and bioaccumulation behaviour. In case manufacturers are willing to generate information on environmental hazards for the classification of nanomaterials, they may however encounter some difficulties and especially with regard to the assessment of the degradation and bioaccumulation behaviour of nanomaterials.

Stakeholder views:

CEFIC

Hazard criteria of CLP apply to nanomaterials as to any other chemical. There are no "nano-specific" hazards. See:

- Donaldson, K and Poland, CA; Nanotoxicity: challenging the myth of nano-specific toxicity; Current Opinion in Biotechnology 2013, 24:724–734
- Krug, H.: "Nanosafety Research — Are We on the Right Track?"; Angewandte Chemie Intern. Ed., Special Issue: Nanotechnology & Nanomaterials, Nanotoxicology & Nanomedicine, Vol. 53, Issue 46,pp 12304–12319, Nov. 10, 2014, http://dx.doi.org/10.1002/anie.201403367

Difficulties with regard to the assessment of the degradation and bioaccumulation behaviour is not specific to nanomaterials but also applies for PSP and inorganics.

ECHA representative

Two steps are needed to ensure that CLP adequately covers nanomaterials:

- agreement of CLH/CLP nano-specific entries
- REACH Annex amendments allowing to generate data on nanomaterials used for CLP purposes

NIA

The ongoing modification of REACH annexes should clarify the question of the registration for nanomaterials. From this, identification and classification of hazardous nanomaterials is no different than that of other substances.

Leitat representative

Possibly the main difficulty with CLP is whether classification for the bulk would be sufficient for nanomaterials, and identify in which cases the 'nano'-size may justify inclusion of additional hazards. CLP does not oblige industry to perform new tests apart from those tests that have to be done according to REACH. In this sense, REACH requirements should be robust enough to cover nanomaterials.

3.4.2 Regulation (EC) No 1907/2006 (REACH)

3.4.2.1 Summary of requirements

The aim of REACH is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. This aim must be achieved by the application of four REACH processes, which are the registration, the evaluation, the authorisation and restriction of chemicals. REACH has shifted the burden of proof to the manufacturers and importers of substances that must generate information and manage the risks linked to the substances they place on the EU market. They must also communicate information to downstream users in the supply chain on how these substances can be used safely. The REACH Regulation is the cornerstone of the EU legislation on chemicals.

3.4.2.2 Specific references to nanomaterials

There are currently no references to nanomaterials in REACH. However, nanomaterials fall under the definition of substances under REACH. Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

There is currently no definition of nanomaterials given in the REACH Regulation. This has a potential impact for the application of the substance identification requirements for nanomaterials[150]. Nanomaterials are not mentioned in the general objectives of REACH. However according to Commission Communication Nanomaterials in REACH' (CA/59/2008 rev. 1) manufacturers, importers and downstream users must, pursuant to the REACH objectives, ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment independently of the size or form and for all their identified uses.

3.4.2.3 Identification of nanomaterials under REACH through registration

According to Article 6 of REACH manufacturers and importers of a substance of one tonne or more per year must submit a registration dossier to ECHA. This is the application of the no data no market principle. As already mentioned above there is no reference to nanomaterials in REACH. There is no specific registration information requirements related to nanomaterials. There is no specific obligation to register nanomaterials in a separate dossier compared to the size-unspecifed substance. According to the ECHA guidelines on registration, when the registrant manufactures or imports the substance in the nanoform as well as in the bulk form, the registration dossier should include the information of the substance in both the bulk form and the nanoform. ECHA also updated the IUCLID software used by registrants to submit their registration dossier, to allow registrants to include information on nanomaterials through two options:

- the nanomaterial is a distinct substance and only one composition is included
- the nanomaterial is a form of a substance and/or multiple forms/compositions are included in the IUCLID dossier[151]

However, in practice very few registration dossiers were created for nanomaterials and very few registration dossiers of bulk substances contain information on their nanoforms. As a result of a screening led by ECHA at the end of 2011, 78 registered substances contained some information on nanomaterials, of these only five clearly included nanoforms within the scope of the substance[152].

According to the ECHA update of the workplan on nanomaterials, the current uncertainty caused by lack of explicit requirements for substances in nanoform is causing additional complications and work for ECHA and the registrants. For example, the majority of compliance check decisions requiring more information on nanomaterials are being appealed to the Board of Appeal (i.e. titanium dioxide, silicon dioxide, synthetic amorphous silica, silicic acid, aluminium sodium salt). The current revision of the REACH Annexes is debating this issue; should Annexes to REACH be amended or not to ensure that nanomaterials are characterised in the registration dossiers and that specific information is

[150] For example Section 2 of Annex VI to REACH does not foresee particle size distribution as an identifier
[151] Note that IUCLID 6 will be launched in summer 2016
[152] Information retrieved from ECHA website: http://newsletter.echa.europa.eu/home/-/newsletter/entry/1_12_nanomaterial-reporting

generated, when necessary, for these nanomaterials compared to their bulk form. The revision of the REACH Annexes is subject to an impact assessment not finalized at the time of writing this report. Note that according to the Commission the potential introduction of new REACH information requirements for nanomaterials will not happen in time for the 2018 registration deadline[153].

3.4.2.4 Generation of information on nanomaterials environmental impacts under REACH registration requirements

In case nanomaterials are registered under REACH, registrants will however have some difficulties to provide adequate information on their ecotoxicology and fate and behaviour on the environment due to remaining knowledge gaps on test methods for nanomaterials. As underlined by a background paper related to a 2014 scientific workshop on regulatory challenges in risk assessment of nanomaterials held by ECHA[154], due to the wide range of nanomaterials and their variety of different forms, sizes, shapes and surface characteristics, their environmental fate assessment can become very complex. This background paper stresses that REACH testing strategies and standard test guidelines are in principle applicable for assessing the environmental fate of nanomaterials, there is however a clear need for adaptation and development of test guidelines and discussion on the necessity of introducing nano-specific information into the environmental fate assessment.

Examples of specific challenges to assess environmental fate, persistence and bioaccumulation of nanomaterials as identified by ECHA workshop background paper

Extrapolation of fate data for exposure assessment

Extrapolation of fate data across media, biological species and across nanomaterials with different properties is challenging.

Degradation assessment

Simulation tests for biological degradation in various environmental compartments are applicable in principle, but again the detection and quantification of the nanomaterial is the challenge.

Certain inorganic nanomaterials are still subject to biodegradation (e.g. single-walled carbon nanotubes (SWCNT), multi-walled carbon nanotubes (MWCNT) and fullerene (C60)), they may be assessed by traditional biodegradation tests, but this still needs to be validated.

Bioaccumulation assessment

To determine if and under which circumstances nanomaterials accumulate in the environment and environmental species, more knowledge on the key characteristics that influence the fate, behaviour and kinetics of nanomaterials and implementation of this knowledge within the risk assessment approaches and regulatory frameworks is needed. One of the main challenges in testing the bioaccumulation of nanoparticles is their detection, quantification and characterisation in the various test guidelines that exist.

In the same vein, several academic studies also stress that considerable test method developments are needed in order to obtain environmental assessment methods that can produce relevant information about environmental impacts[155]. An OECD WPMN expert meeting highlighted that the current OECD guidelines for ecotoxicity when applied to nanomaterials[156] are lacking guidance on nanomaterials specific testing issues. They also mention that the current limited natural science understanding of the environmental fate of nanomaterials renders their environmental risk assessment difficult. The OECD is in the process of developing and amending guidelines and

[153] Information retrieved from an Article of ChemicalWatch 'Commission rejects idea of EU nanoregister' published in March 2016 and available at: https://chemicalwatch.com/45776/commission-rejects-idea-of-eu-nano-register

[154] Topical Scientific Workshop Regulatory Challenges in Risk Assessment of Nanomaterials 23-24 October 2014, background paper for the five topics available at: http://echa.europa.eu/documents/10162/5399565/bp_ws_risk_assessment_nanomaterials_en.pdf

[155] Richar Arvidsson, Life cycle assessment and risk assessment of manufactured nanomaterials, Chapter 2.3 of 'Nanoengineering, global approaches to health and safety issues, Patricia I. Dolez

[156] Report Nr.40 at http://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm

guidance. Furthermore, there are also ongoing research projects (e.g. EU FP7, H2020) which are designed to overcome these issues.

3.4.2.5 Nanomaterials under REACH Evaluation

Compliance checks (dossier evaluation)

Over the past two years, ECHA has prepared a number of compliance check decisions on nanomaterials (14 compliance check decisions completed covering 8 different substances in nanoform). ECHA has also received a total of five appeals against ECHA evaluation decisions on nanomaterials (one case in Q4 2014, four cases in Q2 2015). These appeals have challenged ECHA's legal grounds for requesting information on nanomaterials, in the absence of any provisions on nanomaterials in the REACH Regulation. Appeal decisions have been adopted which have annulled ECHA decisions to request information on grades, nanoforms and forms of substances because of a lack of such information requirements under the REACH Regulation, arguing that such request breaches the principle of legal certainty.[157]

Substance evaluation

A number of Member States have initiated substance evaluation activities on nanomaterials. The first final substance evaluation decision for a nanomaterial, Silicon Dioxide, was completed in Q1 2015, and has been appealed by two groups of Registrants. The following nanomaterials are included on the current Community Rolling Action Plan (CoRAP);

- 2012; Silicon dioxide (synthetic amorphous silica SAS) evaluated by the Netherlands[158]
- 2015: Silver evaluated by The Netherlands (draft decision adopted in April 2016)
- 2017: Titanium dioxide evaluated by France
- 2017: Zinc Oxide evaluated by Germany
- 2017- Cerium Oxide evaluated by Germany
- 2017 MWCNT 2017 – evaluated by Germany
- 2018 Carbon black evaluated by France

3.4.2.6 Nanomaterials under restriction and authorisation

No restriction nor authorisation procedure has been launched yet for specific nanomaterials.

3.4.2.7 Conclusion

Difficulties to identify and/or characterise nanomaterials under REACH

There is currently no definition or reference to nanomaterials in the REACH Regulation. However nanomaterials fall under the definition of substances under REACH and are as such expected to be covered by the data addressing the information requirements and the chemical safety assessment, whenever they are covered by the registration. For the moment however REACH does not explicitly require registrants to provide separate dossiers for a bulk substance and its nanoform(s) or does not set specific information requirements for the nanoforms of bulk substances in registration dossiers. In practice very few registration dossiers include references to the nanoform of bulk substances.

The current revision of the REACH Annexes is attempting to address this issue. At the time of writing this report, it is concluded that the current registration requirements under REACH do not allow an adequate identification and/or characterisation of nanomaterials. These nanomaterials 'not registered' could potentially be placed on the market without supporting information from relevant testing and assessment and specific risk management measures apart the ones applying to the bulk substance despite their potentially different characteristics. This is specifically the case for specific nanoforms with a related bulk form (i.e. one not including nano-scale size fractions). This is not the case for certain organic pigments, based on broad particle size distributions, which include nano-scale size fractions.

[157] See appeal decisions (e.g. A-011-2015, A-010-2015) under ECHA website: https://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions?p_p_id=searchdecisions_WAR_boardofappealsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_pos=2&p_p_col_count=3&_searchdecisions_WAR_boardofappealsportlet_javax.portlet.action=searchDecisions

[158] At the time of writing this report the Decision is under Appeal

In the same vein, nanoforms of phase-in bulk substances (substances already in the market before the entry into force of REACH) can benefit from delayed registration (e.g. 2018 for 1-10 tonnes per year per registrant). They are unlikely to be subject to a specific assessment evaluating whether specific tests and specific risk management measures are needed, despite their possible different physiochemical, toxicological and ecotoxicological properties from the phase-in bulk substance.[159].

Knowledge gaps to generate information on environment fate and behaviour and ecotoxicology of nanomaterials

In case nanomaterials are registered under REACH, registrants may encounter difficulties to provide some adequate information on their ecotoxicology and fate and behaviour on the environment due to remaining knowledge gaps on test methods for nanomaterials. Note that this is not a specific issue for nanomaterials but also concerns other categories of substances.

Information gaps on nanomaterials in the supply chain

Since the information in the supply chain relies on the information from the registration dossiers, the potential information gaps in the registration of nanomaterials would therefore have an impact on information in the supply chain (e.g. no specific risk management measures for nanomaterials as the necessity for such measures remains unknown for lack of data). Finally, downstream users can provide information regarding their uses to suppliers of substances. This enables registrants to include these uses in the chemical safety assessment. However, if downstream users use the substance outside the conditions of use foreseen by the exposure scenario provided by the supplier, they must prepare a chemicals safety report in relation to that use.[160] Uses outside the exposure scenario can include changes of exposure due to the generation of new nanoforms by the downstream user (e.g. through grinding, surface modification). No information has been found on whether downstream users have submitted nanospecific exposure scenarios.

Stakeholder views:

CEFIC

Under REACH manufacturers/importers have to ensure safe handling of substances - including nanoforms - along the life cycle, implying that sufficient information is available for a safety assessment including for the purpose of C&L under CLP.

The substance definition under REACH covers nanomaterials also without particle size distribution as an identifier. EU Commission emphasizes that it is up to industry to determine the substance identity of nanomaterials according to the existing provisions in the REACH regulation, Annex VI, and the Guidances

ECHA representative

REACH could generate sufficient and adequate information on nanomaterials through the adoption of the REACH Annexes which should allow gathering information on hazard and fate properties of Nanomaterials to allow for proper ERA or CSR for environmental compartments to be generated. A further extension of the evaluation of such via the exposure and life cycle would probably help to cover both sides hazard/risk and build more complete environmental risk assessments.

NIA:

Two regulatory reviews of the European Commission have acknowledged the fact that the overarching chemical regulation in Europe, REACH, covers nanomaterials as these fall under the definition of ‘substances’ under article 3(1) of the regulation. Article 3(1) does not refer to the size of a substance and therefore covers all particle sizes. NIA regrets that the question to whether REACH covers nanomaterials is still open and believes that the modification of the REACH annexes to nanomaterials will help clarify this issue.

Leitat representative

[159] This is further confirmed by the fact that amendment to the REACH annexes related to nanomaterials will enter into force after the 2018 deadline.
[160] REACH, Article 37(4).

REACH could generate sufficient and adequate information on nanomaterials If it is recognized that differences in size can be related to different physical/chemical properties and toxicity profile. This should be covered by the registrant by generating data for the nanoforms. Currently very often it is not acknowledged that different sizes can lead to different toxicity profiles.

In general REACH and associated legislation and guidance documents should establish:

- specific relevant end-points (physicochemical, (eco)toxicological) for ENMs to address their properties
- standardized tests for ENMs (reproducible results useful for univocal hazard identification)
- adequate methods and tools which can effectively measure/ predict concentrations of ENMs in occupational settings and establishing appropriate dose metrics
- adequate methods and tools which can effectively quantify/ predict releases of materials in the nanoform to the different environmental compartments
- adequate test methods to monitor behaviour and fate of ENMs in environmental compartments

The Notification of ENM in products should be proposed in REACH Regulation as in the Cosmetic Regulation

3.4.3 Directive 2010/75/EU on industrial emission (IED)

3.4.3.1 Summary of requirements

The IED was adopted in 2010. The IED is a recast[161] of:

- Directive 78/176/EEC on titanium dioxide industrial waste;
- Directive 82/883/EEC on the surveillance and monitoring of titanium dioxide waste;
- Directive 92/112/EEC on the reduction of titanium dioxide industrial waste;
- Directive 1999/13/EC on reducing emissions of volatile organic compounds (VOCs);
- Directive 2000/76/EC on waste incineration;
- Directive 2001/80/EC on the limitation of emissions of certain pollutants into the air from large combustion plants (LCPs); and
- Directive 2008/1/EC concerning integrated pollution prevention and control (codified version).

The IED lays down rules on integrated prevention and control of pollution arising from industrial activities giving rise to pollution as referred to in Chapters II to VI of the IED. The IED places emphasis on the prevention, and where that is not practicable, on the reduction of emissions of pollution. The IED aims to protect the environment as a whole by addressing the issue of pollution emissions in an integrated way, i.e. through the reduction of emissions into air, water, and land, and the prevention of the generation of waste, odour, and noise, all through more efficient use of resources. Therefore, in addition to the protection of environment, the IED aims to raise the competiveness of EU industrial activities.

The IED consists of several chapters which deal with different industrial activities.

Chapter I contains general provisions such as the scope of the Directive and definitions of terms used therein, and places a general obligation on competent authorities in Member States to ensure that no installation falling under the scope of the Directive is operated without a permit.

Chapter II concerns the activities listed in Annex I of the Directive. The Chapter contains general principles governing the basic obligations of the operators, what an application for the permit must contains as well as the permit conditions. Chapter II further contains provisions on best available

[161] Recast is adoption of a new legal act which incorporates in a single text both the substantive amendments which it makes to an earlier act and the unchanged provisions of that act. The new legal act replaces and repeals the earlier act. - European Parliament Council Commission Inter-institutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts (2002/C 77/01)

techniques, environmental inspection, public access to information, public participation and access to justice. Finally, Chapter II contains provisions on transboundary effects.

Chapter III applies to combustion plants whose total rated thermal input is equal to or greater than 50 MW, irrespective of the type of fuel used. This Chapter (and corresponding annexes) provides two sets of emission limit values. The first set concerns combustion plants that have been granted a permit or have submitted a complete application for a permit before 7 January 2013, provided that such plants are put into operation no later than 7 January 2014. The second set concerns combustion plants which were granted an exception and which are in operation after 1 January 2016 or those installations containing combustion plants which are not covered by the first set. Furthermore, this chapter provides various possible derogations which can be applied to combustion plants in Member States. Chapter III also contains provisions on monitoring.

Chapter IV applies to waste incineration plants and waste co-incineration plants which incinerate or co-incinerate solid or liquid waste. The Chapter contains additional provisions concerning the application for a permit and permit conditions. Furthermore, the Chapter contains provisions on the control of emissions and their monitoring as well as provisions on how these plants should be operated and how waste should be delivered and received. Emission limit values are indicated in the corresponding annex.

Chapter V concerns installations and activities using organic solvents. As was CLPC the case with large combustion plants and waste incineration plants and waste co-incineration plants, this chapter contains provisions on compliance with emission limit values, monitoring of emissions, etc. Emission limit values are indicated in the corresponding annexes.

Chapter VI is applicable to installations producing titanium dioxide. This chapter contains provisions prohibiting the disposal of certain types of waste and provisions on the control of emissions into water and air, as well as their monitoring.

This Directive applies to a large range of industrial activities that are potential emission sources of ultrafine particles and/ or nanomaterials. The directive also contains several requirements related to hazardous substances or hazardous waste which are defined based on the hazard categories set under the CLP regulation[162]. Such requirements would apply to nanomaterials or nanowaste classified as hazardous (see also findings on the EU waste legislation section).

Control measures applying to hazardous substances under the IED:
Monitoring
Periodic monitoring of soil and groundwater in relation to relevant hazardous substances likely to be found on site and having regard to the possibility of soil and groundwater contamination at the site of the installations (Article 14)

Site closure
Where the activity involves the use, production or release of relevant hazardous substances and having regard to the possibility of soil and groundwater contamination at the site of the installation, the operator shall prepare and submit to the competent authority a baseline report before starting operation of an installation or before a permit for an installation. (Article 22(2))

Upon definitive cessation of the activities, the operator shall assess the state of soil and groundwater contamination by relevant hazardous substances used, produced or released by the installation. Where the installation has caused significant pollution of soil or groundwater by relevant hazardous substances the operator shall take the necessary measures to address that pollution so as to return the site to that state. (Article 22(3))

Substances or mixtures which, because of their content of volatile organic compounds classified as carcinogens, mutagens, or toxic to reproduction under Regulation (EC) No 1272/2008, are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F, shall be replaced, as far as possible by less harmful substances or mixtures within the shortest possible time (Article 58)

[162] Article 3(18) of the ELD defines hazardous substances as 'substances or mixtures as defined in Article 3 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. Hazardous waste is defined under Article 3(38) according to the waste framework directive which in turns relies, among other criteria, on the CLP hazard classification to define hazardous waste.

BAT criteria
The use of less hazardous substances is one of the criteria to determine best available techniques (Annex III)

This Directive finally refers to several specific polluting substances (e.g. under Annex II) and sets related and monitoring requirements for these polluting substances in air and water. Ultrafine particles or nanoparticles are not listed among these specific polluting substances.

3.4.3.2 Conclusions of the 2011 AMEC study[163]

The 2011 AMEC study reviewed the IED and assessed whether it appropriately addressed the prevention and control of ultrafine and nanomaterials emissions from the industrial sources. The study particularly focused on the categories of installations covered by IED and the Best Available Techniques Reference documents (BREFS)[164] on emission limit values and references to abatement technologies.

The study identified that IED provided a fairly good coverage of the types of industries responsible for such emissions. It however underlined potential coverage gaps (installations below the thresholds in Annex I to the IED not covered, only binding emission limit values for large combustion plants and for waste incinerators and road paving with asphalt which is a potential significant source of such emissions not covered by the IED).

The 2011 AMEC study also flagged that the majority of BREFS had a limited coverage of nanomaterials and ultrafine particles. It however considered that the current abatement techniques for dusts and polluting substances implemented at IED industrial sites (e.g. fabric filters, electrostatic precipitators, scrubbers) were likely to have a significant effect in reducing emissions of nanomaterials and ultrafine particles.

The AMEC study concluded that in light of the significant uncertainties and data gaps that currently exist, it was not appropriate to make any changes to the IED to cover nanomaterials and ultrafine particles.

3.4.3.3 Changes since the 2011 AMEC study

The IED has not been amended since the completion of the 2011 AMEC study. However several BREFS were amended or adopted together with related best available technique conclusions. The table below provides an overview of abatement techniques targeting ultrafine or (nano) particles covered under these BREFS. It also includes information on emission limit values set under the best available technique conclusions that must be applied by operators according to Article 15(3) of the IED.

Table 12: Revision to BREFS since the 2011 AMEC study

Year of publication	Installation covered	Example references to abatement techniques targeting ultrafine particles or nanomaterials; BAT conclusions
2012[165]	Iron and steel production	Because of the specific characteristics of sinter dust (high alkali chloride content), the removal efficiency also of a well-designed conventional ESP is not high for the very fine particles. Reference to the 'Corus IJmuiden dry grinding mills' example : The ground ore discharged from the mills is separated into two fractions by the air classifier, the oversized fraction is returned to the mill for further treatment

[163] European Commission, Industrial emissions of nanomaterials and ultrafine particles prepared by AMEC Environment & Infrastructure UK Limited in partnership with the Institute for Occupational Medicine (IOM) and Aether, October 2011, available at: http://bookshop.europa.eu/en/industrial-emissions-of-nano-and-ultrafine-particles-pbKH3013449/?CatalogCategoryID=h2YKABstrXcAAAEjXJEY4e5L

[164] BREFS are the result of the Directive obligation to include in installation permits emission limit values based on Best Available Techniques (BAT). BATs are defined based on an exchange of information between experts from Member States, industry and environmental organisations. This work is co-ordinated by the European IPPC Bureau of the Institute for Prospective Technology Studies at the EU Joint Research Centre in Seville (Spain).

[165] http://eippcb.jrc.ec.europa.eu/reference/BREF/IS_Adopted_03_2012.pdf

Year of publication	Installation covered	Example references to abatement techniques targeting ultrafine particles or nanomaterials; BAT conclusions
		while the fine, correctly sized particles are fed forward to the wetting and mixing stage. **The very fine particles are captured in an electrostatic precipitator and are returned to the product stream**, the ESP being an integral part of the classification system. The AIRFINE scrubber allows for the simultaneous removal of the finest dust particles (including alkali and heavy metal chlorides) and other noxious components of the waste gas. Scrubbing and suppressed combustion: applying a wet system first, coarse particles are removed in a wet separator, then fine particles are removed by venturi scrubbers. The dust concentration in the BOF gas after scrubbing is usually between 15 and 50 mg/Nm3 , but can also be less than 10 mg/Nm3 The BAT conclusions do not contain emission levels for ultrafine or nanoparticles
2013[166]	Manufacture of glass	The electrostatic precipitator for nanoparticles is based on a different technique for charging the particles (diffusion charging) which shows a better efficiency with fine particles. The system consists of a two-stage device that uses a 'sonic jet charger' inside which ions are produced and blown into the flue-gas duct by sonic velocity airflow. (See section 6.8) The charged cloud scrubber (CCS) technique can remove soluble gaseous pollutants (e.g. SO2, HCl, HF, NH3) in addition to fine and ultrafine particles. The BAT conclusions do not contain emission levels for ultrafine or nanoparticles
2013[167]	Production of cement , lime and magnesium oxide	Electrostatic precipitators are very efficient devices for collecting ultrafine particles (< 0.5 µm), providing the particles have the ability to agglomerate. ESPs are of a heavy-duty design leading to high applicability and also relatively insensitive to disturbances in the process. Existing ESP installations can often be upgraded without the need for total replacement, thereby limiting costs. This may be done by fitting more modern electrodes or installing automatic voltage control on older installations. The BAT conclusions do not contain emission levels for ultrafine or nanoparticles
2013[168]	Tanning of hides and skins	No reference to abatement methods for ultrafine or nano particle The BAT conclusions do not contain emission levels for ultrafine or nanoparticles
2014[169]	Production of pulp paper and board	- Waste water treatment Advanced waste water treatment in the pulp and paper industry is mainly focused on additional biological membrane reactors, membrane filtration techniques such as micro-, ultra- or nanofiltration, ozone treatment and evaporation. Due to the relative lack of full-scale experience, the sometimes relatively high costs and the increased complexity of the water treatment, there are only currently a few full-scale applications of tertiary treatment of waste water mill effluent. - Air emissions Electrostatic precipitators are very efficient devices for collecting ultrafine particles (<0.5 µm), providing the particles have the ability to agglomerate, e.g. as recovery boiler dust. In kraft pulp recovery boilers, the particle size allows a good separation efficiency of the ESP. No aerosols are formed

[166] http://eippcb.jrc.ec.europa.eu/reference/BREF/GLS_Adopted_03_2012.pdf
[167] http://eippcb.jrc.ec.europa.eu/reference/BREF/CLM_Published_def.pdf
[168] http://eippcb.jrc.ec.europa.eu/reference/BREF/CLM_Published_def.pdf
[169] http://eippcb.jrc.ec.europa.eu/reference/BREF/PP_revised_BREF_2015.pdf

Year of publication	Installation covered	Example references to abatement techniques targeting ultrafine particles or nanomaterials; BAT conclusions
		during combustion. The BAT conclusions do not contain emission levels for ultrafine or nanoparticles
2014[170]	Refining of mineral oil and gas	Cyclones are used to reduce dust concentrations in the 100 – 500 mg/Nm^3 (milligrams per normalilsed cubic metre) range. A novel cyclone design, called the rotating particulate separator (RPS), is able to effectively remove particles of >1 μm; this design, however, has a limited capacity compared to the conventional cyclone. Third cyclones achieve a 90 % reduction of particulate emissions (100 – 400 mg/Nm^3). Modern multi-cyclones used as third-stage cyclones achieve an 80 % reduction of particulate emissions to about 50 mg/m^3. Electrostatic precipitator ESPs are capable of collecting dust including very fine particles at high efficiencies. ESPs can achieve values of <10 – 50 mg/Nm^3 (95% reduction or higher with higher inlet concentrations only). However, a penetration 'window' exists in the submicron (0.1 – 1μm) size range where the collection efficiency lowers. The BAT conclusions do not contain emission levels for ultrafine or nanoparticles
2015[171]	Wood-based panels production	No reference to abatement methods for ultrafine or nano particles The BAT conclusions do not contain emission levels for ultrafine or nanoparticles

3.4.3.4 Conclusion

Since the IED has not been amended, the potential coverage gaps identified in the 2011 AMEC study concerning industrial activities emitting ultrafine particles or nanomaterials of this directive remain valid (e.g. road paving with asphalt not covered). The majority of the BREFs adopted after the completion of the 2011 study provides information on abatement techniques targeting nano or ultrafine particles (e.g. electrostatic precipitators or fabric filters). Furthermore, some studies have outlined the important role of the industrial sectors in the emission of ultrafine or nano particles[172] and their related potential health impacts[173]. However the recent BAT conclusions covering important industrial emitters of ultrafine/nano particles (e.g. refining of mineral oil and gas, production of cement, lime and magnesium oxide) do not contain any specific emission limit values for these particles. This is considered as a potential implementation gap. Finally as mentioned above, the IED contains several control measures applying to substances classified as hazardous under the CLP Regulation (e.g. monitoring or site closure requirements). However as described in the analysis of the CLP Regulation, there are still some issues with regard to the identification and classification of hazardous nanomaterials under CLP.

[170] http://eippcb.jrc.ec.europa.eu/reference/BREF/REF_BREF_2015.pdf
[171] http://eippcb.jrc.ec.europa.eu/reference/BREF/WBPbref2016.pdf
[172] R. Fernández-Camachoa, S. Rodrígueza, b, J. de la Rosaa, A.M. Sánchez de la Campaa, A. Alastueyc, X. Querolc, Y. González-Castanedoa, I. Garcia-Orellanad, S. Navae, Ultrafine particle and fine trace metal (As, Cd, Cu, Pb and Zn) pollution episodes induced by industrial emissions in Huelva, SW Spain, Atmospheric Environment, volume 61, December 2012 available at: http://www.sciencedirect.com/science/article/pii/S1352231012007674
[173] See Klara Slezakova, Simone Morais and Maria do Carmo Pereira, *atmospheric nanoparticles and their impacts on public health*, Intech 2014 available at: http://www.intechopen.com/books/current-topics-in-public-health/atmospheric-nanoparticles-and-their-impacts-on-public-health

3.4.4 Regulation (EC) No 166/2006 of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register (PRTR Regulation)

3.4.4.1 Summary of Requirements

As set out in Article 1, this Regulation establishes an integrated pollutant release and transfer register at the EU level in the form of a publicly accessible electronic database implementing the UNECE Protocol on Pollutant Release and Transfer Registers. To that end it lays down rules for its functioning and to facilitate public participation in environmental decision-making, as well as contributing to the prevention and reduction of pollution of the environment.

This database must include information on releases to air, water and land of certain types of pollutants (listed under Annex II) by certain categories of facilities (Annex II), off-site transfer of waste and releases of pollutants from diffuse source. The database on line must present data in both aggregated and non-aggregated forms, so that releases and transfers can be searched for and identified by:

- facility, including the facility's parent company where applicable, and its geographical location, including the river basin;
- activity;
- occurrence at Member State or Community level;
- pollutant or waste, as appropriate;
- each environmental medium (air, water, land) into which the pollutant is released;
- off-site transfers of waste and their destination, as appropriate;
- off-site transfers of pollutants in waste water;
- diffuse sources;
- facility owner or operator.

This Regulation was subject to an evaluation and fitness check (REFIT) in 2015. The REFIT does not affect the current evaluation of the Regulation in relation to nanomaterials.

3.4.4.2 Coverage of nanomaterials or ultrafine/nano particles

Annex I to the PRTR Regulation contains a long list of chemical substances with 91 entries. There are however no specific entry points for nanomaterials or the nanoforms of these chemical substances.

3.4.4.3 Conclusion

The PRTR database provides comprehensive information on releases of 91 substances. However, it does not contain any specific entry points for nanomaterials or the nanoforms of these chemical substances (e.g. cadmium) and for ultrafine particles. Such entry points would provide relevant information for policy makers, scientists and the public on exposure concentrations in natural compartments of these substances. There are however still knowledge gaps in the monitoring of the releases of nanomaterials in the environment. This is may be one of the reasons why nanomaterials and ultrafine particles are not covered or planned to be covered in the PRTR Regulation.

3.5 Other legislation potentially relevant due to environment exposure pathways of nanomaterials

3.5.1 Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)

3.5.1.1 Summary of requirements

The BPR harmonises the EU rules concerning the sale and use of biocidal products, whilst ensuring high levels of protection of human and animal health and the environment. Biocidal products are used to control harmful organisms, but their properties can pose significant risks to humans, animals and the environment. The BPR defines 22 categories of biocidal products. To control these risks the BPR active substances must be approved for use in a biocidal product after being assessed by an evaluating Member State and discussed ECHA's Biocidal Products Committee (BPC). The approval

decision is published as a Commission Regulation. Active substances not approved under the BPR cannot be used in biocidal products placed on the EU market. Finally, all biocidal products require an authorisation granted by Member States before being placed on the market. The BPR contains several provisions on nanomaterials.

3.5.1.2 Definition of nanomaterials

Article 3(1)(z) provides a definition of nanomaterials as a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials. It then adds that for the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows:

- 'particle' means a minute piece of matter with defined physical boundaries,
- 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components
- aggregate' means a particle comprising strongly bound or fused particles

This definition is inspired by the Commission Recommendation but it only reflects the first part of the Recommendation definition without including the reference to the lower threshold in case of environment, health and safety or competitiveness concerns. The Commission is empowered to adapt the definition of nanomaterials and to decide at the request of MS whether a substance is a nanomaterial or not. Note that the Biocidal Product Committee, based on a request from the Commission pursuant to Article 75(g) of the BPR had to provide an opinion on whether an active substance (AGS-20: silver adsorbed on silicon dioxide[174]) was considered a nanomaterial or not.

