PROJECT FINAL REPORT

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4.1 Final publishable summary report

Executive Summary

Nanotechnology is a fast growing industry producing a wide variety of manufactured nanomaterials (MNMs) and numerous potential applications. This growth will result in an increased (potential for) exposure to humans and the environment, which, if not managed properly, could lead to increased risk to the health of workers and the general public. The NANEX project aimed to develop a catalogue of exposure scenarios for MNMs taking account of the entire lifecycle of these materials. Exposure scenarios generally include information on the substance, the process and activities, the presence of any risk management measures, and estimates of exposure and are therefore an important tool for managing exposure. Within the REACH regulations, exposure scenarios are used to describe the operational conditions and risk management measures that are required to ensure that exposure levels are safe. However, carrying out a risk assessment was outside the scope of the NANEX project and therefore only available exposure information was considered in the development of the scenarios. The scenarios developed in the NANEX project should therefore not be considered as evidence for safe use. NANEX focussed on carbon nanotubes (CNTs), nano-sized titanium dioxide (nano-TiO_2) and nano-sized silver (nano-Ag). In total, 62 exposure scenarios were developed using publicly available data and data collected in several large-scale sampling campaigns. 57 Scenarios were related to occupational exposure and 5 to consumer exposure. As there was little or no empirical exposure information available for the development of consumer exposure scenarios, exposure estimate for these scenarios were based on exposure estimation models and default or worst case assumptions. In contrast, all of the occupational exposure scenarios were developed using measurement data from the literature or from sampling campaigns. Information on environmental release was not available for the activities described in the occupational exposure scenarios, and the information available on consumer use of MNM-containing products was deemed too limited to be of use for running environmental release models. In parallel, NANEX carried out case studies in partnership with several companies that manufactured MNMs. During these case studies, exposure scenarios were developed for CNTs, nano-Ag, and nano-TiO_2; mainly for manufacture, but also for some downstream use. Compared to the exposure scenarios that were based on data from the open literature and measurement surveys, more detailed information on operating conditions and risk management measures were available for the development of the case study scenarios. Based on the information collected during the project, a comprehensive analysis of key data gaps and research needs was carried out. A list of minimum data needs was established outlining categories of information that should be included when describing results from exposure studies of MNMs, and includes both nano-specific and generic data needs. Short-term research priorities include i) establishing harmonised methods for data collection/reporting (e.g. exposure metrics), ii) verification of effectiveness of risk management measures, and iii) development of risk management strategies to be applied while waiting for development of more detailed exposure and risk assessment methodologies. Longer term research priorities focus on i) increased collection of high quality data over the life cycle of MNMs, ii) the development of more advanced understanding of MNM exposure and the key exposure determinants, and iii) development, calibration and validation of MNM-specific exposure estimation models.

Project Context and Objectives

Nanotechnology is a fast growing industry producing a wide variety of manufactured nanomaterials (MNMs) and numerous potential applications. Since the publication in 2004 of the Royal Society and Royal Academy of Engineering review of the opportunities and uncertainties of nanotechnology[1] there have been numerous reviews published considering the potential risk from exposure to nanoparticles. The reviews have been remarkably consistent and some of their findings can be summarised as follows:

- There is a potential risk to health and the environment from the manufacture and use of nanoparticles;
- There is a lack of knowledge about what these risks are and how to deal with them; and
- The lack of data makes it difficult for manufacturers, suppliers and users to have effective risk management procedures and comply with regulatory duties.

Many nanoparticles and other MNMs are currently only produced on a bench-scale, in small quantities and with relatively few exposed workers. However, other MNMs are mass produced and some industrial sectors make use of nanoparticles in significant quantities, such as in paints and coatings, cosmetics, catalysts and polymer composites.[2] In addition, MNMs will vary widely in their potential to cause health effects in humans following exposure. Total production of MNMs is likely to grow rapidly as is the diversity of MNMs and their applications. Consequently, the potential for exposure to humans and the environment is also likely to increase rapidly.

Human exposure to MNMs and environmental release of these materials can occur during all the life cycle stages of these materials. The main life cycle stages for MNMs are shown in Figure 1 and can be summarised as: i) manufacturing of nanoparticles, ii) formulation of nanomaterials and nanoproducts, iii) industrial use of nanomaterials or products; iv) professional and consumer uses of nanoproducts; v) service life of nanoproducts; and vi) waste life stage nanoproducts. If not managed properly, the increased potential for exposure to MNMs during all these life cycle stages will lead to an increased risk to human health and the environment.

To make an assessment of the potential for exposure to MNMs information is required on i) the mechanism of release of nanoparticles from a wide range of production processes, formulations and use; ii) the effectiveness of risk management measures; iii) the range of exposure levels (human and environmental) experienced during the life cycle stages of the nanomaterials; and iv) the availability and applicability of tools to assess exposure, including measurement methods and models.

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[1] The Royal Society and The Royal Academy of Engineering (2004) Nanoscience and nanotechnologies: opportunities and uncertainties. ISBN 0 85403 604 0.

[2] Boxall et al (2007) Current and future predicted environmental exposure to engineered nanoparticles. Sand Hutton, UK: Central Science Laboratory.

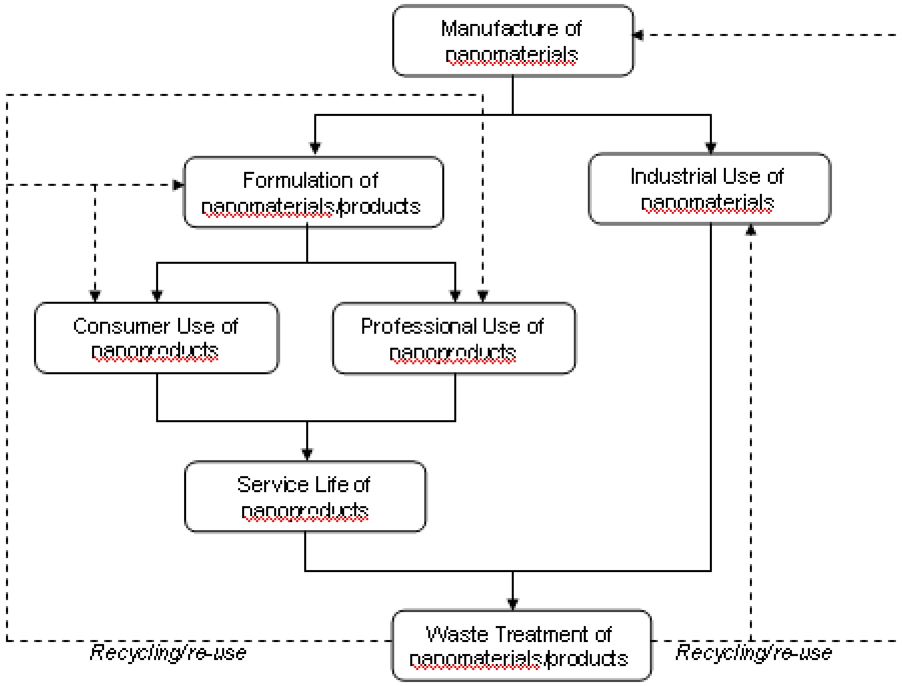

Figure 1: Simplified overview of life cycle stages of manufactured nanomaterials

Exposure scenarios are an essential tool for estimating exposure and risk. Exposure scenario descriptions generally include information on the substance, the process and activities, the presence of any risk management measures, and estimates of exposure. Within REACH exposure scenarios are defined as sets of information describing the conditions under which the risk associated with the identified use(s) of a substance can be controlled, including operational conditions and risk management measures. Exposure scenarios are the basis for quantitative exposure assessment but are also used as a communication tool in the supply chain. There are currently no provisions in REACH referring specifically to MNMs. However, as REACH deals with chemical substances, in whatever size, shape or physical state, it follows that MNMs are implicitly covered by REACH.

Due to the lack of information on the toxicology of NMMs and the paucity of quantitative (personal) exposure data it will not be possible to develop exposure scenarios (as defined under the REACH regulations) that ensure that exposures are sufficiently controlled to prevent risk to human health and to the environment. However, it may be feasible to develop “exposure scenarios” for specific data rich applications of certain MNMs. Although such exposure scenarios may not be integrated into a quantitative risk assessment, they can be used to benchmark different exposure scenarios with respect to state-of-the-art process operations and control measures and provide guidance to reduce exposure.

The aim of the NANEX project was to develop a catalogue of exposure scenarios for MNMs relevant for human exposure taking account of the entire lifecycle of these materials. NANEX focussed on carbon nanotubes (CNTs), nano-sized titanium dioxide (nano-TiO_2) and nano-sized silver (nano-Ag) and had the following specific objectives:

1. To describe generic requirements for the development of exposure scenarios for MNMs.
2. To collect and review exposure data, exposure metrics, risk management measures and existing models for the development of occupational and consumer exposure scenarios.
3. To collect and review data on environmental release, risk management measures, and existing models for estimating environmental release and exposure during various life cycle stages.
4. To carry out a number of case illustrations in collaboration with industrial partners.
5. To develop a library of exposure scenarios based on information collected during the project.

