elni REVIEW

No2/2012

ISSN 1618-2502

ENVIRONMENTAL LAW NETWORK INTERNATIONAL

RÉSEAU INTERNATIONAL DE DROIT DE L´ENVIRONNEMENT

INTERNATIONALES NETZWERK UMWELTRECHT

elni REVIEW

CONTENTS

Editorial

Water is a precondition for human, animal and plant life as well as an indispensable resource for the economy. Thus, according to the *European Commission* the protection of water resources, of fresh and salt water ecosystems and of the water we drink and bathe in is therefore one of the cornerstones of environmental protection in Europe. Against this background the present issue of *elni Review* focuses on the legal framework for (the protection of) water in Europe and explains, among other things, how far it can cope with possible threats from emerging technologies and to what extent some of the legislation has been implemented in specific member States of the EU. Moreover, insights are provided into some new political or scientific initiatives to further develop the legal framework for protecting water.

First off, *Catherine Ganzleben* and *Steffen Foss Hansen* examine whether Directive 2000/60/EC ('Water Framework Directive', WFD), which aims to reduce and minimise the concentrations of dangerous chemicals in European waters, and related legal requirements include the right instruments to capture nanomaterials. They also consider whether techniques are available to allow for monitoring nanomaterials in surface waters and review data from modelling exercises that estimate concentrations of nanomaterials in EU waters.

Subsequently, *Ana Barreira* provides an overview of the main elements of the Union's Marine Strategy Framework Directive (MSFD) and analyses how Spain, as an EU country with 8000 km of coastal fringe, is complying with the directive and will review its marine governance framework.

The third article is by *Thomas Ormond* and takes another perspective, evaluating how far international and European legal instruments for the regulation of ship dismantling (potentially) ensure the safe and environmentally sound recycling of European ships in regions like South Asia.

Sarolta Tripolszky explains the concept of the term 'water services' in her contribution and outlines the economic and legal consequences of a narrow and broad definition. In this context and with specific reference to a collective complaint started by the NGOs EEB and WWF in 2006 against 11 EU member states to enforce the correct implementation of the WFD, she also describes the development of this legal instrument.

The final article with a focus on water is by *Marga Robesin* and describes current discussions on the question of how to achieve substantial water footprint reduction, focusing in particular on certification and labelling.

A second series of contributions to this issue of the *elni Review* covers a variety of other up-to-date legal issues, including the advancement and legal implementation of the concept of 'sustainable development'. To this end, *Eckard Rehbinder*, who attended the United Nations Conference on Sustainable Development (Rio+20) in Rio de Janeiro in June 2012, shares some critical comments on the summit outcome.

The following contribution by *Peter de Smedt, Hendrik Schoukens* and *Tania Van Laer* examines the anchoring of sustainable development in the Belgian Constitution, discusses the concept's juridical enforceability and subsequently analyses the consequences of this qualification for the application in the jurisprudence.

In a further article *Julian Schenten* and *Martin Führ* present empirical data obtained by several survey methods focusing on companies which manufacture and/or use nanomaterials. They analyse the findings under the perspective of the degree to which REACH (Regulation EC 1907/2006) promotes innovations for sustainability in the field of nanomaterials.

In June 2012 the EU General Court adopted long awaited decisions in two cases in which it interprets for the first time Regulation 1367/2006 ('Aarhus Regulation') – *Anaïs Berthier* examines what real added value these two decisions have with regards to access to justice.

Finally, in a statement by *Almut Gaude* from BUND, the German branch of Friends of the Earth (FoE), the NGO expresses its perspective on the Rio+20 conference outcome.

We hope you enjoy reading the current journal. Contributions for the next issue of the *elni Review* are very welcome and may be sent to the editors by mid-February 2013.

Julian Schenten/Martin Führ

Nanomaterials as priority substances under the Water Framework Directive

Catherine Ganzleben and Steffen Foss Hansen

1 Introduction

Nanomaterials are particles in the nano-scale that may be manufactured, occur naturally or be produced unintentionally through processes such as combustion.[1] This article focuses on nanomaterials that are a designed product of a deliberate manufacturing process, commonly referred to as 'engineered' nanomaterials (ENM). The scale of application of nanomaterials is very broad with ENM used in a wide range of industrial sectors, including healthcare, agriculture, transport, energy, materials and information and communication technologies. A recent European Commission Staff Working Paper[2] reviewed the applications of nanomaterials and presented industry estimates of the global volume of nanomaterials on the market at 11.5 million tonnes, with a market value of approx. €20 billion. Although the recent economic decline impacts upon industrial sectors involving nanomaterials, recovery is expected to be rapid.[3]

Concentrations of substances manufactured by man in the environment have been found to increase in direct proportion to their use in society[4]. We can therefore expect increasing environmental exposure to ENM in surface waters, air, groundwater and soils,[5] as well as human exposure via the environment. With regards to surface waters, relevant exposure pathways include both point and diffuse source emissions. Point source emissions include effluents released from urban waste water treatment plants and manufacturing installations, as well as the direct use of nanomaterials in environmental remediation of soils and water. Diffuse sources include emissions along the product lifecycle, including waste disposal in landfills and transport in leachate, as well as the spreading of sewage sludge on land and subsequent seepage into water bodies.

While Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[6] deals with the manufacturing and import of chemicals, the Directive 2000/60/EC establishing a framework for Community action in the field of water policy[7] (hereafter WFD) aims to reduce and minimise the concentrations of dangerous chemicals in European waters. Chemical pollutants of EU-wide concern are identified as 'priority substances' and their discharge, emissions and losses are targeted for progressive reduction. No nanomaterials are included in the current list of priority substances and nanoforms of listed substances are not given specific consideration. At the same time, based on the size of the market for nanomaterials and the wide range of application, we can expect that nanomaterials are making their way into European Waters.

In a Communication published on 3 October 2012 entitled the 'Second Regulatory Review on Nanomaterials',[8] the European Commission made a specific reference to the WFD, noting that "*revisions of the selection process for priority substances under the water legislation [..] incorporating various nanomaterial aspects, are already being pursued.*" In this article, we review the procedures for identifying priority substances under the WFD and consider whether they can capture nanomaterials. We also consider whether techniques are available to allow for monitoring nanomaterials in surface waters and review data from modelling exercises that estimate concentrations of nanomaterials in EU waters.

2 WFD goals regarding chemical pollution

The WFD aims to protect surface waters, transitional waters, coastal waters and groundwater, to promote long-term sustainable water use, to prevent the further

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1 Commission Recommendation of 18 October 2011 on the definition of nanomaterial 2011/696/EU (Official Journal L 275 , 20/10/2011 pp.38–40) provides a definition of the term nanomaterial intended for use under specific legislative provisions, and states that "'*nanomaterial' means 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.*" However, this definition is considered more relevant for products containing nanomaterials and less relevant for nanomaterials released into environmental media.

2 European Commission, 2012, Commission Staff Working Paper, Types and uses of nanomaterials, including safety aspects.

3 Stefan Schlag, Bala Suresh, Masahiro Yoneyama and Vivien Yang, 2012, Nanoscale chemicals and materials, HIS Chemicals.

4 Wiesner M, Characklis G & Brejchova D, 1998, Metals in Surface Waters, in eds., Allen H Garrison A and Luther GL, Ann Arbor Press, Ann Arbor, MI, 1998.

5 US House Committee on Science, Hearing on Societal Implications of Nanotechnology, April 9, 2003, 108th Congress, House Committee on Science, Washington, DC, 2003.

6 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, pp. 3-280.

7 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, pp. 1-82.

8 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.

deterioration and to protect and enhance the status of aquatic ecosystems. The WFD aims to control and reduce chemical pollution of surface waters and sets a goal of 2015 for achieving 'good surface water status' in the EU, with a final deadline of 2027. Achieving 'good surface water status'[9] includes the requirement for surface waters to show 'good chemical status' as well as 'good ecological status'. This article focuses principally on the mechanisms in place under the WFD to promote good chemical status for surface waters and asks whether nanomaterials can be captured under those mechanisms.

2.1 *Priority substances*

The key mechanisms with which the WFD addresses chemical pollution of surface waters is through the selection and regulation of substances of EU-wide concern, known as priority substances. The identification of pollutants posing a risk to or via aquatic environment and their categorisation as priority substances is foreseen under Article 16 of the WFD. As a first step in 2001, Decision 2455//2001/EC[10] established a list of 33 priority substances. In 2008, this was replaced by Directive 2008/105/EC on environmental quality standards (EQS) in their field of water policy (EQSD)[11] which confirmed the designation of the 33 substances as priority or priority hazardous substances[12] and set EQS for those substances. The EQSD also includes EQS for eight other pollutants previously regulated under earlier pieces of legislation in surface waters. Some priority substances are identified as priority hazardous substances because of their persistence, bioaccumulation and/or toxicity or equivalent level of concern, criteria consistent with the criteria for Substances of Very High Concern (SVHCs) under REACH. The current 33 priority substances include a range of industrial chemicals, plant protection products and metals/metal compounds, with no nanoforms of these substances or specific nanomaterials included.

A good chemical status is reached for a surface water body when it meets the EQS set for all the priority substances and for eight other pollutants listed in Annex I of the EQSD. Member States are required to monitor priority substances in surface water bodies, and to report exceedances to the Commission. They are also required to take action to meet the quality standards in the EQSD by 2015. To this end, a programme of measures for the progressive reduction of discharges, emissions and losses of priority substances and the cessation or phasing-out of discharges emissions and losses of priority hazardous substances should have been made operational by 2012.

The WFD (Art. 16(4)) requires the Commission to review the list of priority substances at least every four years and in 2012 the Commission put forward a proposal for a Directive amending the WFD and the EQSD as regards priority substances in the field of water policy[13]. The proposal includes an additional 15 priority substances, six of which are designated as priority hazardous substances. No nanomaterials are included in the proposal.

As mentioned above, nanomaterials are included neither as priority substances under the EQSD, nor in the 2012 proposal. However, given the concerns expressed in the literature regarding environmental exposure to nanomaterials in European waters, it is relevant to consider whether the procedures used to select substances as priority substances *could* be applied to ENM.

3 Methodology for identifying priority substances

Art. 16(2) of the WFD sets out strategies for combating pollution and calls for a science-based methodology for selecting priority substances on the basis of their significant risk to or via the aquatic environment. The risk-based assessment methodology should take 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 the monitoring of widespread environmental contamination; and
– other proven factors which may indicate the possibility of widespread environmental contamination, such as production, use volume and use pattern of the substance concerned.