3.5.1.3 Approval of active substances and authorisation of biocidal products

The BPR specifies that the approval of an active substance does not cover the corresponding nanoform. In other words, the Regulation considers that nanomaterials may not have the same properties and related environmental and health impacts of their corresponding bulk substances. In the same vein the BPR also requires that where nanomaterials are used in biocidal products, the risk to human health, animal health and the environment must be assessed separately. Finally, biocidal products that contain nanomaterials are not eligible for the simplified authorisation procedure. The simplified authorisation aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health. So far one active substance, synthetic amorphous silicon dioxide was approved as a nanomaterial[175] and silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) is under review[176].

3.5.1.4 Information requirements related to environmental risks

Point 9 of Annex II to the BPR sets several information requirements related to ecotoxicology (e.g. toxicity to aquatic organisms, terrestrial toxicity, effects on birds) of active substances. Point 10 of Annex II sets several information requirements related to the environmental fate and behaviour of the active substance (e.g. fate and behaviour in water and sediments). Similarly, Point 9 and 10 of Annex III to the BPR set several information requirements related respectively to the ecotoxicology and fate and behaviour of biocidal products. The information requirements related to the environment are very comprehensive and should cover all environment exposure pathways of nanomaterials in biocidal products including nanomaterials used as co-formulants.

Concerning the testing methods to provide information on nanomaterials active substances and biocidal products, respectively Annex II point 5 and Annex III point 5, they require that when test methods are applied to nanomaterials, an explanation must be provided of their scientific

[174] Biocidal Products Committee (BPC) Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 HeiQ AGS-20 ECHA/BPC/001/2014 Adopted 10 April 2014 available at: https://echa.europa.eu/documents/10162/21680461/bpc_opinion_heiq_ags-20_en.pdf

[175] Commission Implementing Regulation (EU) No 408/2014 of 23 April 2014 approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products for product-type 18. OJ L 121, 24.4.2014.

[176] http://echa.europa.eu/substance-information/-/substanceinfo/100.066.069

appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials. There are therefore no specific testing methods mentioned in BPR.

According to a scientific paper published in 2016 on the EU regulation of nanobiocides, current OECD technical guidelines for ecotoxicity of nanomaterials are lacking specific guidance on nanomaterials specific testing issues[177]. It however acknowledges that nanomaterials specific guidance should become available soon a result of ongoing activities within the OECD. This study identifies the following challenges for applicants when testing ecotoxicity of nanomaterials:

- Material characterisation
- Preparation of the NP suspensions
- Composition of the media
- Concentration of the NM used in the test as well as dynamic changes during incubation

It stresses that applicants will have to be explorative in their testing of nanomaterials for some time to come. The study also outlines that there is currently no guidance accompanying the BPR on how to provide nano-specific test results, or how to justify the scientific appropriateness of the current test methods for the testing of nanomaterials.

3.5.1.5 Other control measures on nanomaterials in Biocidal Products

Member States must report every five years on information on the use of nanomaterials in biocidal products. There is for the moment no specific guidance/template for this reporting obligation. Such measure should provide a good understanding of the use of nano-biocides in the EU. It remains to be seen how this reporting mechanism will be implemented. Furthermore, the five-year timeframe might be too long to take action in the event that monitoring of the use of nanomaterials in biocidal products and assessment of the potential risks thereof identifies any potentially significant emerging issues. The BPR sets also specific content labelling requirements for nanomaterials contained in treated articles and biocidal products[178].

3.5.1.6 Conclusion

The BPR is the most advanced and comprehensive EU legislation with regard to the regulation of nanomaterials. It requires a specific approval and authorisation procedure respectively for nanomaterials used as active substances and nanomaterials in biocidal products and co-formulants, acknowledging that the nanoforms of active substances may not have the same properties. Apart from this specific hazard and risk assessment, the BPR also contains other relevant control measures such as specific labelling requirements for nanomaterials used in biocidal products and a Member State reporting obligation every five years on information on the use of nanomaterials in biocidal products and potential risks thereof. However, potential issues remain with regard to the application and implementation of this Regulation:

- The current lack of adequate methods to test the ecotoxicology and fate and behaviour of nanomaterials in the environment.
- The lack of guidance accompanying the BPR on how to provide nano-specific test results, or how to justify the scientific appropriateness of the current test methods for the testing of nanomaterials
- The five-year timeframe for Member States reports which might be too long to adequately monitor the use of nanomaterials in biocidal products and potential risks thereof.
- The BPR does not contain a mandatory obligation for manufacturers to report on the quantities of nanomaterials in biocidal products placed on the EU market.

[177] Anna Brinch, Steffen Foss Hansen, Nanna B. Hartmann and Anders Baun EU Regulation of Nanobiocides: Challenges in Implementing the Biocidal Product Regulation (BPR) (February 2016) available at: http://www.mdpi.com/2079-4991/6/2/33

[178] The word nano in brackets of nanomaterials must be written in labels of treated articles and biocidal products.

3.5.2 Cosmetics Products Regulation (EC) No 1223/2009 (Cosmetic Regulation)

3.5.2.1 Summary of requirements

The aim of the Cosmetic Regulation is to harmonise rules, simplify procedures, strengthen the regulatory framework regarding cosmetic products and to ensure a high level of protection of human health.

The Regulation provides for safety rules and imposes obligations on the manufacturers and on persons designated as 'responsible' for a cosmetic product. A safety assessment must be carried out before the cosmetic product is placed on the market and a product information file kept for each product. The Regulation establishes a notification procedure, which requires that information on the cosmetic product is communicated to the European Commission before the placing on the market, and after it (labelling). It also contains provisions regarding consumer protection content labelling, product claims, access to information for the public, and market surveillance.

Finally this Regulation set restrictions and/or specific provisions for certain substances in cosmetic products, including substances classified as CMR or as nanomaterials.

The environmental impacts of cosmetics (e.g. washed-off cosmetics into waste water and water bodies) are not covered under this Regulation. Clause no. 5 states that these concerns are considered through the application of REACH.

3.5.2.2 Coverage of nanomaterials in the Cosmetic Regulation

Nanomaterial definition

According to Article 2(1) of the Cosmetic Regulation nanomaterial means an insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. This Definition is different to the definition of nanomaterials as adopted under the Commission Recommendation 2011/696/EU. On this aspect Article 2(3) of this Regulation requires that in view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt the definition to technical and scientific progress and to definitions subsequently agreed at international level. Since the adoption of the Cosmetic Regulation the definition of nanomaterials has not been amended. At the time of writing, a minor revision to the definition is expected to be published in the second half of 2016.

Control measures applying to nanomaterials

Article 10 of the Cosmetic Regulation requires that all substances included in cosmetics must be subject to a specific assessment in Accordance with Annex I (safety report requirements). This obligation applies to any person responsible for the placing on the market of cosmetics containing nanomaterials. With regard to nanomaterials, Annex I requires that particular consideration must be given to any possible impacts on the toxicological profile due to particle size, including nanomaterials.

In view of the implementation of this requirement, the Scientific Committee on Consumer Safety has adopted a guidance on the safety assessment of nanomaterials in cosmetics[179]. This guidance does not cover the potential environmental impact of cosmetic products, as these concerns should be addressed under REACH.

Article 13 of the Cosmetic Regulation requires that prior to placing the cosmetic product on the market the responsible person must submit, by electronic means among others, information to the Commission on the presence of substances in the form of nanomaterials and their identification including the chemical name (IUPAC) and other descriptors and the reasonably foreseeable exposure conditions.

Article 16 on nanomaterials details the content of the notification for nanomaterials under Article 13.

Information requirement on notified nanomaterial in cosmetic products:

- The identification of the nanomaterial including its chemical name (IUPAC) and other

[179] Scientific Committee on Consumer Safety (SCCS), Guidance on the safety assessment of nanomaterials in cosmetics. Available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf

descriptors as specified in point 2 of the Preamble to Annexes II to VI;

- The specification of the nanomaterial including size of particles, physical and chemical properties;
- An estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;
- The toxicological profile of the nanomaterial;
- The safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;
- The reasonably foreseeable exposure conditions.

Article 16(4) requires that in the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission must without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. If as a result of the SCCS opinion, the Commission considers that there is a potential risk to human health, including when there is insufficient data, the Commission can amend Annexes II[180] and III[181] under comitology.

Article 16(10) requires that by January 2014, the Commission must make available to the public a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. According to the same Article, the Commission must also submit to the European Parliament and the Council an annual status report, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section. However the Commission has not yet fulfilled these obligations.

Article 19 on labelling for consumer information requires that all ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word 'nano' in brackets.

Finally, according to Article 14 UV-filters and others than those listed in Annex VI[182] must not be used in cosmetic products. At the time of writing this report, the Commission following the opinion of the SCCS allowed the use of tris-biphenyl triazine[183] as a UV-filter and, zinc oxide nanomaterial under certain conditions.[184] Note that at the time of writing this report the Commission has adopted a draft Regulation to authorise nanoscale titanium dioxide[185]. Finally, the SCCS has published a final opinion on nanoforms of different silica used in cosmetic products[186]

3.5.2.3 Conclusion

The Cosmetic Regulation contains very comprehensive and stringent control measures on the health impacts of nanomaterials used in cosmetics (e.g. safety assessment, specific notification requirements). It also sets specific content labelling[187] and public information requirements on nanomaterials used in cosmetic products. Despite that cosmetic products end up in the environment (e.g. through waste water systems) there are no measures or information requirements on the potential environmental impacts of nanomaterials used in cosmetics under the Cosmetic Regulation.

[180] List of substances prohibited in cosmetic products
[181] List of substances which cosmetic products must not contain except subject to the restrictions
[182] Annex VI is amended by Commission Regulation after the Scientific Opinion of the Scientific Committee on Consumer Safety.
[183] Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products Text with EEA relevance, OJ L 238, 9.8.2014
[184] Commission Regulation (EU) 2016/621 of 21 April 2016 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 106, 22.4.2016.
[185] http://data.consilium.europa.eu/doc/document/ST-6779-2016-INIT/en/pdf
[186] The SCCS concluded that the evidence, both provided in the submission and that available in scientific literature, is inadequate and insufficient to allow drawing any firm conclusion either for or against the safety of any of the individual SAS material, or any of the SAS categories, that are intended for use in cosmetic products.
[187] This is not a hazard labelling

Such environmental assessment is covered by the REACH Regulation. Indeed substances used in cosmetic products are not exempted from REACH. REACH only provides that the Chemical Safety Report under the registration dossier does not need to include consideration of the risk to human health of end users from the use of substances in cosmetic products. However as mentioned in the section on REACH, the current version of REACH, at least the registration phase, is currently not the adequate tool to generate information on ecotoxicology, environmental fate and behaviour of nanomaterials. The European Commission reporting obligation on cosmetics with nanomaterials placed on the market is at the time of writing this report not yet fulfilled.

3.5.3 Regulation (EC) No 1107/2009 on plant protection products (PPP)

3.5.3.1 Summary of requirements

The PPPs Regulation applies to products containing active substances, safeners or synergists, and intended for one of the following uses:

- protecting products against all harmful organisms
- influencing the life processes of plants

They are mainly used in the agricultural sector, but are also used in forestry, horticulture, amenity areas and in domestic gardens. PPPs contain at least one active substance.

Before an active substance can be used within a PPP in the EU, it must be approved by the European Commission (EU positive list approval procedure).

Active substances are subject to an intensive evaluation and peer-review by Member States and the European Food Safety Authority before an approval is granted by the Commission (2.5 to 3.5 years). Components including safeners and synergists are subject to the same approval procedure.

There is a zonal procedure for PPP authorization. The EU is divided into three parts, the northern, middle and southern zone. PPP are intended to be authorized within the zone by the evaluation of one-member state. The other members comment this assessment and adopt it to their regional conditions (including applying national risk mitigation measures).

Before a plant protection product can be placed on the market it must be authorised for use by the Member States concerned. After considering specific local variations in climate, cropping patterns and diet, the Member State can grant a full authorisation of the product, and authorisation restricted to certain crops, or reject the authorisation. The data requirements for plant protection product approval by Member States, and the criteria by which the EU and Member States evaluate these products are harmonised at EU level. Data requirements for the authorisation of PPPs are listed in the Regulation (EU) No 284/2013.

3.5.3.2 Reliance on the CLP classification for the application of the active substance approval

The approval procedure of active substances relies among other criteria on the CLP classification of substances. The classification of an active substance under certain categories of CLP can lead directly to non-approval (e.g. mutagen category 1A or 1B). Other substances classified under CLP (e.g. category 1A or 1B carcinogens) can however still be approved if human exposure is negligible. Substances meeting the criteria to be classified as hazardous under CLP are considered substances of concern and are therefore excluded to the approval procedure for basic procedure. Active substances classified as category 1A or 1B carcinogens are excluded from the derogation approval requirements necessary to control a serious danger to plant health which cannot be contained by other available means.

3.5.3.3 Use of nanomaterials in PPPs

According to the presentation of Thomas Bucheli from the Institute for Sustainability Sciences at a Joint Research Centre workshop on "*Nanotechnology for the agricultural sector: from research to the field*" in 2014, there have been a lot of research and development on nanomaterials to be used in plant protection products. Most nanomaterial plant protection products patents are on fungicides and insecticides and on additives (e.g. to control release, dispersion aid, transport media, protecting agents and photocalysts). He stressed that most patent and scientific papers refer to nonsolid nanomaterials.

He provided examples of nanomaterials that could be used in plant protection products such as silver nanoparticles as active ingredients in fungicides, TiO2 nanoparticles as additives (photocatalysts) in pesticides like imidacloprid, ZnO nanoparticles as active ingredients in fertilizers and hydroxyapathite

urea-coated particles as additives in fertilizers for controlled release. He underlined that not many products were available on the market (e.g. polymer nanoparticles with the advantage of coating leaves as an active pesticide ingredients in use in Canada).

At the same workshop, Alejandro Perez-de-Luque, from the University of Sheffield explained that the use of nanocapsules and nanoparticles for plant protection products offers important advantages (e.g. no degradation by external agents or the crop plant itself allowing the use of a reduced amount of active compounds for plant treatments, potential reduction of leaching and water contamination). He did however stress that there were not yet sufficient studies on the potential toxicity of some nanomaterials (nanosilver, nanogold, etc.) on plants, animals and the environment that could accumulate in vegetal and animal tissues and end-up in the food chain[188].

3.5.3.4 Conclusion

Unlike the Biocidal Product Regulation, the PPP does not contain specific information and assessment requirements for nanomaterials. This is considered as a potential legal gap considering that a lot of efforts from economic operators are currently placed on research and development on nanomaterials in plant protection products which may soon be ready to be placed on the market. There are also lot of knowledge gaps on the potential (eco)toxicity of certain plant protection products nanomaterials used on plants, animals and the environment. In view of these potential developments and potential risks some countries such as the US and Switzerland, unlike the EU, have set specific 'nano' requirements in the approval procedure of plant protection products. Finally, the PPP Regulation relies on the CLP Regulation to implement the active substance approval procedures. However (see CLP analysis), there are still some issues with regard to the identification of any nanospecific hazards and subsequent classification of hazardous nanomaterials under CLP.

Stakeholder views

NIA

The PPR regulation is one of the most stringent regulations with regard to EHS requirements. It requires a thorough evaluation of the environmental impacts of products by the European Food Safety Agency prior to their placing on the market which would identify any toxicological issues a substance, in the nanoscale or not, could cause. The PPR does therefore not need to have specific requirements for nanomaterials.

3.5.4 EU food legislation

3.5.4.1 Summary of requirements

The EU food legislation is regulating the different aspects of food safety. It can be divided into eight different groups of legislation.

- The EU framework legislation on food: Regulation (EC) No 178/2002;
- The food improvement agents regulatory package (food additives, food enzymes and food flavourings);
- Legislation on food supplements/food fortification;
- Legislation on foodstuffs for particular nutritional uses;
- The Regulation on novel foods and novel food ingredients;
- Legislation on materials in contact with food;
- Legislation on contaminants and residues in food;
- Legislation on feed.

Among these groups of legislation several regulations are covering or referring to nanomaterial in food or in contact with food (i.e. food information for consumers, plastic and active and intelligent

[188]European Commission JRC scientific and policy reports, Proceedings of a workshop on "Nanotechnology for the agricultural sector: from research to the field " (2014) available at: file:///C:/Users/florent/Downloads/LFNA26625ENN_002.pdf

materials in contact with food, food intended for young children and special medical purpose, novel food).

3.5.4.2 Regulation (EU) 2015/2283 on novel foods (novel food Regulation)

The new Novel Foods Regulation aims to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interest. It defines novel food based on different categories of food that were not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union. One of the categories of novel food is food consisting of engineered nanomaterials. Article 3(f) of the novel food Regulation defines engineered nanomaterials as any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. It then adds that properties that are characteristic of the nanoscale include:

- those related to the large specific surface area of the materials considered; and/or
- specific physico-chemical properties that are different from those of the non-nanoform of the same material.

The novel food Regulation sets a centralised authorisation system for novel foods in order to simplify and speed up the authorisation procedure. The European Food Safety Authority (EFSA) conducts a scientific risk assessment for the novel food application and the Commission based on EFSA scientific opinion submits to the Standing Committee on Plants, Animals, Food and Feed a draft authorisation decision which will then be adopted, amended or rejected according to the examination procedure set under Article 5 of Regulation (EU) No 182/2011.

In case of food or vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013 consisting of nanomaterials, the novel food Regulation requires authorisation applicants to provide an explanation of the test methods scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.

Finally, the Novel Food Regulation contains a delegated act procedure under Article 31 to adjust and adapt the definition of engineered nanomaterials to technical and scientific progress or to definitions agreed at international level.

3.5.4.3 Regulation (EC) No 450/2009 on active and intelligent materials intended to be in contact with food

The general principles applicable to food contact materials are set out in Regulation (EC) No 1935/2004 stating that materials and articles in contact with food shall only be authorised if it is demonstrated that they do not present risks to human health. Within this framework, Regulation (EC) No 450/2009 lays down specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.

Pursuant to the Article 3 of this Regulation 'active materials and articles' are defined as materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food; and are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food. This Article also defines 'intelligent materials and articles' as materials and articles which monitor the condition of packaged food or the environment surrounding the food.

Pursuant to Article 5(1) of this Regulation only substances which are included in the 'Community list' of authorised substances can be used in components of active and intelligent materials and articles. By way of derogation, Article 5(2) establishes that substances used in components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier may be used in components of active and intelligent materials and articles without being included in the Community list. However, Article 5(2)(c)(ii) specifies that this rule does not apply to substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale.

3.5.4.4 Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

The general principles applicable to food contact materials are set out in Regulation (EC) No 1935/2004 stating that materials and articles in contact with food shall only be authorised if it is demonstrated that they do not present risks to human health. Within this framework, Regulation (EU) No 10/2011 lays down specific rules on plastic materials and articles intended to come into contact with food for their safe use.

Pursuant to Article 5 only the substances (i.e. monomers or other starting substances, additives, polymer production aids excluding solvents, macromolecules obtained from microbial fermentation) included in the Union list of authorised substances can be used in the manufacture of plastic layers in plastic materials and articles. Several nanomaterials have been authorised to be used in plastic materials and articles intended to come into contact with food:

- titanium nitride
- butadiene, ethyl acrylate, methyl methacrylate, styrene copolymer crosslinked with divinylbenzene, in nanoform
- butadiene, ethyl acrylate, methyl methacrylate, styrene copolymer not cross-linked, in nanoform
- butadiene, ethyl acrylate, methyl methacrylate, styrene copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform

Nanomaterials authorised to be used in plastic as food contact material: Carbon Black (FCM No. 411; nano SiO2 (FCM No. 504) and Nano TiN (FCM N. 807), ZnO(2016) are at the time of writing this report under assessment.

According to Article 9 the reference to the nanoform of substances must be explicitly mentioned in the Annex I authorisation list.

Applicants for inclusion of a substance in the Union list of authorised substances must provide, according to the EFSA guideline information on the identity of the substance, the physical and chemical properties of substances, the intended application of substance, data on migration of substances, data on residual content of substance in the food contact material and microbiological properties of substances, toxicological data[189]. This guideline clearly states that it does not cover any consideration of environmental aspects such as persistence in the environment, ecological impact of their constituents and their fate after the food contact material has been submitted to waste disposal treatment.

Pursuant to Article 14 and Article 13, in plastic multi-layer material or article and in multi-material multi-layer materials and articles the composition of each plastic layer must comply with this Regulation. However, by way of derogation, a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier may not be manufactured with substances not listed in the Union list or in the provisional list. However, this derogation does not apply to substances in nanoforms.

3.5.4.5 Regulation (EU) No 1169/2011 on the provision of food information to consumers

This Regulation establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information, taking into account the need to provide sufficient flexibility to respond to future developments and new information requirements

According to Article 3, all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word ‘nano’ in brackets.

This Regulation defines ‘engineered nanomaterial’ as any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts,

[189] Information retrieved from EFSA, note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation

either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

It adds that properties that are characteristic of the nanoscale include:

- those related to the large specific surface area of the materials considered; and/or
- specific physico-chemical properties that are different from those of the non-nanoform of the same material.

3.5.4.6 Regulation No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

This Regulation establishes compositional and information requirements for infant formula and follow-on formula; processed cereal-based food and baby food; food for special medical purposes, total diet replacement for weight control. It sets a Union list of substances that may be added to one or more of the categories of these specific categories of food and lays down the rules applicable to the updating of that list. Nanomaterials are defined according to Regulation (EU) No 1169/2011.

Article 9(2) requires that these categories of food referred must not contain any substance in such quantity as to endanger the health of the persons for whom it is intended. It adds that for substances which are engineered nanomaterials, compliance with the requirement referred to in the first subparagraph shall be demonstrated on the basis of adequate test methods, where appropriate.

3.5.4.7 Conclusion

Several pieces of legislation on food contain specific measures related to nanomaterials. They adequately cover the potential health and safety risks of nanomaterials for consumers. These pieces of legislation do not cover environmental hazards of nanomaterials. With regard to edible nanomaterials in food, no specific risks for the environment have yet been identified.[190] Concerning nanomaterials in food packaging, the directive packaging waste should be the appropriate framework to control potential environmental risks.

3.6 Conclusions / Gap analysis

3.6.1 Legislation covered in the 2011 regulatory review

3.6.1.1 EU waste legislation

A study commissioned by the German Government of January 2015 suggests establishing a distinction between the terms “nanowastes” and “nanomaterial-containing wastes”.

Nanowastes mainly consist of nanomaterials and can be collected separately. They normally originate from the manufacture and use of nanomaterials. Nanomaterial-containing wastes are wastes from end-of-life products which contain nanomaterials.

This distinction seems necessary as waste exclusively consisting of one nanomaterial are an exception. The distinction seems key when it comes to application of existing regulatory management controls. Important knowledge gaps include a lack of engineered nanomaterial hazard characterisation, understanding their behaviour in landfill environments and missing quantitative data on toxicity. Current research suggests that due to their unique physicochemical properties and characteristics such as size, shape, surface area and chemical reactivity, nanomaterials that occur as manufacturing waste by-products could require more stringent disposal requirements than for the parent products. However, whereas manufacturers of nanomaterials should well know the composition of their production wastes, due to the lack of communication in the supply chain of the content of nanomaterials, the safe disposal of wastes containing nanomaterials cannot be ensured. Knowledge gaps and lacking combination of data are therefore a challenge to effective application of existing waste legislation.

As nanomaterials are neither specifically regulated nor excluded from European waste legislation, in theory all legal requirements for waste also apply to nanowaste and nanomaterial-containing waste.

[190] There is no information or scientific findings about potential active/unmetabolized nanomaterials leaving the body entering the waste water steam.

However, as mentioned in the detailed analysis, effective application of EU waste legislation to nanomaterials is being impeded by the need to further develop scientific knowledge of nanomaterials and to understand their fate and behaviour in landfills. Currently, nanomaterial-containing waste is managed along with conventional waste "without sufficient knowledge of the associated risks and impacts on the environment".

In EU law, waste and chemicals legislation are interrelated via the hazard criteria. If substances with a specific hazardous property are contained in waste above the concentration limits defined in the respective legal texts the waste is to be classified as hazardous. Therefore, information on the hazardous properties of substances is decisive for the classification of wastes.

3.6.1.2 EU water legislation

The release of nanomaterials in fresh and marine waters occurs through a number of different exposure pathways and, as such, is inevitable. Exposure pathways include both point source emissions (e.g. nanomaterials in urban waste waters, through cosmetics washed off people's bodies, disinfectants, paints, detergents, etc.) and diffuse source emissions (e.g. nanomaterials in groundwater and surface waters from pesticide-contaminated agricultural runoffs, landfills and sewage sludge).

Once present in surface waters, nanomaterials will aggregate to some extent and they may associate with suspended solids or accumulate in living tissues. One issue is that nanomaterials have the potential to interact with and alter the bioavailability of other hazardous substances, in some cases enhancing bioaccumulation or toxicity. The bioaccumulation of cadmium in fish, for example, was found to be enhanced in the presence of titanium dioxide (TiO2) nanoparticles.[191]

The lack of reliable ecotoxicological data, in part due to particle impurities, suspension preparation methods, particle aggregation, etc. means that there is, at present, very little information available on the impacts of nanomaterials on aquatic ecosystems[192]

As mentioned by the CLP ECHA guidelines on the application of CLP criteria[193] (see Section 3.4.1), the environmental hazard classification of a substance under the CLP Regulation is principally concerned with the aquatic environment. The basis of the identification of hazard is the aquatic toxicity of the substance or mixture, and information on the degradation and bioaccumulation behaviour. Information on the aquatic toxicity of nanomaterials, and more specifically on their degradation and bioaccumulation behaviour, is limited.

Degradation assessment

According to a background paper related to a 2014 ECHA scientific workshop on regulatory challenges in risk assessment of nanomaterials[194], simulation tests for biological degradation in various environmental compartments are applicable in principle, but the detection and quantification of the nanomaterial is a challenge. This report stresses that degradation of nanomaterials may also be identified as changes at the nanomaterial surfaces.

Bioaccumulation behaviour assessment

This background paper also underlines that to determine if and under which circumstances nanomaterials accumulate in the environment and environmental species, more knowledge on the key characteristics that influence the fate, behaviour and kinetics of nanomaterials and implementation of this knowledge within the risk assessment approaches and regulatory frameworks is needed.

However, the increasing use of engineered nanomaterials in a number of products and processes means that the volumes of nanomaterials that will enter the aquatic environment are likely to keep

[191] EEA, *Hazardous substances in Europe's fresh and marine waters – An overview*, EEA technical report, No 8/2011, Copenhagen, 2011, p33-34.
[192] Steffen Foss Hansen, Catherine Ganzleben, Anders Baun, 'Nanomaterials and the European Water Framework Directive', *European Journal of Law and Technology*, Vol. 2, No. 3 (2011), p6.
[193] Guidance on the Application of the CLP Criteria available at: http://echa.europa.eu/documents/10162/13562/clp_en.pdf
[194] ECHA, Topical Scientific Workshop Regulatory Challenges in Risk Assessment of Nanomaterials 23-24 October 2014, available at: http://echa.europa.eu/documents/10162/5399565/bp_ws_risk_assessment_nanomaterials_en.pdf

growing. In addition, the hazard characteristics of some nanomaterials, such as functionalized carbon nanotubes, nano-scale silver and zinc oxide, justifies that careful attention is paid to these substances and their impact on the aquatic environment.

The EU water-related legislative framework is critical in reducing and phasing out the release of hazardous substances, including – in theory – in nano forms, into aquatic ecosystems in general and in our drinking water in particular.

Although nanomaterials are not currently defined under any of the water-related Directives, they may fall under the definition for 'hazardous substances' (Article 2(29)) or 'pollutants' (Article 2(31)) in the Water Framework Directive. Because neither definition refers to particle size, nano forms of certain groups of substances, such as metals and their compounds, are already, in theory, covered by these definitions.

In practice, there are two possible ways to cover nanomaterials under the water-related legislation:[195]

1. Categorising the nanomaterials most widely used (and thus released in the aquatic environment) as 'priority substances' under the Water Framework Directive. Such categorisation would trigger a number of obligations for the Member States in relation to the control of these substances, not only under the Water Framework Directive but also under a number of other pieces of legislation (e.g. the EQS, the MSFD, etc.)
2. Implementing measures that are appropriate for the control, reduction and phasing-out of nanomaterials into aquatic ecosystems, from monitoring to setting emission limit values, adapting 'end-of-pipe' techniques to control the emission of nanomaterials and adapting current BAT to nanomaterials.

The two options are not mutually exclusive. The development of appropriate control measures, mostly related to the advancement of technology and science, may even be a more likely option than the categorisation of nanomaterials as 'priority substances' (see section on the Water Framework Directive). In addition, because there is no specific reference to size in the definition of 'pollutants', the nano form of a number of pollutants or groups of pollutants are already technically covered by the Water Framework Directive and thus could be controlled were appropriate techniques developed.

3.6.1.3 Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III Directive)

The Seveso Directive mainly relies on the CLP Regulation to establish risk management measures for certain types of industrial facilities. As mentioned in the analysis of the CLP Regulation, there are however still some issues with regard the identification and classification of hazardous nanomaterials under CLP. Furthermore, the current quantity thresholds under the Seveso Directive may not be adequate to reflect the potential specific properties of nanomaterials. Finally, unlike in the original Commission proposal for a revised Directive, the adopted Seveso Directive does not contain an adequate mechanism to adapt in a rapid manner Annex I if there were evidence of potential major-accident hazard of specific hazardous substances (including hazardous nanomaterials) in industrial facilities.

3.6.1.4 Ambient Air Quality Directive 2008/50/EC

Several scientific papers identified potential health and environmental hazards of ultrafine particles and airborne nanomaterials confirming that this ambient air pollution is an area of growing health concern. Furthermore, in recent years there has been some scientific progress in the monitoring of these particles and in the understanding of their atmospheric formation, dispersion, physical and chemical transformation. However, the Ambient Air Quality Directive does not contain specific control measures (e.g. limit values) and monitoring requirements related to ultrafine particles and air-borne nanomaterials. There are indeed still many regulatory challenges with regard to the implementation of control and monitoring measures for ultrafine particles and airborne nanomaterials (e.g. difficulties and uncertainties in setting safe levels of ultrafine particles and airborne nanomaterials exposure, lack of adequate monitoring instruments, lack of monitoring standard methods). The focus on the control of potential emission sources should therefore be the priority of decision makers. The EU has for

[195] Steffen Foss Hansen, Catherine Ganzleben, Anders Baun, 'Nanomaterials and the European Water Framework Directive', *European Journal of Law and Technology*, Vol. 2, No. 3 (2011).

example set in place very stringent requirements on diesel vehicles emissions of ultrafine particles (Euro-5 and Euro-6 vehicle standards).

3.6.1.5 Regulation (EC) No 66/2010 on the EU Ecolabel

There is no consistent approach in the coverage of nanomaterials under the different Ecolabel criteria decisions. The older criteria that were not amended since 2012 do not contain any criteria on nanomaterials, nanoforms or forms of substances.

The criteria decisions to exclude hazardous substance under EU ecolabel products mainly rely on the CLP classification of hazardous substance. They also exclude substances of very high concern under REACH. The majority of these decisions require the applicants to demonstrate that all forms of substances used are not falling under certain categories of hazardous substances under CLP and are not substances of very high concern under REACH. However as mentioned in the CLP analysis there is a limited number of classified nanomaterials under the CLP Regulation despite that the information on substances must relate to their different forms. Furthermore, there is currently limited available information on nanomaterials to classify them under CLP (e.g. data gaps on nanomaterials under REACH). Finally, there are still considerable knowledge gaps on the determination of environmental hazards of nanomaterials (e.g. toxicity of the substance or mixture, and information on the degradation and bioaccumulation behaviour) for their classification under CLP.

As mentioned in the previous 2011 study the Ecolabel decisions rely on CLP and REACH to exclude hazardous nanomaterials from EU ecolabel products. However, these two regulations are currently not adequate to identify hazardous nanomaterials.

3.6.2 Additional EU environmental legislation not covered in the 2011 regulatory review

3.6.2.1 CLP Regulation

No specific references to nanomaterials or nanoform of substances, but information on a substance and mixture must relate to the forms or physical state in which the substance or the mixture is placed on the market. Only a limited number of nanomaterials had a specific classification entry. The classification of substances and/or mixtures relies on available information on substances. There is no obligation to generate information on health and environmental hazards of substances even though there is no adequate and reliable information on such hazards (e.g. often the case for nanomaterials). In case manufacturers are willing to generate information on environmental hazards for the classification of nanomaterials, they may however encounter some difficulties and especially with regard to the assessment of the degradation and bioaccumulation behaviour of nanomaterials.

3.6.2.2 REACH

No references to nanomaterials in REACH. However, nanomaterials would fall under the definition of substances under REACH. Very few registration dossiers include references to the nanoform of size-unspecified substances. The current registration requirements under REACH do not clearly impose the identification and/or characterisation of nanomaterials. Nanomaterials ‘not registered’ can therefore be placed on the market without an assessment evaluating whether specific specific tests and specific risk management measures, apart the ones applying to the bulk substance despite their potential different characteristics, are needed. Nanoforms of phase-in bulk substances may also benefit from delayed registration and are unlikely to be subject to an assessment evaluating whether specific specific tests and specific risk management measures are neeed, even though they could have different physiochemical, toxicological and ecotoxicological properties than the phase-in bulk substance.