6. To identify gaps in knowledge with respect to development of exposure scenarios and define research needs for occupational, consumer and environmental release/exposure scenarios.
7. To disseminate information to stakeholders.

NANEX was a 12-month project and started on 1 December 2009. The work was carried out within 9 complementary work packages (WPs) (Figure 2). **WP1** and **WP9** dealt with the project management and scientific coordination. **WP2** principally served two functions; firstly, to provide the format for describing occupational and consumer exposure scenarios; and, secondly to develop the library of exposure scenarios (together with WP7). **WP3** reviewed the open literature and data generated by two major measurement campaigns (NANOSH, NanoINNOV) to develop occupational exposure scenarios. In addition, the performance of several existing exposure estimating models for use with nanomaterials was evaluated. **WP4** reviewed the open of consumer exposure to MNMs and attempted to build consumer exposure scenarios for the MNMs. **WP5** reviewed the literature on environmental releases of MNM to assess availability and applicability of existing i) models, ii) experimental settings and iii) analytics. **WP6** developed real-life exposure scenarios in collaboration with industrial partners. **WP7** integrated the information compiled over the course of the project, identified gaps in existing information, developed recommendations and described research needs. Finally, **WP8** coordinated the dissemination activities.

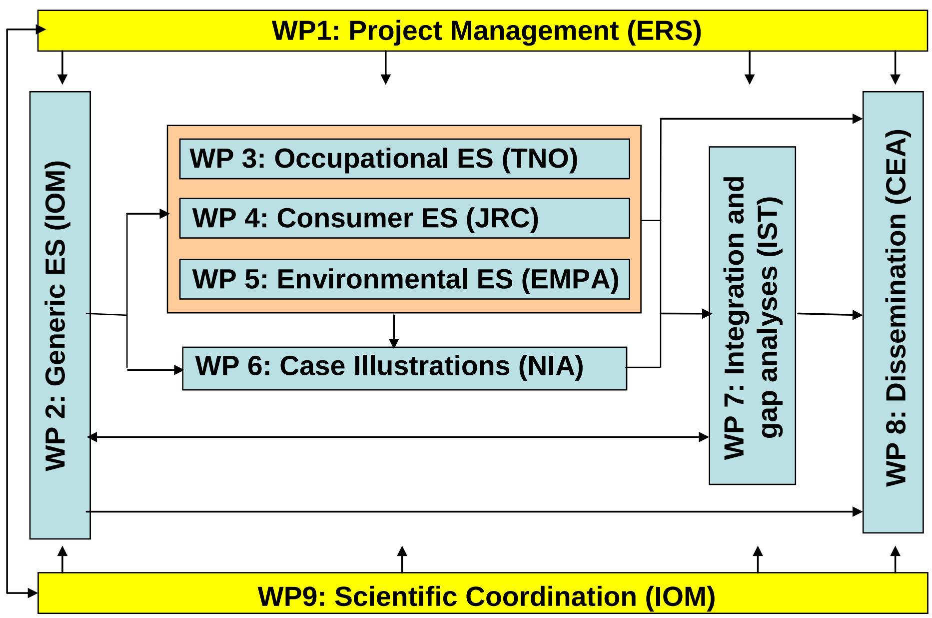

Figure 2 Overview of Work Packages of NANEX

Description of main S&T results/foreground

This section first provides brief summaries of the activities and results from WPs 2, 3, 4, 5 and 6, followed by a more extensive description of the findings from work WP7. The latter WP integrated the results and identified knowledge gaps and research needs.

Development of generic exposure scenario descriptions (WP2)

During the NANEX workshop in March 2010 in Lausanne the exposure scenario format was discussed with NANEX and external partners. It was decided to follow the latest REACH Guidance[3], which provides four slightly different scenario formats for use and downstream use by workers and use and downstream use by consumers. The Exposure Scenario format consists of a title section followed by a number of contributing exposure scenarios, one of which deals with environmental release and exposure. The format for describing exposure scenarios provided by the REACH guidance document was adopted by NANEX and used in the development of the NANEX Exposure Scenario Database. This database was used by subsequent work packages to collate occupational and consumer exposure scenarios. In addition, a separate database was developed, in collaboration with WP7, for extracting Meta data from relevant references from the peer-reviewed and other literature (NANEX Exposure References Database). These two databases were combined within a single Access Database and distributed to the NANEX partners.

WP2 also obtained relevant exposure information from the literature and by searching information from other current and recent projects funded by the European Commission and other organisations.

A list of generic exposure scenario titles was developed for the three candidate MNMs.

Occupational exposure (WP3)

Based on 33 literature references, 22 exposure scenarios were derived and entered into the NANEX Exposure Scenario Database. A total of 14 exposure scenarios for CNT were developed, generating 35 contributing exposure scenarios describing some facet of occupational exposure. Most of them were related to exposure scenarios in production/synthesis of carbon-based nanomaterials or handling material (weighing, removing, sonication, etc.). Two exposure scenarios addressed tasks related to the machining of composites containing CNTs. A total of 5 exposure scenarios for nano-TiO_2 were developed, generating 12 contributing exposure scenarios. Of these, only two contained sufficient details; for the remaining exposure scenarios, only some elements of the exposure scenario template could be completed. Three of the exposure scenarios related to the production of nano-TiO_2 and two related to the production of materials containing nano-TiO_2. Only two occupational exposure scenarios could be developed for nano-Ag; one exposure scenario described manufacturing in wet chemistry process, while the second was related to handling nano-Ag in a fume hood.

Based on the data sets of the two large measurement campaigns (NANOSH project (FP6) and the NanoINNOV project (CEA)), 35 exposure scenarios, consisting of 48 contributing scenarios, were derived. Most exposure scenarios were for CNTs (n=14), which were predominantly related to research-scale activities. Most nano-TiO_2 scenarios (n=8) were on commercial-scale manufacturing and formulation. Only 2 exposure scenarios could be built for nano-Ag, whereas 11 exposure scenarios were built other substances, including other metal-oxides.

From the process of developing these exposure scenarios, several main conclusions could be drawn. Most studies reported in the literature or as part of the measurement campaigns had an explorative character and were focused on concentration/emission analysis. Therefore, as reported, these studies did not include most of the information that is necessary to build exposure scenarios (e.g. amount used, frequency of activities). Basic characterization of the products used and operational conditions were often not described. Most concentration/emission- related measurement results were task-based and subsequently it is difficult to assign a process category (PROC), as the same tasks can cover multiple PROCs. The most important observation was the lack of harmonization of the measurement strategy and the analysis and reporting of measurement data.

[3] ECHA (2010) Guidance on information requirements and chemical safety assessment. Exposure scenario format. In Part D: Exposure scenario building. In Part F: CSR format. Version 2 May 2010.

At this stage it was not possible to build exposure scenarios combining different information sources (e.g., individual studies or references). This was mainly due to the heterogeneity in the level and quality of the description of the context (e.g., differences related to material characteristics, processes, quantities handled, control systems) and in the exposure evaluation (e.g., the absence of standards addressing different measurement strategies, equipment and data treatment).

Information required to address the environmental release from the occupational exposure scenarios was similarly lacking from both the open literature sources as well as from the measurement campaigns. Only in some rare occasions was information such as total quantities produced/year and information related to air emissions (presence of vent hoods) reported. No data were reported related to water treatment.

ECETOC TRA and Stoffenmanager were evaluated with respect to their applicability for estimating exposure to nanoparticles. Both models are based on a source- receptor approach distinguishing emission, transport, immission and personal exposure. It was concluded that both models should, in principal, be able to predict exposure to nanoparticles. However, the different categories within each model variable are not particularly suitable for activities associated with MNMs and lack the required level of resolution. This means that in practice many situations may fall into the same category, resulting in the same or similar exposure estimates. Refinement of these categories in view of typical activities for MNM handling, amount of handling categories, etc., is needed. Both first tier models only provide mass concentration as proxy for exposure, whereas typical devices used for nanoparticle exposure assessment use particle concentration as an exposure metric. Since (nano) devices usually have size-windows up to 1000 nm, the contribution of particles below 1000 nm to mass concentration will be low and might only affect variations in the lower mass concentration ranges of the current model estimates. This indicates the need for recalibration of the models for nano exposure. No correlation was observed between the model estimates (for mass concentration) and the measured (particle-number) concentrations. (However mass estimates would not necessarily correlate well with number estimates in any case as this would depend on the size distribution.) In addition, no differences in the estimates were observed between Stoffenmanager (activity-based) and ECETOC TRA (extrapolated for full day exposure). The variability of the measured particle number concentrations was much larger than the variability of the Stoffenmanager and ECETOC TRA exposure (mass concentration) predictions. This again suggests that there is a need to refine the models to increase the resolution in the exposure estimates. As has been demonstrated, due to lack of data or contextual information in the data sets, not the entire range within the model parameters categories could be used, resulting in loss of power of discernment between exposure scenarios.