On this basis, the European Commission developed the Combined Monitoring-based and Modelling-based Priority Setting (COMMPS) scheme, in collaboration with experts from interested parties[14]. The COMMPS

9 As defined under Art. 2(18) of the WFD.

10 Decision 2455//2001/EC establishing a list of priority substances, OJ L 331, 15.12.2001, p. 1-5.

11 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, OJ L 348, 24.12.2008, p. 84.

12 Priority Hazardous Substances are substances that have been selected from the priority substances due to their persistency, toxicity and liability to bioaccumulate (PTBs), or due to their exhibiting properties which give rise to 'equivalent level of concern'.

13 Proposal for a Directive amending the WFD and EQSD (COM(2011)876).

14 Klein, W., Denzer, S., Herrchen, M., Lepper, P., Muller, M., Sehrt, R., Storm, A., Volmer, J. 1999. Final Report Revised Proposal for a List Priority Substances in the Context of the Water Framework Directive (COMMPS

scheme is a so-called scoring method in which functional relationship and weight factor are combined into one or more ranking lists of substances[15]. The 2008 list of 33 priority substances was developed using this scheme.

However, the COMMPS scheme was subsequently criticised by the Scientific Committee on Health, Toxicity, Ecotoxicity and the Environment (CSTEE) as relying too heavily on monitoring data, in a context where the available datasets are incomplete and cover only those substances that were considered historically relevant to monitor. As such, the CSTEE argued that the resulting list of priority substances cannot faithfully represent the current water pollution problems and that a second system should be incorporated "*to allow inclusion in the final list of substances with a high potential risk for aquatic organisms for which no monitoring information is available to date*"[16].

Nanomaterials represent a series of emerging pollutants for which historical dataset are not available and hence this change is highly relevant. Hansen et al (2011)[17] reviewed the applicability of the COMMPS procedure to nanomaterials and concluded that most nanomaterials would never even be considered under the procedure, due to the focus on well-documented pollutants and the heavy reliance on monitoring and modelling data.

The approach adopted for the second list of priority substances was somewhat broader[18] and involved a combination of five parallel approaches to generate separate but complementary lists of substances, from which those substances included in the final proposal were drawn under expert review. The five approaches to prioritising substances are considered briefly below, together with an indication of the relevance of each approach to nanomaterials.

3.1 Hazardous properties

The approach considered least likely to apply to nanomaterials focused specifically on priority hazardous substances, listing substances exhibiting hazardous properties relevant to the aquatic environment and already identified substances classified as or proposed as (i.e. on the candidate list) substances of very high concern (SVHC) under REACH, under the Stockholm Convention on Persistent Organic Pollutants[19], and PBTs identified under Existing Substances Regulation (EEC) No.793/93[20]. To date, this does not include any nanomaterials.

3.2 Targeted risk assessments

This approach replied on targeted risk assessments that had been voluntarily undertaken and focused on two specific substances, neither of which were nanomaterials. However, should a Member State or other stakeholder take the initiative to undertake a voluntary risk assessment targeted to a specific nanomaterial that they consider to be of concern, it may be possible to bring the nanomaterial on to the shortlist for priority substances via this channel, should the evidence of risk be convincing.

3.3 Other sources

Another approach through which a specific nanomaterial could theoretically be proposed involved the consideration of other sources. This included those substances listed under Annex III of the EQSD, as well as substances of concern proposed by Member States and by a non-governmental organisation, the European Environmental Bureau. Neither of these sources included any nanomaterials specifically, although Annex III includes several metals of which nanoforms exist. The opportunity for Member States and other stakeholders to propose substances of concern, backed up with supporting evidence, may also provide a future avenue for specific nanomaterials, should reliable evidence become available.

3.4 EU-Level risk assessments

A fourth approach that may capture nanomaterials in the future relied on EU-level risk assessments carried out under the Existing Substances Regulation (EEC) No.793/93, the Plant Protection Products legislation Directive 91/414/EEC (Regulation (EC) No1107/2009) and Biocides Directive 98/8/EC. Given that no nanomaterial had been reviewed under these pieces of legislation at the time of short-listing, this could not provide an avenue for a nanomaterial to enter into the procedure. However, legislation on biocides has subsequently been reviewed and on 22 May 2012 the revised regulation concerning the

Procedure). Declaration ref.: 98/788/3040/DEB/E1. Schmallenberg: Fraunhofer-Institut.

15 Lerche, D., Sørensen, P.B., Larsen, H.S., Carlsen, L., Nielsen, O.J. 2002. Comparison of the combined monitoring-based and modelling-based priority setting scheme with partial order theory and random linear extensions for ranking of chemical substances. Chemosphere 49(6): 637-649.

16 INERIS-International Office for Water. 2009. Implementation of requirements on Priority substances within the Context of the Water Framework Directive (contract 07010401/2008/508122/ADA/D2). Prioritisation process: Monitoring-based ranking.

17 Hansen, S.F., Ganzleben, C., Baun, A. 2011. Nanomaterials and the European Water Framework Directive, European Journal of Law and Technology, Vol 2(3).