Within the framework of the current revision of the REACH Annexes it is being discussed how Annexes to REACH should be amended to ensure that nanomaterials are characterised and/or identified in the registration dossiers and what specific information should be generated for nanomaterials.

In case nanomaterials are registered under REACH, registrants may encounter difficulties to provide some adequate information on their ecotoxicology and fate and behaviour on the environment due to remaining knowledge gaps on test methods for nanomaterials.

Since the information in the supply chain relies on the information from the registration dossiers, the potential loopholes in the registration of nanomaterials would therefore impact information in the supply chain.

There is no information on whether or not downstream users prepare chemical safety reports concerning the use of substances leading to the generation of nanomaterials (e.g. through grinding, surface modification) outside the scope of the exposure scenario.

3.6.2.3 Directive 2010/75/EU (IED)

Ultrafine particles or nanoparticles are not listed among specific polluting substances under IED. Installations below the thresholds in Annex I to the IED, road paving with asphalt are not covered by the Directive even though they are considered major contributors of emissions of ultrafine particles. Only binding emission limit values for large combustion plants and for waste incinerators. BAT conclusions cover important industrial emitters of ultrafine/nano particles but do not contain any specific emission limit values for these particles.

3.6.2.4 Regulation (EC) No 166/2006 (PRTR Regulation)

The PRTR database provides comprehensive information on releases of 91 substances. However, it does not contain any specific entry points for nanomaterials or the nanoforms of these chemical substances (e.g. cadmium) and for ultrafine particles. Entry points for selected nanomaterials would provide relevant information on exposure concentrations in natural compartments of these substances. There are however still knowledge gaps in the monitoring of the releases of nanomaterials in the environment. This is may be one of the reasons why nanomaterials and ultrafine particles are not covered or planned to be covered in the PRTR Regulation.

3.6.3 Other potentially relevant legislation

3.6.3.1 Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)

The BPR is the most advanced and comprehensive EU legislation with regard to the regulation of nanomaterials. It requires a specific approval and authorisation procedure respectively for nanomaterials used as active substances and nanomaterials in biocidal products, acknowledging that the nanoforms of active substances may not have the same properties. Apart from this specific hazard and risk assessment, the BPR also contains other relevant control measures such as specific labelling requirements for nanomaterials used in biocidal products and a Member State reporting obligation every five years on information on the use of nanomaterials in biocidal products and potential risks thereof. However, potential issues remain with regard to the application and implementation of this Regulation:

- The current lack of adequate methods to test the ecotoxicology and fate and behaviour of nanomaterials in the environment.
- The lack of guidance accompanying the BPR on how to provide nano-specific test results, or how to justify the scientific appropriateness of the current test methods for the testing of nanomaterials
- The five-year timeframe for Member States reports which might be too long to adequately monitor the use of nanomaterials in biocidal products and potential risks thereof.

The BPR does not contain a mandatory obligation for manufacturers to report on the quantities of nanomaterials in biocidal products placed on the EU market**.**

3.6.3.2 Cosmetics Products Regulation (EC) No 1223/2009 (Cosmetic Regulation)

The Cosmetic Regulation contains very comprehensive and stringent control measures on the health impacts of nanomaterials used in cosmetics. It also sets specific content labelling and public information requirements on nanomaterials used in cosmetic products. There are no measures or information requirements on the potential environmental impacts of nanomaterials used in cosmetics under the Cosmetic Regulation. Such environmental assessment is covered by the REACH Regulation. Substances used in cosmetic products are not exempted from REACH. REACH only provides that the Chemical Safety Report under the registration dossier does not need to include consideration of the risk to human health of end users from the use of substances in cosmetic products. However as mentioned in the section on REACH, the current version of REACH, at least the registration phase, is currently not the adequate tool to generate information on ecotoxicology, environmental fate and behaviour of nanomaterials. The European Commission has not yet published a report on cosmetics with nanomaterials placed on the market at the time of writing this report**.**

3.6.3.3 Regulation (EC) No 1107/2009 on plant protection products (PPP)

Unlike the Biocidal Product Regulation, the PPP does not contain specific information and assessment requirements for nanomaterials. This is considered as a potential legal gap considering that a lot of efforts from economic operators are currently placed on research and development on nanomaterials in plant protection products which may soon be ready to be placed on the market. There are also lot of knowledge gaps on the potential (eco)toxicity of certain plant protection products nanomaterials used on plants, animals and the environment. In view of these potential developments and potential risks some countries such as the US and Switzerland, unlike the EU, have set specific 'nano' requirements in the approval procedure of plant protection products. Finally, the PPP Regulation relies on the CLP Regulation to implement the active substance approval procedures. However, there are still some issues with regard to the identification of any nanospecific hazards and subsequent classification of hazardous nanomaterials under CLP.

3.6.3.4 EU food legislation

Several pieces of legislation on food contain specific measures related to nanomaterials. They adequately cover the potential health and safety risks of nanomaterials for consumers. These pieces of legislation do not cover environmental hazards of nanomaterials. This is quite obvious with regard to edible nanomaterials in food as no specific risks for the environment have yet been identified in this case.[196] This may be a problem with regard to food packaging. However, the directive packaging waste would be the most appropriate framework to control environmental risks of nanomaterials in food contact materials.

3.6.4 Overview of EU legislation coverage of nanomaterials

Table 13 provides a summary of the coverage of EU legislation in relation to nanomaterials.

Table 13: EU legislation coverage of nanomaterials

EU legislation	Nanospecific provision	Amended since 2011	Conclusions
Legislation covered in the 2011 regulatory review			
Waste Framework Directive 2008/98/EC		×	Categorisation of hazardous waste based on the CLP Regulation. The art waste treatment technologies remain not adequate to capture nanomaterials leading to implementation gaps of the Waste Framework Directive. There are knowledge gaps on nanomaterial in waste streams
Decision 2000/532/EC (European Waste Catalogue)		×	The absence of a specific category of nanomaterial-containing waste The challenge to determine hazardous properties of nanomaterials in waste/nanowaste based on concentration limits and based on the CLP Regulation
Directive 2000/53/EC on end-of life vehicles (EoLV Directive)		×	Reliance on CLP to identify 'hazardous nanomaterials
Directive 1999/31/EC on the Landfill of Waste (Landfill Directive)			Reliance on the CLP Regulation to categorise hazardous waste Knowledge gaps on nanomaterials behaviour in landfills and the health and environmental risks they may entail.
Directive 2011/65/EU (RoHS Directive)	×	×	Article 6 specifically mentions that when reviewing the list of restricted substances, the Commission must take into account several criteria (e.g. negative impacts during EEE waste management operations, uncontrolled or diffuse release into the environment) for substances including substances of very small size or with a very small internal or surface structure. This key provision of the ROHS Directive is considered to be an

[196] There is no information or scientific findings about potential active/unmetabolized nanomaterials leaving the body and entering the waste water steam.

EU legislation	Nanospecific provision	Amended since 2011	Conclusions
			adequate tool to restrict hazardous nanomaterials in EEE. Such periodic review procedure may lead to the generation of new information on nanomaterials in EEE and their related potential environmental risks.
Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) (recast)	×	×	This Directive invites the Commission to evaluate whether amendments to Annex VII are necessary to adequately control nanomaterials. To date, no evaluation assessing amendment needs with regard to treatment requirements under Annex VII have been carried out nor any delegated acts adopted.
Directive 94/62/EC on packaging and packaging waste (Packaging Directive)		×	Effective implementation of the Packaging Directive provisions to packaging containing nanomaterials is hampered by poor knowledge on nanomaterials characteristics, releases to the environment and behaviour. The current provisions of the Packaging Directive would be adequate to cover nanomaterials if there were no such knowledge gaps.
Directive 86/278/EEC (Sewage Sludge Directive)			The Sewage Sludge Directive does not currently not seem to be an adequate tool to detect monitor and control the use of hazardous nanomaterials in the treatment of sewage sludge.
The Water Framework Directive		×	The creation of a 'watch list' mechanism under the EQS Directive (see next row) has the potential to facilitate the inclusion of substances in nanoform in the list of priority substances and the implementation of related monitoring and control measures under the Water Framework Directive
The Environmental Quality Standards Directive	×	×	The changes brought by the inclusion of the new Article 8 in the EQSD open the door to the possible inclusion of nanomaterials in the list of priority substances, despite the lack of monitoring data. This would then have a ripple effect on the other water-related pieces of legislation.
The Groundwater Directive		×	Nanomaterials are in principle captured under Annex II, Point 2 of the Directive, which refers to man-made synthetic substances. Should specific nanomaterials be identified as pollutants of groundwater in a Member State then threshold values should be established for those nanomaterials against which maximum concentration in ground water is allowed. The list of threshold values is to be updated in response to information on new pollutants, groups of pollutants or indicators of pollutants. However, issues related to the coverage of nanomaterials under the Directive are tightly linked with those for the Water Framework Directive and the EQSD, relating to the absence of techniques for the detection and monitoring of nanomaterials and problems with establishing quality standards.
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.
The Urban Waste Water Treatment Directive		×	The technical requirements of the Urban Waste Water Directive do not specifically consider the presence of nanomaterials in urban wastewater 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, there is no strong case for focusing on nanomaterials when other hazardous substances are not specifically considered.
Directive 2008/56/EC stablishing a framework for community action in the field of marine environmental policy (Marine Strategy			Member States should take into account the substances and threshold values defined under the Water Framework Directive and the EQSD for the definition of GES in the marine environment. More specifically, the minimum requirements used to assess the adequacy of Member States' GES definitions included coverage of all priority substances of the EQS Directive. Thus, considering the strong linkages between the Water

EU legislation	Nanospecific provision	Amended since 2011	Conclusions
Framework Directive – MSFD)			Framework Directive, the EQSD and the MSFD, were some nanomaterials designated as 'priority substances' under the Water Framework Directive, they would, in theory, also need to be regulated in the marine environment. All the limitations previously mentioned in relation to the lack of ecotoxicological data and difficulties with monitoring of nanomaterials in water are valid for the marine environment as well.
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso Directive)		×	The Directive relies on CLP classification to set risk management measures. The current quantity thresholds under the Seveso Directive may not be adequate to reflect the potential specific properties of nanomaterials. Finally, the Seveso Directive does not contain an adequate mechanism to adapt in a rapid manner Annex I if there were evidence of potential major-accident hazard of specific hazardous substances (including hazardous nanomaterials) in industrial facilities.
Ambient Air Quality Directive 2008/50/EC		×	The Ambient Air Quality Directive does not contain specific control measures and monitoring requirements related to ultrafine particles and air-borne nanomaterials.
Regulation (EC) No 66/2010 on the EU Ecolabel		×	The older criteria that were not amended since 2012 do not contain any criteria on nanomaterials, nanoforms or forms of substances. The criteria decisions to exclude hazardous substance under EU ecolabel products mainly rely on the CLP classification of hazardous substance. They also exclude substances of very high concern under REACH.
Additional EU environmental legislation not covered in the 2011 regulatory review			
Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)		×	Limited number of classified nanomaterials under the CLP Regulation. Limited available information to classify nanomaterials under the CLP Regulation. Generation of new information on environmental hazards of chemical substances not compulsory Challenges in the determination of environmental hazards of nanomaterials in view of the CLP classification
Regulation (EC) No 1907/2006 (REACH)		×	Lack of clear provisions to ensure adequate identification and characterisation of nanomaterials under REACH. Knowledge gaps to generate information on environment fate and behaviour and ecotoxicology of nanomaterials Information gaps on nanomaterials in the supply chain
Directive 2010/75/EU on industrial emission (IED)			The majority of the BREFs provides information on abatement techniques targeting nano or ultrafine particles. However, the recent BAT conclusions covering important industrial emitters of ultrafine/nano particles (e.g. refining of mineral oil and gas, production of cement, lime and magnesium oxide) do not contain any specific emission limit values for these particles Reliance on the CLP classification to trigger certain control measures (e.g. monitoring or site closure requirements)
Regulation (EC) No 166/2006 of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register			No specific entry points for nanomaterials or the nanoforms of these chemical substances (e.g. cadmium) and for ultrafine particles. Knowledge gaps in the monitoring of the releases of nanomaterials in the environment. This is may be one of the reasons why nanomaterials and ultrafine particles are not covered or planned to be covered in the PRTR Regulation.
Other legislation potentially relevant due to environment exposure pathways of nanomaterials			
Regulation (EU) No 528/2012 concerning the making available on	×	×	The BPR is the most advanced and comprehensive EU legislation with regard to the regulation of nanomaterials. Potential However, potential issues remain:

EU legislation	Nanospecific provision	Amended since 2011	Conclusions
the market and use of biocidal products (BPR)			• The current lack of adequate methods to test the ecotoxicology and fate and behaviour of nanomaterials in the environment. • The lack of guidance accompanying the BPR on how to provide nano-specific test results, or how to justify the scientific appropriateness of the current test methods for the testing of nanomaterials • The five-year timeframe for Member States reports which might be too long to adequately monitor the use of nanomaterials in biocidal products and potential risks thereof. • The BPR does not contain a mandatory obligation for manufacturers to report on the quantities of nanomaterials in biocidal products placed on the EU market.
Cosmetics Products Regulation (EC) No 1223/2009 (Cosmetic Regulation)	×	×	The Cosmetic Regulation contains very comprehensive and stringent control measures on the health impacts of nanomaterials used in cosmetics. There are no measures or information requirements on the potential environmental impacts of nanomaterials used in cosmetics under the Cosmetic Regulation. Such environmental assessment is covered by the REACH Regulation, which is currently not the adequate tool to generate information on ecotoxicology, environmental fate and behaviour of nanomaterials.
Regulation (EC) No 1107/2009 on plant protection products (PPP)		×	The PPP does not contain specific information and assessment requirements for nanomaterials. This is considered as a potential legal gap considering that a lot of efforts from economic operators are currently placed on research and development on nanomaterials in plant protection products which may soon be ready to be placed on the market. There are also lot of knowledge gaps on the potential (eco)toxicity of certain plant protection products nanomaterials used on plants, animals and the environment. The PPP Regulation relies on the CLP Regulation to implement the active substance approval procedures
Regulation (EU) 2015/2283 on novel foods (novel food Regulation)	×	N/A	Definition of engineered nanomaterials. In case of food or vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013 consisting of nanomaterials, authorisation applicants must provide an explanation of the test methods scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.
Regulation (EC) No 450/2009 on active and intelligent materials intended to be in contact with food	×		Substances used in components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier may be used in components of active and intelligent materials and articles without being included in the Community list. However, such exemption does not apply to substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale.
Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	×	×	Several nanomaterials have been authorised to be used in plastic materials and articles intended to come into contact with food (e.g titanium nitride, butadiene, ethyl acrylate, methyl methacrylate, styrene copolymer crosslinked with divinylbenzene, in nanoform). The reference to the nanofrom of substances must be explicitly mentioned in the Annex I authorisation list. Information on Environmental aspects such as persistence in the environment, ecological impact of their constituents and their fate after the food contact material has been submitted to waste disposal treatment are not required under the authorisation procedure A plastic layer which is not in direct contact with food and is separated from

EU legislation	Nanospecific provision	Amended since 2011	Conclusions
			the food by a functional barrier may not be manufactured with substances not listed in the Union list or in the provisional list. However, this derogation does not apply to substances in nanoforms
Regulation (EU) No 1169/2011 on the provision of food information to consumers	×	×	All ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word 'nano' in brackets. This Regulation defines 'engineered nanomaterial'
Regulation No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	×	N/A	Nanomaterials are defined according to Regulation (EU) No 1169/2011. This food must not contain any substance in such quantity as to endanger the health of the persons for whom it is intended. For substances which are engineered nanomaterials, compliance with this requirement must be demonstrated on the basis of adequate test methods, where appropriate.

3.7 Case studies

3.7.1 Diiron Trioxide or red iron oxide

Case study summary: Diiron trioxide

Description of the nanomaterial and its lifecycle

- Iron oxides exist naturally and can also be produced synthetically in a variety of shapes and sizes in the range of several nm to a few µm
- Nano-size transparent iron oxide is used primarily in transparent paints and specialty applications such as cosmetics, pharmaceuticals and specialty paper
- There is no reason to believe that the waste handling of nano-sized iron oxide containing products would be different compared to conventional product, but quantitative data is very limited
- Nanomaterial containing waste is expected to be recycled, landfilled or incinerated
- During incineration it has been found that the vast majority of the iron oxides remain in the residue ash and only a small amounts of elemental iron was found in the released aerosols
- Nano iron oxide is expected to be distributed mainly into soils/sediments and would be expected to behave as natural occurring iron oxide shortly after release into the environment

Review of applicable regulatory provisions and status of implementation

- Diiron Trioxide nanomaterial has been registered under REACH. Registration dossier provides comprehensive information on this chemical substance, which indicates that the submitted material contains nanoparticles, but does not conform to the EC definition of a nanomaterial.[2]
- Diiron trioxide is not considered as a hazardous substance for health and the environment according to the CLP Regulation criteria.
- Diiron Trioxide is not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive and is unlikely to be part of it in the future due to its non-toxicity on health and the environment.
- No specific treatment measures have been set for Diiron Trioxide in EU waste legislation. Wastes containing Diiron Trioxide are unlikely to be considered hazardous waste.
- Diiron Trioxide is not prohibited or restricted under the Cosmetic Regulation. Prior to being

placed on the market, cosmetic products using nanomaterials such as Diiron Trioxide must be notified to the Commission. The reference to nano Diiron Trioxide must be indicated in the packaging of cosmetic products.

- Diiron Trioxide is not used in food and therefore not regulated under the food legislation.

3.7.1.1 Description of the nanomaterial and its lifecycle

Iron oxides exist naturally and can also be produced synthetically under controlled conditions by thermal decomposition of iron salts, precipitation of iron compounds or through vapor synthesis enabling a high degree of consistency from batch to batch. The synthetic iron oxides can be produced in a variety of shapes e.g. spherical, acicular, rhombohedral and cubric and by modifying the shapes and sizes of the particles, different colors e.g. red, yellow, black and brown and in all kinds of different shades can be produced. Synthetic Diiron Trioxide (Fe2O3) or red iron oxide is also known as Pigment Red 101 and is the manufactured version of natural red hematite and "usually the crystal size of iron oxides lies in the range of several nm to a few μm"[197,198]. Diiron trioxide nanomaterial is assumed to be uncoated.

Major uses

Iron oxide pigments are used in a various of applications e.g. porcelain, rubber, paper, plastics, fabrics and leather finishes. Red iron oxides are specifically used in primers for automobiles and in steel structures. Although coloured the pigment particles become transparent in the binder, if the particle size is small enough and the difference between the refractive index of the pigment and that of the binder is low.[197,198] Nano-size transparent iron oxide is used primarily in transparent paints that enable e.g. wood grain to be visible while still protecting the wood from of detrimental effects of sunlight exposure and for specialty applications such as cosmetics, pharmaceuticals and specialty paper. [197,198]

End of life issues

At the moment, there is no reason to believe that the waste handling of nano-sized iron oxide containing products would be different compared to conventional products and it is assumed that existing waste-handling infrastructure would be also be used for products containing nano-sized iron oxide. Quantitative data for the end-of-life phase of products containing nanomaterials is in general very limited and hence nanomaterial containing waste is therefore expected to be recycled, landfilled or incinerated.

In a laboratory experiment, Sotiriou et al. (2016)[199] has investigated the thermal decomposition of polyethylene containing 50–100 nm Fe2O3 particles when the temperature of the tube furnace was 500 and 800 °C. It was found that the far majority of the iron oxides remain in the residue ash. Only a small amounts of elemental Fe was found in the released aerosols while it being unclear what form the iron oxides are in e.g. solid nanoparticles. As in the case of nanosilica and nanosilver, it has to be noted that incineration of nanomaterial containing waste is a complex process that is highly dependent on the configuration and operating conditions and the physicochemical characteristics of the nanoparticles.

Intrinsic properties and environmental fate

Nano iron oxide is expected to be distributed mainly into soils/sediments due to the low water solubility of nano iron oxide and would be expected to behave as naturally occurring iron oxide shortly after release into the environment. The possibly of dissolution is considered to be negligible and biodegradation in different environmental compartments is not to be expected. Release to the atmosphere would presumably result in deposition to land, ending up in soils and sediment.

[197] Chemical Economics Handbook 2011. Inorganic color pigments. IHS
[198] Cornell and Schwertmann 2003The Iron Oxides: Structure, Properties, Reactions, Occurrences and Uses. Second edition, 2003. By Rochelle M. Cornell, Udo Schwertmann, Wiley-VCH http://onlinelibrary.wiley.com/book/10.1002/3527602097
[199] Sotiriou, G.A., Singh, D., Zhang, F. et al. 2016. Thermal decomposition of nano-enabled thermoplastics: Possibleenvironmental health and safety implications Journal of Hazardous Materials 305 (2016) 87–95

3.7.1.2 Review of applicable regulatory provisions and status of implementation

The description of red iron oxide and its lifecycle in the paragraphs above allows to identify (e.g. through the use, exposure pathways) the EU legal texts that apply to this substance.

Information generated on Diiron Trioxide under the REACH Regulation

Diiron Trioxide nanomaterial has been registered under REACH under CAS Number 1309-37-1. This substance is manufactured and/or imported in the European Economic Area in 100 000 - 1 000 000 tonnes per year. No evaluation procedure has been launched against this nanomaterial. Registration dossier provides comprehensive information on this chemical substance[200]. As part of the physical and chemical properties reported on in the registration, particle size distribution (Granulometry) was determined according to OECD Guideline 110 (Particle Size Distribution / Fibre Length and Diameter Distributions). The pigment was dispersed in distilled water and subjected to ultrasound (100W) for 1 minute. Single or aggregrated particles were placed and scanned on a transmission electron microscopy and a particle distribution was counted. According to the registration the tested material form was a "nanomaterial" and based on a total of 1002 counted particles the mass median diamater was 118 ± 83 nm based on the equivalent circle diameter. However, 39 ± 2.8% of all particles of the measured test material were found to be between 1 nm and 100 nm and hence the lead registrant concluded that diiron trioxide is not a nanomaterial according the European Commission's definition[201].

This illustrates a potential practical issue with the treatment of nanomaterials under REACH. A lead registrant has registered iron trioxide, and specifically referred to it as a nanomaterial in physical and chemical properties reported on in the registration. The size distribution of a sample of the particles was counted, and the size distribution of this sample did not conform with the European Commission definition of nanomaterials. However, nanoforms of this and other substances are specifically used because of their nano-scale properties. Other material samples from the lead registrant, and/or samples from other suppliers may conform with the European Commission definition.

Classification of Diiron Trioxide under the CLP Regulation

According to the ECHA classification and labelling inventory, Diiron trioxide is not considered as a hazardous substance for health and the environment according to the CLP Regulation criteria[202].

Diiron Trioxide under the Cosmetic Regulation

Diiron Trioxide is used in Cosmetic products as a colorant inorganic compound. It is not prohibited or restricted under the Cosmetic Regulation. Prior to being placed on the market, cosmetic products using nanomaterials such as Diiron Trioxide must be notified to the Commission including information among others on their reasonably foreseeable exposure conditions. The reference to nano Diiron Trioxide must be indicated in the packaging of cosmetic products.

Diiron Trioxide under water legislation

A potential environmental pathway for Diiron Trioxide is wastewater (e.g. cosmetic wash-off paints in water runoffs). The Urban Waste Water Directive does 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, there is no strong case for focusing on nanomaterials and more specifically Diiron Trioxide which is unlikely to have ecotoxic properties, when hazardous substances (for which evidence on hazard and exposure scenarios is considerably more robust) are not specifically considered.

Diiron Trioxide is not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive and is unlikely to be part of it in the future due to its non-toxicity on health and the environment.

Diiron Trioxide under waste legislation

[200] https://echa.europa.eu/registration-dossier/-/registered-dossier/15552/1
[201] https://echa.europa.eu/registration-dossier/-/registered-dossier/15552/4/6
[202] https://echa.europa.eu/registration-dossier/-/registered-dossier/15552/2/1

Diiron Trioxide waste is covered by the EU waste legislation since the Waste Framework Directive defines 'waste' as "any substance or object which the holder discards". Therefore, the Directive applies to discarded materials that contain Diiron Trioxide or Diiron Trioxide waste. No specific treatment measures have been set for Diiron Trioxide in waste. Due to the non-toxicity on health and the environment of this substance waste that contain Diiron Trioxide or Diiron Trioxide waste are unlikely to be considered hazardous waste.

Diiron Trioxide under food legislation

No food use was identified.

3.7.1.3 Recommendations to address gaps in implementation

No specific recommendations are suggested since there does not seem to be significant uncertainty in the non-health and environmental toxicity of Diiron Trioxide and as a result no legal and implementation gaps concerning the application of the EU legislation to this chemical substance.

3.7.2 Nanosilver

Case study summary: Nanosilver

Description of the nanomaterial and its lifecycle

- Nanosilver is commercially available as flakes, grains, and sold in suspensions and as a dry powder.
- Nanosilver can be synthesized and produced via an advancing variety of methods
- Major uses of nanosilver include consumer uses personal care products, clothing, cleaning products and supplements. Other uses that are common in the EU are electronics, medical devices and biocidal uses
- Many applications of nanosilver in consumer products such as for instance cosmetics and textiles will lead to nanosilver ending up in the wastewater treatment plants
- Silver release from wastewater treatment plants to ground and surface waters is expected to be low, but it might still be an issue for some species. Accumulation of nanosilver on arable soils and plant uptake of nanosilver might also be an issue to consider
- Nanosilver is expected to undergo a number of transformation processes upon release to the environment (e.g. reduction/oxidation, dissolution and aggregation/agglomeration)

Review of applicable regulatory provisions and status of implementation

- An evaluation substance procedure led by the Netherlands on nanosilver is on-going. It was triggered due to the lack of information on the 'nanoform' of silver in the silver registration dossier.
- Only one out of 24 notifications under C&L Inventory refers to the 'form' nanomaterial, whereas nanosilver is widely used and manufactured
- As part of the review programme of active substances in biocidal products Sweden's competent authority, KEMI, is assessing 8 silver substances including their nanoforms since 2006.
- Within the framework of the EU Ecolabel Regulation nanosilver is banned from EU ecolabel absorbent hygiene products and rinse-off cosmetic products and textile products.
- Nanosilver is not aprohibited substances in the Cosmetic Regulation. Prior being place on the market cosmetic products using nanosilver must be notified to the Commission. The reference to nanosilver must be indicated in the packaging. Nanosilver is not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive
- The Waste Framework Directive applies to discarded materials that contain nanosilver or nanosilver waste. No specific treatment measures have been set for nanosilver in waste or nanosilver waste. The treatment of such waste will depend on whether or not it is considered as a hazardous waste under the Directive. The classification of hazardous waste is based on the CLP Regulation. However, there is no consensus on the classification of nanosilver.
- The Sewage Sludge Directive does not contain any reference to silver or any other

nanomaterials.

Recommendations

- Ensuring that adequate information on the different forms of nanosilver is provided under the REACH Registration
- Adequate classification on CLP of the different forms of nanosilver based on up to date information
- Adequate information and classification of the different forms of nanosilver respectively under REACH and CLP will ensure that the adequate control measures in the environmental downstream legislation would be applied.
- Assess the need to add nanosilver to the list of priority substances under the water legislation considering accumulated exposures of different forms of Ag in relation to environmental no observed effect concentrations (NOECs)
- Developing provisions for specific control of nanowaste streams

3.7.2.1 Description of the nanomaterial and its lifecycle

Nanosilver is nanoform of silver and it is commercially available as flakes, grains, etc. and sold in suspensions and as a dry powder. Nanosilver is often surface modified with for instance dextran, citrate and polysacchartide as it will aggregate in its pure form[203].

SCENIHR found that different chemical oxidation states such as for instance metallic silver [Ag^0] or silver cations [most common Ag^+]) are present in consumer products and in the natural environment and silver compounds can appear as salts, nano sized (between 1-100 nm) and large particles in consumer products[204]. SCENIHR reviewed the safety, health and environmental effects of nanosilver and nanosilver's role in antimicrobial resistance. As part of the work the main life cycle stages of nanosilver were identified i.e. production, consumer and medical uses and waste handling.

As for many other chemical, direct and indirect release into the environment might occur during production[205]. Many applications of nanosilver in consumer products such as for instance cosmetics and textiles will lead to nanosilver ending up in the wastewater treatment plants. It is believed that the vast majority will effectively bind to solid matter and be converted to Ag_2S, which again can and is expected to undergo various transformation processes in natural environments, such as stabilisation in dispersions, formation of bound residues or release of silver ions. If retained in the wastewater treatment plant, the resulting sludge will end up in arable soils in many European countries where it might accumulate or be taken up by plants[206]. If not retained in the wastewater treatment plants, nanosilver could be released to ground and surface waters.

During use of solid products, nanosilver might be release directly into the environment during use through abrasion and wear and tear. Nanosilver containing solid waste could either be recycled, landfilled or incinerated. Incineration of nanomaterial containing waste has been noted to be a complex process that is highly dependent on the configuration and operating conditions and the physicochemical characteristics of the nanoparticles. During incineration AgNPs be either melted, remain in the slag or become airborne. If airborne, the majority of them are expected to be captured by filtration[207]. Slag and filters will either be landfilled or used in construction materials[208]. Nanosilver used in medical applications such as bandages in hospitals has to be collected and treated as

[203] Mikkelsen, S.H., Hansen, E., Christensen, T.B., Baun, A., Hansen, S.F., Binderup, M-L. 2011. Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials. Environmental Project **No. 1370** 2011. Copenhagen: Danish Ministry of the Environment. Danish Environmental Protection Agency

[204] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission

[205] Ganzleben, C., Hansen, S.F. 2012. Environmental Exposure to Nanomaterials – Data Scoping Study. Service Contract No.07.0307/2011/610874/ETU/D.3. Brussels: Milieu

[206] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission

[207] Pourzahedi and Eckelman 2015 dx.doi.org/10.1021/es504655y | Environ. Sci. Technol. 2015, 49, 361−368

[208] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission

hazardous waste and are transported to medical waste incineration plant[209]. Any nano-scale silver present in medical waste would be expected to be effectively destroyed by the incineration process, resulting in trace levels of silver in ash streams[210].

How it is produced

Nanosilver can be synthesized and produced via an advancing variety of methods. According to SCENIHR[211] the use of citrate, borohydride, two-phase (water-organic) systems, organic reducers, and inverse micelles in the synthesis process fall under what could be considered conventional methods. Unconventional methods include laser ablation, radiocatalysis, vacuum evaporation of metal, and the Svedberg method of electrocondensation[212]. Properties such as size, shape and specific surface area can be modified by using silver salts as a starting material and then add various surface active agents and coatings[213].

Major uses

Major uses of nanosilver include consumer uses personal care products, clothing, cleaning products and supplements. Other uses that are common in the EU are electronics, medical devices and biocidal uses[214].

End of life issues

When reviewing waste handling of nanosilver containing products, SCENIHR[215] assumed that the existing waste-handling infrastructure would be used for nanomaterial products in an analogues way as conventional products. While noting that quantitative data for the end-of-life phase of products containing nanomaterials is very limited, SCENIHR found that nanomaterial containing waste in general could either be recycled by melting or by more advanced separation and purification, landfilled or incinerated.

Incineration of nanomaterial containing waste has been noted to be a complex process that is highly dependent on the configuration and operating conditions and the physicochemical characteristics of the nanoparticles. In European incinerators, the required combustion temperature above the grates of the plant is at least 850ºC for at least two seconds for non-hazardous waste. The melting temperature of Ag-nanoparticles varies and can be down to only 200°C whereas bulk silver melts at 962°C[216]. During incineration Ag nanoparticles either remain in the slag or become airborne. If airborne, the majority of them are expected to be captured by filtration, but it has been estimated that between 0.05% and 1% of the total Ag nanoparticles can be released into the atmosphere[217]. In a study on environmental exposure assessment of nanoparticles from solid waste, Boldrin et al.[218] noted that main challenges in relation to further research within nanomaterials e.g. nanosilver and waste were related to: 1) transformation of nanomaterials within waste treatment technologies, 2) release mechanisms under conditions relevant for waste disposal, 3) exposure assessment performed at the local level within a precise context, 4) the characterisation of nanowaste and the development of appropriate analytical methods and 5) a definition of appropriate regulatory limit values and

[209] Pourzahedi and Eckelman 2015 dx.doi.org/10.1021/es504655y | Environ. Sci. Technol. 2015, 49, 361−368
[210] Pourzahedi and Eckelman 2015 dx.doi.org/10.1021/es504655y | Environ. Sci. Technol. 2015, 49, 361−368
[211] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission
[212] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission
[213] Mikkelsen, S.H., Hansen, E., Christensen, T.B., Baun, A., Hansen, S.F., Binderup, M-L. 2011. Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials. Environmental Project No. 1370 2011. Copenhagen: Danish Ministry of the Environment. Danish Environmental Protection Agency
[214] Hansen, S.F., Heggelund, L., Mackevica, A. 2015. Nanoproducts: What is Actually Available to European Consumers? Environmental Science Nano. DOI: 10.1039/c5en00182j
[215] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission
[216] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission
[217] Pourzahedi and Eckelman 2015 dx.doi.org/10.1021/es504655y | Environ. Sci. Technol. 2015, 49, 361−368
[218] Boldrin, A., Hansen, S.F., Baun, A., Hartmann, N., Astrup, T.F. 2014. Environmental exposure assessment framework for nanoparticles in solid waste. Journal of Nanoparticle Research 16:2394 DOI 10.1007/s11051-014-2394-2

nanowaste data reporting. While calling for more thorough investigation of flue gas cleaning technologies with respect to the incineration and combustion of a wide variety of ENM types in solid waste, Boldrin et al. also called for an investigation of how physicochemical and hydraulic conditions in a landfill may affect both the matrix material and the transformation of the ENMs themselves.