Consumer exposure (WP4)

The generic exposure scenarios identified in WP2 relevant for consumers were: i) nano-silver (nano-Ag) in textiles, ii) nano-TiO_2 in cosmetics, and iii) carbon nanotubes (CNTs) in composite materials used in consumer products. Due to lack of data, the last two scenarios were restricted to nano-TiO_2 in sunscreens and CNTs in textiles, respectively. The above exposure scenarios were partly developed using various modules from a number of exposure estimation models.

Due to the relatively limited information available, the literature review was broadened to cover other MNMs, not just the literature that was relevant to nano-Ag, nano-TiO_2 and CNTs. This provided a more general picture on the available information on exposure to MNMs in consumer products. Information sources which could contribute to building exposure scenarios were entered into the NANEX Exposure References Database.

The review of models for estimating consumer exposure revealed that for dermal exposure the existing models might also be used for MNMs as the underlying equations do not appear to rely on nano-specific properties. The tools should, however, be used with care as they are not yet validated nor calibrated for MNMs and as the output (the exposure estimate) is given in a mass-based metric. There are greater limitations in the currently available inhalation exposure estimation models. These modules do not consider the nano-specific properties of the materials that could affect the exposure, e.g. agglomeration effects. Therefore, inhalation exposure models should be used with even greater care. It should be noted that the model analysis in this WP is purely theoretical as no MNM exposure data were available to allow for a validation of these models.

For the three generic exposure scenarios considered in this WP, the information about CNTs in textiles was most limited. Slightly more is known about the presence of nano-Ag in textiles. However, limited information on the potential release/migration from the textiles both in terms of quantities and form of silver released (e.g., ions, nanoparticles or silver embedded in worn off textile fibres) made it very difficult to develop realistic exposure scenarios and estimates. Thus for CNTs and for nano-Ag in textiles, very rough and worst-case assumptions had to be made. More is known about application of sunscreen and three different sunscreen applications were considered (liquid, spray and lip balm). Based on (worst-case) assumptions about duration and frequency of use, reasonable worst-case exposure scenarios and estimates could be developed for dermal exposure. However, the underlying lack of information on the exact content of nano-TiO_2 in sunscreens introduces high uncertainty in the exposure estimation.

For the spray application, estimates found in the literature were confirmed with the spray module in ConsExpo and indicate the potential for very high peak indoor concentrations. This needs further attention, as do other spray applications with MNM-containing products. It should be noted that existing spray exposure models do not properly account for agglomeration effects that occur with airborne nanoparticles.

It is known that MNMs are used widely in consumer products, but there is a significant gap in information available in the public domain which would enable building consumer exposure scenarios and estimating consumer exposure. In particular, information about MNM content in and release from consumer products is lacking.

Models cannot currently fill the information gap as they are not yet validated for MNMs. Based on theoretical considerations, however, modules for estimating dermal exposure may be used with care, whereas inhalation modules seem less applicable.

It should be noted that many consumer products contain MNMs in solid matrices, which is likely to significantly reduce the potential for consumer exposure. On the other hand, MNMs are also used in liquid consumer products, introducing the potential for dermal exposure and for inhalation due to spray applications. Given the widespread presence of MNMs in consumer products, almost all consumers (including possible susceptible subpopulations) may become exposed if MNMs are released.

Environmental release (WP5)

There is scientific agreement that manufactured nanomaterial (MNM) production, use and disposal leads to release of MNM to the environment. However, very little is known about such environmental emissions. IIn addition to looking at exposures triggered by local emissions/point sources, as is done for occupational and consumer exposure assessments, the evaluation of environmental release and exposure to MNM must also consider emissions from diffuse sources that cover the whole life cycle of MNM and MNM containing products. As with many pollutants, most of the MNM release stems from non-point sources such as wearing or washing textiles containing MNM, or using MNM-containing cosmetics, sunscreen etc. Such sources are probably the most important and the most difficult to control. In this respect MNM are not different to other chemicals in consumer products. However, for pollutants emitted as nano-sized particles, a quantitative (and qualitative) detection is difficult. Currently there are almost no measurement techniques and data available to quantify MNM emissions and concentrations in the environment. Especially, distinguishing engineered nano-scaled particles from background particles at the same size is difficult. Such a distinction becomes particularly difficult when measurements of ubiquitous background aerosol concentrations show higher values than process-specific concentrations (Maynard 2006)[4]. Quantifying the portion of released airborne nanoparticles attaching to background aerosols is also difficult (Savolainen et al. 2010)[5]. Mass spectrometry (MS) promises reliable results for quantifying MNM environmental concentrations. In particular, field-flow fractionation-inductively coupled plasma mass spectrometry (FFF–ICP–MS) methods are increasingly used. In the future such methods should

[4] Maynard, AD (2006). Nanotechnology: assessing the risks. *Nanotoday* 1 (2): 22-33.
[5] Savolainen, K. et al (2010). Nanotechnologies, engineered nanomaterials and occupational health and safety - A review. *Safety Science* 48 (8): 957-963.

aim at allowing simultaneously sizing and analyzing particles in their original environment using size separation of the sample with quantitative and elemental evaluation of the size fractions.

One of the first analytical studies on environmental release of MNMs (Kaegi et al. 2008)[6] reports the detection of manufactured nano-TiO_2 in water leaching from exterior facades. Further experimental works show evidence for release of nano-sized Ag from commercial textiles during washing (Benn and Westerhoff 2008[7]; Geranio et al. 2009[8]). Other studies have been published that quantified concentrations of filterable Ti (smaller 700 nm) in sewage treatment plant effluents (Kiser et al. 2009)[9]. However, the method is not specific for engineered TiO_2 and includes all particulate Ti smaller than 700 nm. Based on mass spectrometry C_{60} and, C_{70} fullerenes and N-methylfulleropyrrolidine C_{60} in wastewater effluents were recently detected as well (Farré et al. 2010)[10].

However, for quantifying MNM release to the environment, measurements have to analyze the total ***amount*** of MNM reaching a particular environmental compartment and not simply to quantify the MNM ***concentrations*** in that compartment. Hence, measurements that provide only concentrations in indoor air or sewage water etc. are not useful without indications of the corresponding total air volume and air exchange rates or the time dependent stream flow. Also studies conducted to investigate air pollution in occupational settings that only provide MNM concentrations in indoor air do not assist in quantifying environmental release.

In addition to single measurements, a handful of modelling studies have investigated MNM release to the environment. Some of them evaluated release to the environment from single MNM-containing products during the consumption phase (Blaser et al. 2008[11]; Boxall et al. 2008[12]). Life cycle based release modelling was carried out as well (Mueller and Nowack 2008)[13]. Recently, stochastic/probabilistic mass partitioning models (Gottschalk et al. 2009[14]; Gottschalk et al. 2010a[15] and 2010b[16]) were developed and implemented to estimate environmental release throughout the whole life cycle of MNM and MNM-containing products (MNM production and manufacturing of products, use, recycling and disposal), and to quantify as far as possible the distinct model input uncertainties. Sewage sludge, wastewater, and waste incineration of products containing MNM were shown to be the major flows through which MNMs end up in the environment. Release results for the MNMs TiO_2, ZnO, Ag, and CNT were provided. Relevant release to water, sediments and soils was observed for the metallic materials, whereas for the carbon-based MNM only marginal amounts reach the environment

Distinct uncertainties limit conceptualization and parameterization of all these models. More reliable data on MNM production and application amounts and empirical information on release coefficients for all mentioned life cycle stages of MNM-containing products and environmental compartments are needed. To improve and validate such release assessments, we need urgently need more empirical information on MNM production amounts. Quantitative indications on the allocation of the produced volume to the relevant product categories (e.g. cosmetics, plastics etc.) that contain the MNM are needed. Empirical (experimental/analytical) release information for the main release sources during the MNM life stages is needed as well (MNM production and

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[6] Kaegi R et al (2008) Synthetic TiO2 nanoparticle emission from exterior facades into the aquatic environment. Environ. Pollut. 156, 233-239.

[7] Benn, TM. and Westerhoff P (2008). Nanoparticle silver released into water from commercially available sock fabrics. *Environ. Sci. Technol.* 42 (11): 4133-4139.

[8] Geranio L.et al (2009). The behavior of silver nanotextiles during washing. *Environ. Sci. Technol.* 43 (21): 8113-8118.

[9] Kiser, MA et al (2009). Titanium Nanomaterial Removal and Release from Wastewater Treatment Plants. *Environ. Sci. Technol.* 43 (17): 6757-6763.

[10] Farré M et al (2010). First determination of C60 and C70 fullerenes and N-methylfulleropyrrolidine C60 on the suspended material of wastewater effluents by liquid chromatography hybrid quadrupole linear ion trap tandem mass spectrometry. *J Hydrol.* 383 (1-2): 44-51.

[11] Blaser SA et al (2008). Estimation of cumulative aquatic exposure and risk due to silver: Contribution of nano-functionalized plastics and textiles. *Sci.Total Environ.* 390 (2-3): 396-409.

[12] Boxall ABA et al (2008). Current and future predicted environmental exposure to engineered nanoparticles. Sand Hutton, UK, Central Science Laboratory.

[13] Mueller NC and Nowack B (2008). Exposure modeling of engineered nanoparticles in the environment. *Environ. Sci. Technol.* 42 (12): 4447-4453.