18 The approach is presented in Commission Staff Working Paper, Technical Background, SEC(2011) 1544 final.

19 UNEP, 2009, Stockholm Convention on Persistent Organic Pollutants (POPs), 2009 revised text and annexes, available online at: http://chm.pops.int.

20 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L084 , 05/04/1993, pp.1-75.

placing on the market and use of biocidal products was adopted[21]. The regulation will take effect from 1 September 2013, with a transitional period for certain provisions. The regulation is the first piece of legislation to incorporate Commission Recommendation 2011/696/ EU on the definition of a nanomaterial[22]. Importantly, the Regulation requires that, when nanomaterials are used in a product, the risk to human health, animal health and the environment be assessed under a separate risk assessment specific to the nanoform. We can therefore expect the generation of risk assessments under the new Biocides Regulation, which may then serve as an avenue for bringing nanomaterials into consideration as priority substances.

3.5 Simplified risk-based assessment

The final approach involved the use of a simplified risk-based assessment procedure, the approach that builds on exposure data to systematically review substances without being reliant upon a champion for a specific substance. Due to this apparent breadth, we will investigate the approach and its potential application to nanomaterials in greater depth. The procedure essentially included two distinct approaches, a monitoring-based methodology and a modelling-based methodology. Both approaches entail an assessment of exposure data and ecotoxicity data, with substances ranked in terms of their risk ratio (Predicted Environmental Concentration/Predicted No-Effect Concentration). The crucial difference relates to the type of exposure data used, be it monitoring or modelling data. The two methodologies and their application to nanomaterials are discussed below.

3.5.1 Monitoring-based approach

The monitoring-based methodology for the identification of priority substances used direct evidence of the presence of substances in the environment by drawing on environmental exposure data from analytical measurement techniques applied to water, sediment and biota samples from rivers, lakes, transitional and coastal waters. Here, we consider the main elements of the monitoring-based approach and discuss whether they might be applied to nanomaterials.

Monitoring is conducted by Member States in fulfilment of their monitoring requirements under the WFD[23]. In the WFD, requirements for monitoring are set out in Article 8 and Annex V, and require Member States to carry out surveillance monitoring and operational monitoring programmes and where relevant, investigative monitoring of chemical status. In terms of the quality elements to monitor, Article 8 and Annex V of the WFD require that Member States monitor all priority substances and other pollutants discharged in significant quantities.

Raw monitoring datasets have been submitted by all Member States (except Malta), with reported data including 14.6 million analyses from 19,900 stations in 28 countries (EU Member States plus Norway) and covering 1,151 substances. As an initial ranking step, substances had to be monitored in at least four countries to be selected for further consideration, eliminating all but 316 substances.

EU-wide exposure data is not available for any nanomaterial; indeed at this point in time no Member State is monitoring nanomaterials within the regulatory context of the WFD. Regarding progress to date in the detection and analysis of ENM in aquatic systems, researchers consistently report that undertaking reliable measurements of ENM in natural waters is a challenging task.[24] Key methodological issues include how to ensure the comparability and reproducibility in analytical determinations and how to adapt protocols to specific ‘nano’ properties in contrast to soluble compounds[25]. Researchers report challenges in distinguishing ENM from the high background of natural and incidental nanoparticles,[26] problems with the insensitivity of current detection methods to the low concentrations of nanomaterials (relevant concentrations may be in the range of µg L-1–pg L-1), and difficulties in isolating the nanomaterials fraction in water[27]. In addition, it is important to recognize that even the slightest change in physico-chemical properties can make two nanomaterials of the same molecular form very

21 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L167/55, 1-123.

22 Commission Recommendation of 18 October 2011 on the definition of nanomaterial, OJ L275/38.

23 INERIS-International Office for Water. 2009. Implementation of requirements on Priority substances within the Context of the Water Framework Directive (contract 07010401/2008/508122/ADA/D2). Prioritisation process: Monitoring-based ranking.

24 Baun A, Hartman NB, Grieger KD and Hansen SF (2009) Setting the limits for engineered nanoparticles in European surface waters – are current approaches appropriate?” Journal of Environmental Monitoring 11 pp1774-1781; Hassellöv M, Readman JW, Ranville JF and Tiede K (2008) Nanoparticle Analysis and Characterization Methodologies in Environmental Risk Assessment of Engineered Nanoparticles, Ecotoxicology 17(5) pp344-361; Christian P, Von der Krammer F, Baalousha M, Hofmann T (2008) Nanoparticles: structure, properties, preparation and behaviour in environmental media. Ecotoxicology 17:326-343.

25 Hansen SF, Baun, A, Tiede K, Gottschalk F, van der Meent D, Peijnenburg W, Fernandes T and Riediker M (2011) Consensus report based on the NanoImpactNet Workshop, Environmental fate and behaviour of nanoparticles – beyond listing of limitations, Bilthoven, October 7th 2009, NanoImpactNet, DTU, Denmark.

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

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

different from each other in terms of characterization and environmental fate and behaviour.[28] At the same time, the number of studies is increasing and some dedicated research teams are beginning to report successes with particular methods for specific classes ENMs[29] rather than for generic ENM. Given the current technical limitations, it will still be some time before Member States can consistently monitor environmental concentrations of nanomaterials in situ in a regulatory context. Clearly then, monitoring data on any specific nanomaterial from a minimum of four Member States is not available to feed into the monitoring-based methodology for the identification of priority substances.