According to SCENIHR[219] silver release from wastewater treatment plants to ground and surface waters is expected to be low, but it might still be an issue for some species. Accumulation of nanosilver on arable soils and plant uptake of nanosilver might also be an issue to consider.

Intrinsic properties and environmental fate

Nanosilver is expected to undergo a number of transformation processes upon release to the environment. Reduction/oxidation, dissolution and aggregation/agglomeration are presumed to be the dominant properties whereas photochemical reactions are believed to be of lesser importance (Hartmann et al. 2014).

Dissolution and subsequent speciation is of high importance for the fate and behaviour of nanosilver in the environment and the process and kinetics of dissolution is subject to numerous research projects under FP7 and Horizon2020. Current theoretical models assume that the dissolution rate either increases with decreasing particle diameter or that the dissolution is dependent on the initial particle size than on the aggregation occurring in the media[220]. The presence of silver sulphides has been found to contribute significantly to the fate and behaviour of nanosilver and although silver sulphides are highly stable and are usually considered as not bioavailable, recent studies suggests that some unexplained mechanisms may result in uptake of nanosilver transformed to sulphide compounds[221].

Hartmann et al.[222] (2014) have noted that the interaction of nanosilver to suspended solids in surface waters along with aggregation/agglomeration is likely to result in a transfer to the sediments, where it may accumulated, be transformed, or depending on physical, chemical, and biological conditions.

3.7.2.2 Review of applicable regulatory provisions and status of implementation

The description of nanosilver and its lifecycle in the paragraphs above allows to identify (e.g. through the use, exposure pathways) what are the EU legal texts that apply to nanosilver.

Information generated on nanosilver under the REACH Regulation

Silver has been registered under the REACH Regulation by more than 40 registrants. The registration dossier contains information on the bulk substance silver and several of its nanoforms (CAS N 7440-22-4). Nanosilver is being evaluated by the Netherlands[223], at the time of writing this report. The following justification was provided for starting the evaluation: '*Silver is a widely used material for which more than 50 registrations are received. All registrations for silver are submitted under CAS-nr 7440-22-4. Transformation of the metallic nanoform in ionic form and vice versa may influence the behaviour of silver (including bioavailability and related ecotoxicity). In addition, the size-related environmental behaviour and ecotoxicological effects in the aquatic compartment, including the STP, and the terrestrial compartment pose a concern for the safe use of the nanoform(s) of silver to the environment. Therefore, it is necessary to evaluate the substance characterization, environmental behaviour and ecotoxicity of the nanoforms of silver.*'[224] In April 2016, the ECHA Member State Committee adopted a draft decision that two registered nanoforms were well characterised, and there was no requirement to provide further information on the size, surface area and surface treatment of

[219] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR 2014. Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. European Commission
[220] Hartmann, N.B., Skjolding, L.M., Hansen, S.F., Kjølholt, J., Gottschalck, F., Baun, A. 2014. Environmental fate and behaviour of nanomaterials New knowledge on important transformation processes Environmental Project No. 1594, 2014. Copenhagen: The Danish Environmental Protection Agency
[221] Lowry GV, Gregory KB, Apte SC, Lead JR (2012b). Transformations of Nanomaterials in the Environment. Environmental Science & Technology, 46:6893-6899
[222] Hartmann, N.B., Skjolding, L.M., Hansen, S.F., Kjølholt, J., Gottschalck, F., Baun, A. 2014. Environmental fate and behaviour of nanomaterials New knowledge on important transformation processes Environmental Project No. 1594, 2014. Copenhagen: The Danish Environmental Protection Agency
[223] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180697558
[224] http://echa.europa.eu/documents/10162/de5700b2-7589-420b-a058-c45847993801

the nanomaterial. It agreed that toxicity tests on *Daphnia* water fleas, algae and microorganisms were necessary, but only for the smallest nanomaterial[225].

The Final decision was adopted in July 2016. In order to check the registrants' hypothesis that the driver for silver toxicity for all nanoforms registered is the silver ion and that read-across use of toxicity values from ionic to nanosilver is thus a 'worst case' approach, the decision requests ecotoxicity testing (on algae, long term toxicity on aquatic invertebrates and on soil microorganisms) on the smallest nanoform with the highest specific surface area that is covered by the REACH registration dossier. Further fate testing will have to be undertaken only if any of the ecotoxicity tests show higher toxicity for nanosilver as compared to ionic silver. At the time of writing, information on the uses for each individual nanoform has been requested.

Classification of nanosilver under the CLP Regulation

According to the classification and labelling inventory, one notification of classification of silver among 24 notifications refers to the 'form' nanomaterial, whereas nanosilver is widely used and manufactured. It classifies silver including its nanomaterial form as very toxic to aquatic life (H400), and very toxic to aquatic life with long lasting effects (H410). Several notifiers do not set any classifications under CLP for nanosilver.[226] However, the REACH dossier on silver includes a classification of nanosilver ((Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); Acute M-factor 1000; Chronic M-factor 100).

Nanosilver evaluation under Biocidal Product EU legislation

All existing biocidal product active substances already in the market before 14 May 2000 are subject to a review programme according to the previous Biocidal Product Legislation Directive 98/8/EC. Rules on the review programme of active substances are set under the European Commission Regulation (EC) No 1451/2007. There are around 300 active substances to evaluate and originally the review programme was planned to end in 2010, although it has been extended until December 2024. Sweden's competent authority, KEMI, is working on the assessment of silver substances within the review programme. KEMI has been working on the assessment of 8 different silver substances including their nanoforms (elemental silver, reaction mass of titanium dioxide and silver chloride, silver nitrate, silver sodium hydrogen zirconium phosphate, silver phosphate glass, silver zinc zeolite, silver copper zeolite and reaction mass of silicon dioxide and silver) since 2006.

Nanosilver under the EU Ecolabel Regulation

In October 2014 the Commission adopted a decision establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products. Point 6.6 of the Annex to this Decision explicitly mentions that nanosilver particles must not be intentionally added to the product or to any homogeneous part or material of it.

In December 2014, the Commission adopted a decision establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products[227]. It applies to rinse-off substance or mixture falling under the scope of Regulation (EC) No 1223/2009 intended to be placed in contact with the epidermis and/or the hair system with a view exclusively or mainly to cleaning them (toilet soaps, shower preparations, shampoos), to improve the condition of the hair (hair conditioning products) or to protect the epidermis and lubricate the hair before shaving (shaving products). The criteria to award the EU ecolabel to these products relevant for nanomaterials are:

- Toxicity to aquatic organisms (critical dilution volume)
- Biodegradability
- Excluded or limited substances and mixtures

Among the list of substances to be excluded from rinse-off cosmetic products, criterion 3 refers to nanosilver.

[225] Chemical Watch , MSC agrees nanosilver substance evaluation,
[226] Information retrieved from Classification and Labelling Inventory
[227] 2014/893/EU: Commission Decision of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products (notified under document C(2014) 9302)

In June 2014, the Commission adopted a decision establishing the ecological criteria for the award of the EU Ecolabel for textile products[228]. The Appendix of the textile decision sets an EU label textile restricted substance list. Table (e) includes restrictions applying to finishing processes. It provides that biocides must not be incorporated into fibres, fabrics or the final product in order to impart biocidal properties. It mentions nanosilver as an example of such biocides.

Nanosilver under the Cosmetic Regulation

Nanosilver is increasingly used in cosmetic products. Nanosilver is not included in the list of prohibited substances in the Cosmetic Regulation (Annex II). Prior being place on the market cosmetic products using nanomaterials such as nanosilver must be notified to the Commission including information among others on their reasonably foreseeable exposure conditions. The reference to nanosilver must be indicated in the packaging of cosmetic products.

Nanosilver under water legislation

A significant environmental pathway for Nanosilver is wastewater although according to a recent publication by Li et al. (2016), on the basis of field analysis of representative wastewater treatment plants in Germany, more than 96.4% of silver-based nanoparticles from wastewater influent are removed through wastewater treatment plants[229]. The Urban Waste Water Directive does 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, there is no strong case for focusing on nanomaterials. and more specifically nanosilver, when other hazardous substances (for which evidence on hazard and exposure scenarios is considerably more robust) are not specifically considered.

Nanosilver is not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive.

Nanosilver under waste legislation

Nanosilver waste is covered by the EU waste legislation since the Waste Framework Directive defines ‘waste’ as “any substance or object which the holder discards”. Therefore, the Directive applies to discarded materials that contain nanosilver or nanosilver waste. No specific treatment measures have been set for nanosilver in waste or nanosilver waste. The treatment of such waste will depend on whether or not it is considered as a hazardous waste under the Directive. Hazardous waste is subject to more stringent and specific control and treatment measures. The classification of hazardous waste is based on the CLP Regulation. However as identified above nanosilver, notifiers of classification of silver under CLP very rarely refer to the nanoform and there is no consensus on its classification (not classified to very toxic to aquatic life with long lasting effects).

An important part of nanosilver present in wastewater may end-up in sewage sludge. The Sewage Sludge Directive establishes limit values for concentrations of heavy metals (cadmium, copper, nickel, lead, zinc, mercury and chromium) in soil, in sludge for use in agriculture, and for concentrations of amounts of heavy metals which may be added annually to agriculture land based on a 10-year average. It does not contain any literal reference to nanomaterials. It does not fix specific limit values for the nano-form of these heavy metals, or any other specific nanomaterials such as nanosilver. There is no reason to conclude that a limit value for nanosilver, or any other nanomaterial, is required, but this does illustrate that the question is yet to be addressed.

3.7.2.3 Recommendations to address gaps in implementation

The following measures are recommended:

- Ensuring that adequate information on the different forms of nanosilver is provided in REACH Registration dossiers as a result of evaluation

[228] 2014/350/EU: Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (notified under document C(2014) 3677)

[229] Li L., Stoiber M., Wimmer A., Xu Z., Lindenblatt C., Helmreich B., Schuster M., 2016. To What Extent Can Full-Scale Wastewater Treatment Plant Effluent Influence the Occurrence of Silver-Based Nanoparticles in Surface Waters? Environ. Sci. Technol. 50 (12), 6327-6333.

- Adequate classification on CLP of the different forms of nanosilver based on up to date information (REACH evaluation procedure on-going)
- Adequate information and classification of the different forms of nanosilver respectively under REACH and CLP will ensure that the adequate control measures in the environmental downstream legislation would be applied (e.g. specific measures for hazardous substances)
- Assess the need to add nanosilver to the list of priority substances under the water legislation
- Assess the need to develop provisions for specific control of nanowaste streams.

Stakeholder views:

Representatives of Precious metals and Rhenium consortium

Specific risk management options (RMO) should be identified as a result of a RMO analysis (RMOA). If any risk is associated to (nano)silver, then this should be assessed in more depth in a dedicated RMOA on this substance and the various forms and uses potentially posing a risk to human health or the environment. According to ECHA's recent integrated screening approach, it would be more efficient to conduct an RMOA after the ongoing Substance Evaluation delivers its expected output. Suggesting a specific way forward for (nano)silver before the Substance Evaluation addresses identified concerns would be counter-productive and go against ongoing initiatives.

Nanosilver is not a substance or a standalone nanomaterial. It is a specific form of silver which undergoes transformation in the environment. It is incorrect to assume that nanosilver would exist in the nanoform in water, and hence incorrect to recommend that a specific form of silver is added to the list of substances under scrutiny under the Water Framework Directive.

It is noted that particle size should be taken into account for the selection of substances for possible inclusion in the watch list. Before making particle size a criterion to monitor or limit the emission to/presence in water of any substance, the size should be proven to influence the effects potential. Being a nanomaterial does not predispose a hazardous effect. The hazard profile is vertically specific to each substance and its various forms, not horizontally generic to a specific size across all substances.

3.7.3 Synthetic Amorphous Nanosilica

Case study summary: Synthetic Amorphous Nanosilica

Description of the nanomaterial and its lifecycle

Silica (or silicon dioxide) is abundant in nature and amorphous nanosilica can be produced in a number of different ways in all kinds of sizes and surface area and functionalizations. Synthetic amorphous nanosilica may consist of spherical or pseudo-spherical nanoparticles, nanotubes, films, powder or rodlike nanoforms. Most nanoparticles are in the 10 – 30 nm size range, and high aspect ratio nanoparticles have also been developed for use as fillers.

Amorphous nanosilica is of most relevance for industrial purposes and products. Major uses of nanosilica include cement, paints, solid lubricants, cosmetics, food (E551), tyres and biocides as well as biomedical applications. An important source of environmental exposure has been identified to be the wear of tyres, but many applications of nanosilica in consumer products such as for instance cosmetics and food products will lead to nanosilica leaching and/or ending up in the wastewater treatment plants.

Nanosilica is expected to be distributed mainly into soils/sediments due to the low water solubility and vapour pressure of nanosilica. Nanosilica is expected to be indistinguishable from the natural soil and sediments.

Review of applicable regulatory provisions and status of implementation

Silicon dioxide has been registered under REACH and a decision on substance evaluation was adopted in March 2015 requesting registrants to provide additional information on e.g. uses, physicochemical properties and toxicity. The decision has been appealed by registrants and at the time of writing this report the Appeal decision was not yet adopted.

Only one notification of Silica among 42 notifications under C&L Inventory refers to the 'form' nanomaterials. Synthetic amorphous silicon dioxide was approved as an active substance to be used in insecticides. Silica is not prohibited or restricted under the Cosmetic Regulation. Prior being placed on the market cosmetic products using nanosilica must be notified to the Commission.

A reference to nano-silicon dioxide must be indicated in the packaging of cosmetic products. Silicon dioxide is not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive. The Waste Framework Directive applies to discarded materials that contain nanosilica or nanosilica waste. No specific treatment measures have been set for nanosilica in waste or nanosilver waste. The treatment of such waste will depend on whether or not it is considered as a hazardous waste under the Directive. The classification of hazardous waste is based on the CLP Regulation. However, there are uncertainties about the classification of silica under CLP. According to the classification and labelling inventory, one notification of silica among 42 notifications referred to the form nanomaterials. It classifies silicon dioxide as a substance that causes serious eye irritation and that may cause respiratory irritation. All the other CLP hazardous categories entries are not complete because data are lacking, or are conclusive but not sufficient for classification. The Sewage Sludge Directive does not contain any reference to nanosilica or any other nanomaterials.

Silicon dioxide is authorised as an additive in all types of plastics without restrictions under the Union list of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Recommendations

- Ensuring provision of adequate information on the nanoform of silicon dioxide under the REACH Registration
- Adequate classification on CLP based on up to date information (REACH evaluation procedure on-going)
- Adequate information and classification respectively under REACH and CLP will ensure that the adequate control measures in the environmental downstream legislation would be applied (e.g. specific measures for hazardous substances)
- Developing provisions for specific control of nanowaste streams.

3.7.3.1 Description of the nanomaterial and its lifecycle

Silica (or silicon dioxide) is abundant in nature and amorphous nanosilica can be produced in all kinds of sizes and surface area. The discussion in this case study focuses on amorphous nanosilica rather than crystalline nanosilica, as this is of most relevance for industrial purposes and products. Synthetic amorphous nanosilica may consist of spherical or pseudo-spherical nanoparticles, nanotubes, films, powder or rodlike nanoforms. Most nanoparticles are in the 10 – 30 nm size range, and high aspect ratio nanoparticles have also been developed for use as fillers.

Nanosilica is often functionalized with organogroups and metals other than silica[230]. As for many other chemicals, direct and indirect release into the environment might occur during production[231]. An important source of environmental exposure has been identified to be the wear of tyres, but many applications of nanosilica in consumer products such as for instance cosmetics and food products will lead to nanosilica leaching and/or ending up in the wastewater and enter the wastewater treatment plants and subsequently into the environment[232].

[230] Mikkelsen, S.H., Hansen, E., Christensen, T.B., Baun, A., Hansen, S.F., Binderup, M-L. 2011. Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials. Environmental Project **No. 1370** 2011. Copenhagen: Danish Ministry of the Environment. Danish Environmental Protection Agency

[231] Ganzleben, C., Hansen, S.F. 2012. Environmental Exposure to Nanomaterials – Data Scoping Study. Service Contract No.07.0307/2011/610874/ETU/D.3. Brussels: Milieu

[232] COMMISSION STAFF WORKING PAPER Types and uses of nanomaterials, including safety aspects Accompanying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials {COM(2012) 572 final} http://ec.europa.eu/health/nanotechnology/docs/swd_2012_288_en.pdf

How it is produced

Nanosilica can be produced on a number of different ways e.g. sol-gel method and high-temperature hydrolysis in a hydrogen oxygen flame.

Major uses

Nanosilica is used in numerous applications including cement, paints, solid lubricants, cosmetics, food (E551), tyres and biocides. Nanosilica is also used in a range of biomedical applications such as surgical tools and medical equipment. According to Wang et al. around 70% of nanosilica is applied in paints and polymers.

End of life issues

At the moment, there is no reason to believe that the waste handling of nanosilica containing products would be different compared to conventional products and it is assumed that existing waste-handling infrastructure would be also be used for nanosilica products. While quantitative data for the end-of-life phase of products containing nanomaterials is in general very limited, nanomaterial containing waste is therefore expected to be recycled, landfilled or incinerated.

Using probabilistic modeling, Wang et al.[233] estimated that the release of nanosilica from paints and polymers would mainly go to landfills and recycling followed by entering a wastewater treatment plant. Leaching from landfills of nanosilica and during recycling might occur, but is not well studied. Once in the wastewater treatment plant, nanosilica is assumed to be captured in the sludge and release from wastewater treatment plants to ground and surface waters is expected to be low. If the sludge is used as a fertilizer accumulation of nanosilica on arable soils and plant uptake might also be an issue to consider.

As in the case of nanosilver, it has to be noted that incineration of nanomaterial containing waste is a complex process that is highly dependent on the configuration and operating conditions and the physicochemical characteristics of the nanoparticles. During incineration nanosilica might either remain in the slag or become airborne. If airborne, the majority of them nano-silica particles are expected to be captured by filtration, but some would be released into the atmosphere. More research is needed to establish whether and to what extent this happens

Intrinsic properties and environmental fate

Nanosilica is expected to be distributed mainly into soils/sediments due to the low water solubility and vapour pressure of nanosilica and nanosilica is expected to be indistinguishable from the natural soil and sediments due to its chemical identity similarities with inorganic soil matter. The possibly of dissolution into silicic acid is considered to be negligible and biodegradation in different environmental compartments is not to be expected.[234] Release to the atmosphere would presumably result in deposition to land, ending up in soils and sediment[235].

3.7.3.2 Review of applicable regulatory provisions and status of implementation

Information generated on silicon dioxide under the REACH Regulation

Silicon dioxide has been registered under REACH. Under the REACH evaluation procedure, synthetic amorphous silica has been evaluated by The Netherlands due to initial grounds for concern relating to the substance characterisation, nanoparticles and toxicity of different forms of the substance. A Decision on substance evaluation was adopted in March 2015[236]. It requests registrants to provide additional information on the physicochemical properties of each SAS form and each surface treated SAS, additional toxicological information for the four SAS forms and additional information on the

[233] Wang, Y,,m Kalinina, A., Sun, T., Nowack, B. 2016. Probabilistic modeling of the flows and environmental risks
of nano-silicaScience of the Total Environment 545–546 (2016) 67–76

[234] Assessment Report. Synthetic amorphous silicon dioxide (Rentokil Initial) Product-type 18 (Insecticide) March 2014 RMS: FRANCE, https://circabc.europa.eu/sd/a/b8085681-e864-4ceb-ae41-4d652d295322/Synthetic%20amorphous%20Silicon%20dioxide%20%28assessment%20report%20as%20finalised%20on%2013.03.2014%29.pdf

[235] Wang, Y,,m Kalinina, A., Sun, T., Nowack, B. 2016. Probabilistic modeling of the flows and environmental risks
of nano-silicaScience of the Total Environment 545–546 (2016) 67–76

[236] http://echa.europa.eu/documents/10162/37907533-3ffb-4032-b9e9-96a62c557a9d

uses of each individual form of SAS. This decision has been appealed by registrants on the ground, among others, that the agency has no competence under the REACH Regulation to request information on 'forms' of substances.[237] At the time of writing this report the Appeal decision was not yet adopted.

Classification of Silicon Dioxide under the CLP Regulation

According to the classification and labelling inventory, one notification of Silica among 42 notifications referred to the form nanomaterials. It classifies silicon dioxide as a substance that causes serious eye irritation and that may cause respiratory irritation. All the other CLP hazardous categories entries are not completed. The reasons given for non-classification of nanosilica under CLP are that "data are lacking, or that data are conclusive but not sufficient for classification". The great majority of notifiers do not set any classifications under CLP for silicon dioxide.[238]

Silicon dioxide under the Biocidal Product Regulation

Synthetic amorphous silicon dioxide was approved as an active substance to be used in insecticides (product-type 18)[239] and Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (as a nanomaterial formed by aggregates and agglomerates) is under review[240].

Silicon dioxide under the Cosmetic Regulation

Silicon dioxide is used in Cosmetic products. It is not prohibited or restricted under the Cosmetic Regulation. Prior to being placed on the market, cosmetic products using nanomaterials such as silicon dioxide must be notified to the Commission including information among others on their reasonably foreseeable exposure conditions. The reference to nano-silicon dioxide must be indicated in the packaging of cosmetic products. The SCCS has published a final opinion on nanoforms of different silica used in cosmetic products. The SCCS concluded that the evidence, both provided in the submission and that available in scientific literature, is inadequate and insufficient to allow drawing any firm conclusion either for or against the safety of any of the individual SAS material, or any of the SAS categories that are intended for use in cosmetic products[241].

Silicon dioxide under water legislation

A potential environmental pathway for synthetic amorphous silica is wastewater (e.g. cosmetic wash-off paints in water runoffs). The Urban Waste Water Directive does 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, there is no strong case for focusing on nanomaterials. and more specifically nanosilica, when other hazardous substances (for which evidence on hazard and exposure scenarios is considerably more robust) are not specifically considered.

Silicon dioxide is not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive.. Note however that the Environmental Quality Standards Directive 2008/105/EC has been recently amended in 2013 and the new Article 8 foresees the constitution by the Commission of a watch list of substances to gather monitoring data in view of future reviews of the list of priority substances. The selection of these substances now should take into account among others intrinsic properties of substances including where relevant particle size. This could open the door to the possible inclusion of hazardous nanomaterials in the watch list and where relevant in the list of priority substances.

[237] http://echa.europa.eu/documents/10162/13574/a_015_2015_announcement_en.pdf

[238] Information retrieved from Classification and Labelling Inventory at: http://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/50736

[239] Commission Implementing Regulation (EU) No 408/2014 of 23 April 2014 approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products for product-type 18. OJ L 121, 24.4.2014.

[240] http://echa.europa.eu/substance-information/-/substanceinfo/100.066.069

[241] Scientific Committee on Consumer Safety SCCS OPINION ON Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form)

Silicon dioxide under waste legislation

Silicon dioxide waste is covered by the EU waste legislation since the Waste Framework Directive defines 'waste' as "any substance or object which the holder discards". Therefore, the Directive applies to discarded materials that contain silicon dioxide or silicon dioxide waste. No specific treatment measures have been set for silicon dioxide in waste or silicon dioxide waste. The treatment of such waste will depend on whether or not it is considered as a hazardous waste under the Directive. Hazardous waste is subject to more stringent and specific control and treatment measures. The classification of hazardous waste is based on the CLP Regulation. However as identified above, notifiers of classification of silicon dioxide under CLP very rarely refer to the nanoform and there is no consensus on its classification (either not classified or causes serious eye irritation and that may cause respiratory irritation).

As mentioned above an important part of silicon dioxide present in wastewater (e.g. cosmetic products wash-off) may end-up in sewage sludge. The Sewage Sludge Directive establishes limit values for concentrations of heavy metals (cadmium, copper, nickel, lead, zinc, mercury and chromium) in soil, in sludge for use in agriculture, and for concentrations of amounts of heavy metals which may be added annually to agriculture land based on a 10-year average. It does not contain any literal reference to nanomaterials. It does not fix specific limit values for the nano-form of these heavy metals, or any other specific nanomaterials such as silicon dioxide.

Silicon dioxide under EU food legislation

Silicon dioxide is authorised as an additive in all types of plastics without restrictions under the Union list of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. EFSA considered in a 2014 opinion that: 'the information provided demonstrates adequately the absence of isolated primary nanoparticles in the basic silicon dioxide and in the silanated silicon dioxide since only aggregates larger than 100 nm along with larger agglomerates were observed using two independent measurement techniques, one of which was transmission electron microscopy (TEM)'.

3.7.3.3 Recommendations to address gaps in implementation

The following measures are recommended:

- Ensuring provision of adequate information on the nanoform of silicon dioxide under the REACH Registration
- Adequate classification on CLP based on up to date information (REACH evaluation procedure on-going)
- Adequate information and classification respectively under REACH and CLP will ensure that the adequate control measures in the environmental downstream legislation would be applied (e.g. specific measures for hazardous substances)
- Developing provisions for specific control of nanowaste streams if needed based on information generated under REACH and CLP..

3.7.4 Quantum Dots

Case study summary: Quantum dots

Description of the nanomaterial and its lifecycle

Quantum dots (QDs) or semiconductor nanocrystals are metal based nanoparticle semiconductors that exhibit modifiable optical properties due to quantum confinement. Quantum dots are typically spherical or cylindrical, with dimensions of a few nanometres or less. The core is most commonly cadmium-based, but there is an on-going effort to develop cadmium-free QDs. The shell can consist of for instance ZnS and CdS and vary in thickness and composition whereas the cap can consist of for instance silica, polymers and peptides. QDs can furthermore be conjugated to proteins, oligonucleids, small molecules and other biological molecules. QDs are used in computing, biological, biological devices, photovoltaic devices, light emitting devices and photodetector devices. Indications are that 90% of the total mass of QDs is used for light emitting devices (e.g. LEDs).

Different methods exist when it comes to the production of QDs. Top-down methods include e.g. molecular beam epitaxy (MBE) whereas bottom-up techniques include wet-chemical and vapour-phase methods.

QDs vary to a great extent which means that the relevant environmental transformation processes that might be relevant have to be evaluated on a case-by-case evaluation. Very little is known about the environmental fate of specific QDs, but the processes of agglomeration/aggregation, sedimentation, and NOM adsorption are however considered to be the most important processes.

Review of applicable regulatory provisions and status of implementation

Cadmium sulphide, Zinc sulphide and Cadmium telluride are registered under REACH but there is no reference to its nanoforms. There is no registration dossier for Mercury (II) Sulfide (HgS) and for Cadmium selenide (CdSe). Cadmium sulphide is included in the candidate list for possible inclusion in Annex XIV of substances of very high concern and is restricted under entry 28 of Annex XVII to REACH (e.g. not placed on the market for supply to the general public above certain concentration limits).

Cadmium sulphide is classified as a substance that may - among other - cause cancer according to the EU harmonised classification and labelling whereas Mercury (II) Sulfide (HgS) and Cadmium selenide (CdSe) are self-classified under CLP. Quantum dots are not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive. However, cadmium and its compounds are included in the priority list.

Cadmium containing quantum dots used in colour converting II-VI LEDs ((< 10 µg Cd per mm2 of light-emitting area) are exempted from prohibition of the use of certain substances in EEE under the ROHS Directive. Liquid crystal displays of a surface greater than 100 square centimetres and all those back-lit with gas discharge lamps must be removed from any separately collected WEEE.

Recommendations

- Provision of adequate information on the nanoform of substances used in quantum dots under the REACH Registration
- Adequate classification on CLP (current substances are not classified or when classified no reference to their nanoform)
- Adequate information and classification respectively under REACH and CLP will ensure that the adequate control measures in the environmental downstream legislation would be applied (e.g. specific measures for hazardous substances)
- Review under Article 6 of the RoHS Directive to verify whether nanomaterials used in quantum dots should be prohibited or not
- Developing provisions for specific control of nanowaste streams
- Assess the need to introduce specific controls on quantum dots nanomaterials in EU ecolabel electronic equipment products (e.g. televisions and personal computers)

3.7.4.1 Description of Quantum Dots and their lifecycle

Quantum dots (QDs) or semiconductor nanocrystals are metal based nanoparticle semiconductors that exhibit modifiable optical properties due to quantum confinement. By definition, quantum dots are particles with physical dimensions in the order to 3-7 nm, composed of crystals from groups II to VI or III to V elements.[242,243] Quantum dots are typically spherical, or in some cases cylindrical. Normally QDs consist of a semiconductor crystal core, a shell and a cap. The core is most commonly cadmium-based e.g. cadmium selenide and cadmium telluride and is between 10-50 atoms in diameter, but there is an on-going effort to develop cadmium-free QDs.[242] The shell can consist of for instance ZnS and CdS and vary in thickness and composition to improve/control optical properties. The cap can

[242] Gensch, C-O., Baron, Y., Blepp, M., Deubzer, O. 2014. Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive) Final Report – Pack 4 Report for the European Commission DG ENV under Framework Contract No ENV.C.2/FRA/2011/0020. Available: *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/20140422_RoHS2_Evaluation_Ex_Requests_2013-1-5_final.pdf.*

[243] Valizadeh A., Mikaeili, H., Samiei, M., Mussa Farkhani, S., Zarghami., N et al. Nanoscale Research Letters 2012, 7:480.

consist of for instance silica, polymers and peptides and is used to enhance solubility. QDs can furthermore be conjugated to proteins, oligonucleids, small molecules and other biological molecules with the purpose of getting them to bind directly to areas of interest for biolabelling and biosensing.

How it is produced

Different methods exist when it comes to the production of QDs. Top-down methods include molecular beam epitaxy (MBE), ion implantation, e-beam lithography, and X-ray lithography. Bottom-up techniques include wet-chemical and vapour-phase methods. Wet-chemical methods mainly follow the conventional precipitation methods with careful control of parameters for a single solution or mixture of solutions. Vapour-phase methods begin with processes in which layers are grown in an atom-by-atom process on a substrate.

Major uses

QDs are used in computing, biological, biological devices, photovoltaic devices, light emitting devices and photodetector devices. Indications are that 90% of the total mass of QDs is used for light emitting devices (e.g. LEDs). QDs are believed to have a bright potential within these areas. For instance , there is a high potential for the use of QDs in biological application specifically related to the use of QDs to track macromolecules in the cell, tracking various cells in the tissue, labelling organelles and cells, biomarker detection in various cancers, imaging and sensing of infectious diseases [244,245].

End of life issues

QDs used in biomedical imaging are generally expected to enter directly into the municipal wastewater treatment system. QDs found in displays e.g. LEDs and lighting can ultimately end up in air, soil or water depending on how it has been disposed of. According to Balde et al.[246] 40% of all WEEE generated in Europe is recovered (separated) by collection systems, while the remaining 60% enters the general mixed-waste stream. Little knowledge exists about the fate of QDs in the waste streams specifically. The behavior of quantum dots in landfills is poorly understood and no quantitative emission data is yet available[247]. Five Winds International[248] report that 79% of the cadmium present in Telecom and IT equipment accumulate in the fly ash and flue gas cleaning residue when incinerated, while 20% ended up in the slag and 1% was emitted to the air. Cadmium released via these pathways would not be expected to retain its nano-scale properties. Slag and filters will either be landfilled or used in construction materials landfill and cadmium leaches from incineration residues that are landfilled. The emissions to air are assumed to be deposited to soils and water surfaces.

Intrinsic properties and environmental fate

QDs vary to a great extend with regard to chemical compositions and the possibility of ‘tuning’ the specific properties of QDs which means that the relevant environmental transformation processes that might be relevant have to be evaluated on a case-by-case evaluation. Very little of known about the environmental fate of specific QDs such as CSE, but the processes of agglomeration/aggregation, sedimentation, and NOM adsorption are however considered to be the most important processes[249].

In a material flow analysis and probabilistic modeling of the environmental release of QDs in Denmark, Gottschalk et al.[250] found that the majority of the QDs will end up in recycling at the end of

[244] Ghasemi Y, Peymani P, Afifi S: Quantum dot: magic nanoparticle for imaging, detection and targeting. Acta Biomed 2009, 80(2):156–165.
[245] Valizadeh A., Mikaeili, H., Samiei, M., Mussa Farkhani, S., Zarghami., N et al. Nanoscale Research Letters 2012, 7:480
[246] Baldé, C.P., Wang, F., Kuehr, R. and Huisman, J., 2015. *The global e-waste monitor – 2014*. United Nations University, IAS – SCYCLE, Bonn, Germany.
[247] Sun, T.Y., Gottschalk, F., Hungerbühler, K., Nowack, B., 2014. Comprehensive probabilistic modelling of environmental emissions of engineered nanomaterials. Environmental Pollution 185 69-76.
[248] Five Winds International, 2001. Toxic and Hazardous Materials in Electronics -An Environmental scan of toxic and hazardous materials in IT and telecom products and waste. *For Environment Canada*
[249] Hartmann, N.B., Skjolding, L.M., Hansen, S.F., Kjølholt, J., Gottschalck, F., Baun, A. 2014. Environmental fate and behaviour of nanomaterials New knowledge on important transformation processes Environmental Project No. 1594, 2014. Copenhagen: The Danish Environmental Protection Agency
[250] Gottschalk, F., Nowack, B., Lassen, C., Kjølholt, J., Christensen, F. 2015. Nanomaterials in the Danish environment Modelling exposure of the Danish environment to selected nanomaterials Environmental project No. 1639, 2015. Danish EPA

its life cycle, because of effective collection and recycling of end-of-life products (mainly light-emitting devices) in which QDs may be used. No more than 1% was estimated to go into waste incineration or be deposited in landfills. Hardly 10% of the total mass material is distributed somewhat equally to the natural compartments i.e. aquatic, terrestrial, or air environments.