[14] Gottschalk F et al (2009). Modeled environmental concentrations of engineered nanomaterials (TiO2, ZnO, Ag, CNT, fullerenes) for different regions. *Environ. Sci. Technol.* 43: 9216-9222.

[15] Gottschalk F et al (2010). Probabilistic material flow modeling for assessing the environmental exposure to compounds: Methodology and an application to engineered nano- TiO2 particles. *Environmental Modelling & Software* 25 (3): 320-332.

[16] Gottschalk, F., T. Sonderer, R. W. Scholz and B. Nowack (2010). Possibilities and Limitations of Modeling Environmental Exposure to Engineered Nanomaterials by Probabilistic Material Flow Analysis. *Environ. Toxicol. Chem.* 29 (5): 1036-1048.

nanoproducts' manufacture processes, MNM products consumption and disposal). Only very few data concerning the released form (single nanoparticles or larger pieces, e.g. in agglomerated form) are available. Information on bioaccumulation, a potential endpoint for many materials, is almost completely missing as well.

Case Illustrations (WP6)

In total, four industrial case studies were carried out during the NANEX project.

1. nano-TiO_2
2. nano-TiO_2 (Mn-doped)
3. nano-Ag
4. Multi-walled Carbon Nanotubes (MWCNTs)

During these case studies real-life exposure scenarios were developed in the context of REACH, requiring detailed exposure information for occupational, consumer and environmental release/exposure scenarios. In total, 12 Exposure Scenarios, consisting of 41 contributing exposure scenarios were developed. Compared to the exposure scenarios that were developed based on the open literature and the measurement surveys, more detailed information on operating conditions and risk management measures were available for the development of the case study scenarios.

The NANEX case-illustrations were used to check the applicability of the generic exposure scenarios, providing direct input into the gap analysis conducted in WP7. During the discussion of the ES Case-Studies, however, it became clear that the Case-Studies could serve as nanomaterial product-specific examples only and that no generalisation with regard to practices within an entire nanomaterial type-specific branch could be based on these individual ES Case-Illustrations.

Integration and Gap analyses (WP7)

Overall, 63 distinct references were entered into the NANEX Exposure References Database. Thirty-three of these were relevant to occupational exposure, of which 32 were peer-reviewed articles and 1 was a report or book. Sixteen were relevant to consumer exposure, of which 2 were websites, 9 were peer-reviewed journals, and 5 were reports or books. Thirteen studies were relevant to environmental release, of which 10 were peer-reviewed articles, 1 was a non-peer-reviewed article, and 2 were reports or books. (Two of these references were also considered relevant to consumer exposure). Additionally, reference information on REACH guidance (n=1) and human exposure estimating models (n=2) were included in the database. About 40% of the references in the database were published in 2009 or 2010.

Many of the individual references studied several distinct activities or processes, so it was necessary to further subdivide references into the individual activities described. The NANEX Exposure References Database was designed in a way that made it possible to link several activities to one reference without having to re-enter the basic information for the reference. Each activity entered into the database (whether the only activity described in a reference or one of several) is termed an 'entry' for the purposes of this report. The completed NANEX Exposure References Database contained a total of 114 entries, of which 81 were considered relevant for occupational exposure, 20 were considered relevant for consumer exposure, and 13 for environmental release.

Occupational references

WP3 focused on identifying publicly available literature relevant to occupational exposure to nano-Ag, nano-TiO_2, and CNTs. The 33 distinct references added to the reference database included 32 peer-reviewed articles and 1 report or book. Eighteen of these references, all peer-reviewed, were classified as highly relevant for building exposure scenarios (as opposed to having limited relevance). In general, a 'highly relevant reference' contains data or information that is directly useful for building an exposure scenario. A reference with 'limited relevance' may lack key information needed for exposure scenarios, such as exposure estimates or context under which the MNM is used. These 18 references were associated with 55 entries in the reference database. Reasons cited for a reference having limited relevance were generally related to the following:

- Unclear if particles were truly nanoparticles (no particle characterization), particularly for studies on TiO_2
- No description of exposure circumstances or concentrations
- Study did not have a primary focus on substances that were of specific interest for NANEX

All of the highly relevant references addressed inhalation exposure. Only one of these (Maynard et al. 2004) also quantitatively measured the potential for occupational dermal exposure.

Distribution of studies by generic exposure scenario

All references were initially categorized by which generic exposure scenario(s). Over 75% of the reference entries describe exposure during activities associated with primary manufacturing of the three MNMs of interest (i.e., harvesting and subsequent handling of MNMs), which were often at the small/ pilot scale in research facilities. When including only references that were considered highly relevant, over half of the entries were related to CNTs. Including all references, there was an increase in information on TiO_2 (Figure 3). Due to uncertainties in size distribution of the TiO_2, the relevance of these studies for building nano-TiO_2 exposure scenarios was unknown. No references described occupational exposure during production of textiles containing nano-Ag and and three could be associated with a possible professional use of products containing one of the three MNMs under study (cutting of carbon nanofiber- or nanotube- containing composites) (Mazzuckelli et al. 2007[17]; Bello, et al. 2009[18]; Methner et al., 2010[19])

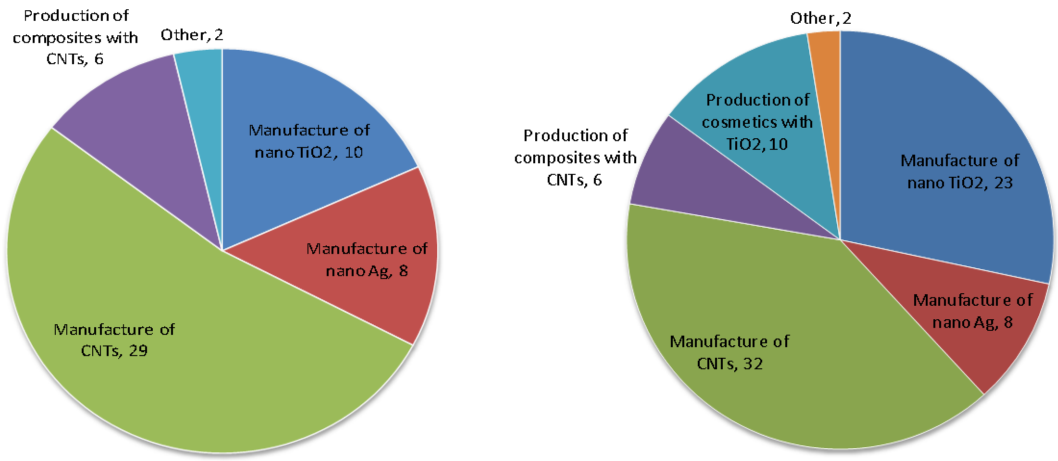

Figure 3. Distribution of reference database entries describing various generic exposure scenarios, total number of entries per scenario shown. Left chart includes highly relevant references only while right chart includes all references.

Methodological quality assessment

The database included several questions meant to assess the appropriateness of the technical methods used in the study. However, as there is no well-established guidance on evaluating ENM exposure studies, these questions were subject to the experience and opinion of the reviewer. The questions were aimed to assess the scientific soundness of the methods as well as their utility specifically for characterizing exposure levels to MNMs. The highly relevant references were found to have provided, from a general perspective, a detailed description of methods used to measure MNMs (14/18) and to have used state-of-the-art methods (15/18). However, when considering specific facets of study design, some limitations were noted. For example, only 2 studies provided a detailed description of quality control procedure, such as instrument calibration. Categories of methodological weaknesses that were identified included:

[17] Mazzuckelli LF et al (2007). Identification and characterization of potential sources of worker exposure to carbon nanofibers during polymer composite laboratory operations. *J. Occup. Environ. Hyg.* 4 (12): D125-130.

[18] Bello D et al (2009). Exposure to nanoscale particles and fibers during machining of hybrid advanced composites containing carbon nanotubes. *J Nanopart. Res.* 11: 231-249.

[19] Methner M et al (2010). Nanoparticle Emission Assessment Technique (NEAT) for the identification and measurement of potential inhalation exposure to engineered nanomaterials--Part B: Results from 12 field studies. *J. Occup. Environ. Hyg.* 7 (3): 163-176.

- Not monitoring particles in micro size range
- Not using methods for characterizing morphology or chemical identity to complement measurements of particle concentrations using real-time methods
- Too few details present to make an assessment

Particle characterization
There was a section of the database devoted to particle characterization, in which the reviewers could summarize the methods used to characterize the particles under study as well as the results. As expected, there were a wide variety of methods and levels of reporting of particle characteristics. In most references, there was little to no information on the physical or chemical properties of the MNM under study other than the generic name. Nearly every study used one or more real time particle counting instruments that gave size distribution and number concentration of airborne particles. Most studies additionally collected filter samples for analysis by electron microscopy to verify particle sizes or to examine the morphology and composition of airborne particles. It is particularly important to use other methods in addition to real time particle counters, as these instruments are not selective and cannot differentiate between ambient particles and the particles of interest. Further, they are optimized for counting spherical particles of unit density, which are not representative of the diversity of MNM material properties. In general, most of the references that examined particle size/morphology concluded that particles (both Ag and TiO_2) and carbon nanotubes/nanofibers are highly agglomerated in air, with detection of primary particles or agglomerates less than 100 nm in at least one dimension infrequent.