In the subsequent prioritization of these 316 substances, EU-wide exposure data was generated from the amalgamated data sets, in the form of Predicted Environmental Concentration (PEC) for each analysed fraction (whole water, dissolved metals in water, sediment below 2mm, below 63µm, below 20µm, fish and invertebrates). In practice, problems arose because of measurements below the analytical determination limit. In such cases, two PEC calculations were calculated, one using only quantified values (PEC1), the other using all available data (PEC2). In the latter, data below the determination limit was replaced by half its value, as recommended by Directive (2009/90/EC) laying down technical specifications for chemical analysis and monitoring of water status.[30] Should monitoring of nanomaterials be implemented in a regulatory context, it can be expected that a high proportion of the measurements would verify the presence of specific nanomaterials, but be below the analytical determination limit.

The next step addressed the effects, drawing on available ecotoxicity data in the literature for the different fractions covered by the monitoring data. For water, direct ecotoxicity was considered and a Predicted No Effect Concentration (PNEC) was calculated according to the methods laid down in the 2003 Technical Guidance Document on Risk Assessment[31]. Regulators would encounter challenges in applying this step to nanomaterials. Data on chronic and acute effects is rarely available, even for the most tested nanomaterials such as C60 and carbon nanotubes[32]. In addition, the reliability and interpretation of available ecotoxicity data is hampered due to factors such as: particle impurities, suspension preparation methods, release of free metal ions, and particle aggregation[33]. The indirect aquatic effect scores are calculated from the measured bioconcentration factors (BCF) or the octanol-water partitioning coefficient (Kow) as a measure for the bioaccumulation potential. For nanomaterials, reliable measured BCFs are at present not available for the most commonly tested nanomaterials and the traditionally used extrapolations based on K_{ow}-values are not meaningful for nanomaterials[34]. Finally, effects on humans such carcinogenicity, mutagenicity, reproductive and chronic effect from oral uptake of nanomaterials remain largely unexplored[35].

As a next step, substances were prioritised and ranked using algorithms to calculate risk ratios, where PEC was divided by associated PNEC. In a final step, substances were reviewed by an expert group for EU representativeness and for quality and reliability of the monitoring data, with unreliable data discarded and the results recalculated, before selected substances were short-listed for final review.

In assessing the potential for applying the monitoring-based methodology to nanomaterials, we can identify the same limitations as applied to the COMMPS procedure, namely a lack of monitoring data for nanomaterials and of ecotoxicological data. While noting that the monitoring-based prioritisation provides an excellent basis for prioritisation, INERIS recognised that it overlooks substances that may pose

28 Hansen, S.F., Ganzleben, C., Baun, A. 2011. Nanomaterials and the European Water Framework Directive, European Journal of Law and Technology, Vol 2(3).

29 See for example: Chen Z, Westerhoff P, Herckes P, 2008, Quantification of C60 Fullerene Concentrations in Water, Environmental Toxicology and Chemistry, 27:9:1852-1859; Reed RB, Higgins CP, Westerhoff P, Tadjiki S and Ranville JF, Overcoming challenges in analysis sof polydisperse metal-containing nanoparticles by single particle inductively coupled plasma mass spectrometry, due to be published in the Royal Society of Chemistry.

30 Commission Directive 2009/90/EC laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status, OJ L201/36-38.

31 European Commission, 2003. Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) N° 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Office for Official Publications of the European Communities, Luxembourg.

32 Baun, A., Hartman, N.B., Grieger, K.D, Hansen, S.F. 2009. Setting the limits for engineered nanoparticles in European surface waters - are current approaches appropriate? Journal of Environmental Monitoring 11: 1774-1781; Stone, V., Hankin, S., Aitken, R., Aschberger, K., Baun, A., Christensen, F., Fernandes, T., Hansen, S.F., Hartmann, N.B., Hutchinson, G., Johnston, H., Micheletti, G., Peters, S., Ross, B., Sokull-Kluettgen, B., Stark, D., Tran, L. 2010. Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES). Available: http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report (Accessed February 1, 2010).

33 Hartmann, N.B., Von der Kammer, F. Hofmann, T., Baalousha, M., Ottofuelling, S., A. Baun. 2010 Algal testing of titanium dioxide nanoparticles-Testing considerations, inhibitory effects and modification of cadmium bioavailability. Toxicology 269: 190-197.

34 Hansen, S.F., Ganzleben, C., Baun, A. 2011. Nanomaterials and the European Water Framework Directive, European Journal of Law and Technology, Vol 2(3).

35 Stone, V., Hankin, S., Aitken, R., Aschberger, K., Baun, A., Christensen, F., Fernandes, T., Hansen, S.F., Hartmann, N.B., Hutchinson, G., Johnston, H., Micheletti, G., Peters, S., Ross, B., Sokull-Kluettgen, B., Stark, D., Tran, L. 2010. Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES). Available: http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report (Accessed February 1, 2010).

a risk to or via the aquatic environment but that are not monitored. They explained that the modelling approach (discussed below) is expected to fill in the gap for non-monitored substances[36].