According to Gottschalk et al., the currently more or less insignificant environmental release is reflected by the fact that the current use volumes are low, that the applications that are far away from discharging any components to the natural environment and the recycling and landfilling processes are highly regulated in Denmark. Once in the environment, fast transformation of the core/shell structure of the QDs is to be expected due to changes in redox conditions, pH, and light conditions. MUA-coated QDs has similarly been found to be unstable over a 48 hour test whereas PEO-coated QDs remained stable, highlighting the fact that coatings is of major importance when it comes to the environmental fate of ODs[251].

3.7.4.2 Review of applicable regulatory provisions and status of implementation

This review focuses on the main materials used in cadmium quantum dots which are Cadmium sulphide (CdS), Cadmium selenide (CdSe), Zinc Sulfide (Zns), and Mercury (II) Sulfide (HgS) and Cadmium telluride (CdTe).

Quantum dots substances under the REACH Regulation

Cadmium sulphide is registered under REACH but there is no reference to its nanoform. It is also included in the candidate list for possible inclusion in Annex XIV of substances of very high concern (carcinogenic, equivalent level of concern having probable serious effects to human health). Finally as a substance classified as carcinogen category 1B, it is restricted under entry 28 of Annex XVII to REACH (e.g. not placed on the market for supply to the general public above certain concentration limits)[252].

Zinc sulphide and Cadmium telluride are registered under REACH but there is no information on their nanoforms. There is no registration dossier for Mercury (II) Sulfide (HgS) and for Cadmium selenide (CdSe).

Classification of quantum dots under the CLP Regulation

Cadmium sulphide is according to the EU harmonised classification and labelling (CLP00) a substance that may cause cancer, causes damage to organs through prolonged or repeated exposure, is harmful if swallowed, is suspected of causing genetic defects, is suspected of damaging fertility and the unborn child and may cause long lasting harmful effects to aquatic life[253]. Mercury (II) Sulfide (HgS) and Cadmium selenide (CdSe) are self-classified under CLP (i.e. they do not have a harmonized entry). Concerning Zinc sulphide, according to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified[254].

Quantum dots under water legislation

Quantum dots are not part of the list of priority substances and related Environmental Quality Standards for priority substances in water bodies set under the Water Framework Directive. Note however that Cadmium and its compounds are included in the priority list (Annex I entry 6).

The Environmental Quality Standards Directive 2008/105/EC has been recently amended in 2013 and the new Article 8 foresees the constitution by the Commission of a watch list of substances to gather monitoring data in view of future reviews of the list of priority substances. The selection of these substances now should take into account among others intrinsic properties of substances including where relevant particle size. This could open the door to the possible inclusion of hazardous nanomaterials in the watch list and where relevant in the list of priority substances.

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[251] Pace, H. E., Lesher, E. K. and Ranville, J. F., 2010. Influence of stability on the acute toxicity of CdSe/ZnS nanocrystals to Daphnia magna. *Environmental toxicology and Chemistry*, 29(6), p.1338-1344.

[252] Information retrieved from ECHA website: http://echa.europa.eu/fr/substance-information/-/substanceinfo/100.013.771

[253] Information retreived from ECHA website: http://echa.europa.eu/fr/substance-information/-/substanceinfo/100.013.771

[254] Information retrieved from ECHA website: http://echa.europa.eu/fr/substance-information/-/substanceinfo/100.013.866

Quantum dots under waste legislation

Quantum dots waste is covered by the EU waste legislation since the Waste Framework Directive defines 'waste' as "any substance or object which the holder discards". Therefore, the Directive applies to discarded materials that contain quantum dots or quantum dots waste.

No specific treatment measures have been set for quantum dots in waste or quantum dots waste. The treatment of such waste will depend on whether or not it is considered as a hazardous waste under the Directive. Hazardous waste is subject to more stringent and specific control and treatment measures. The classification of hazardous waste is based on the CLP Regulation. However, as identified above, notifiers of classification of quantum dot substances under CLP do not refer to the nanoform and several of the substances used in quantum dots are not classified.

The ROHS Directive is a relevant legal text to control the use of substances in quantum dots since it applies to electric and electronic equipment (EEE). This Directive prohibits the use of certain substances in EEE above certain concentration limits such as cadmium. However, there are exemptions to this prohibition this is the case for Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm2 of light-emitting area) for use in solid state illumination or display systems. The colour converting component in LEDs consists of cadmium containing quantum dots. In January 2015 the Commission proposed extending the exemption until 2017 and adding a new exemption (39b) relating to Cadmium in downshifting cadmium based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0.2 µg Cd per mm2 of display screen area).[255] However, the European Parliament objected to the Commission Delegated Directive,[256] therefore triggering a new assessment.[257] At the time of writing this report, the ROHS Directive does not set specific restrictions for materials used in quantum dots.

Article 6 specifically mentions that when reviewing the list of restricted substances the Commission must take into account several criteria (e.g. negative impacts during EEE waste management operations, uncontrolled or diffuse release into the environment) for substances including substances of very small size or with a very small internal or surface structure. Therefore, this key provision of the ROHS Directive is considered to be an adequate tool to restrict hazardous nanomaterials in EEE (such as potential hazardous substances used in quantum dots). Such periodic review procedure may lead to the generation of new information on nanomaterials in EEE and their related potential environmental risks.

The WEEE Directive 2012/19/EC lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste from electrical and electronic equipment. Article 8 read in conjunction with Annex VII requires that liquid crystal displays (together with their casing where appropriate) of a surface greater than 100 square centimetres and all those back-lit with gas discharge lamps must be removed from any separately collected WEEE. This measure may ensure that quantum dots used in screens in EEE are removed from WEEE prior being recycled and recovered.

3.7.4.3 Recommendations to address gaps in implementation

The following measures are recommended:

- Provision of adequate information on the nanoform of substances used in quantum dots under the REACH Registration
- Adequate classification on CLP (current substances are not classified or when classified no reference to their nanoform)
- Adequate information and classification respectively under REACH and CLP will ensure that the adequate control measures in the environmental downstream legislation would be applied (e.g. specific measures for hazardous substances)

[255] Proposal for Commission delegated Directive of 30.1.2015 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applications, C(2015) 383 final.
[256] European Parliament resolution on the Commission delegated directive ../.../EU amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applications (2015/2542(DEA)), B8-0464/2015, 13.5.2015.
[257] Details relating to the new assessment are available at: http://rohs.exemptions.oeko.info/index.php?id=261

- Review under Article 6 of the RoHS Directive to verify whether nanomaterials used in quantum dots should be prohibited or not
- Developing provisions for specific control of nanowaste streams if needed as a result of information from REACH and CLP
- Assess the need to introduce specific controls on quantum dots nanomaterials in EU ecolabel electronic equipment products (e.g. televisions, personal computers).

4 Prospective view regarding implementation for advanced materials

4.1 Introduction

Terms such as “materials” and “advanced materials” are very broad and inclusive terms.[258] Lukkassen and Meidell[259] distinguish between three kinds of materials:

- Standard materials used in products that is exposed to noncritical environments and low-stress applications
- Standard engineering materials, which are used in products that must have general bearing and wear properties and finally,
- High-performance materials or advanced engineering materials, which are used in products that must have superior properties (extreme service environments, superior chemical resistance, wear resistance and loading properties).[260]

Advanced engineering materials or just advanced materials is one of six technologies that are been identified as “Key Enabling Technologies” (KETs) by the European Commission. The other five are: Advanced manufacturing technologies, Nanotechnology, Industrial biotechnology, Photonics and Micro- and nanoelectronics.[261, 262] Advanced materials are used in most manufacturing industries and overall with other KETs is the rule rather than the exception.[262,263]

It is often said and claimed that Advanced materials offer major improvements in a wide variety of different fields, e.g. in aerospace, transport, building and health care and that they facilitate recycling, the reduction of environmental waste and hazards, lower carbon footprint and energy demand as well as limiting the need for scarce raw materials. Areas with major potential are believed to be energy €19bn (e.g. catalysts and batteries) and environment €12bn (e.g. polymers and smart packaging). Health (e.g. tissue engineering), transport (e.g. lightweight materials) and ICT (e.g. optical fibres and semiconductors) are also areas with major potential, but actual information about market size is not publicly available.[264]

4.2 Methodology

4.2.1 Overview

Our approach to delivering this task drew on the methods already developed and described in relation to nanomaterials in general, but recognising the unique features of advanced materials subject area. This task represents one of the first efforts to systematically categorise and define advanced materials at the EU level in the context of reviewing their coverage by environmental legislation and the extent to which they are relevant to the incorporation of nanomaterials.

In order to identify examples of emerging nanotechnologies and advanced materials, governmental and non-governmental reports and reviews were scanned, and a literature search carried out. The technologies and advanced materials identified were classified using the nomenclature and definitions and conventions cited above in order to test workability.

Our experience with using the different definitions of advanced materials was used to propose a classification of advanced materials and develop the associated methodology for regulatory review that, as required by the service request, that addressed at minimum the question of scope (e.g. is a

[258] EU, 2013, DAMADEI Design and Advanced Materials as a Driver of European Innovation.
[259] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,
[260] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,
[261] EU, 2016, http://ec.europa.eu/growth/industry/key-enabling-technologies/index_en.htm
[262] http://ec.europa.eu/DocsRoom/documents/11082/attachments/1/translations/en/renditions/native
[263] http://s3platform.jrc.ec.europa.eu/eye-ris3
[264] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC1257&from=EN

'smart material' a substance or an article?) and enabled potential overlap with other pieces of legislation (e.g. GMO, product legislation) to be evaluated.

4.2.2 Determining the classes and definitions of advanced materials

Classification of advanced materials

The first step was to determine the key classes of advanced materials (AMs). The principal information on the classes of advanced materials and related definitions was sourced from a literature review.

As a first step different approaches used in the reference sources to cluster advanced materials were evaluated.

With the advanced materials being such a rapidly developing discipline, established approaches were found to have shortcomings in describing current developments. In order to identify an appropriate definition and classification of Advanced Materials, a strengths and weaknesses analysis was carried out, considering the following broad criteria:

- Does the classification provide sufficient information on the key characteristics of the material?
- Can a material belong to one or more categories within a given categorisation type?
- Is the classification clear?
- Is the classification of the nanomaterial in line with other approaches worldwide?
- Is the classification system future-proof (e.g. is it flexible enough to accommodate new developments and inventions in the advanced materials science)?

Definitions

Information on the definitions of the specific classes of advanced materials was collated. Definitions of some classes of advanced materials are better established than others. For example, a polymer is already defined by OECD and in REACH Article 3(5):

"a polymer is defined as a substance meeting the following criteria: (a) Over 50 percent of the weight for that substance consists of polymer molecules (see definition below); and, (b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance".

In the context of the above definition:

A "polymer molecule" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant.

A "monomer unit" means the reacted form of a monomer substance in a polymer (for the identification of the monomeric unit(s) in the chemical structure of the polymer the mechanism of polymer formation may, for instance, be taken into consideration).

A "sequence" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units. This continuous string of monomer units can possibly follow any network within the polymer structure.

"Other reactant" refers to a molecule that can be linked to one or more sequences of monomer units but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.

The information on definition was sought from existing EU-level legislation, national level legislation if applicable but also relevant standard institutes. For example in the context of bio-based materials, terms and definitions related to "bio-based products" are already established by the European Committee for Standardization (CEN). It should be noted that standardisation of some of the aspects of advanced materials is relatively recent – for example the standard defining general terms to be used in the field of bio-based products (EN 16575), was only published by CEN in August 2014. The review was designed to capture this and more recent developments in order to suggest clear definitions that could be further used in establishing regulatory coverage.

4.2.3 Estimation of the future presence in the environment and the potential for exposure

The project aim was to find information that could be used to complete an estimation of the future presence in the environment and the potential for exposure of advanced materials. However, despite an extensive search, no relevant information to enable this analysis was identified. Some market estimations in monetary terms of the importance of the Key Enabling Technologies were identified, for instance in the UK and in a few cases for the specific advanced materials categories that we have identified. No information was identified on production, market distribution, market penetration, release during use, etc. No data was suggested from the expert interviews or the stakeholder workshop. This indicates that the information that would be needed for such an analysis is not publically available, and highly unlikely to exist at all.

4.2.4 Regulatory review

Coverage of advanced materials was examined for the relevant legislation identified in Section 3. In addition to environmental legislation which is the focus of Section 3, advanced materials may also be affected by other types of legislation e.g. the legislative provisions relating to genetically modified organisms (GMO). GMO products are currently regulated by the following EU legislation:

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed
- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs

Potential application of this legislation to some classes of advanced materials (in this case the bio-based materials) necessitates investigation of how well these are covered and whether there are potential gaps in the regulation, and risks that are not mitigated at this stage. Any additional legislation that should be considered in the context of advanced materials was also identified.

Building on the high level exposure pathways for advanced materials, the review of the relevant environmental legislation followed the framework defined for the regulatory review, specifically:

1. Are advanced materials covered in the general objectives?
2. Does the legislation rely on a list of products and are advanced materials (or any of the categories) included in the list?
3. What are the tools used to control? EQS, ELVs? Are they also effective for advanced materials?
4. Can sources of advanced materials in the environment be identified?
5. Are there examples of any advanced materials that are potentially relevant to those sources?
6. Are relevant exposure pathways controlled?
7. Are thresholds/limits applicable to advanced materials in terms of volume and associated risks?
8. Are monitoring requirements (criteria, measurements, thresholds, regularity, monitoring – e.g. by an authority of self-monitoring) applicable to advanced materials in terms of volume and associated risks? Are they feasible for advanced materials?
9. Enforcement – is there a need for specific elements covering advanced materials?
10. What are the penalties for noncompliance and are these relative to the risks posed by advanced materials?
11. How is the legislation being implemented, are there gaps that throw up concerns regarding application to advanced materials?

Where relevant, overlaps in the existing regulatory controls were highlighted.

4.3 Definitions of Advanced materials

Advanced materials have multiple definitions based on a review of relevant literature (see Table 14).

Table 14: Overview of the definitions of Advanced materials identified in this study

Institution/entity/author	Definition
UK Technology Strategy Board[265]	Materials, and their associated process technologies, with the potential to be exploited in high value-added products
UK Technology Strategy Board *cited in* Featherston and O'Sullivan[266]	Materials designed for targeted properties. Both completely new materials such as graphene or high temperature superconductors and those that are developments on traditional materials such as alloys or composites may be described as an advanced material. Such materials show novel or improved structural (strength, hardness, flexibility) and/or functional properties (electronic, magnetic, optical).
National Institute for Standards and Technology[267]	Materials that have been developed to the point that unique functionalities have been identified and these materials now need to be made available in quantities large enough for innovators and manufacturers to test and validate in order to develop new products.
Rensselaer[268]	All new materials and modifications to existing materials to obtain superior performance in one or more characteristics that are critical for the application under consideration. Advanced materials are materials that are early in their product and/or technology lifecycle, that have significant room for growth in terms of the improvement of the performance characteristics (technology lifecycle) and their sales volume (product lifecycle.)
Lukkassen and Meidell [269]	High-performance materials or advanced engineering materials, which are used in products that must have superior properties (extreme service environments, superior chemical resistance, wear resistance, and loading properties)
DAMADEI[270]	An advanced material is any material that, through the precise control of its composition and internal structure, features a series of exceptional properties (mechanical, electric, optic, magnetic, etc) or functionalities (self repairing, shape change, decontamination, transformation of energy, etc) that differentiate it from the rest of the universe of materials; or one that, when transformed through advanced manufacturing techniques, features these properties or functionalities.

265 Technology Strategy Board, 2008, Advanced Materials Key Technology Area 2008-2011, http://www.nibec.ulster.ac.uk/uploads/documents/advanced_materials_strategy.pdf
266 Featherston and O'Sullivan, 2014, A review of international public sector strategies and roadmaps: a case study in advanced materials, http://www.ifm.eng.cam.ac.uk/uploads/Resources/Featherston__OSullivan_2014_-_A_review_of_international_public_sector_roadmaps-_advanced_materials_full_report.pdf
267 NIST, 2010, Manufacturing and Biomanufacturing: Materials Advances and Critical Processes, http://www.nist.gov/tip/cur_comp/upload/manufacturing_biomanufacturing_matls_adv_crit_proc_04_2010_wp.pdf
268 Rensselaer, Lally School of Management and Technology, Rensselaer Polytechnic Institute (2004), Advanced Materials Sector Report, Technology Roadmap Project for the Centre for Economic Growth, Lally School of Management and Technology, Rensselaer Polytechnic Institute: Troy, New York, The United States of America.
269 Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,
270 EU, 2013, DAMADEI Design and Advanced Materials as a Driver of European Innovation.

One of the broadest definitions is to refer to Advanced Materials as "materials that represent advances over the traditional materials"[271].

A definition adopted by the Commission is:

"An advanced material is any material that, through the precise control of its composition and internal structure, features a series of exceptional properties (mechanical, electric, optic, magnetic, etc) or functionalities (self-repairing, shape change, decontamination, transformation of energy, etc) that differentiate it from the rest of the universe of materials; or one that, when transformed through advanced manufacturing techniques, features these properties or functionalities.[272]"

4.4 Categorisation of Advanced materials

One of the popular ways in which advanced materials are often categorized are by industry, by application or by a material sub-group. For instance, Advanced materials for Oil & Gas, Advanced materials for engineering applications and Composite materials.[273]

However, there is no agreed single categorisation system for advanced materials. Furthermore, different classes of advanced materials are of not clearly defined or defined differently in different literature sources.[266]

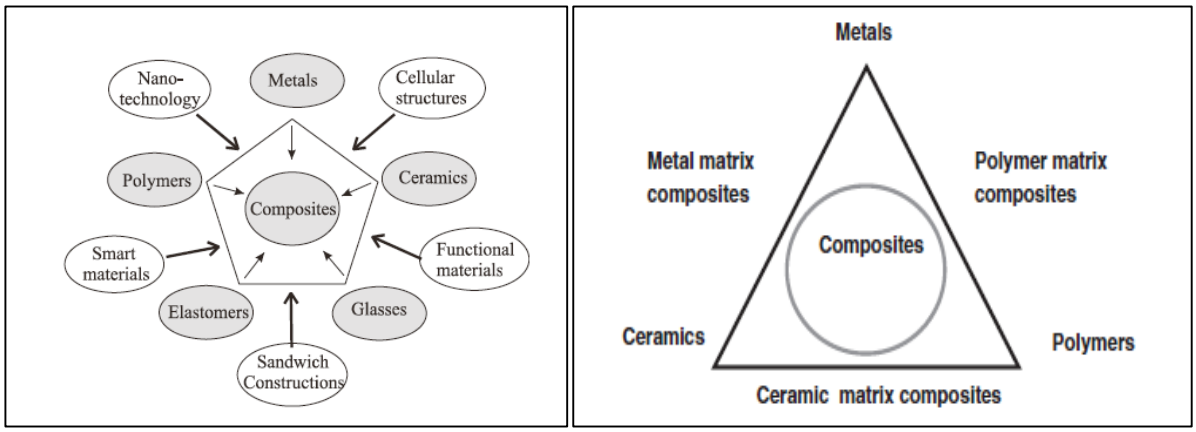
Distinct advanced materials classes such as metals, polymers or ceramics, etc., become extensively more important in manufacturing of finished components and systems for the medical, energy, aerospace and other sectors[274]. These distinct classes of advanced materials: metals, polymers, ceramics, glasses and composites, have different structural and atomic characteristics and hence exhibit different properties and are suitable for different applications and sectors. Other classes of advanced materials often referred to in literature are for example:

- active materials (multifunctional or adaptive materials, are capable of modifying in a reversible and controllable manner any one of their particular properties whenever external physical or chemical stimuli operate on them),
- advanced composites (material having one of the following features: it is manufactured artificially, mixing the components in such a way that the dispersion of one material into another may be undertaken in a controlled manner to attain an optimal set of properties; it has two or more physically and/or chemically different phases or constituent parts, which are non-inter soluble and appropriately arranged and separated by a defined inter-phase; its properties are uniquely superior in a specific aspect and cannot be attained by its constituent components separately).

A few classification systems of classical and advanced materials evolving around composites have been suggested in the literature e.g. Lukkassen and Meidell [275]and Baykara et al.[276]

[271] EU, 2013, DAMADEI Design and Advanced Materials as a Driver of European Innovation.
[272] EU, 2013, DAMADEI Design and Advanced Materials as a Driver of European Innovation.
[273] TechCnnect World Innovation Conference & Expo, 2015,, Advanced Materials, http://www.techconnectworld.com/World2015/industry/AdvancedMaterials_Industry.html
[274] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/283886/ep10-new-and-advanced-materials.pdf
[275] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,
[276] Baykara et al. 2015, The Journal of High Technology Management Research 26 (2015) 77–87, DOI: 10.1016/j.hitech.2015.04.008

Table 15: Classical schemes for advanced materials classification (Source: Lukkassen and Meidell[277] and Baykara et al.[278])



Having defined advanced materials as noted in Table 14, NIST generally categorises advanced materials into: 1) Nanomaterials e.g. CNTs, 2) Superalloys, alloys and smart materials e.g. aluminum, magnesium, titanium, smart materials[279], 3) Composites e.g. polymer- matrix composites, 4) Ceramics e.g. sodium zirconium phosphate (NZP) ceramics, zirconia-based macroporous ceramics and biodegradable ceramics such as tricalcium phosphate and hydroxyapatite and 5) Glasses e.g. high-performance glass substrates and bioactive glass scafford[280].

Similarly, Lukkassen and Meidell categorize advanced materials into composites, polymers, smart materials, sandwich constructions, nanotechnology, functional materials and cellular structures.[281] (see Table 16).

Table 16: Categorization of advanced materials based on Lukkassen and Meidell[282]

Category	Definition	Examples
Composites	Materials that combine two or more materials that when combined offer properties e.g. strength, stiffness, density which are more desirable than the properties of the individual materials	Spidersilk, fiber (glass, boron, aramid, carbon, carbon nanotubes, graphite) reinforced plastics, ceramic matrix composites, metal and polymer matrix composites, aerogel, bio-inspired materials
Polymers	"…a large molecule formed by the union of at least five identical monomers; it may be natural, such as cellulose or DNA, or synthetic…"	Thermosoftenings, thermosettings and plastics with special properties e.g. lightweight, and corrosion and electrically resistant

[277] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,
[278] Baykara et al. 2015, The Journal of High Technology Management Research 26 (2015) 77–87, DOI: 10.1016/j.hitech.2015.04.008
[279] Smart materials are 'materials that receive, transmit, or process a stimulus and respond by producing a useful effect that may include a signal that the materials are acting upon it' Haarvey 2002 cited in Featherston and O'Sullivan[31]
[280] NIST, 2010, Manufacturing and Biomanufacturing: Materials Advances and Critical Processes,
[281] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,
[282] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,

Category	Definition	Examples
Smart materials	Materials that are able to transform other forms of energy to mechanical energy and, sometimes, vice versa thereby changing either their properties (mechanical, electrical, appearance), structure, composition, or functions	Photo- and thermachromic materials that change reversibly color with changes in light intensity and temperature; Electroluminescent materials produce a brilliant light of different colors when stimulated electronically; Piezoelectric materials produce an electric field when exposed to a change in dimension caused by an imposed mechanical force
Sandwich constructions	Sandwich constructions can be defined as constructions built up by two thin skins separated by a lightweight structured core making the construction lighter and bend and bulking resistant	Applications where weight savings are critical e.g. aircraft and in portable structures
Nanotechnology	Technologies based on nanoparticles which is a new functional material with length from 1 to 100nm	Carbon nanotubes, nanocomposites, flexible ceramics
Functional (FGM) gradient	Materials that have a gradual variation of material properties from one end to another	High-temperature structural applications in, e.g., turbine airfoils and combustors
Cellular solids and structures	Cellular solids can be defined as an assembly of cells with solid edges of faces, packed together so that they fill space. Cellular structures can either consist of two-dimensional structures or three-dimensional structures	Aluminium foams, polymeric foams, refractory foams

The Technology Strategy Board in the UK also subdivided Advanced materials into four broad major categories: Structural, Functional, Multifunctional and Biomaterials.[283] (See Table 17).

Table 17: Categorisation of Advanced Materials based on Technology Strategy Board[284]

Category	Definition	Examples
Structural	n.a.	Metals, metallic alloys and metal matrix composites (MMC); polymers and polymer matrix composites; ceramics and ceramic matrix composites; together with concretes, glasses and natural materials, e.g. wood.
Functional	Materials which generally exhibit some non-structural properties	Electronic, magnetic or optical, and are incorporated into associated functional devices and systems; for example, microelectronics, photonics and electrical machines.
Multifunctional	n.a.	Damage tolerant, self-diagnostic and self-healing materials; fully-integrated structural/power generating materials.

[283] Technology Strategy Board, 2008, Advanced Materials Key Technology Area 2008-2011, http://www.nibec.ulster.ac.uk/uploads/documents/advanced_materials_strategy.pdf
[284] Technology Strategy Board, 2008, Advanced Materials Key Technology Area 2008-2011, http://www.nibec.ulster.ac.uk/uploads/documents/advanced_materials_strategy.pdf

Category	Definition	Examples
Biomaterials	Materials applied to a biological system or materials derived from a biological source. In some cases, these may be combined.	Bioresorbables and bioactive materials, together with novel manufacturing routes to achieve new properties in existing materials; new interfacial structures for the control of biomaterial-tissue interactions; and the integration of sensing systems into biomaterials for in-situ implant monitoring; biopolymers and biomass-generated polymers including celluloses, starches, chitosan and proteins
Nanotechnology	Less than 100 nm.	Thin films and surface coatings (1-D); nanotubes, wires and fibres (2-D); and nanoparticles, quantum dots and nanocrystalline materials (3-D).

The DAMADEI project has categorised Advanced materials into “Active materials”, “Advanced composites”, etc. (see Table 18).

Table 18: Categorisation of Advanced Materials based on DAMADEI[270]

Category	Definition	Examples
Active materials	Active materials, also called smart, multifunctional or adaptive materials, are capable of modifying in a reversible and controllable manner any one of their particular properties (colour, shape or viscosity, generate electricity, etc.) whenever external physical or chemical stimuli operate on them (light, sound, temperature, voltage).	Alloys, polymers, ceramics and ferromagnetic alloys with shape memory; Electro active and magneto active materials; Phase-change materials, Photoactive materials (Electroluminescent, Fluorescent, Phosphorescent), Chromo active materials (photo, thermo and electro)
Advanced composites	Composites can be defined as: • being manufactured artificially (thus excluding any natural materials such as wood), mixing the components in such a way that the dispersion of one material into another may be undertaken in a controlled manner to attain an optimal set of properties; • having two or more physically and/or chemically different phases or constituent parts, which are non-inter soluble and appropriately arranged and separated by a defined inter-phase; • having properties that are uniquely superior in a specific aspect and cannot be attained by its constituent components separately.	Fibre composites mixed with conventional material such as carbon or glass fiber to improve the damping properties of the material while ensuring good mechanical properties
Advanced manufacturing	• Shaping technologies, which use pre-shapes to obtain the required geometry such as plastic and metal injection, PIM, sintering, vacuum casting, RIM, electroforming, etc. • Subtractive technologies, which obtain the required geometry by subtracting material from a larger geometry such as mechanizing, electroerosion, waterjet cutting, laser cutting, etc. • Additive technologies (AM) which obtain the geometry by adding	3D printing

Category	Definition	Examples
	material through virtual geometry, without the use of pre-shapes and without subtracting material	
Advanced textiles and fibers	• Not defined by DAMADEI, but elsewhere • defined as textiles that are manufactured • primarily for their technical and functional • properties[285]	3D fabrics, non-woven textiles, spider silk fibers
Coatings	Liquid or solid-liquid coating that are to transform and/or modifying the functionality of a material through its surface	Anti-graffiti, anti-corrosion, fire-resistant, anti-fungal, anti-friction, anti-grease and oils, anti-bacterial, self-cleaning, dry lubricants, self-releasing, polishing, photocatalytic products
Nanotechnology	Control of matter at molecular level, which is smaller than a micrometer, normally on scales of 1 to 100 nanometers	Carbon nanotunes, graphene
Gels and foams	Materials with high porosity (>95% of their volume is occupied by air) and high surface area, which provides them with unique characteristics e.g. extremely low thermal conductivity and sound velocity and high optical transparency. Their density oscillates between 0.4 g/cm3 and 0.004 g/cm3.	• Foams from recycled material and/or the recycling of polymer foams, such as polyurethane and polystyrene; • Metallic foams made from aluminum, steel, lead and other metals with remarkable characteristics such as high stiffness, high resistance to compression and much lower density than non-foamed metal; • Ceramic foams with density control.
High-performance polymers	Compostable, degradable and/or conventional polymers (or a mixture of them) that have been modified and reinforced with bio-fibers and/or nanocharges that result in materials with very advanced properties for innovative applications	Hemp fiber-filled plasticised PVC which can be used in injection, intrusion and calendering processes, made of approximately 30% hemp fibre combined with other recyclable substances
Light alloys	Structural materials with high specific strength, which is the resistance or strength of a material divided by its density.	• Duraluminum with considerable increased mechanical strength compared to Aluminium used for the construction of planes and airships; • titanium alloyed with niobium and nickel to exploit specific properties such as superconductivity and shape memory effect;

[285] South Carolina Department of Commerce 2008, Advanced Materials, http://sccommerce.com/sites/default/files/document_directory/Advanced_Materials__Industry_Growth_and_Change_in_South_Carolina_2008.pdf

Category	Definition	Examples
		• Beryllium alloyed with with Si, Cu, Co, Ni and Fe providing highly heat-, corrosion- and magnetic-resistant materials used e.g. for supersonic aircraft and X-ray tubes

Finally, the Materials Science and Engineering Expert Committee (MatSEEC) of the European Science Foundation has divided Advanced Materials into three overarching clusters, namely "advanced classics", "bio- and functional materials", and "nanomaterials", which consist of a total of 11 categories of materials[286] (see the first column of Table 19). MatSEEC does not provided detailed definitions and examples of all of the 11 classes of materials, but these can be gathered from other sources as, for instance, done in columns two and three of Table 19.