Context and sampling strategy
In addition to technical methods, the presence of information on study context was also reviewed, such as frequency and duration of an activity, operational conditions, and presence of ventilation. Most or all of this information was missing in nearly every study reviewed.

Although not assessed directly, the study reviewers additionally noted that many studies lacked information on sampling strategy, such as where and how many samples were taken, how samples were processed, and how data were analyzed following the study. Although information on context and strategy is not nano-specific, both types of information are important for interpreting results and comparison with results from other studies and tend to be easily collected or noted.

Airborne concentrations/estimates of exposure
The concentration measurements were reported using a diverse set of metrics collected by a variety of instruments, including total particle number, particle number binned into particle size ranges, and mass per unit volume (mg/m^3). The measurements between different studies were not directly comparable because of differences in principles of operations and thresholds for detection between instruments.

Consumer references
Work package 4 focused on three generic consumer exposure scenarios: nano-Ag in textiles, nano-TiO_2 in cosmetics, and CNTs in textiles. However, there was so little publicly available information on consumer exposure to MNMs that the work package chose to review all identified available information on consumer exposure to MNMs, without limiting themselves to just those references relevant to the materials or scenarios of interest in NANEX. Using this broadened approach, the work package considered over 20 books, reports, websites or peer-reviewed articles relevant to consumer exposure to MNMs. Many of these references contained too little specific information to be useful for building exposure scenarios. For example, several references generally described the breadth of uses of MNMs in consumer products or food-related products, which is informative for understanding the potential for exposure to MNMs, but not for building substance- and use-specific exposure scenarios. Therefore, only those studies or reports (as well as models and websites) with some relevance to the exposure scenarios targeted in NANEX were included in the NANEX Exposure References Database, and these were further designated as being of high or of limited relevance. Ultimately, WP4 identified 9 separate peer-reviewed journal articles, 5 reports or books and 2 websites with enough relevance to enter into the database. Of these, 4 of the peer-reviewed journals, 3 of the reports or books and 1 of the websites were considered highly relevant to the exposure scenarios of interest for NANEX.

Some of the reasons cited for a reference having limited relevance included:

- Unspecified chemical composition of particles used in the study
- More relevant to medical use than consumer use
- Information provided is too generic

The 8 highly relevant references yielded 11 entries in the reference database which were about evenly split between nano-TiO_2 and nano-Ag. There were no highly relevant entries related to consumer uses of CNTs (in textiles or otherwise). The entries on silver described use of nano-Ag in socks and fabrics, bathroom cleaners and wound dressings. The entries on TiO_2 addressed uses in sunscreens and coated surfaces. Nine entries mentioned dermal exposure, 5 mentioned inhalation, and 2 mentioned ingestion. Only 2 of the highly relevant entries contained original data on exposure or release (Hsu and Chein 2007[20]; Kulthong et al. 2010[21]): one measured particle emissions from nano-TiO_2 treated surfaces, the other the release of Ag from nano-Ag treated textiles into artificial sweat. The remaining references presented modelled exposure estimates or descriptions of content and uses of MNMs in products (Figure 4).

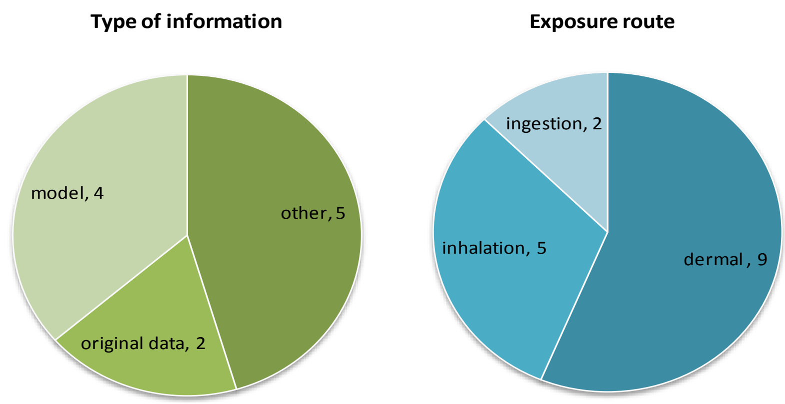

Figure 4 Distribution of entries from highly relevant references on consumer exposure by type of information and route of exposure (n=11). Left: entries containing modelled exposure estimates, original data, or other information (ie, literature reviews or MNM use inventories). Right: entries on each of three routes of exposure (some entries included more than one route of exposure).

WP4 concluded that there are many inventories and references that describe uses of MNMs in consumer products, but there is very little information available to assist in estimating consumer exposure for these MNMs.

Environmental references

In addition to considering exposures triggered by local emissions/point sources, as is done for occupational and consumer exposure assessments (WP3 and WP4, respectively), the evaluation of environmental release and exposure to MNM (WP5) must consider an immense diffusive emission source setting covering the whole life cycle of MNM and MNM-containing products. However, the amount of data currently available covers only a very small fraction of what is required in such a release framework. Very limited scientific information is available on MNM environmental release, fate and effects on organisms in the environment. Additionally, methods for detecting MNM in the environment are limited. For this reason, WP5 focused on the discussion of relevant MNM release assessment parameters for the most important release sources and pathways, such as MNM production, application and disposal as well as temporal and geographical MNM use distribution, which are crucial for framing MNM emission models as well as experimental and analytic studies.

In parallel, WP5 added 13 references to the reference database which were associated with the link between consumer exposure and environmental release. Although experimental results at companies producing MNM demonstrate worker exposure to these materials, the exposure estimates provided in these occupational studies

[20] Hsu L and Chein H (2007). Evaluation of nanoparticle emission for TiO_2 nanopowder coating materials. *J. Nanopart. Res.* 9 (1): 157-163.
[21] Kulthong K et al (2010). Determination of silver nanoparticle release from antibacterial fabrics into artificial sweat. *Part. Fibre Toxicol.* 7: 8.

are not suitable for estimating environmental release. The references on environmental release were nearly evenly split between modelling and experimental studies. Since studies on environmental release are so few in comparison to the potential sources, and analytical methods still need development, it is not productive to evaluate the methods used in the studies. The strengths and weaknesses of the modelling studies are discussed in more detail in WP5.

NANEX Exposure Scenario database

An exposure scenario consists of the main activity described (given by the title of the exposure scenario), plus contributing exposure scenarios which describe individual activities that, taken together, form the main activity of the exposure scenario. For example, an exposure scenario for 'industrial spray painting' (an example provided in ECHA guidance on exposure scenarios) could have several contributing exposure scenarios including 'conditions for mixing and filling of equipment (manually)', 'manual spraying with local exhaust ventilation', and 'robot spraying (closed-automated)' (ECHA 2010)[22]. Additionally, each exposure scenario has an 'environmental contributing exposure scenario' that describes quantities and conditions of release to the environment associated with the activities described in the exposure scenario (Figure 5).

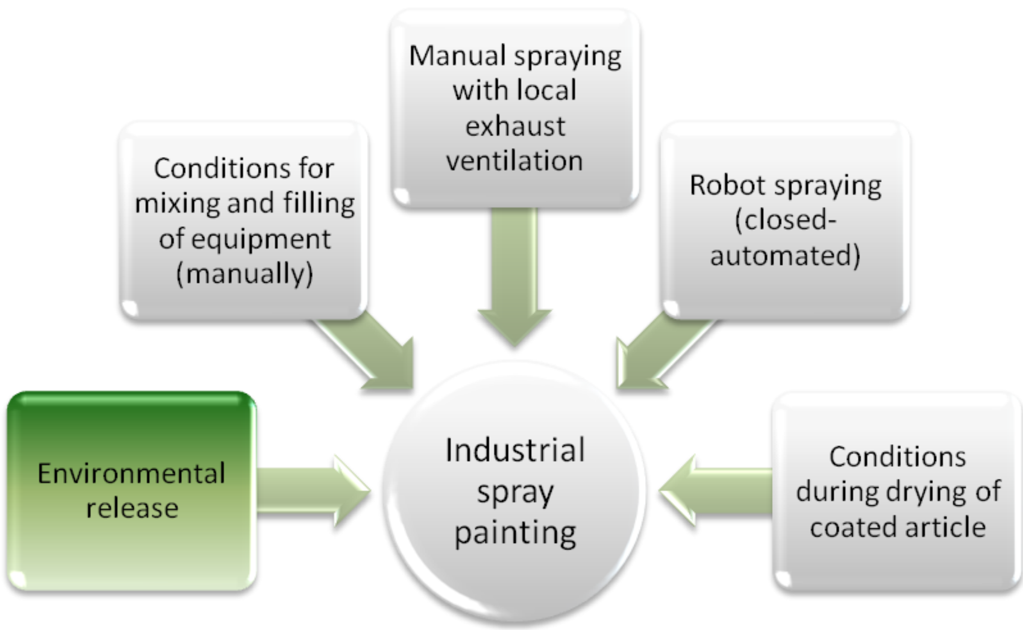

Figure 5 Structure of an Exposure Scenario for industrial spray painting, from an example provided in ECHA guidance. This example shows five contributing exposure scenarios, of which one represents environmental release.