3.5.2 Modelling-based approach

The modelling-based approach was specifically designed to capture those substances for which monitoring data is not available, in particular emerging pollutants. A discussion of their application to nanomaterials is therefore highly relevant to the questions of whether nanomaterials can be brought under the WFD as priority substances.

The modelling-based approach to prioritising substances is described in a JRC report[37] and further discussed in a 2011 article by Daginnus et al[38]. The first step was generating a starting list provided by EU Member States, stakeholders and non-governmental organisations comprising 2,034 substances, which were evaluated according to a hazard assessment, with a focus on the aquatic system, and an exposure assessment. Substances were then analysed and ranked in terms of their risk ratio, PEC/PNEC resulting in a short list of 78 substances.

Regarding hazard, substances were assessed and prioritised on the basis of presenting persistent, bioaccumulative, toxic and endocrine disruptive properties (being on the endocrine disruptors list categories 1 and 2), as well as for being very persistent and very bioaccumulative (vPvB). This hazard assessment suffers from the same limitations in ecotoxicity data as discussed under the monitoring-based approach.

The assessment of exposure then relied on the collection of data on substance use in products in the IUCLID database and SPIN. The IUCLID database[39] contains data collected through an obligation on producers and importers of high-production-volume chemicals and low-production-volume chemicals. The SPIN database[40] contains data from Nordic countries on the use of substances in products and was used when no data were found in IUCLID, applying an extrapolation factor to derive a European tonnage. To the best of our knowledge, the SPIN database does not contain specific data on nanomaterials, since the databases collate data and are searchable by Chemical Abstract Service (CAS) Number. The majority of nanomaterials have the same CAS Number as the bulk form of the substance. This implies that data on nanoscale materials is collated with data on bulk scale materials. Many nanomaterials do not yet have CAS Number, including for example carbon nanotubes. For those nanomaterials with CAS Numbers., i.e. C60 and C90 fullerenes, no data was found on the SPIN database. We were unable to search the IUCLID database since it is not open access, however it may be reasonable to assume that common problems apply. Hence it is concluded that this approach to data collection does not currently yield any specific data on nanomaterials.

The risk ranking stage demands exposure data in the form of PEC. In calculating PEC, the approach demanded data on the use of substances in specific industrial activities, use, use pattern and annual production volumes and tonnage fractions used in specific products. The application of the risk ranking stage to nanomaterials would be hampered by the absence of publically available production volume data for specific nanomaterials (and nanoforms thereof) and volume allocations to specific products.

In their discussion of the modelling-based approach, the authors of the JRC report stress that the approach is intended to take into account substances for which no monitoring data is available and which could pose a risk to aquatic organisms and to human health. However, they note that the approach did not consider metals and organometalic compounds for which physic-chemical and toxicological data were absent. This is because the existing correlations and property predictors in the models are designed for organic chemicals and resulting predictions may not be valid for metals and organometalic compounds. This calls into question the applicability of the model to nanomaterials, the fate and behaviour of which is influenced by different physical forces to classical bulk chemicals due to their specific properties (e.g. small size, large surface area and the wide variation in physico-chemical properties across nanoforms). In addition, researchers suggest that it will be nanoforms of metal nanomaterials that pose the greatest risk to the aquatic environment[41]. However, were specific aspects of fate and behaviour to be clearly understood, it is possible that with substantial efforts the model could be re-calibrated to serve specific nanoforms.

36 INERIS-International Office for Water. 2009. Implementation of requirements on Priority substances within the Context of the Water Framework Directive (contract 07010401/2008/508122/ADA/D2). Prioritisation process: Monitoring-based ranking.

37 K. Daginnus, S. Gottardo, A. Mostrag-Szlichtyng, H. Wilkinson, P. Whitehouse, A. Paya-Pérez and J. M. Zaldívar (2010). A modelling approach for the prioritisation of chemicals under the Water Framework Directive. JRC Scientific and Technical Report EUR 24292 EN.

38 Daginnus K, Stefania G, Payá-Pérez A, Whitehouse P, Wilkinson H and Zaldívar J-M, 2011, A model-based prioritisation exercise for the European Water Framework Directive, International Journal of Environmental Research and Public Health, Vol 8: 435-455.

39 http://iuclid.echa.europa.eu/.

40 http://www.spin2000.net.

41 Aschberger K, Micheletti C, Sokull-Klüttgen B, Frans M. Christensen FM. 2011. Analysis of currently available data for characterising the risk of engineered nanomaterials to the environment and human health — Lessons learned from four case studies, Environment International, 37(6): 1143-1156; Stone et al. 2009. Engineered nanoparticles: review of health and environmental strategy" ENRHES, JRC.

4 Modelling nanomaterials in surface waters

In terms of what data *are* available from other modelling approaches, initial data on PEC for nanomaterials in surface waters is available from a number of published studies using modelling. The earliest data relied on mass flow analysis to model emissions of nanomaterials to the environmental compartments and estimate PEC in terms of mass concentrations.[42] Gottschalk et al. subsequently built on this earlier work with a number of studies using probabilistic mass flow analysis to generate data in the form of mass concentrations, with their 2009 article providing the only EU-wide PEC estimates for a range of nanomaterials.[43] They refined their model in later studies (2010, 2011) to consider the influence of geographical variability, including river flow and point source emissions to water.[44]

The work of Tiede et al. (2011)[45] estimated emissions of nanomaterials from both point and diffuse sources and generated both mass concentrations and particle number concentrations of a wide range of nanomaterials in surface waters, suggesting that nanomaterials with the highest surface water mass PEC are likely to be the metals, specifically nano-TiO2, nano-Ag, nano-ZnO and possibly silica-based nanomaterials. Johnson et al (2011)[46] modelled nano-Ag mass concentrations in rivers in England and Wales based on measurements of colloidal and particulate Ag in the influents and effluents of waste water treatment plants. This represents the only attempt to use data from analytical measurements in modelling when generating PEC for surface waters.