Table 19: Potential categorization and definitions of key categories of advanced materials

Category	Definition	Examples
1. Multi-functional materials	Structural materials designed to have integrated electrical, magnetic, optical, locomotive, power generative, and possibly other functionalities that work in synergy to provide advantages that reach beyond that of the sum of the individual capabilities[287].	Thin-Wire Plasmonic Composites, Thermo-reversible cross-linked polymer, sensors for structural health monitoring[288]
2. Multistructural materials		
3. Metamaterials and artificially structured functional materials	Metamaterials are engineered structures designed to interact with electromagnetic radiation in a desired fashion. They usually comprise an array of structures smaller than the wavelength of interest. These so-called meta-atoms can interact with the electric and magnetic components of light in a way that natural atoms do not.[289] Metamaterials are an arrangement of artificial structural elements, designed to achieve advantageous and/or unusual (electro-magnetic) properties[290]	Biosensors, superlensing, cloaking, light emitting diodes[291], nanocomposites with graded electrical and magnetic composites providing broadband response, anisotropic architectures using top-down 3D printing or bottom-up self-assembly and clustering; new inorganic crystalline materials with contrived permittivities and permeabilities derived from inter-penetrating lattices with decoupled magnetic and electrical field responses; and tuneable metamaterials where external magnetic or electric fields, temperature or even light are used to contrive anisotropic properties gradients or variable frequency response.[292]
4. Nano-enabled materials in metallurgy, forestry, energy	Materials improved enabled the use of some form of nanotechnology	Nanoscale magnetic material mixtures, doped, micro- and nanostructured high-ZT thermoelectric alloys, nanostructured energetic metal/alloy powders, novel

[286] MatSEEC, 2013, Materials Science and Engineering Expert Committee (MatSEEC) Materials Science and Engineering in Europe: Challenges and Opportunities Science Position Paper http://www.esf.org/fileadmin/Public_documents/Publications/MatSEEC_ChallengesOpportunities.pdf
[287] http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.131.6441&rep=rep1&type=pdf
[288] http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.131.6441&rep=rep1&type=pdf
[289] http://www.nature.com/subjects/metamaterials
[290] https://ec.europa.eu/research/industrial_technologies/pdf/metamaterials-brochure_en.pdf
[291] https://ec.europa.eu/research/industrial_technologies/pdf/metamaterials-brochure_en.pdf
[292] Grant, 2013, New and Advanced Materials, Future of Manufacturing Project: Evidence Paper 10, Foresight, Government Office for Science, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/283886/ep10-new-and-advanced-materials.pdf

Category	Definition	Examples
efficiency, etc.		nanocrystalline metal hydrides, bulk nanostructured Al and Cu alloys[293]
5. Bio and bio-based materials	A bio-based material is a material intentionally made from substances derived from living (or once-living) organisms[294] whereas a biomaterial is defined as a substance that has been engineered to take a form which, alone or as part of a complex system, is used to direct, by control of interactions with components of living systems[295,296]	Bio-based materials include cellulose fibers, soy oil based plastic and lubricants made from vegetable oils[297] whereas biomaterials include joint replacement, bone cement, heart valves and surgical sutures[298]
6. Bio-inspired materials	Synthetic materials whose structure, properties or function mimic those of natural materials or living matter[299]	Light-harvesting photonic materials that mimic photosynthesis, structural composites that imitate the structure of nacre, and metal actuators inspired by the movements of jellyfish[300]
7. Materials for targeted surface properties		
8. Metals and alloys	Metals and alloys are materials that are typically hard, malleable, and have good electrical and thermal conductivity. Alloys are made by melting two or more elements together, at least one of them a metal. They have properties that improve those of the constituent elements, such greater strength or resistance to corrosion[301]	TiAl intermetallics for the use in turbine blades, aero engines and gas turbines[302], NiAl alloy catalysts, bulk nanostructured Al and Cu alloys for advanced electrical conductors with high strength and electrical conductivity[303]
9. Ceramics,	Ceramics are inorganic, nonmetallic materials (such as carbides, oxides and nitrides) made by shaping at a high temperature. Ceramics are hard, brittle, heat- and corrosion-resistant, and most often have a crystalline structure[304]	Cement, glass, and composites including natural fibres reinforcement
10. Polymers	Polymer is already defined by OECD and in REACH Article 3(5): *"a polymer is defined as a substance meeting the following criteria: (a) Over 50 percent of the weight for that substance*	Highly stretchable autonomous self-healing elastomer[305], self-assembled block copolymers[306], Bio-mimetic molecules, Recycled plastic boardwalks[307]

[293] MatSEEC, 2012, Metallurgy Europe, https://www.google.dk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjxzOyjzp_MAhWkCpoKHXzLDkQQFggbMAA&url=http%3A%2F%2Fwww.esf.org%2Ffileadmin%2FPublic_documents%2FPublications%2Fmetallurgy_europe.pdf&usg=AFQjCNFpJZ-i3wz77iu5ls7LZG7Qupl7tA
[294] https://en.wikipedia.org/wiki/Bio-based_material
[295] http://www.journals.elsevier.com/biomaterials/
[296] http://www.nature.com/subjects/biomaterials
[297] https://en.wikipedia.org/wiki/Bio-based_material
[298] https://en.wikipedia.org/wiki/Biomaterial#Applications
[299] http://www.nature.com/subjects/bioinspired-materials
[300] http://www.nature.com/subjects/bioinspired-materials
[301] http://www.nature.com/subjects/metals-and-alloys
[302] MatSEEC, 2013, Materials Science and Engineering Expert Committee (MatSEEC) Materials Science and Engineering in Europe: Challenges and Opportunities Science Position Paper
[303] MatSEEC 2012, Metallurgy Europe – A Renaissance Programme for 2012-2022 Science Position Paper, http://www.esf.org/fileadmin/Public_documents/Publications/metallurgy_europe.pdf
[304] http://www.nature.com/subjects/ceramics
[305] http://www.nature.com/nchem/journal/vaop/ncurrent/full/nchem.2492.html
[306] http://www.nature.com/articles/natrevmats201618

Category	Definition	Examples
	consists of polymer molecules (see definition below); and, (b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance". In the context of the above definition: *A "polymer molecule" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant.* *A "monomer unit" means the reacted form of a monomer substance in a polymer (for the identification of the monomeric unit(s) in the chemical structure of the polymer the mechanism of polymer formation may, for instance, be taken into consideration).* *A "sequence" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units. This continuous string of monomer units can possibly follow any network within the polymer structure.* *"Other reactant" refers to a molecule that can be linked to one or more sequences of monomer units but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.*	
11. Soft materials	Soft materials are materials that can be easily deformed by thermal stresses or thermal fluctuations at about room temperature[308]	Liquids, polymers, foams, gels, colloids, granular materials, as well as most soft biological materials[309]

The lack of single nomenclature as well as dynamically progressing research and development landscape, poses difficulties in terms of minimising risks to the environment and human health via environmental legislation. In addition, multiple classes of advanced materials and different methods of

[307] Smith, F. 2010, The UK's Adcand Material Sector – High Material Value, Avalon Consultation Service Ltd, https://avaloncsl.files.wordpress.com/2013/01/avalon-the-uk_s-advanced-materials-sector-s-2010.pdf
[308] http://www.nature.com/subjects/soft-materials
[309] http://www.nature.com/subjects/soft-materials

their production may mean that certain legislation is applied only to a narrow category of advanced materials.

A strengths and weaknesses analysis was carried out, considering the following broad criteria:

- Does the classification provide sufficient information on the key characteristics of the material?
- Can a material belong to one or more categories within a given categorisation type?
- Is the classification clear?
- Is the classification of the nanomaterial in line with other approaches worldwide?
- Is the classification system future-proof (e.g. is it flexible enough to accommodate new developments and inventions in the advanced materials science)?

This analysis is summarised in Table 20.

Table 20: Analysis of categorisation schemes

Categorization scheme	Clear classification?	Key characteristics sufficient?	Unique material categorization?	Internationally consistent?	Future-proof?
Lukkassen and Meidell[310]	Y	Y	N	N	Y
Technology Strategy Board[311]	N	N	N	Y	Y
DAMADEI[270]	Y	Y	N	Y	Y
Potential categorization based on MatSEEC[312]	Y	Y	N	Y	Y

Most of the categorisation schemes suggested for advanced materials provide a clear classification of the advanced material categories that they include in their scheme although they differ substantially in regard to the number of advanced material categories that they do include e.g 5 versus 11. For the majority of the schemes, sufficient information is provided on the key characteristics of the different categories of advanced materials. A few schemes entail advanced material categories that are not defined or explained in a great detail and some also seem to include unique categories of materials not widely recognized as an advanced material category. Most of the suggested schemes enable materials to belong to one or more categories which seems to be due to the overall enabling and pervasive nature of advanced materials and their applications rather than a drawback of the suggested schemes themselves. Finally, all the schemes seem to be future-proof as they are flexible enough to accommodate new developments and inventions in the advanced materials science and new advanced material categories can easily be added to the suggested schemes.

[310] Lukkassen and Meidell, 2007, Advanced Materials and Structures and their Fabrication Processes, Narvik University College, HiN,

[311] Technology Strategy Board, 2008, Advanced Materials Key Technology Area 2008-2011, http://www.nibec.ulster.ac.uk/uploads/documents/advanced_materials_strategy.pdf

[312] MatSEEC, 2013, Materials Science and Engineering Expert Committee (MatSEEC) Materials Science and Engineering in Europe:
Challenges and Opportunities Science Position Paper
http://www.esf.org/fileadmin/Public_documents/Publications/MatSEEC_ChallengesOpportunities.pdf

On the basis of this analysis, it is proposed to adopt the categorization developed on the basis of the DAMADEI classification for the subsequent stages of this analysis.

4.5 Regulatory aspects of Advanced Materials

In the context of regulatory coverage of advanced materials, it is particularly important to understand whether advanced materials can be defined using one of the definitions already set under EU legislation. Whether an advanced material is defined using one of the following terms, may influence whether it is or is not considered within a scope of specific EU legal text: The end uses of these advanced materials may also influence their regulatory coverage. The table below also includes relevant definitions based on the end-use of products and substances:

Table 21: Definitions used in EU legislation relevant to Advanced Materials

Term	Description
Substance under REACH Regulation	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
Mixture under REACH Regulation	A mixture or solution composed of two or more substances
Article under the REACH Regulation	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition
Substances which occur in nature under REACH Regulation	A naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
Alloy under REACH Regulation	A metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.
Organism under Directive 2001/18/EC on the deliberate release of GMOs	Any biological entity capable of replication or of transferring genetic material.
Genetically modified organisms under Directive 2001/18/EC on the deliberate release of GMOs	An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination through the following techniques: recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagationtechniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.
Nanomaterial according to Commission Recommendations on the definition of nanomaterials 2011/696	A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.
Particle according to Commission Recommendation on the definition of nanomaterials	A minute piece of matter with defined physical boundaries.

Term	Description
2011/696	
Agglomerate according to Commission Recommendation on the definition of nanomaterials 2011/696	A collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.
Aggregate according to Commission Recommendation on the definition of nanomaterials 2011/696	A particle comprising of strongly bound or fused particles.
Biological agents according to Directive 2000/54/EC on biological agents at work	Micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity.
Bio-based products according to Commission website[313]	Bio-based products are wholly or partly derived from materials of biological origin, excluding materials embedded in geological formations and/or fossilised. In industrial processes, enzymes are used in the production of chemical building blocks, detergents, pulp and paper, textiles, etc. By using fermentation and bio-catalysis instead of traditional chemical synthesis, higher process efficiency can be obtained, resulting in a decrease in energy and water consumption, and a reduction of toxic waste. As they are derived from renewable raw materials such as plants, bio-based products can help reduce CO_2 and offer other advantages such as lower toxicity or novel product characteristics (e.g. biodegradable plastic materials). There is currently no EU legal definition of bio-based products
Product according to the general product safety Directive 2001/95/EC	"product" shall mean any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.
Medicinal product according to Directive 2001/83/EC on medicinal products for human use	Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Medical device according to Directive 93/42/EEC	medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease, • diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, • investigation, replacement or modification of the anatomy or of a physiological process, • control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;
Implantable medical devices according to Directive 90/385/EEC	'active implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the

[313] http://ec.europa.eu/growth/sectors/biotechnology/bio-based-products/index_en.htm

Term	Description
	procedure.
Food according to Regulation (EC) No 178/2002	Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.
Food additives according to Regulation (EC) No 1333/2008	'food additive' shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.
Enzyme according to Regulation (EC) No 1332/2008	'food enzyme' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms: • containing one or more enzymes capable of catalyzing a specific biochemical reaction; and • added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods;
Extraction solvents according to Directive 2009/32/EC	Extraction solvent means a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which is removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.
Cosmetic products according to Regulation (EC) No 1223/2009	Cosmetic products means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.
Plant Protection Products according to Regulation (EC) No 1107/2009	Products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses: • protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products; • influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient; • preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives; • destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants; checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.
Biocidal products according to Regulation (EC) No 528/2012	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, — any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
Detergents under Regulation	Detergent' means any substance or mixture containing soaps and/or other surfactants

Term	Description
(EC) No 648/2004	intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes. Other products to be considered as detergents are: • 'Auxiliary washing mixture, intended for soaking (pre-washing), rinsing or bleaching clothes, household linen; • 'Laundry fabric-softener', intended to modify the feel of fabrics in processes which are to complement the washing of fabrics; • 'Cleaning, intended for domestic all purposes cleaners and/or other cleaning of surfaces (e.g.: materials, products, machinery, mechanical appliances, means of transport and associated equipment, instruments, apparatus, etc.); • 'Other cleaning and washing mixtures', intended for any other washing and cleaning processes.
Definition of construction products under Regulation (EU) No 305/2011	Any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works;
Ingredients in tobacco products according to Directive 2014/40/EU	'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;
Definition of waste under the Waste Framework Directive 2009/98/EC	'waste' means any substance or object which the holder discards or intends or is required to discard. Bio-waste means biodegradable garden and park waste, food and kitchen waste from households, restaurants, caterers and retail premises and comparable waste from food processing plants. 'waste oils' means any mineral or synthetic lubrication or industrial oils which have become unfit for the use for which they were originally intended, such as used combustion engine oils and gearbox oils, lubricating oils, oils for turbines and hydraulic oils;
Electrical and electronic equipment under EEE Directive 2011/65/EU and WEEE Directive 2012/19/EU	'electrical and electronic equipment' or 'EEE' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current.
By products under Regulation (EC) No 1069/2009 concerning animal by-products not intended for human consumption	Animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen; 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-product.

Table 22 below sets out a preliminary analysis of advanced material classifications under EU legislation, and highlights potential issues which may need to be addressed in due course.

Table 22: Preliminary analysis of advanced material classifications under EU legislation based on the DAMADEI classification

Category	Definition	Examples	Classification & coverage under EU legislation	Potential legal issues
Active materials	Active materials, also called smart, multifunctional or adaptive materials, are capable of modifying in a reversible and controllable manner any one of their particular properties (colour, shape or viscosity, generate electricity, etc.) whenever external physical or chemical stimuli operate on them (light, sound, temperature, voltage).	Alloys, polymers, ceramics and ferromagnetic alloys with shape memory; Electro active and magneto active materials; Phase-change materials, Photoactive materials (Electroluminescent, Fluorescent, Phosphorescent), Chromo active materials (photo, thermo and electro)	Articles under REACH Regulation RoHS Directive and WEEE Directive if used in Electronic and Electric Equipment Active food contact material under Regulation (EC) No 450/2009 on active and intelligent materials intended to be in contact with food	None
Advanced composites	Composites can be defined as: • being manufactured artificially (thus excluding any natural materials such as wood), mixing the components in such a way that the dispersion of one material into another may be undertaken in a controlled manner to attain an optimal set of properties; • having two or more physically and/or chemically different phases or constituent parts, which are non-inter soluble and appropriately arranged and separated by a defined inter-phase; • having properties that are uniquely superior in a specific aspect and cannot be attained by its constituent components separately.	Fibre composites mixed with conventional material such as carbon or glass fiber to improve the damping properties of the material while ensuring good mechanical properties	Mixtures under REACH Regulation	None
Advanced manufacturing	• Shaping technologies, which use pre-shapes to obtain the required geometry such as plastic and metal injection, PIM, sintering, vacuum casting, RIM, electroforming, etc. • Subtractive technologies, which obtain the required geometry by subtracting	3D printing	Electronic and Electric equipment subject to RoHS Directive and WEEE Directive Article under REACH	None

Category	Definition	Examples	Classification & coverage under EU legislation	Potential legal issues
	material from a larger geometry such as mechanizing, electroerosion, waterjet cutting, laser cutting, etc. • Additive technologies (AM) which obtain the geometry by adding material through virtual geometry, without the use of pre-shapes and without subtracting material		Products under the product safety regulation	
Advanced textiles and fibers	Not defined by DAMADEI, but elsewhere defined as textiles that are manufactured primarily for their technical and functional properties[314]	3D fabrics, non-woven textiles, spider silk fibers	Regulation (EU) No 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products	None
Coatings	Liquid or solid-liquid coating that are to transform and/or modifying the functionality of a material through its surface	Anti-graffiti, anti-corrosion, fire-resistant, anti-fungal, anti-friction, anti-grease and oils, anti-bacterial, self-cleaning, dry lubricants, self-releasing, polishing, photocatalytic products	Substance and mixtures under REACH Biocidal product under Regulation (EU) No 528/2012 Coating falling under Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes	None
Nanotechnology	Control of matter at molecular level, which is smaller than a micrometer, normally on scales of 1 to 100 nanometers	Carbon nanotubes, graphene	Substance under REACH and CLP Regulation	All legal issues mentioned under this report.
Gels and foams	Materials with high porosity (>95% of their volume is occupied by air) and high	Foams from recycled material and/or the recycling of polymer	Substances and mixtures under REACH	None

[314] South Carolina Department of Commerce 2008, Advanced Materials, http://sccommerce.com/sites/default/files/document_directory/Advanced_Materials__Industry_Growth_and_Change_in_South_Carolina_2008.pdf

Category	Definition	Examples	Classification & coverage under EU legislation	Potential legal issues
	surface area, which provides them with unique characteristics e.g. extremely low thermal conductivity and sound velocity and high optical transparency. Their density oscillates between 0.4 g/cm3 and 0.004 g/cm3.	foams, such as polyurethane and polystyrene; Metallic foams made from aluminum, steel, lead and other metals with remarkable characteristics such as high stiffness, high resistance to compression and much lower density than non-foamed metal; Ceramic foams with density control.	Construction Product under Regulation on construction products Products under the product safety regulation	
High-performance polymers	Compostable, degradable and/or conventional polymers (or a mixture of them) that have been modified and reinforced with bio-fibers and/or nanocharges that result in materials with very advanced properties for innovative applications	Hemp fiber-filled plasticised PVC which can be used in injection, intrusion and calendering processes, made of approximately 30% hemp fibre combined with other recyclable substances	Substance under REACH with specific derogations to the REACH obligations. According to Article 2(9) of REACH polymers do not have to be registered, but according to Article 6(3) of REACH, the monomer substance(s) and other substances of the polymers that have not already been registered by an actor up the supply chain, are to be registered if both the following conditions are met: - the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) (i.e. free or unbound monomers shall not be considered when checking this condition); - the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year (the total quantity in this context is the total quantity of monomer or	The European Commission may according to Article 138(2) of the REACH Regulation present legislative proposals with requirements for the registration of polymers once a practicable and cost-effective way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established. Such criteria have not yet been established. Furthermore, the definition of polymers under REACH may not be adequate for high-performance polymers

Category	Definition	Examples	Classification & coverage under EU legislation	Potential legal issues
			other substance ending up in the final polymer unbound or chemically bound to the polymer)	
Light alloys	Structural materials with high specific strength, which is the resistance or strength of a material divided by its density.	Duraluminum with considerable increased mechanical strength compared to Aluminium used for the construction of planes and airships; titanium alloyed with niobium and nickel to exploit specific properties such as superconductivity and shape memory effect; Beryllium alloyed with with Si, Cu, Co, Ni and Fe providing highly heat-, corrosion- and magnetic-resistant materials used e.g. for supersonic aircraft and X-ray tubes	Alloys are considered as special mixtures under REACH (Annex I(0.11)) they are not subject to registration as such but the alloying elements are. Components not important for the properties of alloys can be considered as impurities and do not need a separate registration dossier	None

5 Conclusions

5.1 Nanomaterials emissions inventory

It has been possible to develop a preliminary qualitative inventory of nanomaterial releases to five media: air, land, water, recycling and waste disposal for 188 engineered nanomaterials. This inventory was based primarily on a database of nanomaterial manufacture and importation that has been developed and applied by the French authorities. Similar databases have been developed in other EU Member States, but none is of suitable completeness and quality to form the basis of a nanomaterial inventory.

The nanomaterials identified as having a potentially "high" release to one or more environmental pathways (defined as being above the 98th percentile release for one or more pathways in one or more assessment years) were as follows:

Table 23: Nanomaterials identified as having a potentially "high" environmental release relative to other nanomaterials

Substance and CAS/EC number	Nanoform
Aluminium oxide CAS number: 1344-28-1 EC number: 215-691-6	Plate-like or spherical particles with size typically in the range 10 – 50 nm
Boehmite (Al(OH)O) CAS number: 1318-23-6 EC number: 215-284-3	Likely to be similar to aluminium oxide
Calcium carbonate CAS number: 471-34-1 EC number: 207-439-9	Cubic or hexagonal particles of size typically 10 - 80 nm
Mixture of ceria and zirconia CAS number: 53169-24-7 EC number: TBC	Average ceria particle size is between 5 and 105 nm, with most registrations in the 10-20 nm range. Zirconia particle size may be between 20 nm and 150 nm particle size. "Nano active Cerium Oxide [has] a high specific surface area, aggregated dry powder that can be dispersed in various carrier fluids to significantly reduce the particle size."
Silicon dioxide, or variations of CAS number: 7631-86-9 EC number: 231-545-4	May consist of spherical silica nanoparticles; silica nanotubes, silica films. Most particles in 10 – 30 nm size range
Titanium dioxide CAS number: 13463-67-7 EC number: 236-675-5	Most particles in 30 – 50 nm size range
Zinc oxide CAS number: 1314-13-2 EC number: 215-222-5	Most particles in 10 – 30 nm size range
Carbon black CAS number: 1333-86-4 EC number: 215-609-9	Carbon black nanoparticles are normally only present during the manufacturing process. Carbon black consists of more than 96% amorphous carbon and of small quantities of oxygen, hydrogen, nitrogen, and sulphur. Most of these elements are concentrated on the surface. It is produced from small spherical particles with sizes in the range of 15–300 nm. These particles melt into aggregates of 85–500 nm in aerodynamic diameter. On the basis of their primary particle size, all Carbon Black materials are considered as nano-structured materials.
Copolymer of vinylidene chloride CAS number: 9002-86-2 EC number: None	No data found
Polyvinyl chloride CAS number: 9002-86-2 EC number: None	No data found
Fuller's earth CAS number: 8031-18-3 EC number: None	

Substance and CAS/EC number	Nanoform
Kaolin CAS number: 1332-58-7 EC number: 8031-18-3	"Hyper-platy, nano-dimensional thickness crystals" are used to provide water resistant packaging.
Silicic acid, aluminium sodium salt CAS Number: 1344-00-9 EC Number: 215-684-8	Likely to be similar to silica
Silicic acid, magnesium salt CAS Number: 1343-88-0 EC Number: 215-681-1	Likely to be similar to silica
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide] CAS number: 5102-83-0 EC number: 225-822-9	Irregularly shaped particles with diameter distributed from c. 1000 nm down to c. 20 nm.
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide] CAS number: 5567-15-7 EC number: 226-939-8	
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione CAS Number: 413-920-6 EC Number: None	
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione CAS Number: 54660-00-3 EC Number: 601-713-5	
Calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate CAS number: 7023-61-2 EC number: 230-303-5	
Clindamycin hydrochloride CAS number: 21462-39-5 EC number: 244-398-6	No data found
Cerium oxide isostearate CAS number: None EC number: None	Most cerium oxide particles in 10 – 20 nm size range.
Cerium and iron oxide isostearate CAS number: None EC number: None	Most cerium oxide particles in 10 – 20 nm size range. Most iron oxide particles in 5 to 50 nm size range
Iron oxide isostearate CAS number: None EC number: None	Most iron oxide particles in 5 to 50 nm size range
Lactose CAS number: 63-42-3 EC number: 200-559-2	No data found
Silver CAS number: 7440-22-4 EC number: 231-131-3	Most silver particles in <50 nm size range.
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite CAS number: 308068-56-6 EC number: 231-153-3	75% of MWCNT registrations are in the <50 nm size range

Substance and CAS/EC number	Nanoform
Piroxicam CAS number: 36322-90-4 EC number: 252-974-3	No data found

Building on this analysis, a preliminary quantitative inventory has been developed for 12 priority nanomaterials. Estimated releases for 2015 are as follows: emissions estimates were also made for 2025 and 2035 (see Table 10).

Table 24: Preliminary estimate of production and release quantities in Europe of prioritised nanomaterials (T) for 2015

Chemical name	Estimated quantity produced/ imported (Europe 2015), T	Preliminary release inventory (2015), T				
		Air	Land	Water	Recycling	Waste
Aluminium oxide	16000	9.0	4.8	19	3522	5921
Mixture of ceria and zirconia	2300	1.2	0.32	1.3	381	658
Silicon dioxide, or variations of spherical silica nanoparticles; silica nanotubes, silica films	22000	150	124	23	3378	6501
Titanium dioxide	92000	183	340	140	17814	30868
Zinc oxide	200	6.0	18.5	28	16	50
Carbon black	1480000	881	290	1077	348354	578525
Clindamycin hydrochloride	340	0.31	17	5.2	0	105
Cerium oxide isostearate	41	5.9	0.515	0.10	5.7	12
Cerium and iron oxide isostearate	200	29	2.50	0.5	28	60
Silver	100	0.099	6.4	0.34	11	26
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite	1200	0.64	0.17	0.70	199	343
Piroxicam	4.0	0.0036	0.20	0.061	0	1.2

As a preliminary strategic evaluation, these emissions estimates had significant uncertainty (quantitative estimates were estimated to be reliable to approximately one order of magnitude). There is a limit to the robustness of a generic inventory such as that reported here. While improvements could be made to this inventory, to develop more detailed and accurate release inventories would require attention on a substance by substance basis.

Estimated release quantities to environmental media (air, land and water) are small for most substances, in the context of releases of size-unspecified materials such as those reported via the European Pollutant Release and Transfer Register (PRTR).[315] For example, the total quantity of particulate matter (PM_{10}) released to air from the European Union in 2014 was 116,000 tonnes. The estimated release quantity of carbon black released to the atmosphere in 2015 was 881 tonnes, 0.8% of the EU PRTR inventory figure.

5.2 Regulatory review

Overall, the current version of the EU environmental legislation analysed under this study does not adequately address any potential hazards associated with the nano-scale properties of nanomaterials. One of the main reasons is that the REACH and CLP Regulations do not effectively identify and generate information on nanomaterials, whereas a great number of downstream environmental laws (e.g. waste, water, air emissions) relies on these two instruments to trigger their risk management measures for hazardous chemical substances.

[315] http://prtr.ec.europa.eu/

Furthermore, at the time of writing this report there are still scientific knowledge gaps on nanomaterials toxicity and behaviour in environmental media which impedes an effective implementation of the EU environmental acquis for such chemical substances. Some pieces of EU legislation have recently been amended to address potential risks from nanomaterials (e.g. ROHS Directive, EU ecolabel criteria decisions, Biocidal Product Regulation, a number of EU food laws, the Cosmetic Regulation). There is however no consistent approach across the all EU acquis on the regulation of nanomaterials.

For example, the EU "Recommendation on the definition of a nanomaterial" (2011/696/EU) is a useful reference point for defining nanomaterials, although it presents some practical issues. These were highlighted by JRC,[316] and a number of recommendations were made for improving the definition. However, despite the existence of this definition, there is no consistency in the definitions and terms used across the EU legislation to characterise nanomaterials (e.g. nanoforms, substances of very small size or with a very small internal or surface structure, particle size). This leads to potential legal uncertainties and different interpretations at the implementation phase.

5.3 Advanced materials

Advanced materials can be categorized in a number of different ways e.g. by industry, by application or by a material sub-group and there is no agreed single categorisation system for advanced materials.

The categorisation schemes reviewed here for most parts provide a clear classification of the advanced material categories but they differ substantially in regard to the number of advanced material categories and the extent to which these are defined. Most of the suggested schemes enable materials to belong to one or more categories which seems to be due to the overall enabling and pervasive nature of advanced materials and their applications rather than a drawback of the suggested schemes themselves. Finally, all the schemes seem to be future-proof as they are flexible enough to accommodate new developments and inventions in the advanced materials science and new advanced material categories can easily be added to the suggested schemes.

In the context of regulatory coverage of advanced materials, it is particularly important to understand whether advanced materials or a specific category of advanced materials e.g. nanomaterials and high-performance polymers can be said to fall under definitions already set under EU legislation. For instance, the definition of polymers under REACH may not be adequate for high-performance polymers. A substantial effort is needed in order to ensure that existing definitions cover relevant categories of advanced materials. Limited or no regulatory coverage issues are foreseen if they do fall under existing definitions, whereas it might be unclear how advanced materials are regulated, if they do not. As with nanomaterials, a preliminary analysis identified some regulatory issues with other categories of Advanced Materials which would need to be resolved in due course.

[316] Joint Research Centre (2015), "Towards a review of the EC Recommendation for a definition of the term "nanomaterial": Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation"

6 Recommendations

6.1 Nanomaterials emissions inventory

The inventory developed as part of this project relied on the French database of nanomaterial manufacture and imports. It is recommended that the development of a Europe-wide database would bring advantages for future inventory and environmental risk studies. The French system could be used as an informative model for this inventory. It would be helpful for any such database to provide quantitative data on the end-use of nanomaterials covered in the database.

6.2 Regulatory review

It is recommended that attention is given to addressing the gaps identified in the regulatory review to ensure appropriate regulation of nanomaterials in the environment.

Test methods are fundamental to identifying the nano aspects of the materials as well as any hazards or risks resulting from the nano-scale material structure. Available test methods should be reviewed, and where relevant updated as soon as possible and as soon at the work programme of the Working Party on Manufactured Nanomaterials (WPMN) and International Standards Organisation (ISO) allows. Where necessary, new methods should be developed to address gaps in the test methods.

6.3 Advanced materials

On the basis of this review, it is proposed to adopt the categorization developed on the basis of the DAMADEI classification for the purposes of regulatory discussions about advanced materials. An effort is needed to ensure that specific categories of advanced materials are indeed covered by definitions already set under EU legislation e.g. REACH.

Whereas R & D efforts into advanced materials and production value are well-covered by, for instance, the KET Observatory, a better overview is needed of the current annual manufacturing, production and commercialization of advanced materials in general and the different categories of advanced materials. This could be included in, for instance, KET Observatory's annual reporting. It might furthermore be helpful to set up an inventory with information of the locations of companies, universities, government laboratories, and organizations working with advanced materials in the EU and what kinds of specific advanced materials they work with.

Based on our review of the literature on advanced materials and environmental, health and safety as well as the feedback collated at the workshop for selected experts, it is not at this point in time possible to identify any risks that might be associated with specific categories of advanced materials, except for nanomaterials. This reflects the limited state of development of advanced materials, other than nanomaterials. Further expert consultation and stakeholder engagement would be useful in order to explore what the risks might be and how they might best be investigated and handled.

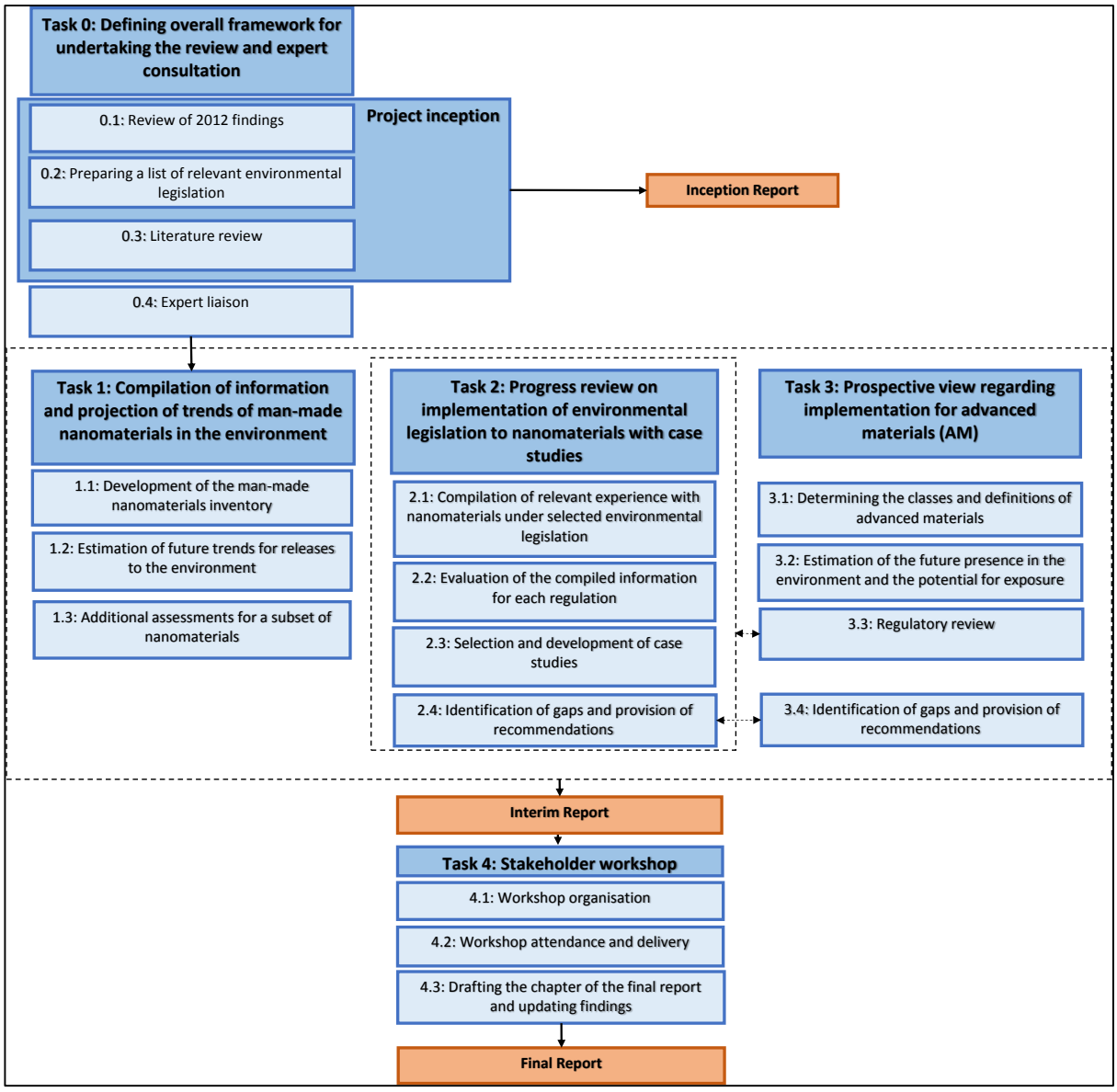
Appendices

Appendix 1: Overall study approach

A1.1 Study overview

Our approach to the programme of work is illustrated in the following sections. The figure below provides a summary overview of the project Tasks and key deliverables.

Figure 3: Overview of project methodology



The draft findings of Tasks 1, 2 and 3 were presented to selected experts at the workshop delivered as part of Task 4. The feedback collated at and following the workshop was used to update the findings and deliver the final report from the study.

A1.2 Stakeholder engagement

A1.2.1 Stakeholder consultation

The consultation programme was carried out using a format of semi-structured telephone interviews. Below we outline key steps in this process.