At the outset of the NANEX project, WP2 developed a list of generic exposure scenarios that were of interest for the NANEX project. These covered the three MNMs of interest (nano-TiO_2, nano-Ag, and CNTs), and various consumer and occupational exposure scenarios that could be associated with each of these MNMs. This list was intended to guide, but not restrict, the development of exposure scenarios in the project.

WPs 3 and 4 entered 62 exposure scenarios into the exposure scenario database, of which 57 were related to occupational exposure and 5 to consumer exposure.[23] Within these exposure scenarios, there were 107 occupational contributing exposure scenarios and 24 consumer contributing exposure scenarios. No information on environmental release was available for the activities described in the occupational exposure scenarios.

[22] ECHA (2010). Guidance on information requirements and chemical safety assessment: Exposure Scenario Format. Helsinki, Finland, European Chemicals Agency (ECHA). Version 2.
[23] The case study exposure scenarios are not included in this analysis.

Although estimates of environmental release from consumer uses of MNM-containing products could theoretically be developed using the estimates of consumer use and MNM content of these products, the added step of estimating European market penetration of these products was deemed too uncertain to pursue developing quantitative estimates of release. Therefore, no contributing environmental exposure scenarios were developed in the NANEX project.

Due to the wide differences in publicly available information available on consumer and occupational exposure, the corresponding two work packages took a necessarily different approach to building the exposure scenarios. The consumer work package, with nearly no empirical information available on which to base exposure scenarios, relied on existing exposure estimation models and assumptions to build exposure scenarios for the 5 existing or projected consumer products containing the MNMs of interest to NANEX.[24] Various exposure estimation models were used to estimate dermal, inhalation and/or ingestion exposure. The use descriptors associated with these activities, both for the purposes of running the models and for filling in the exposure scenarios, were either the default parameters used in these models or conservative worst-case use patterns (e.g., constant use of a product). Information from the literature review was used to estimate potential MNM content in the various products. In the case of CNT-enabled textiles, no information was available on CNT content or release, so worst-case estimates were used.

The occupational work package could make use of a relatively wider range of studies covering many activities related to the handling of MNMs to build exposure scenarios. Therefore, the occupational work package did not rely on models or projected uses of MNMs to create exposure scenarios (although modelling was performed to complement and compare to experimental results). Instead, measurements and information describing specific use conditions were used to build exposure scenarios. Both publicly available information and results from sampling campaigns by partner institutions were used.[25]

At the outset of the project, the occupational work package was encouraged to combine studies as much as possible to make fewer, but more well supported, exposure scenarios. However, it immediately became clear that too little is defined with regards to MNM exposure to evaluate the similarity or relatedness of activities for the purposes of building exposure scenarios. For example, there were several studies of pouring or otherwise handling CNTs in a laboratory, but differences existed from site to site, such as the use of exposure mitigation measures, volumes handled, and properties of CNT being manipulated. Similarly, exposure measurements from different studies of a similar activity can have different metrics and sampling times. For the most part just one set of information could be used to build each occupational exposure scenario.

All of the exposure scenarios (both consumer and occupational) were categorized according to the categories developed by WP2 (Figure 6), with some modifications to the category titles (to improve categorisation). The diversity of potential applications considered was higher for CNTs than for nano-TiO_2 or nano-Ag, but exposure scenarios could, for the most part, only be developed for production of CNTs or handling of CNTs in laboratory settings. Similarly, most of the exposure scenarios developed for TiO_2 were related to production than downstream applications (both consumer and occupational). For nano-Ag, exposures scenarios were generally either related to the production of nano-Ag or their use in textiles. Additionally, several occupational exposure scenarios were developed for MNMs other than those initially considered within the NANEX scope, which are listed according to title in Table 1.

[24] The consumer exposure scenarios covered 5 activities: use of socks with nano-Ag (adults and children), service life of a t-shirt containing nano-Ag (adults and children), application of wound dressing containing nano-Ag, use of personal care products containing nano-TiO_2 (adults and children), and use of CNT-enabled textiles.

[25] Data from two workplace MNM measurement campaigns in Europe were made available to the NANEX project. One was the NANOSH project (funded by the Framework Programme 6 of the European Commission), which conducted air sampling at several worksites throughout Europe. Datasets describing 16 exposure scenarios were available for inclusion in NANEX. The other was the NANO- INNOV project, run by CEA (Commissariat à l'Energie Atomique et aux Energies Alternatives) in France, which has collected samples at worksites and laboratories handling or generating MNMs throughout France. A selection was done over the hundred measurements taken, and 18 activities were kept. Datasets describing those activities were available in time for inclusion in NANEX. Neither of these two projects publicly released their data during the NANEX project duration.

For many of the exposure scenarios that were developed, information was missing in some or several fields. According to REACH guidance, and in line with the life cycle approach, each exposure scenario must include a contributing environmental exposure scenario. There was not sufficient information available on environmental release of MNMs to develop environmental contributing exposure scenarios for the uses of MNMs covered in NANEX. In general, the occupational contributing exposure scenarios that were developed using data from sampling campaigns were significantly more comprehensive than those developed using publicly available data, especially in terms of descriptions of quantities of MNMs used and measures used to mitigate exposure (Figure 7. The exposure scenarios developed from the literature tended to not provide much detail beyond product characteristics (which themselves were often not detailed) and exposure estimates. In many cases, the consumer contributing exposure scenarios seemed to have more information than many of the occupational contributing exposure scenarios, however, as noted previously, very little quantitative information was available on consumer exposure and the information used in these exposure scenarios was highly uncertain.

Table 1. Exposure scenarios (ES) developed for MNMs other than nano-Ag, nano-TiO_2, and CNTs

Exposure scenarios for other MNMs	**# of ES**
Handling of products containing carbon black	1
Handling of carbon black	2
Production and handling of metal-based NPs in a gas-phase production	1
Synthesis of fullerenes	1
Production of carbon nanomaterial (not otherwise specified)	2
Handling of fullerenes	1
Opening of epitaxy frame by molecular beam with a Ti target	1
Metal oxides released from bed deposition equipment	1
Preparation and deposition of nanoZnO solution for use as ink.	1
Maintenance of a SiO_2 plasma enhanced CVD instrument	1
Cleaning of growth furnace producing nanothread Si	1
Autocombustion of lanthane, strontium, cobalt, and iron	1