More recently, researchers have developed kinetic models that incorporate the specific fate and behaviour mechanisms identified as influencing nanomaterials in water. Praetorius et al. (2012)[47] modelled the transport, transformation and interaction nano-TiO_2 with naturally occurring particles, while Arvidsson et al (2011)[48] modelled the influence of sedimentation and dissolution processes on nano-TiO_2. Quik et al (2011)[49] developed a model of fate and behaviour that can be tailored to the removal rates of specific nanoforms, if known. These studies have all generated PEC based on particle number concentration, rather than mass concentration. Further work is required to refine these models and to test their robustness against empirical data from analytical measurements.

Regarding its use under the WFD, mass concentration-based PEC could theoretically be fed into a revised risk ranking system under the modelling-based exposure assessment step of the simplified risk-based assessment procedure used to identify priority substances. However, only one study to date (Gottschalk et al. 2009) provides EU-wide data for a range of nanomaterials, with other studies limited to individual countries or stretches of rivers. In addition, the robustness of results is limited by uncertainties in the input data on production and use.

In terms of data from kinetic studies in the form of PEC based on particle number concentration, the risk-ranking step could presumably be adapted to accept these specific metrics. This would, however, impact on the comparability of results with other non-nano pollutants and preclude effective ranking of nanomaterials against other pollutants.

5 Options for generating data on nanomaterials to feed into models

The robustness of data resulting from modelling methods are limited by the use of unreliable production volume data, fractions attributable to specific products, as well as uncertainties regarding emissions estimated from products and processes. Exposure assessment for nanomaterials would benefit significantly from an increase in the availability of accurate, up-to-date data on production volumes for nanomaterials and product allocation.

In some countries action will be taken in the near future to require reporting, meaning that governments have recognised the data gap and taken steps to address it. The French government has established a compulsory reporting scheme for nanomaterials placed on the market by producers, importers or distributers. Information requirements include an annual declaration of the identity, the quantity and the uses of the nanomaterials, as well as the identity of recipients down the supply chain. The first declarations are required in 2013 and will relate to nanomaterials manufactured, imported or distributed in 2012. Decree 2012-232[50] sets requirements for who has to report and what data they have to provide and will enter into force on January 1 2013.

42 Mueller, N., Nowack, B. (2008) Exposure Modeling of Engineered Nanoparticles in the Environment. Eviron Sci Technol 42: 4447-4453.

43 Gottschalk F, Sonderer T, Scholz RW, Nowack B (2009) Modelled environmental concentrations of engineered nanomaterials (TiO2, ZnO, Ag, CNT, fullerenes) for different regions. Environmental Science and Technology, 43, 9216-9222.

44 Gottschalk F, Scholz RW, Nowack B, (2010) Probabilistic material flow modelling for assessing the environmental exposure to compounds: methodology and an application to engineered nano-TiO2 particles, Environmental Modelling & Software 25: 320-332; Gottschalk F, Ort C, Scholz RW and Nowack B, 2011, Engineered nanomaterials in rivers – Exposure scenarios for Switzerland at high spatial and temporal resolution, Environmental Pollution 159: 3439-3445.

45 Tiede K, Westerhoff P, Hansen SF, Fern GJ, Hankin SM, Aitkin RJ, Chaudry Q and Boxall ABA (2011) Review of the risks posed to drinking water by man-made nanoparticles, DWI 70/2/246, FERA, UK.

46 Johnson et al. (2011) Centre for Ecology and Hydrology (CEH), Exposure assessment for engineered silver nanoparticles throughout the rivers of England and Wales, CEH, UK.

47 Praetorius A, Scheringer M and Hungerbühler K (2012) Development of Environmental Fate Models for Engineered Nanoparticles—A Case Study of TiO2 Nanoparticles in the Rhine River, Environmental Science & Technology *46* (12): 6705-6713.

48 Arvidson R, Molander S, Sandén BA, Hassellöv M (2011) Challenges in Exposure Modelling of Nanoparticles in Aquatic Environments, Human and Ecological Risk Assessment: An International Journal, 17:1, 245-262.

49 Quik JTK, Vonk AI, Hansen SF, Baun A, Van De Meent D (2011) How to assess exposure of aquatic organisms to manufactured nanoparticles? Environment International 37(6): 1068-77.

50 Décret n° 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l'état nanoparticulaire pris en application de l'article L. 523-4 du code de l'environnement.

The Danish government has also decided to go ahead with plans to create a national register of products containing nanomaterials, with further details expected in 2013. Belgium and Italy have also indicated that they plan to establish registers[51].