Identifying relevant consultees: The objective of the stakeholder consultation was to gather additional evidence on the most obvious gaps in the evidence. A list of consultees was discussed and agreed with DG ENV.

Prior to the consultation: The consultees were initially contacted by email introducing the study and presenting the list of key questions and topic areas that we were seeking to discuss (see the section on the proforma for the consultation below).

Telephone consultation: Given the purpose of the stakeholder consultation, follow up to initial consultee responses took place by telephone. Some stakeholders preferred to submit written evidence: however, direct semi-structured interviews with experts based on our previous experiences provided greater insights as they allowed the interviewer to react to respondents' comments and direct the discussion at any point to the topics of greatest relevance.

Table 25 List of organisations consulted

Organisation / expert	Organisation / expert
Industry	**Members of the research and academic community**
Cosmetics Europe	JRC
European Medicines Agency	Members of the EU NanoSafety Cluster
Nanotechnology Industry Association	Members of the EU NanoREG
National Nanotechnology Initiative (NNI) (USA)	Technische Universität Dresden, Germany
Eurometaux	University of Gothenburg, Sweden
Industrial Minerals Association Europe	Centre of Ecology & Hydrology, United Kingdom
SwedNanotech	Heriot-Watt University, United Kingdom
NSG Group (glass manufacturer)	ETSS
TechUK, ICT manufacturing trade association	The European Technology Platform for Advanced Engineering Materials and Technologies (especially members of the Working Group 3)
BREC Solutions Ltd, consultant	Nanonext.nl
42 TEK	Centre for BioNano Interactions, Ireland
CEFIC	US Environmental Protection Agency
BASF, Germany	Environment Canada
Unilever, United Kingdom	**Non-Governmental Organisations (NGOs)**
Clariant France	European Environmental Bureau
EU and Member State experts (authorities, other organisations)	Worldwide Fund for Nature
ECHA	Center for International Environmental Law
Finnish Safety and Chemicals Agency	ClientEarth
Institute for Environmental Protection and Research/ Italy	**Experts in other disciplines**
Danish Environmental Protection Agency/ Denmark	International Solid Waste Association
The Nanosciences Foundation (France)	Veolia
The Observatory for Micro and NanoTechnologies (France)	WAREG (European Water Regulators)
Ministry of Infrastructure and Environment, The Netherlands	EurEau, trade association for Europe's drinking water and waste water service operators.
Scientific Committee On Emerging And Newly Identified Health Risks (Scenihr)	
Scientific Committee on Consumer Safety	

A single consultation proforma was developed, and completed by stakeholders and/or by the interviewer as appropriate. The proforma is set out in Table 26.

Table 26 Consultation proforma for semi-structured interviews

Part 1 Information on releases of man-made nanomaterials and future trends	Y / E / N. Use the box below the table to provide any information
1. Can you point to information sources on current production volumes or other relevant statistics to assist in quantifying environmental releases of nanomaterials?	
2. Can you point to any information on future trends in production, use and/or environmental releases of nanomaterials in the next 5 to 15 years? Are you aware of any new materials expected to enter production over that timescale?	
3. Can you point to any measurement data on releases of nanomaterials, or the presence of nanomaterials in the environment?	
4. Are there properties of nanomaterials that you expect will change once in the environment, which have not been pointed out previously e.g. in the RIP-oN2/3 reports, or Danish EPA report on environmental fate? http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon2.pdf http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon3.pdf http://www2.mst.dk/Udgiv/publications/2014/08/978-87-93178-87-8.pdf	
Part 2 Progress review of implementation of environmental legislation to nanomaterials with case studies	
5. What is your experience / view on the implementation of the EU environmental legislation to nanomaterials (see list of legislation below)?	
6. Are you aware of any implementation problems related to the definition of nanomaterials?	
7. Is sufficient information available concerning how to prevent releases into the environment of nanomaterials during their production? throughout the supply chain, e.g., through SDS? during product use?	
8. What information would be needed to ensure the safe management and disposal of nanomaterials at product end of life (with supporting evidence if available)?	
9. Are measurements and other technical instruments available for enforcement of provisions on nanomaterials, and are they applied in practice to monitor environmental media for presence of nanomaterials?	
10. How is the legislation being implemented – are there gaps that throw up concerns regarding application to nanomaterials? if yes how could these gaps be removed?	
Part 3 Prospective view regarding advanced materials	
11. What specifications are you aware of for categorising advanced nanomaterials? What is your experience of using these definitions in dealing with regulators or other stakeholders?	
12. Are you aware of existing data on the production or use of advanced materials?	
13. Are you aware of any quantitative estimates related to the releases of advanced materials to the environment?	
14. How would you describe emerging trends (with supporting evidence if available)?	
15. What are the key gaps in the existing evidence with regard to fate of advanced materials in the environment (with supporting evidence if available)?	
16. What is your experience with the implementation of environmental legislation to advanced materials?	
Space for further information	

A1.2.2 Stakeholder workshop

This was followed up by a workshop which was held on 21 June 2016. The aims of the workshop were:

1. To present interim findings from Tasks 1, 2 and 3
2. To listen to and discuss stakeholder feedback on the study findings
3. To enable stakeholder views to be taken into account in developing the study report

Stakeholder views were communicated and discussed at the meeting, and were also subsequently provided in writing. All relevant views and comments have been considered in finalising this report. The workshop programme was as follows:

Time	Activity
10:00-10.30	Registration and coffee
10:30-10:40	Chair welcome (Ricardo Energy & Environment/DG ENV), introduction, housekeeping and workshop evaluation
10:40-11.00	Keynote speech (Andrej Kobe, European Commission) Workshop objective: to check/validate project team findings
11.00-12.00	Findings from the study (Project Team)
	11.00 – 11.20: Regulatory aspects and key developments since 2nd Regulatory Review: Florent Pelsy
	11.20 – 11.40: Current uses and environmental releases of nanomaterials of environmental interest; prioritisation: Mark Broomfield
	11.40 – 12.00: Future developments and wider view: can we start a discussion of Advanced Materials, or carry out useful stress-testing the regulatory system in relation to advanced materials: Steffen Foss Hansen
12.00-12:20	External presentation 1: Research perspective *Professor Kenneth Dawson, University College Dublin: Brief peer review of the Inception Report; relevant current research initiatives*
12.20-12.35	External presentation 2 ECHA perspective *Laurence Deydier, ECHA: brief regulatory implementation perspective, in relation to REACH and other relevant regulatory instruments*
12.35-12.45	Introduction to plenary discussion
12.45-13.45	Networking lunch
13:45-14:00	External presentation 3: NGO perspective *David Azoulay: NGO perspective on regulatory issues*
14:00-14:15	External presentation 4 (e.g. Industry perspective) *Blanca Serrano Ramon, CEFIC: regulatory issues encountered by chemicals industry*
14.15-16.30	**Plenary Discussion** Discussion topics included: • Existing information and projections of trends for nanomaterials and advanced materials; prioritisation • Practical experience in implementation of environmental legislation to nanomaterials and advanced materials • Advanced materials: new challenges and applicability of current legislation
16:30-16:45	Plenary discussion/Q&A session and explanation of the next steps (further evidence gathering)
16:45	Close

Appendix 2 – Usage categories for materials listed in French production database for 2015

Generic chemical name	Usage category	Estimated %
Aluminium hydroxide	Durable materials	40%
Aluminium hydroxide	Paints & Coatings: Durable material	40%
Aluminium hydroxide	Fillers: Construction material	10%
Aluminium hydroxide	Ceramics: Durable material	5%
Aluminium hydroxide	Paper products: Short lifetime	5%
aluminium hydroxide oxide	Durable materials	40%
aluminium hydroxide oxide	Paints & Coatings: Durable material	40%
aluminium hydroxide oxide	Fillers: Construction material	10%
aluminium hydroxide oxide	Ceramics: Durable material	5%
aluminium hydroxide oxide	Paper products: Short lifetime	5%
aluminium oxide	Durable materials	40%
aluminium oxide	Paints & Coatings: Durable material	40%
aluminium oxide	Fillers: Construction material	10%
aluminium oxide	Ceramics: Durable material	5%
aluminium oxide	Paper products: Short lifetime	5%
antimony nickel titanium oxide yellow	Plastics & Polymers: Durable material	20%
antimony nickel titanium oxide yellow	Paints & Coatings: Durable material	20%
antimony nickel titanium oxide yellow	Dye, Pigment	20%
antimony nickel titanium oxide yellow	Construction materials	20%
antimony nickel titanium oxide yellow	Pharmaceuticals: Pharma	20%
barium titanium trioxide	Scientific R&D: R&D	100%
Boehmite (Al(OH)O)	Durable materials	40%
Boehmite (Al(OH)O)	Paints & Coatings: Durable material	40%
Boehmite (Al(OH)O)	Fillers: Construction material	10%
Boehmite (Al(OH)O)	Ceramics: Durable material	5%
Boehmite (Al(OH)O)	Paper products: Short lifetime	5%
Calcium carbonate	Plastics & Polymers: Durable material	3%
Calcium carbonate	Adhesives: Durable material	3%
Calcium carbonate	Food additive	0.5%
Calcium carbonate	Paper products: Short lifetime	90%
Calcium carbonate	Cosmetics	0.5%
Calcium carbonate	Paints & Coatings: Durable material	3%
calcium hydrogenorthophosphate	Paints & Coatings: Durable material	80%
calcium hydrogenorthophosphate	Dye, Food Dye, Pigment: Food additive	15%
calcium hydrogenorthophosphate	Lab chemicals: R&D	5%
Silicon carbide	Lab chemicals: R&D	10%
Silicon carbide	Rubber Products: Textile - Type 2	80%
Silicon carbide	Scientific R&D: Durable material	10%
Cerium dioxide	Adhesives: Short lifetime	1%
Cerium dioxide	Surface treatments (non metal): Durable	50%

Generic chemical name	Usage category	Estimated %
	material	
Cerium dioxide	Electronics: Durable material	20%
Cerium dioxide	Paints & Coatings: Durable material	15%
Cerium dioxide	Fillers / Mastics: Construction material	10%
Cerium dioxide	Fine Chemicals: Durable material	4%
cerium tetrahydroxide	Fine Chemicals: Durable material	100%
Cerium zirconium oxide	Scientific R&D: R&D	100%
Chromium iron oxide	Paints & Coatings: Durable material	33%
Chromium iron oxide	Dye, Pigment	33%
Chromium iron oxide	Plastics & Polymers: Durable material	34%
Cobalt aluminate blue spinel	Construction materials	100%
Copper (II) nitrate hydrate	Other: Durable material	100%
Copper oxide	Dye, Pigment	40%
Copper oxide	Scientific R&D: R&D	20%
Copper oxide	Fine Chemicals: Durable material	40%
diantimony pentoxide	Dye, Food Dye, Pigment: Durable material	50%
diantimony pentoxide	Plastics & Polymers: Durable material	50%
diiron trioxide	Plastics & Polymers: Durable material	50%
diiron trioxide	Machines and electronics: Durable material	50%
Hydroxyapatite calcostrontique	Pharmaceutical: Pharma	100%
iron hydroxide oxide	Composite manufacture: Durable material	99.9%
iron hydroxide oxide	Cosmetics: Cosmetic	0.1%
iron hydroxide oxide yellow	Composite manufacture: Durable material	99.9%
iron hydroxide oxide yellow	Cosmetics: Cosmetic	0.1%
lanthanum phosphate	Scientific R&D: R&D	100%
Mixture of cerium dioxide and zirconium dioxide	Vehicles: Durable material	100%
nickel monoxide	Metal alloy and ceramic manufacture: Durable material	100%
pentacalcium hydroxide tris (orthophosphate)	Dental/medical use: Pharma	100%
Silicon dioxide, or variations of	Elastomers, carriers, polymers, plastics: Durable material	82%
Silicon dioxide, or variations of	Detergents & cosmetics: Cosmetic	7%
Silicon dioxide, or variations of	Sealants: Durable material	5%
Silicon dioxide, or variations of	Paints & Coatings: Durable material	2%
Silicon dioxide, or variations of	Inks & toners: Short lifetime	2%
Silicon dioxide, or variations of	Food additive	2%
Solid solution of bismuth oxyhalide	Composite manufacture: Durable material	100%
titanium dioxide	Paints and coatings: durable materials	65%
titanium dioxide	Textiles: Textiles Type 2	5%
titanium dioxide	Construction Materials	22%
titanium dioxide	Inks & toners: Short lifetime	3%
titanium dioxide	Food additive	2%
titanium dioxide	Pharmaceuticals	1%
titanium dioxide	Cosmetics	2%
tricobalt tetraoxide	Composite manufacture: Durable material	100%

Generic chemical name	Usage category	Estimated %
triiron tetraoxide	Composite manufacture: Durable material	100%
tungsten disulphide	Lubricants & greases: Cosmetic	100%
tungsten trioxide	Composite manufacture: Durable material	100%
Yttrium zirconium oxide	Composite manufacture: Durable material	100%
zinc oxide	Paints, rubber and ceramics: Durable material	40%
zinc oxide	Concrete additive: Construction material	30%
zinc oxide	Cosmetics	25%
zinc oxide	Cigarette filters: short lifetime	5%
silver	Textiles: Textile - Type 1	100%
carbon	Durable materials	100%
Carbon black	Durable materials	95%
Carbon black	Short lifetime material: Short lifetime	5%
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite	Composite manufacture: Durable material	100%
2-Propenoic acid, 2-methyl-,methyl ester, polymer with 2-ethylhexyl 2-propenoate	Plastics & Polymers: Durable material	100%
2-Propenoic acid, 2-methyl-,methyl ester, polymer with butyl 2-propenoate and ethenylbenzene	Plastics & Polymers: Durable material	100%
2-Propenoic acid, 2-methylmethyl ester, polymer with 1,3-butadiene and ethenylbenzene	Plastics & Polymers: Durable material	100%
2-Propenoic acid, 2-methylmethyl ester, polymer with 1,3-butadiene ethenylbenzene and ethyl-2-propenoate	Plastics & Polymers: Durable material	100%
2-Propenoic acid, 2-methylmethyl ester, polymer with 1,3-butadiene, butyl 2-propenoate and ethylbenzene	Plastics & Polymers: Durable material	100%
Boron Nitride (and) Titanium Dioxide [nano] (and) Dimethicone (and) Isododecane (and) Ethylene/VA Copolymer	Durable materials	50%
Boron Nitride (and) Titanium Dioxide [nano] (and) Dimethicone (and) Isododecane (and) Ethylene/VA Copolymer	Textiles: Textile - type 2	5%
Boron Nitride (and) Titanium Dioxide [nano] (and) Dimethicone (and) Isododecane (and) Ethylene/VA Copolymer	Construction materials	45%
Butadiene-butyl acrylate-ethyl acrylate-methyl methacrylate copolymer	Plastics & Polymers: Durable material	100%
Cellulose	Textiles: Textile - type 2	100%
Vinyl chloride copolymer	Plastics & Polymers: Durable material	100%
Emulsion of polysiloxanes	Durable materials	100%
Mica (and) Titanium Dioxide (and) Cyclopentasiloxane (and) Dimethicone (and) Isododecane (and) Ethylene/VA Copolymer	Durable materials	50%
Mica (and) Titanium Dioxide (and) Cyclopentasiloxane (and) Dimethicone (and) Isododecane (and) Ethylene/VA Copolymer	Textiles: Textile - type 2	5%
Mica (and) Titanium Dioxide (and) Cyclopentasiloxane (and) Dimethicone (and) Isododecane (and) Ethylene/VA Copolymer	Construction materials	45%
nanocristaux d'amidon	Plastics & Polymers: Durable material	100%
Poly 2,3-Dichloro-1,3-butadiene	Plastics & Polymers: Durable material	100%
Poly(styrene-coacrylonitrile)	Plastics & Polymers: Durable material	100%
Poly(tetrafluoroethylene)	Plastics & Polymers: Durable material	100%
Vinyl polychloride	Plastics & Polymers: Durable material	100%
Polymethyl methacrylate	Plastics & Polymers: Durable material	100%
polystyrene based particles coated with anti-human CRP F(ab)2 fragments	Plastics & Polymers: Durable material	100%
Polyvidone	Plastics & Polymers: Durable material	100%
Styrene, oligomers	Plastics & Polymers: Durable material	100%
Attapulgite	Machines and electronics: Durable material	100%

Generic chemical name	Usage category	Estimated %
Fuller's earth	Cosmetics	25
Fuller's earth	Textiles	40%
Fuller's earth	Pharmaceuticals	5%
Fuller's earth	Paper manufacturing: short lifetime	30%
Kaolin	Paper Products: Short lifetime	53%
Kaolin	Ceramics: Durable material	30%
Kaolin	Refractories: Construction material	7%
Kaolin	Paints & Coatings: Durable material	5%
Kaolin	Rubber Products: Durable material	5%
Montmorillonite	Drilling muds etc: Short lifetime	90%
Montmorillonite	Pharmaceuticals: Pharma	10%
Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	Cosmetics	20%
Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	Biocide: Biocide	0%
Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	Fine Chemicals: R&D	80%
Aluminum magnesium sodium silicate	Elastomers, carriers, polymers, plastics: Durable material	82%
Aluminum magnesium sodium silicate	Detergents & cosmetics: Cosmetic	9%
Aluminum magnesium sodium silicate	Sealants: Durable material	5%
Aluminum magnesium sodium silicate	Paints & Coatings: Durable material	2%
Aluminum magnesium sodium silicate	Inks & toners: Short lifetime	2%
Aluminum sodium silicate	Elastomers, carriers, polymers, plastics: Durable material	82%
Aluminum sodium silicate	Detergents & cosmetics: Cosmetic	9%
Aluminum sodium silicate	Sealants: Durable material	5%
Aluminum sodium silicate	Paints & Coatings: Durable material	2%
Aluminum sodium silicate	Inks & toners: Short lifetime	2%
Calcium silicate	Elastomers, carriers, polymers, plastics: Durable material	82%
Calcium silicate	Detergents & cosmetics: Cosmetic	9%
Calcium silicate	Sealants: Durable material	5%
Calcium silicate	Paints & Coatings: Durable material	2%
Calcium silicate	Inks & toners: Short lifetime	2%
Lithium magnesium sodium silicate	Elastomers, carriers, polymers, plastics: Durable material	82%
Lithium magnesium sodium silicate	Detergents & cosmetics: Cosmetic	9%
Lithium magnesium sodium silicate	Sealants: Durable material	5%
Lithium magnesium sodium silicate	Paints & Coatings: Durable material	2%
Lithium magnesium sodium silicate	Inks & toners: Short lifetime	2%
Magnesium silicate	Elastomers, carriers, polymers, plastics: Durable material	82%
Magnesium silicate	Detergents & cosmetics: Cosmetic	9%
Magnesium silicate	Sealants: Durable material	5%
Magnesium silicate	Paints & Coatings: Durable material	2%
Magnesium silicate	Inks & toners: Short lifetime	2%
Zirconium praseodymium yellow zircon	Coating: Durable material	100%
[[4-[[4-(anilino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-	Organic dye/pigment (textile): Textile type	61.25%

Generic chemical name	Usage category	Estimated %
ylidene]methyl]phenyl]amino]benzenesulphonic acid	2	
[1,3,8,16,18,24-hexabromo-2,4,9,10,11,15,17,22,23,25-decachloro-29H,31Hphthalocyaninato(2-)-N29,N30,N31,N32]copper	Organic dye/pigment (ink): Short lifetime	16.25%
[1-[[(2-hydroxyphenyl)imino]methyl]-2-naphtholato(2-)-N,O,O']copper	Organic dye/pigment (Paint/coating): Durable	11.25%
1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-(2-furoyl)piperazine monohydrochloride	Organic dye/pigment (Plastic): Durable	11.25%
1-(4-methyl-2-nitrophenylazo)-2-naphthol		
1,1'-[(6-phenyl-1,3,5-triazine-2,4-diyl)diimino]bisanthraquinone		
1,4-bis(butylamino)anthraquinone		
1,4-bis(mesitylamino)anthraquinone		
1-[(2,4-dinitrophenyl)azo]-2-naphthol		
1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol		
12H-phthaloperin-12-one		
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-Nphenylbutyramide]		
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]		
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methoxyphenyl)-3-oxobutyramide]		
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]		
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]		
2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-Nphenylbutyramide]		
2,2'-methylenebis(6-(2Hbenzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)		
2,4-dihydro-5-methyl-2-phenyl-4-(phenylazo)-3Hpyrazol-3-one		
2,9-bis(3,5-dimethylphenyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone		
2,9-bis(p-methoxybenzyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone		
2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone		
2,9-dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione		
2,9-dimethylanthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone		
2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide		
2-[(4-chloro-2-nitrophenyl)azo]-N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-oxobutyramide		
2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide		
2-[(4-chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide		
2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide		
2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-Nphenylbutyramide		
2-[(p-nitrophenyl)azo]acetoacetanilide		
2-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzoic acid		
29H,31H phthalocyaninato(2-)-N29,N30,N31,N32 copper		
29H,31H-Phthalocyanine		
2-cyano-2-[2,3-dihydro-3-(tetrahydro-2,4,6-trioxo-5(2H)-pyrimidinylidene)-1Hisoindol-1-ylidene]-Nmethylacetamide		
2-Naphthacenecarboxamide,4-(dimethylamino)-1,4,4a,5,5a,6,11,12aoctahydro-3,5,10,12,12apentahydroxy-6-methyl-1,11-dioxo-,monohydrochloride, [4S-(4Î±,4aÎ±,5Î±,5aÎ±,6Î±,12aÎ±)]-		
3,3'-(1,4-phenylenediimino)bis[4,5,6,7-tetrachloro-1H-isoindol-1-one]		
3,3'-[(2,5-dimethyl-pphenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(5-chloro-otolyl)benzamide]		
3,3'-[(2-chloro-5-methyl-pphenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(3-chloro-otolyl)benzamide]		

Generic chemical name	Usage category	Estimated %
3,3'-[(2-chloro-5-methyl-pphenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-[2-(4-chlorophenoxy)-5-(trifluoromethyl)phenyl]benzamide]		
3,3'-[(2-methyl-1,3-phenylene)diimino]bis[4,5,6,7-tetrachloro-1H-isoindol-1-one]		
3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthrylene)diimino]bis[Ncyclohexyl-2,4,6-trimethylbenzenesulphonamide		
3,4,5,6-tetrachloro-N-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolyl]phthalimide		
3,6-bis(4-chlorophenyl)-1H,2H,4H,5H-pyrrolo[3,4-c]pyrrole-1,4-dione		
3,6-Bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione		
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione		
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione		
3-[(4-chloro-2-nitrophenyl)azo]-2-methylpyrazolo[5,1-b]quinazolin-9(1H)-one		
3-hydroxy-4-[(2-methoxy-5-nitrophenyl)azo]-N-(3-nitrophenyl)naphthalene-2-carboxamide		
3-hydroxy-4-[(2-methyl-4-nitrophenyl)azo]-N-(otolyl)naphthalene-2-carboxamide		
3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide		
4,10-dibromodibenzo[def,mno]chrysene-6,12-dione		
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]		
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]		
4,4'-diamino[1,1'-bianthracene]-9,9',10,10'-tetraone		
4,5,6,7-tetrachloro-3-[[3-methyl-4-[[4-[(4,5,6,7-tetrachloro-1-oxo-1Hisoindol-3-yl)amino]phenyl]azo]phenyl]amino]-1H-isoindol-1-one		
4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide		
4-[(2,5-dichlorophenyl)azo]-3-hydroxy-Nphenylnaphthalene-2-carboxamide		
4-[(2,5-dichlorophenyl)azo]-N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-hydroxynaphthalene-2-carboxamide		
4-[[4-(aminocarbonyl)phenyl]azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide		
4-[[4-(aminocarbonyl)phenyl]azo]-N-(2-ethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide		
4-[[5-[[[4-(aminocarbonyl)phenyl]amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide		
5,12-dihydro-2,9-dimethylquino-[2,3-b]acridine-7,14-dione		
5,12-dihydroquino[2,3-b]acridine-7,14-dione		
5,5'-(1H-isoindole-1,3(2H)-diylidene)dibarbituric acid		
5-[(2,3-dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl)azo]barbituric acid		
6,15-Dihydroanthrazine-5,9,14,18-tetrone		
8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine		
ammonium iron(3+)hexakis(cyano-C)ferrate(4-)		
barium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate		
benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-, N-Me derivatives,molybdatephosphates		
Benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-, N-Me derivs.,molybdatetungstatephosphates;		
Benzenamine, N,Ndimethyl-,oxidized,molybdatetungstate phosphates		
benzenamine, oxidized		
Benzoic acid, 2,3,4,5-tetrachloro-6-cyano-,methyl ester, reaction products with pphenylenediamine and sodium methoxide		

Generic chemical name	Usage category	Estimated %
bis[[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthyl]methylene]cyclohexa-2,5-dien-1-ylidene]diethylammonium]dicopper(1+) hexa(cyano-C)ferrate(4-)		
bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione		
C.I. Pigment Orange 72		
C.I. Pigment Red 184		
C.I. Pigment Red 49:2		
calcium 4,5-dichloro-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulphonatophenyl)-1Hpyrazol-4-yl]azo]benzenesulphonate		
calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate		
Copper, [29H,31Hphthalocyaninato(2-)-N29,N30,N31,N32]-,brominated chlorinated		
Danofloxacin mesylate		
diisopropyl 3,3'-[(2,5-dichloro-1,4-phenylene)bis[iminocarbonyl(2-hydroxy-3,1-naphthylene)azo]]bis[4-methylbenzoate]		
dimethyl 2-[[1-[[(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]terephthalate		
Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-,molybdatetungstatephosphate		
ferrate(4-), hexakis(cyano-C)-, methylated 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]benzenamine copper(2+) salts		
hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl)xanthylium, sodium salt		
hydrogen bis[2-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]benzoato(2-)]chromate(1-), compound with 2-ethylhexylamine (1:1)		
manganese, 4-[(5-chloro-4-methyl-2-sulfophenyl)azo]-3-hydroxy-2-naphthalenecarboxylic acid complex		
methyl 4-[[(2,5-dichlorophenyl)amino]carbonyl]-2-[[2-hydroxy-3-[[(2-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]benzoate		
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-2-[(4-nitrophenyl)azo]-3-oxobutyramide		
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide		
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-methyl-4-[(methylamino)sulphonyl]phenyl]azo]naphthalene-2-carboxamide		
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-oxo-2-[[2-(trifluoromethyl)phenyl]azo]butyramide		
N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide		
N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide		
N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide		
N-(5-chloro-2-methoxyphenyl)-2-[(2-methoxy-4-nitrophenyl)azo]-3-oxobutyramide		
N-(5-chloro-2-methylphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide		
N,N'-(2-chloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]		
N,N'-(2-chloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]		
N,N'-(3,3'-dimethyl[1,1'-biphenyl]-4,4'-diyl)bis[2-[(2,4-dichlorophenyl)azo]-3-oxobutyramide]		
N,N'-[6,13-diacetamido-2,9-diethoxy-3,10-triphenodioxazinediyl]bis(benzamide)		
N,N'-phenylene-1,4-bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]		
Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes		

Generic chemical name	Usage category	Estimated %
polychloro copper phthalocyanine sodium bis[2,4-dihydro-4-[(2-hydroxy-5-nitrophenyl)azo]-5-methyl-2-phenyl-3H-pyrazol-3-onato(2-)]chromate(1-) sodium bis[3-[[1-(3-chlorophenyl)-4,5-dihydro-3-methyl-5-oxo-1H-pyrazol-4-yl]azo]-4-hydroxy-Nmethylbenzenesulphonamidato(2-)]cobaltate(1-) sodium bis[4-hydroxy-3-[(2-hydroxy-1-naphthyl)azo]-N-(3-methoxypropyl)benzene-1-sulphonamidato(2-)]chromate(1-) strontium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (1:1) tetramethyl 2,2'-[1,4-phenylenebis[imino(1-acetyl-2-oxoethane-1,2-diyl)azo]]bisterephthalate tetrasodium hexacyanoferrate tinidazole Voriconazole		
Amlodipine Besylate	Pharmaceutical	100%
clindamycin hydrochloride	Pharmaceutical	100%
clotiazepam	Pharmaceutical	100%
copper chlorophthalocyanine	Pharmaceutical	100%
Donepezil hydrochloride	Pharmaceutical	100%
doxepin hydrochloride	Pharmaceutical	100%
Fluconazone	Pharmaceutical	100%
glipizide	Pharmaceutical	100%
Cerium oxide isostearate	Vehicles, Machines and electronics: Durable material	20%
Cerium oxide isostearate	Cosmetics: Cosmetic	15%
Cerium oxide isostearate	Leather: Textile - Type 1	5%
Cerium oxide isostearate	Fuels: Fuel additive	15%
Cerium oxide isostearate	Lubricants & greases: Short lifetime	15%
Cerium oxide isostearate	Dye, Food Dye, Pigment: Durable material	15%
Cerium oxide isostearate	General Manufacturing: Durable material	15%
Cerium iron oxide isostearate	Vehicles, Machines and electronics: Durable material	20%
Cerium iron oxide isostearate	Cosmetics: Cosmetic	15%
Cerium iron oxide isostearate	Leather: Textile - Type 1	5%
Cerium iron oxide isostearate	Fuels: Fuel additive	15%
Cerium iron oxide isostearate	Lubricants & greases: Short lifetime	15%
Cerium iron oxide isostearate	Dye, Food Dye, Pigment: Durable material	15%
Cerium iron oxide isostearate	General Manufacturing: Durable material	15%
Iron oxide isostearate	Vehicles, Machines and electronics: Durable material	20%
Iron oxide isostearate	Cosmetics: Cosmetic	15%
Iron oxide isostearate	Leather: Textile - Type 1	5%
Iron oxide isostearate	Fuels: Fuel additive	15%
Iron oxide isostearate	Lubricants & greases: Short lifetime	15%
Iron oxide isostearate	Dye, Food Dye, Pigment: Durable material	15%
Iron oxide isostearate	General Manufacturing: Durable material	15%
Lactose	Pharmaceutical	100%
Liposome made of Fully hydrogenated soy phosphatidylcholine (HSPC) / Cholesterol / N-(Carbonylmethoxypolyethylene glycol 2000)-1,2-distearoylsn-glycero-3-phosphoethanolamine sodium salt (MPEG-DSPE)	Pharmaceutical	100%

Generic chemical name	Usage category	Estimated %
MAROPITANT CITRATE MONOHYDRATE	Pharmaceutical	100%
Lipid nanoparticle	Pharmaceutical	100%
SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA	Pharmaceutical	100%
OXYTETRACYCLINE DIHYDRATE	Pharmaceutical	100%
oxytetracycline hydrochloride	Pharmaceutical	100%
Piroxicam	Pharmaceutical	100%
Silane, dichlorodimethyl-,reaction products with silica	Plastics and rubber: Durable material	30%
Silane, dichlorodimethyl-,reaction products with silica	Industrial intermediate: R&D	35%
Silane, dichlorodimethyl-,reaction products with silica	Coating: Durable material	35%
Tulathromycin	Pharmaceutical	100%
Cerium gadolinium oxide	Catalysts: Durable material	100%
Products of R&D	R&D	100%
Sildenafil	Pharmaceutical	100%

Appendix 3 – Semiquantitative release inventory for Europe

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
aluminium hydroxide	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
aluminium hydroxide oxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
aluminium oxide	High	Medium	High	High	High	High	Medium	High	High	High	High	Medium	High	High	High
antimony nickel titanium oxide yellow	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
barium titanium trioxide	Low	Zero	Low	Zero	Low	Low	Zero	Low	Zero	Low	Low	Zero	Low	Zero	Low
Boehmite (Al(OH)O)	High	Medium	High	High	High	High	High	High	High	High	High	High	High	High	High
Calcium carbonate	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
calcium hydrogenorthophosphate	Low	Medium	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Medium	Low	Low	Low
Silicon carbide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Cerium dioxide	Medium	Low	Medium	Medium	Medium	Medium	Low	Medium	Medium	Medium	Medium	Low	Medium	Medium	Medium
cerium tetrahydroxide	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium
Cerium zirconium oxide	Low	Zero	Low	Zero	Low	Low	Zero	Low	Zero	Low	Low	Zero	Low	Zero	Low
Chromium iron oxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Cobalt aluminate blue spinel	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Copper (II) nitrate hydrate	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Copper oxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
diantimony pentoxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
diiron trioxide	Medium	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
Calcium strontium hydroxyapatite	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
iron hydroxide oxide	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
iron hydroxide oxide yellow	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
lanthanum phosphate	Low	Zero	Low	Zero	Low	Medium	Zero	Low	Zero	Low	Medium	Zero	Low	Zero	Low
Mixture of ceria and zirconia	Medium	Medium	Medium	Medium	Medium	High	Medium	Medium	High	High	High	Medium	High	High	High