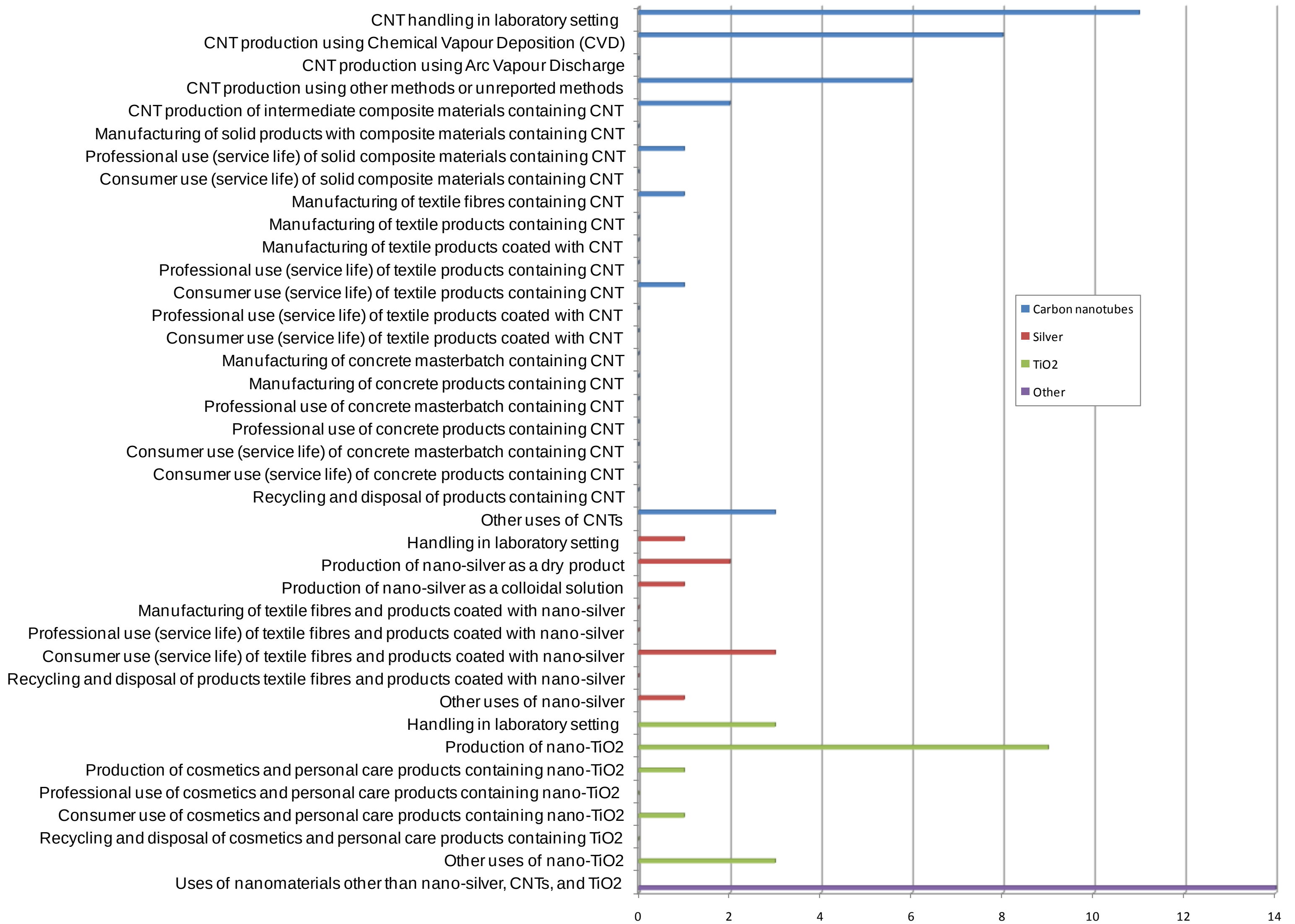

Figure 6 Number of exposure scenarios developed relevant to each category (some exposure scenario fit into more than one category). Very few exposures scenarios were developed for downstream uses of MNMs. See Table 2 for explanation of 'other' MNMs.

Occupational exposure scenarios - literature based

CES ID	1	2	3	4	5	6	7	8	9	10	11	12	93	94	95	96	97	98	99	100	101	102	104	105	137	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135
CES name																																																							
Specification																																																							
Product characteristics																																																							
Amounts used																																																							
Frequency/duration of use																																																							
Human factors not influenced by risk management																																																							
Other given operational conditions affecting exposure																																																							
Tehcnical measures preventing release at source																																																							
Technical measures to control dispersion																																																							
Organisational measures to prevent dispersion, release																																																							
Conditions & measures related to personal protection																																																							
Conditions/measures to prevent release in service life																																																							
Additional advice																																																							
Exposure estimate																																																							

Occupational exposure scenarios - sampling campaigns

CES ID	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	49	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70
CES name																																																				
Specification																																																				
Product characteristics																																																				
Amounts used																																																				
Frequency/duration of use																																																				
Human factors not influenced by risk management																																																				
Other given operational conditions affecting exposure																																																				
Tehcnical measures preventing release at source																																																				
Technical measures to control dispersion																																																				
Organisational measures to prevent dispersion, release																																																				
Conditions & measures related to personal protection																																																				
Conditions/measures to prevent release in service life																																																				
Additional advice																																																				
Exposure estimate																																																				

Consumer exposure scenarios

CES ID	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161
CES name																								
Specification																								
Product characteristics																								
Amounts used																								
Frequency/duration of use																								
Human factors not influenced by risk management																								
Other given operational conditions affecting exposure																								
Tehcnical measures preventing release from articles																								
Technical measures to control dispersion																								
Organisational measures to prevent dispersion, release																								
Conditions & measures related to personal protection																								
Cond. & meas. releated to information and behaviour																								
Conditions/measures to prevent release in service life																								
AdditionalAdvice																								
Exposure estimate																								

Figure 7 (previous page). **Matrices showing information coverage for exposure scenarios developed in NANEX WPs 3 and 4 (human exposure only). In each chart, the leftmost column contains the fields within a contributing exposure scenario, and the subsequent columns (headed by a number) represent the contributing exposure scenarios developed in NANEX. The dark coloured squares indicate information was available, the white squares indicate that no information was reported, and the cross-hatched squares are not applicable to the particular exposure scenario (some fields were present for exposure from articles that were not applicable to scenarios involving the primary substance). Boxes were filled in if any information was available, regardless of level of detail or quality of information provided. The three charts, from top to bottom, represent occupational exposure scenarios developed from the literature, occupational exposure scenarios developed from sampling campaign data, and consumer exposure scenarios.**

Key findings

The majority of the publicly available references identified were associated with occupational exposures during the primary manufacturing of MNMs: there was an almost complete lack of studies describing exposure to downstream users of MNMs, whether in the occupational or consumer setting. There is little information available on the number of MNM users v. producers. However, a recent study demonstrated that in Switzerland, among companies involved in MNM use and handling, most companies are downstream users and only a few companies manufacture MNMs, suggesting that there is a much larger potentially exposed occupational population in the downstream uses of MNMs compared to primary manufacturing (Schmid et al. 2010)[26].

This imbalance is further demonstrated by the distribution of information among the different types of MNMs. Despite the well-documented uses of nano-Ag and nano-TiO_2 in products currently sold on the market, there were significantly fewer entries describing occupational exposure to these materials than CNTs.

The references that were reviewed were generally found to have used state-of-the-art methods to take measurements. One problem that was noted in a few instances was the over-reliance on real time particle counting instruments (i.e., SMPS and OPC) without using other methods to confirm the presence of the particles of interest or describe particle morphology and size distribution. Many studies used electron microscopy to further characterize particles, although electron microscopy has its own limitations, including uncertain deposition efficiency on sampling substrates and problems distinguishing MNMs from background. Another issue that was often noted in the studies was the limited description of the primary particles used in the study; this is probably due to difficulties in obtaining this type of information in field studies, but such information is valuable for developing sampling strategies, interpreting data from instruments, and understanding the relevance for other exposure situations. One shortcoming was the lack of descriptions of sampling strategy and other contextual information.

Very few consumer exposure scenarios were developed compared to occupational exposure scenarios. This reflects the differences in availability of data in the two different exposure domains. All of the information used to build the consumer exposure scenarios were based on estimates and default parameters from the ECETOC TRA and ConsExpo models, modelled estimates from the published literature, and the ECHA Guidance for Consumer Exposure Estimation. As noted in WPs 3 and 4, these models have not been developed or validated for MNMs and are probably not accurate.

The analyses of both the NANEX Exposure Scenario and Exposure References Databases should be interpreted with caution. Since the review of the literature and development of exposure scenarios were conducted by a diverse set of scientists from different institutions in Europe, it is possible that there are some inconsistencies in how information was reported. Additionally, it is difficult to transfer information created for one purpose (e.g., characterization of particle release, epidemiological studies, etc.) into prescribed fields, as existed in both databases. However, a systematic approach employing such fields was necessary for the collection and synthesis of information. Overall, the information collected by the databases is useful for a general understanding of where large gaps in information exist and where further information is needed.

In conclusion the following observations could be made:

[26] Schmid K et al (2010). Nanoparticle usage and protection measures in the manufacturing industry--a representative survey. *J. Occup. Environ. Hyg.* 7 (4): 224-232.

- There is limited information available to build well-informed exposure scenarios covering the life cycle of MNMs for uses which are known to exist.
- Most of the existing quantitative exposure data are associated with small-scale production of MNMs. There is particularly little information available on exposures to downstream users, i.e., consumer and occupational uses of preparations and articles containing MNMs.
- Literature-base studies often do not include descriptions of contextual details, such as room size, presence of ventilation, or typical frequency and duration of an activity.
- Studies assessing inhalation exposure to MNM rely on real time particle counters to measure exposure, yet these instruments cannot distinguish MNMs from background particles. There is an urgent need to develop more selective instrumentation.
- It is important to look at particles of all sizes, particularly since nanoparticles tend to agglomerate into larger particles.
- The current state-of-the-science does not allow for a detailed comparison of data between studies due to differences in particle properties, measurement techniques, and reporting metrics.

It was clear that information used to describe the real-life scenarios developed during the case studies was much more detailed and comprehensive. Unfortunately, a considerable amount of the detail was considered sensitive and confidential information, and therefore, these scenarios could not be included in the library. However, it would be extremely useful if exposure scenarios developed by industry could be shared with exposure and risk assessors in the scientific community and others (e.g. SMEs). In further discussion and collaboration with industry, ways for describing the exposure scenarios without jeopardising the confidential nature of some of the details should be explored.

The initial intention of NANEX was to develop an extensive web-based library of occupational and consumer exposure scenarios that would be publicly available. However, following review of the available exposure scenarios, it was clear that the information available for the scenarios was often not of sufficient quality to be included in a web-based library. One note of caution is that the exposure scenarios developed within the NANEX project, do not describe safe use of the MNMs (as defined under REACH), but rather describe the existing exposure situation (i.e., no risk assessment was carried out). We believe with more measurement data and contextual information becoming available over time (e.g., from EU and other projects), that the expansion of the exposure scenario library would provide a useful source of exposure information for risk assessment and other purposes. However, rigorous quality assurance procedures will need to be developed and applied to ensure that the exposure scenarios are of sufficiently high quality.

Impact, dissemination and exploitation of results.

Exposure assessment plays a critical role in the risk assessment process. Exposure scenarios, whether developed for REACH compliance or otherwise, are a useful tool for evaluating specific exposure situations. They outline the basic information that is necessary for understanding the conditions under which exposure occurs (i.e., amounts used, operational conditions and risk management measures), and the associated exposure estimates.