In addition to actions by States, there are a number of other initiatives to establish nano registries, although they do not draw on mandatory data submissions by producers and are hence less reliable and less comprehensive than the anticipated state registries.

In its recent Communication on nanomaterials,[52] the Commission recognises the essential need for transparency of information on nanomaterials and products containing nanomaterials and committed to the creation of a web platform referencing all relevant information sources, including registries on a national or sector level. In addition, the Commission announced that it will be launching an impact assessment to consider how to increase transparency and ensure regulatory oversight, including an in-depth analysis of data gathering needs, suggesting that EU-level action to improve data availability may be forthcoming. Finally, "*more specific requirements*" for nanomaterials under the REACH Regulation are also foreseen and should generate additional data.

6 Proposed Watch List

The 2012 proposal for a Directive amending the WFD and the EQSD as regards priority substances in the field of water policy[53] includes a provision for a watch-list mechanism. The aim of the proposed watch list is to support future reviews of the priority substances list by generating monitoring data on a list of emerging pollutants. The proposal notes that the list should be dynamic, respond to new information on the potential risks posed by emerging pollutants and avoid monitoring substances for longer than necessary. The proposed mechanism would focus on a maximum of 25 substances or groups of substances, to be monitored at a limited number of monitoring sites. The goal would be to deliver representative data to feed into the process of identifying priority substances. The Commission would be responsible for drawing up the watch list, selecting substances for which the available information indicates that they may pose a significant risk at Union level to or via the aquatic environment. The proposal is currently under consideration by the European Parliament, with a vote due in November 2012. However, early indicators suggest that the proposed Watch List will be adopted, and that in the long run this could present a possible avenue for considering specific nanomaterials. Discussions on nanomaterials and whether they could be included on the watch list could generate additional impetus, in particular though additional funding, for on-going efforts to develop analytical measuring techniques for specific nanomaterials. In the short term, techniques for measuring nanomaterials in aquatic samples for use in a regulatory context are not yet available and nanomaterials are therefore unlikely to be captured under the Watch List.

7 Conclusions

Initial exposure modelling suggests widespread environmental exposure to nanomaterials in surface waters, with particular concerns regarding metal-based nanomaterials. The procedures under the WFD for identifying and controlling emerging pollutants have been reviewed in this article and, while the more targeted routes offer the potential to capture nanomaterials (in particular if proposed by a Member State or stakeholder with an accompanying risk assessment), significant challenges remain in applying the wider simplified risk-based assessment.

We are currently in a situation where analytical monitoring techniques are not able to generate comprehensive monitoring data for nanomaterials in European waters, suggesting that a reliance on modelling-based assessment is preferable to a monitoring-based approach. An objective of the modelling-based approach is to capture emerging pollutants for which monitoring data is not available.

Although modelling data on nanomaterial exposure remains limited, a number of promising models are available and further refinement can be expected over the following years. However, modelling exposure data for nanomaterials remains hampered by data limitations regarding production volumes for specific nanomaterials and fractions attributable to specific products and uses.

Opportunities for modelling exposure to nanomaterials in surface waters and their consideration under the modelling-based approach would be aided significantly by the establishment of mandatory EU-wide reporting systems for manufacturers and producers placing nanomaterials on the market. This would generate reliable data to feed into exposure models for specific nanomaterials, and where possible nanoforms thereof, to provide reliable estimates of PEC in surface waters. Based on this, and together with on-going advances in understanding the fate and behaviour of specific nanomaterials, steps could be taken to recalibrate the modelling-based approach to serve nanomaterials. The picture of exposure must then be combined with an understanding of hazard for specific nanomaterials in order to determine whether a specific nanomaterial should be targeted by the WFD as a priority substance.

51 ENDs Europe 2012 Denmark confirms plans to create nanoregister, Tuesday 18 September 2012.

52 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.

53 Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy, COM(2011) 876 final.

Imprint

Editors: *Regine Barth, Nicola Below, Claudia Fricke, Martin Führ, Gerhard Roller, Julian Schenten, Silvia Schütte*

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The Editors would like to thank **Vanessa Cook** (Öko-Institut) for proofreading the *elni Review*.

We invite authors to submit manuscripts to the Editors as files by email using an IBM-compatible word processing system.

The *elni Review* is the double-blind peer reviewed journal of the Environmental Law Network International. It is distributed twice a year at the following prices: commercial users (consultants, law firms, government administrations): € 52; private users, students, libraries: € 30. Non-members can order single issues at a fee of € 20 incl. packaging. The Environmental Law Network International also welcomes an exchange of articles as a way of payment.

The *elni Review* is published with financial and organisational support from Öko-Institut e.V., and the Universities of Applied Sciences in Darmstadt and Bingen.

The views expressed in the articles are those of the authors and do not necessarily reflect those of elni.

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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.

The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.

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elni

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elni) in 1990 to promote international communication and cooperation worldwide. elni is a registered non-profit association under German Law.

elni coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

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Three organisations currently share the organisational work of the network: Öko-Institut, IESAR at the University of Applied Sciences in Bingen and sofia, the Society for Institutional Analysis, located at the University of Darmstadt. The person of contact is Prof. Dr. Roller at IESAR, Bingen.

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The first issue of the elni Review was published in 2001. It replaced the elni Newsletter, which was released in 1995 for the first time.

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elni conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researches, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

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