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
nickel monoxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
pentacalcium hydroxide tris (orthophosphate)	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
Silicon dioxide, or variations of	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Bismuth oxyhalide solid solution	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
titanium dioxide	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
tricobalt tetraoxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
triiron tetraoxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
tungsten disulphide	Medium	Medium	Low	Zero	Low	Medium	Medium	Low	Zero	Low	Medium	Medium	Low	Zero	Low
tungsten trioxide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Yttrium zirconium oxide	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium
zinc oxide	Medium	High	High	Low	Low	High	High	High	Medium	Medium	High	High	High	Medium	Medium
silver	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
carbon	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Carbon black	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-Propenoic acid, 2-methyl-,methyl ester, polymer with 2-ethylhexyl 2-propenoate	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium	Medium
2-Propenoic acid, 2-methyl-,methyl ester, polymer with butyl 2-propenoate-ethenylbenzene	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-Propenoic acid, 2-methylmethyl ester, polymer with 1,3-butadiene-ethenylbenzene	Medium	Low	Low	Medium	Medium	Medium	Low	Medium	Medium	Medium	Medium	Low	Medium	Medium	Medium
2-Propenoic acid, 2-methylmethyl ester, polymer with 1,3-butadiene ethenylbenzene-ethyl-2-propenoate	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium	Low
2-Propenoic acid, 2-methylmethyl ester, polymer with 1,3-butadiene, butyl 2-propenoate-ethylbenzene	Medium	Low	Medium	Medium	Medium	Medium	Low	Medium	Medium	Medium	Medium	Low	Medium	Medium	Medium

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
Boron Nitride-Titanium Dioxide [nano]-Dimethicone-Isododecane-Ethylene/VA Copolymer	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Butadiene-butyl acrylate-ethyl acrylate-methyl methacrylate copolymer	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Cellulose	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Copolymer of vinylidene chloride	High	Medium	Medium	High	High	High	Medium	High	High	High	High	Medium	High	High	High
Emulsion of polysiloxanes	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Mica-Titanium Dioxide-Cyclopentasiloxane-Dimethicone-Isododecane-Ethylene/VA Copolymer	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Starch nanocrystals	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Poly 2,3-Dichloro-1,3-butadiene	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Poly(styrene-coacrylonitrile)	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low
Poly(tetrafluoroethylene)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Polyvinyl chloride	Medium	Medium	Medium	High	High	High	Medium	High	High	High	High	Medium	High	High	High
Polymethyl methacrylate	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
polystyrene based particles coated with anti-human CRP F(ab)2 fragments	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
polyvidone	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Styrene, oligomers	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Attapulgite	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium
Fuller's earth	Medium	Medium	Medium	Medium	Medium	High	High	Medium	Medium	Medium	High	High	Medium	Medium	Medium
Kaolin	Medium	Medium	High	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium	High	Medium	Medium
Montmorillonite	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	Medium	Low	Low	Zero	Low	Medium	Low	Low	Zero	Low	Medium	Low	Low	Zero	Low
Silicic acid, aluminum magnesium sodium salt	Medium	Medium	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
Silicic acid, aluminum sodium salt	Medium	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium
Silicic acid, calcium salt	Medium	Low	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium	Low	Low	Low	Low
Silicic acid, lithium magnesium sodium salt	Medium	Medium	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium	Medium	Low	Low	Low
Silicic acid, magnesium salt	High	High	High	High	High	High	High	High	High	High	High	High	High	High	High
Zirconium praseodymium yellow zircon	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
[1,3,8,16,18,24-hexabromo-2,4,9,10,11,15,17,22,23,25-decachloro-29H,31Hphthalocyaninato(2-)-N29,N30,N31,N32]copper	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
[1-[[(2-hydroxyphenyl)imino]methyl]-2-naphtholato(2-)-N,O,O']copper	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium
1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-(2-furoyl)piperazine monohydrochloride	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
1,1'-[(6-phenyl-1,3,5-triazine-2,4-diyl)diimino]bisanthraquinone	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
1-[(2,4-dinitrophenyl)azo]-2-naphthol	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	High	Medium	Medium
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methoxyphenyl)-3-oxobutyramide]	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
2,9-bis(3,5-dimethylphenyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2,9-dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low
2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-[(4-chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-Nphenylbutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-[(p-nitrophenyl)azo]acetoacetanilide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
,31Hphthalocyaninato(2-)-N29,N30,N31,N32 copper	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
29H,31H-Phthalocyanine	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12aoctahydro-3,5,10,12,12apentahydroxy-6-methyl-1,11-dioxo-,monohydrochloride, [4S-(4Î±,4aÎ±,5Î±,5aÎ±,6Î±,12aÎ±)]-	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3,3'-(1,4-phenylenediimino)bis[4,5,6,7-tetrachloro-1H-isoindol-1-one]	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
3,3'-[(2,5-dimethyl-pphenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(5-chloro-otolyl)benzamide]	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3,3'-[(2-chloro-5-methyl-pphenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(3-chloro-otolyl)benzamide]	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
3,3'-[(2-chloro-5-methyl-pphenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-[2-(4-chlorophenoxy)-5-(trifluoromethyl)phenyl]benzamide]	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3,4,5,6-tetrachloro-N-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolyl]phthalimide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3,6-bis(4-chlorophenyl)-1H,2H,4H,5H-pyrrolo[3,4-c]pyrrole-1,4-dione	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
3,6-Bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Medium	Medium	Medium	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	High	High	High	High
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	Medium	Medium	Medium	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium	High	Medium	Medium
3-[(4-chloro-2-nitrophenyl)azo]-2-methylpyrazolo[5,1-b]quinazolin-9(1H)-one	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3-hydroxy-4-[(2-methoxy-5-nitrophenyl)azo]-N-(3-nitrophenyl)naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3-hydroxy-4-[(2-methyl-4-nitrophenyl)azo]-N-(otolyl)naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
4,4'-diamino[1,1'-bianthracene]-9,9',10,10'-tetraone	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
4,5,6,7-tetrachloro-3-[[3-methyl-4-[[4-[(4,5,6,7-tetrachloro-1-oxo-1Hisoindol-3-yl)amino]phenyl]azo]phenyl]amino]-1H-isoindol-1-one	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
4-[(2,5-dichlorophenyl)azo]-3-hydroxy-Nphenylnaphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
4-[[4-(aminocarbonyl)phenyl]azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
4-[[4-(aminocarbonyl)phenyl]azo]-N-(2-ethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
4-[[5-[[[4-(aminocarbonyl)phenyl]amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
5,12-dihydro-2,9-dimethylquino-[2,3-b]acridine-7,14-dione	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low
5,12-dihydroquino[2,3-b]acridine-7,14-dione	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
5,5'-(1H-isoindole-1,3(2H)-diylidene)dibarbituric acid	Low	Low	Medium	Medium	Low	Medium	Medium	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium
5-[(2,3-dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl)azo]barbituric acid	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium
6,15-Dihydroanthrazine-5,9,14,18-tetrone	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium
8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Amlodipine Besylate	Low	Medium	Low	Zero	Low	Low	Medium	Low	Zero	Low	Low	Medium	Low	Zero	Low
ammonium iron(3+)hexakis(cyano-C)ferrate(4-)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
barium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-, N-Me derivatives,molybdatephosphates	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-, N-Me derivs.,molybdatetungstatephosphates;	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Benzenamine, N,Ndimethyl-,oxidized,molybdatetungstatephosphates	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
benzenamine, oxidized	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Benzoic acid, 2,3,4,5-tetrachloro-6-cyano-,methyl ester, reaction products with pphenylenediamine-sodium methoxide	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low
bis[[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthyl]methylene]cyclohexa-2,5-dien-1-ylidene]diethylammonium]dicopper(1+) hexa(cyano-C)ferrate(4-)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
C.I. Pigment Orange 72	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
C.I. Pigment Red 184	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
C.I. Pigment Red 49:2	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
calcium 4,5-dichloro-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulphonatophenyl)-1Hpyrazol-4-yl]azo]benzenesulphonate	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	Medium	High	High	High	High	High	High	High	High	High	High	High	High	High	High
clindamycin hydrochloride	Medium	High	Medium	Zero	Medium	Medium	High	High	Zero	Medium	Medium	High	High	Zero	Medium
clotiazepam	Low	Low	Low	Zero	Low	Low	Medium	Low	Zero	Low	Low	Low	Low	Zero	Low
copper chlorophthalocyanine	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
Copper, [29H,31Hphthalocyaninato(2-)-N29,N30,N31,N32]-,brominated chlorinated	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium	Low	Low

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
DANOFLOXACIN MESYLATE	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
diisopropyl 3,3'-[(2,5-dichloro-1,4-phenylene)bis[iminocarbonyl(2-hydroxy-3,1-naphthylene)azo]]bis[4-methylbenzoate]	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Low	Low
dimethyl 2-[[1-[[(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]terephthalate	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
DONEPEZIL HYDROCLORIDE (HCL)	Low	Low	Low	Zero	Low	Low	Medium	Medium	Zero	Low	Low	Medium	Low	Zero	Low
doxepin hydrochloride	Low	Low	Low	Zero	Low	Low	Medium	Low	Zero	Low	Low	Medium	Low	Zero	Low
Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-,molybdatetungstatephosphate	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
ferrate(4-), hexakis(cyano-C)-, methylated 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]benzenamine copper(2+) salts	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Fluconazole	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low
glipizide	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl)xanthylium, sodium salt	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
hydrogen bis[2-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]benzoato(2-)]chromate(1-), compound with 2-ethylhexylamine (1:1)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Cerium oxide isostearate	Medium	Medium	Low	Low	Low	High	Medium	Low	Low	Low	High	Medium	Low	Low	Low
Cerium and iron oxide isostearate	High	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium	High	Medium	Medium	Medium	Medium
Iron oxide isostearate	High	High	Medium	Medium	Medium	High	High	Medium	Medium	Medium	High	High	Medium	Medium	Medium
Lactose	Medium	High	Medium	Zero	Medium	Medium	High	High	Zero	Medium	Medium	High	High	Zero	Medium

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
Liposome based on fully hydrogenated soy phosphatidylcholine (HSPC) / Cholesterol / N-(Carbonylmethoxypolyethylene glycol 2000)-1,2-distearoylsn-glycero-3-phosphoethanolamine sodium salt (MPEG-DSPE)	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
manganese, 4-[(5-chloro-4-methyl-2-sulfophenyl)azo]-3-hydroxy-2-naphthalenecarboxylic acid complex	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low
Maropitant citrate monohydrate	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
methyl 4-[[(2,5-dichlorophenyl)amino]carbonyl]-2-[[2-hydroxy-3-[[(2-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]benzoate	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-2-[(4-nitrophenyl)azo]-3-oxobutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-methyl-4-[(methylamino)sulphonyl]phenyl]azo]naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(2,3-dihydro-2-oxo-1Hbenzimidazol-5-yl)-3-oxo-2-[[2-(trifluoromethyl)phenyl]azo]butyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(5-chloro-2-methoxyphenyl)-2-[(2-methoxy-4-nitrophenyl)azo]-3-oxobutyramide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N-(5-chloro-2-methylphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N,N'-(2-chloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	Low	Low	Low	Medium	Low	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium	Medium
N,N'-(3,3'-dimethyl[1,1'-biphenyl]-4,4'-diyl)bis[2-[(2,4-dichlorophenyl)azo]-3-oxobutyramide]	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
N,N'-[6,13-diacetamido-2,9-diethoxy-3,10-triphenodioxazinediyl]bis(benzamide)	Low	Low	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
N,N'-phenylene-1,4-bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
Lipidic nanoparticle	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Low	Low	Medium	Medium	Medium
Sodium propoxyhydroxypropyl thiosulfate silica	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low	Low	Low	Low	Zero	Low
oxytetracycline dihydrate	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low
oxytetracycline hydrochloride	Low	Medium	Low	Zero	Low	Low	Medium	Medium	Zero	Low	Low	Medium	Low	Zero	Low
piroxicam	Low	Low	Low	Zero	Low	Low	Medium	Low	Zero	Low	Low	Low	Low	Zero	Low
polychloro copper phthalocyanine	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Medium
Silane, dichlorodimethyl-,reaction products with silica	Medium	Low	Low	Low	Low	Medium	Low	Low	Low	Medium	Medium	Low	Low	Low	Medium
sodium bis[2,4-dihydro-4-[(2-hydroxy-5-nitrophenyl)azo]-5-methyl-2-phenyl-3H-pyrazol-3-onato(2-)]chromate(1-)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low

Generic name	2015					2025					2035				
	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste	Air	Land	Water	Recycle	Waste
sodium bis[3-[[1-(3-chlorophenyl)-4,5-dihydro-3-methyl-5-oxo-1H-pyrazol-4-yl]azo]-4-hydroxy-Nmethylbenzenesulphonamidato(2-)]cobaltate(1-)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
sodium bis[4-hydroxy-3-[(2-hydroxy-1-naphthyl)azo]-N-(3-methoxypropyl)benzene-1-sulphonamidato(2-)]chromate(1-)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
strontium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (1:1)	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
tetramethyl 2,2'-[1,4-phenylenebis[imino(1-acetyl-2-oxoethane-1,2-diyl)azo]]bisterephthalate	Low	Low	Low	Low	Low	Low	Low	Medium	Low	Low	Low	Low	Low	Low	Low
tetrasodium hexacyanoferrate	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
tinidazole	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Tulathromycin	Low	Medium	Low	Zero	Low	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low
Voriconazole	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
CGO	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Products of R&D	Low	Zero	Low	Zero	Low	Low	Zero	Low	Zero	Low	Low	Zero	Low	Zero	Low
Sildenafil	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low	Low	Medium	Medium	Zero	Low

Appendix 4 – Characteristics of key nanomaterials

Substance and CAS/EC number	Nanoform	Summary of selected information on potential human toxicity	Ref
Aluminium oxide CAS number: 1344-28-1 EC number: 215-691-6	Plate-like, powder, spherical or pseudo-spherical particles with size typically in the range 10 – 50 nm[30,36]	The key health effects of aluminium compounds are: irritation following inhalation, neurological effects due to drinking water exposure, reproductive toxicity due to oral intake, and irritation following injection. Neurological effects are of greatest concern. Aluminum and aluminum oxide particles are taken up in the cells. They tend to agglomerate unless stabilised by means of additives. The agglomerates, which can also be taken up in the cells, are found in vesicles, i.e. they do not occur freely in the cells and are practically never detected in the cell nucleus. The agglomerated particles can be detected by means of electron microscopy in the cell inclusions. The vesicle membrane protects the remaining cell components from the particles. Toxic properties are those of the chemical species, no data on nano-activity	32, 317
Boehmite (Al(OH)O) CAS number: 1318-23-6 EC number: 215-284-3	Plate-like or rod-like particles in the range 2 to 250 nm[30,36]	The key health effects of aluminium compounds are: irritation following inhalation, neurological effects due to drinking water exposure, reproductive toxicity due to oral intake, and irritation following injection. Neurological effects are of greatest concern. Aluminum and aluminum oxide particles are taken up in the cells. They tend to agglomerate unless stabilised by means of additives. The agglomerates, which can also be taken up in the cells, are found in vesicles, i.e. they do not occur freely in the cells and are practically never detected in the cell nucleus. The agglomerated particles can be detected by means of electron microscopy in the cell inclusions. The vesicle membrane protects the remaining cell components from the particles Toxic properties are those of the chemical species, no data on nano-activity No data on ecotoxicity	32, 317
Calcium carbonate CAS number: 471-34-1 EC number: 207-439-9	Rod-like, spherical, pseudo-spherical, cubic or hexagonal particles of size typically 10 - 80 nm[30,36,318]	Ref. 32 provides data on SrCO3: health hazards of CaCO3 may be similar in nature as chemical structures and properties are similar. Only very high doses of strontium carbonate (SrCO3) can cause cell stress and cause them to die off. Strontium carbonate particles in principle can be taken up by different cell types. No other uptake or behaviour data	32
Mixture of ceria and zirconia CAS number: 53169-24-7 EC number: TBC	Average ceria particle size is between 5 and 105 nm, with most registrations in the 10-20 nm range. Zirconia particle size may be between 20 nm and 150 nm particle size.[30] Nano active cerium oxide in dry powder form has a high specific surface area, and can be dispersed in various carrier fluids to reduce the particle size.	"Little information exists on the effects of cerium dioxide nanoparticles on humans or the environment. Literature sources show that there could be positive and negative effects. There is no danger associated with small amounts of cerium dioxide. Cerium dioxide (CeO2) particles can trigger different reactions in different cells … Inhaled cerium dioxide (CeO2) particles are deposited in the lung. CeO2 however may also serve as scavenger and reduce oxidative stress in the myocardial muscle." "In previous studies, cerium oxide nanoparticles (CeO2) were noticed as only slightly toxic towards environmental organisms." "Uptake of low concentrations of cerium dioxide (CeO2) nanoparticles in human lung cells was proved by means of diffusion … Inhaled cerium dioxide (CeO2) particles are deposited in the lung. No particles could be found in the brains of rats during in vivo tests." "Zirconium dioxide has been proven to have excellent compatibility with bones and the surrounding connective tissue. Likewise zirconium dioxide nanoparticles are non-toxic to other	32, 319

[317] Daniel Krewski, Robert A Yokel, Evert Nieboer, David Borchelt, Joshua Cohen, Jean Harry, Sam Kacew, Joan Lindsay, Amal M Mahfouz, and Virginie Rondeau, "Human health risk assessment for aluminium, aluminium oxide and aluminium hydroxide," J Toxicol Environ Health B Crit Rev. 2007 ; 10(Suppl 1): 1–269

[318] Data taken from https://www.americanelements.com/calcium-carbonate-nanoparticles-471-34-1

[319] MEMPRO Materials, "Material Safety Data Sheet: Ceria - Zirconia Mixed - Oxide Ceramic Nanofibers"

Substance and CAS/EC number	Nanoform	Summary of selected information on potential human toxicity	Ref
		environmental organisms such as bacteria, algae and zebra fish." "In vitro experiments using zirconium dioxide show, that these particles cause adverse effects only in very high doses."	
Silicon dioxide, or variations of CAS number: 7631-86-9 EC number: 231-545-4	May consist of spherical or pseudo-spherical nanoparticles; nanotubes, films, powder or rodlike nanoforms. Most particles in 10 – 30 nm size range[30,36]	"Nanoscaled silicon dioxide occurs almost exclusively in its unstructured amorphous form which so far hasn't shown any negative characteristics in all performed experiments from animal to environmental studies. Silicon is an essential ultra-trace element for the human body and silicon dioxide in its amorphous form is considered to be non-hazardous. On the other hand the crystalline version of silicon dioxide is known to be harmful to humans" "Silicon dioxide (SiO2) is a naturally occurring compound. Therefore it is difficult to distinguish between environmental exposure to engineered SiO2 and naturally occurring SiO2." "Histological studies upon intravenous treatment with silicon dioxide (SiO2) nanoparticles have not revealed any damage to the brains of mice … Agglomeration processes are important factors determining the behaviour of nanoparticles in the aqueous environment. Compared to other nanoparticles, stability of silicon dioxide (SiO2) nanoparticles in aqueous solutions is exceptionally high."	32
		"To compare the pulmonary toxicity between ultrafine colloidal silica particles (UFCSs) and fine colloidal silica particles (FCSs), mice were intratracheally instilled with 3 mg of 14 nm UFCSs and 230 nm FCSs. Histopathologically, lungs exposed to both sizes of particles showed bronchiolar degeneration and necrosis, neutrophilic inflammation in alveoli with alveolar type II cell swelling and particle-laden alveolar macrophage accumulation. UFCSs, however, induced extensive alveolar hemorrhage compared to FCSs from 30 minutes onwards. UFCSs also caused more severe bronchiolar epithelial cell necrosis and neutrophil influx in alveoli than FCSs at 12 and 24 hours postexposure. These findings suggest that UFCSs have greater ability to induce lung inflammation and tissue damages than FCSs"	34
Titanium dioxide CAS number: 13463-67-7 EC number: 236-675-5	Rodlike, spherical, powder or star-shaped nanoforms. Most particles in 30 – 50 nm size range[30,36]	"There is no significant evidence for a nano-specific risk … Only very high concentrations of titanium dioxide show toxic effects. This means that inhalation of titanium dioxide particles, as for all dusty particles, should be avoided even though there is no evidence for significant impairment of the human lung. If swallowed titanium dioxide nanoparticles are not toxic." "Administration of very high doses of nanoscale titanium dioxide (TiO2) causes damage to cells. There are no such high doses in everyday life though." "In vitro studies of lung cells and in vivo studies of test animals have shown that certain doses of titanium dioxide (TiO2) particles may cause damage to the lung or lung cells … Different studies carried out in the recent years have shown that titanium dioxide (TiO2) does not penetrate skin and enter the body" "titanium dioxide (TiO2) particles regardless of their size do not dissolve" Risk of pulmonary inflammation if respired. More demanding exposure guideline set in the US for nano-scale titanium dioxide in view of potential carcinogenic activity. Safety Data Sheet highlights that the chemical, physical and toxicological properties of ceramic nanofibers have not been thoroughly investigated and recorded. However, various toxicological studies indicate that titanium dioxide microfibers show no fibrogenic, carcinogenic or other significant toxicological effects when exposure occurs by relevant routes. Despite his evidence, the IARC has placed Alumina Fiber into a broad group called ceramic fibers. Repeated or prolonged exposure may result in damage to target organs.	32, 39, 34,43, 319
		"Abstract: Anatase-sized (10 and 20 nm) TiO2 particles in the absence of photoactivation induced oxidative DNA damage, lipid peroxidation, and micronuclei formation, and increased hydrogen peroxide and nitric oxide production in BEAS-2B cells, a human	34

Substance and CAS/EC number	Nanoform	Summary of selected information on potential human toxicity	Ref
Zinc oxide CAS number: 1314-13-2 EC number: 215-222-5	Rodlike, spherical, star or kidney-shaped nanoforms. Most particles in 10 – 30 nm size range[30 36]	bronchial epithelial cell line."	
		"Zinc as well as zinc oxide nanoparticles have a positive effect on the human body since zinc is involved in the regulation of many important biological processes. Therefore it is used in zinc ointments and other medical products. But if zinc is applied in high concentrations or in the wrong place (e.g. zinc oxide nanoparticles in the lung) it may have toxics effects causing cell death (zinc fever)." "Most of the in vitro studies carried out reveal a relatively high toxicity of zinc oxide (ZnO) nanoparticles for cells of different tissues and different organisms." " The size of the ZnO particles used in suncreams is in the range of 20 to 60 nm. Before being added, these very small nanoparticles are coated with silicon or aluminum oxide to clog up to form aggregates sized 200 to 500 nm. "Studies have shown that such particles do not get into the body through the healthy skin. Hence, the users of such sun protection products do not incur health risks. Most of the studies carried out so far, however, were based on cell cultures or animal models. Some recent tests of ZnO-containing suncreams on humans under realistic conditions, indeed, revealed small quantities of marked zinc in the blood and urine [3]. The quantities detected only amounted to 1/1000 of the zinc concentration naturally occurring in the blood. It remains to be found out whether zinc was taken up via the skin as ZnO particles or dissolved zinc ions."	32
		Agglomerated spheres, crystalline, "The purpose of this study is to evaluate the acute toxicity of oral exposure to nanoscale zinc powder in mice.The healthy adult male and female mice were gastro-intestinally administered at a dose of 5 g/kg body weight with two size particles, nanoscale zinc (N-Zn) and microscale zinc (M-Zn) powder. The N-Zn treated mice showed more severe symptoms of lethargy, vomiting and diarrhea in the beginning days than the M-Zn mice. Deaths of two mice occurred in the N-Zn group after the first week of treatment. The mortalities were confirmed by intestinal obstruction of the nanoscale zinc aggregation."	34
Carbon black CAS number: 1333-86-4 EC number: 215-609-9	Carbon black nanoparticles are normally only present during the manufacturing process. Carbon black consists of more than 96% amorphous carbon and of small quantities of oxygen, hydrogen, nitrogen, and sulphur. Most of these elements are concentrated on the surface. It is produced from small spherical particles with sizes in the range of 15–300 nm, typically spherical, pseudo-spherical or star-shaped nanoforms.[36] These particles melt into aggregates of 85–500 nm in aerodynamic diameter.[32] On the basis of their primary particle size, all Carbon Black materials are considered as nano-structured materials.[44]	"Carbon Black (CB) is a specific type of elemental carbon in the form of colloidal particles that is generated or produced through incomplete combustion processes or the thermal decomposition of gaseous or liquid hydrocarbons under controlled conditions" "Carbon black nanoparticles of high purity cause responses in organisms only at very high concentrations which are considered to be environmentally unrealistic. However, carbon black may contain contaminants either in the carbon material or on the surface of the particles themselves. Fine dust particles (from sources such as industry exhaust gases, car exhausts and cigarette smoking) consist of amorphous carbon and these particles may be loaded with other chemicals." "In cell culture systems, the addition of medium doses of Carbon Black (CB) induces the formation of reactive oxygen species (ROS) while high doses decrease the viability of the cells." "Nanoscale Carbon Black (CB) particles can be taken up into cells … Administration of Carbon Black (CB) suspensions through the nose of mice causes inflammation of the olfactory nerve … Carbon Black (CB) has the ability to excellently bind many organic substances." This process also happens in the environment.	32
		"On the basis of the available evidence, the SCCS has concluded that the use of carbon black CI 77266 in nano-structured form, with a size of 20 nm or larger at a concentration up to 10% as a colorant in cosmetic products, is considered to not pose any risk of adverse effects in humans after application on healthy, intact skin. This opinion, however, does not apply to applications that might lead to inhalation exposure to carbon black nanoparticles, where the preparation might lead to inhalable particles."	44

Substance and CAS/EC number	Nanoform	Summary of selected information on potential human toxicity	Ref
Copolymer of vinylidene chloride CAS number: 9002-86-2 EC number: None	Likely to be composite with e.g. nano CaCO3, so PVC not in nano form	No data specific to nanoform Likely to be composite with e.g. nano CaCO3, so PVC not in nano form	
Polyvinyl chloride CAS number: 9002-86-2 EC number: None	Likely to be composite with e.g. nano CaCO3, so PVC not in nano form	No data specific to nanoform No information on health impacts specific to nano form of this substance. It is unclear why only a marginal share of PVC production was reported to the French registry. The only PVC form in sub-micron particles are "plastisols", but nanoparticles would not be generated by this route. Advances in metrology may enable PVC to be eliminated from the list. Alternatively, PVC may have been listed as it is used as a composite with e.g. nano CaCO3, so PVC would not be in nano form	
Fuller's earth CAS number: 8031-18-3 EC number: None	No specific data found. May be similar to montmorillonite which consists of c.1 nm thick aluminosilicate layers surface-substituted with metal cations and stacked in c.10 µm-sized multilayer stacks[320]	No data specific to nanoform ECHA infocard indicates that Fuller's Earth is harmful if swallowed, but no significant health risks from likely exposures to nanoform.	
Kaolin CAS number: 1332-58-7 EC number: 8031-18-3	"Hyper-platy, nano-dimensional thickness crystals" are used to provide water resistant packaging.[321]	No data specific to nanoform ECHA infocard indicates that kaolin may cause skin or eye irritation. It is understood that there was some uncertainty regarding conformance of kaolins with the French definition. Consequently, a marginal share of production volume was reported.	
Silicic acid, aluminium sodium salt CAS Number: 1344-00-9 EC Number: 215-684-8	Likely to be similar to silica	Likely to be similar to amorphous silica (see above)	
Silicic acid, magnesium salt CAS Number: 1343-88-0 EC Number: 215-681-1	Likely to be similar to silica	Likely to be similar to amorphous silica (see above)	
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide] CAS number: 5102-83-0 EC number: 225-822-9	Irregularly shaped particles with diameter distributed from c. 1000 nm to c. 20 nm.[322] Particles are normally embedded in the ink polymer or product matrix.	Hoffman et al. found no significant acute effects from inhalation of 5 organic and 2 inorganic (iron oxide based) pigments. Safety Data Sheets indicate no acute toxicity concerns with regard to size-unspecified material. No evidence for specific toxicity of nano form.	323
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide] CAS number: 5567-15-7 EC number: 226-939-8			

[320] Product data from http://www.sigmaaldrich.com/materials-science/nanomaterials/nanoclay-building.html
[321] Product data from http://www.imerys-perfmins.com/pdf/Barrisurf-Technical.pdf
[322] Matthias Henker, Michael Becker, Sarah-Lisa Theisen and Martin Schleß, "Nanoscale pigment particles: Analysis of the migration behaviour from printing ink layers of printed food packaging into the food" (2013) available from: http://www.eupia.org/uploads/tx_edm/DLR_nanoscale_pigment_particles.pdf
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Substance and CAS/EC number	Nanoform	Summary of selected information on potential human toxicity	Ref
3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione CAS Number: 413-920-6 EC Number: None			
3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione CAS Number: 54660-00-3 EC Number: 601-713-5			
Calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate CAS number: 7023-61-2 EC number: 230-303-5			
Clindamycin hydrochloride CAS number: 21462-39-5 EC number: 244-398-6	No data found	Used as an antibacterial agent. Nano form is designed to enhance delivery to affected site. No evidence for specific toxicity of nano form.	
Cerium oxide isostearate CAS number: None EC number: None	Most cerium oxide particles in 10 – 20 nm size range, spherical or pseudo-spherical.[30,36]	"Little information exists on the effects of cerium dioxide nanoparticles on humans or the environment. Literature sources show that there could be positive and negative effects. There is no danger associated with small amounts of cerium dioxide."	
Cerium and iron oxide isostearate CAS number: None EC number: None	Most cerium oxide particles in 10 – 20 nm size range. Most iron oxide particles in 5 to 50 nm size range[30]	"Cerium dioxide (CeO2) particles can trigger different reactions in different cells … Inhaled cerium dioxide (CeO2) particles are deposited in the lung. CeO2 however may also serve as scavenger and reduce oxidative stress in the myocardial muscle." "In previous studies, cerium oxide nanoparticles (CeO2) were noticed as only slightly toxic towards environmental organisms." "Uptake of low concentrations of cerium dioxide (CeO2) nanoparticles in human lung cells was proved by means of diffusion … Inhaled cerium dioxide (CeO2) particles are deposited in the lung. No particles could be found in the brains of rats during in vivo tests."	
Iron oxide isostearate CAS number: None EC number: None	Most iron oxide particles in 5 to 50 nm size range, spherical, pseudo-spherical or star-shaped.[30, 36]	Likely to be be similar to discussion of cerium and iron oxide isostearate above.	
Lactose CAS number: 63-42-3 EC number: 200-559-2	No data found	Used as a pharmaceutical to aid digestion of dairy products. Nano form is designed to enhance delivery to affected site. No evidence for specific toxicity of nano form.	
Silver CAS number: 7440-22-4 EC number: 231-131-3	Most silver particles in <50 nm size range. [30]	"Small amounts of silver nanoparticles are non-hazardous for humans. Only high concentrations of silver nanoparticles could be expected to cause adverse health effects in the human body. At present there is no evidence of risk to the environment but the hazard potential for the environment is likely to be higher as some animal species, notably fish are especially sensitive to silver." "Silver nanoparticles are able to release silver ions outside and/or inside a cell leading to the generation of oxidative stress, dose-dependent reduced cell division or ultimately to cell death … Rodent studies show that silver nanoparticles administered in low doses cause no adverse health effects, although silver could be detected in the organs regardless of the route of exposure. Likewise, the first studies on volunteers with commercially available nano silver products displayed no adverse health effects" "The lung plays a major role as potential uptake pathway of silver nanoparticles via inhalation, as these ultrafine particles may reach the deeper regions of the lung and enter into the bloodstream. Silver and its compounds are taken up by	32

Substance and CAS/EC number	Nanoform	Summary of selected information on potential human toxicity	Ref
		environmental organisms (e.g. mussels, fish) and accumulate in body tissues." "Silver nanoparticles can be absorbed by the body and after overcoming the body barriers – either as nanoparticles or ions – can be transported through the body and accumulate in the organs."	
		A detailed risk assessment of nanosilver has not been performed since too little information is available. … There is a paucity of information on potential resistance mechanisms to Ag-NP. Some of the genetic basis of bacterial resistance to ionic silver has been well documented, notably the expression of well characterised efflux systems. Recent transcriptomic and proteomic data suggest that a decrease in oxidative damage by regulation of anaerobic respiration may be important. Exposure to ionic silver and Ag-NP produces a stress-response and affects gene expression. More data is needed to better understand bacterial response to ionic silver and Ag-NP exposure. Regarding the hazard associated with the dissemination of resistance mechanism following the use of Ag-NP, no documentation is available at this moment. This represents a serious gap in knowledge.	45
Carbon nanofibers, Carbon nanotubes multi-walled, Graphite CAS number: 308068-56-6 EC number: 231-153-3	75% of MWCNT registrations are in the <50 nm size range[30]	"Due to their long and fibre-like structure carbon nanotubes may elicit fibre-like (adverse) biological effects in the lung" "It is not possible to make a general statement on the behaviour of carbon nanotubes once within the body due to numerous differences of used CNTs, various applications and analytical methods … Carbon nanotubes (CNTs) can be internalised through different mechanisms by cells. With the exception of extremely long and stiff carbon nanotubes, internalised CNTs seem to have no significant impact on the cells." Rigid, needle-like MWCNTs with a diameter of >50 nm pose a hazard of causing asthma-like inflammation and DNA damage in the lungs. Thinner (diameter ~ 8-15 nm), tangled MWCNTs do not have such effects. Conflicting evidence on the relative potency of nanomaterials compared to micro-sized particles.[39]	32
Piroxicam CAS number: 36322-90-4 EC number: 252-974-3	No data found	Safety data sheet indicates some health hazards associated with size-unspecified form. No indication of chronic hazards. No evidence for specific toxicity of nano form.	

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