The NANEX project attempted to develop a detailed catalogue of exposure scenarios for MNMs. The ability to build an exposure scenario for MNMs is a basic need for assessing exposure and the associated risks of MNMs, both at the site-specific level and at a more global level. For companies handling MNMs, the skills and instrumentation needed to assess exposure can be costly, limiting their ability to characterize the range of exposure scenarios associated with their processes and products. Information needs to be openly available to promote and assist better product stewardship. At the more global level, the ability to build an exposure scenario for MNMs implies that there is a generalized understanding of how exposure to MNMs is described.

Although several exposure scenarios were developed in the project, they were consistently characterised by missing information or information of dubious accuracy and reliability. It was not possible to infer meaningful or generalizable exposure characterizations for these exposure scenarios. In terms of the toxicological paradigm, the relationship between exposure, dose, and effect are not well defined. Not only does this make it difficult to interpret the health relevance of measurements, but there is no generally accepted health relevant definition of exposure to promote consistency or common terminology among researchers. Most of the studies reviewed had wide differences in amount of information reported and specifics of the situations under study. These limitations, combined with the general lack of knowledge on how MNMs compare to other more traditional chemicals in terms of behaviour in air or use in products, made it inappropriate to generalize information from one situation to another.

In order to better assess and manage risks of MNMs, it is necessary to have data that are comparable and can be integrated to build a body of more advanced knowledge. Currently, the data are not rich enough to allow for building more complex exposure estimation models, to develop (with toxicologists) health relevant measures of exposure, to classify exposure among populations (i.e., for epidemiology studies), to characterize environmental release, or to characterize the key determinants of MNM exposure. In the short-term, it is absolutely essential to assess the effectiveness of risk management measures in order to develop risk management strategies based on best practices, and to harmonize data collection and reporting methods. We suggest that a coherent/harmonized strategy for collecting and reporting data be developed starting with the suggestions provided in this report. These suggestions were developed by scientists specializing in diverse areas of human and environmental exposure. In the longer term, with more harmonization of exposure metrics and data collection, we expect that it will be possible to develop a more advanced understanding of exposure over the life cycle of MNMS, including MNM release, transmission, and behaviour in various media.

Based on the integration of the NANEX findings and the identification of the knowledge gaps, research priorities were developed as well as recommendations of minimum set of data items for reporting of exposure studies on manufactured nanomaterials.

Research priorities

A coherent strategy for exposure assessment, as it relates to risk assessment, needs further development.

In the medium- to long-term, with additional and more harmonized research into exposure to (and hazards of) MNMs, more detailed risk assessments will become feasible. In the short-term, two lines of research should be established; one focusing on risk management strategies while waiting for more specific information and the other focusing on the basic needs for more detailed and consistent research. The latter line of research will make it possible to reach intermediate goals, such as building models and understanding the relationship between operational conditions and measurements.

Specific MNM research needs are described in more detail below, with an indication of a timeline when they could be achieved. (Short-term is 1-2 years, medium-term is 3-5 years, and long-term is 5+ years.)

Risk Management Strategies

Due to lack of and uncertain knowledge on MNM exposure (and hazards) and the expected time span for research to yield such information, an important research focus in the short-term should be on risk management strategies.

- The effectiveness of commonly used risk management measures (RMMs) and good practices (e.g. GoodNanoGuide; ISO TC 229 and other control banding approaches) for controlling/minimizing MNM exposure should be verified. The effectiveness is usually expressed for a reduction of mass concentration; however this should also be verified for other MNM relevant metrics *(short-term)*

Human exposure assessment:
There are several research needs for human exposure assessment, which range from generation of more data (in a harmonized manner) to more advanced use of such data for the development of models. Areas of specific interest include the following:

Need for standardization/harmonization
The existing studies on MNM exposure are highly diverse in terms of sampling strategy, how data are reported, and how thoroughly the activity under study is described. A more consistent approach is needed and ongoing activities for harmonization should be encouraged and supported.

- Library of activities describing activities associated with MNMs (e.g., nano-PROCs), which can be further associated with measurements *(short-term)*
- Minimum set of information to be included in MNM exposure assessments (the list provided in the following section of this report as an example) *(short-term)*
- International harmonization of data generation (measurement strategy, including type of measurements and metrics), data storage and analysis, and reporting. These efforts should enable optimum use of data/information in data poor areas *(short-term)*

Data generation
More research is needed on human exposure to MNMs at all stages in a product life cycle.

- More studies of occupational exposure during full-scale and secondary manufacturing operations, as well as consumer and occupational exposure during use of products containing MNMs, are essential *(short/ medium-term)*

- Further improvement of knowledge about presence of MNMs in consumer products, including a wider coverage and more detailed inclusion of products in inventories, and based on independent evidence is needed. This could happen either by improving information in already existing inventories or developing new inventories (*short / medium-term)*
- The amount of MNMs in consumer products and whether use patterns differ between nano-enabled products and conventional products should be characterized (*short / medium-term)*
- The release of MNMs from MNM-containing products should be characterised (amount and form), for typical occupational and consumer activities (e.g., abrasion during use [for articles]) (*short / medium-term)*
- Since spraying with liquids containing MNMs seems to have a particularly high exposure potential for consumers, more data on such exposures should be generated. Also further research in dermal consumer exposure resulting from applications where MNM-containing products (e.g. liquids) come in direct contact with skin seems justified (*short / medium-term)*

Improving exposure assessment
There are several areas where research is needed to improve exposure assessment methods and the link between exposure assessment and risk assessment.

- Develop methods for characterizing personal exposure, especially considering the multi-factorial nature of exposure to MNMs *(short-term)*
- Develop instrumentation that is more selective for MNMs *(short/medium-term)*
- Create a multi-disciplinary overarching effort to define health-relevant exposure to MNMs, thus bridging the gap between toxicology and exposure assessment *(short / medium / long-term)*

Modelling
Human exposure estimation models that are calibrated and validated for MNMs are urgently needed. However, currently there is a shortage of proper measurement data to be used for validation of exposure models. Understanding the process of exposure is a key factor in building models.

- Existing first tier exposure models should be further reviewed, and if necessary modified, and tested for MNMs for qualitative risk (control) banding *(short / medium-term)*
- Determinants and modifying factors of MNM exposure should be studied in detail. This needs to include all relevant processes involved in emission and dispersion (e.g. homogeneous and heterogeneous coagulation) and take into account the multi-factorial nature of MNM exposure *(medium / long-term)*
- Quantitative exposure models should be developed based on the concepts and specific nano features and aerodynamic modules proposed by Schneider et al (2011)[27] and validated by a populated exposure database *(medium / long-term)*
- It is recommended that data be collected according to the principles outlined in this report (e.g., with respect to information on context, sampling strategy, and data management) so that it can be used for building and validating models *(short / medium / long-term)*

Life cycle and environmental release
High uncertainties characterize the conceptualization and parameterization of the assessment of environmental exposure to MNM. Modelling release is currently the only way for identifying possible environmental compartments that may be affected by emitted MNM. Considering a life cycle perspective is essential for such release modelling. MNM release may occur during all life stages of contaminants (i.e., emissions from MNM products, from MNM production and nanoproducts' manufacturing processes). Mass-partitioning models (Blaser et al. 2008[28]; Boxall et al. 2008[29]; Mueller and Nowack 2008[30]; Gottschalk et al. 2009[31]; Gottschalk et al. 2010[32]) that quantitatively estimate environmental release from such a life cycle perspective are available. However, these models and subsequent environmental release simulations suffer from low quality and/or scarcity of input data. To improve and validate such release assessment we need therefore urgently more empirical information.

- Data (from industry) on MNM production amounts *(short-term)*. Also needed are quantitative indications on the allocation of the produced volume to the relevant product categories (e.g. cosmetics, plastics etc.) that contain the MNM *(short-term)*

- Empirical (experimental/analytical) information for the main release sources during the MNM life stages: MNM production and nanoproducts' manufacturing processes and MNM-containing products consumption and disposal (*short/medium-term*)

- Empirical (experimental/analytical) knowledge regarding the released form, such as whether the MNM are agglomerated or present as single particles or if they are embedded within a matrix (*medium/long-term*)

Recommendations for a minimum set of data items for reporting of exposure studies on manufactured nanomaterials
Several limitations in technology and interpretation of measurement data were identified in the NANEX project. Some of these limitations will take considerable time to address, in particularly technical methods for measuring relevant exposure metrics and establishment of exposure-response relationships. One area where immediate improvement is possible is in more harmonized or standardized reporting of exposure studies,

[27] Schneider et al (2011) Conceptual model for assessment of inhalation exposure to manufactured nanoparticles. JESEE doi:10.1038/jes.201114.
[28] Blaser, S. A., M. Scheringer, M. MacLeod and K. Hungerbuehler (2008). Estimation of cumulative aquatic exposure and risk due to silver: Contribution of nano-functionalized plastics and textiles. *Sci.Total Environ.* 390 (2-3): 396-409.
[29] Boxall, A. B. A., Q. Chaudhry, A. Jones, B. Jefferson and C. D. Watts (2008). Current and future predicted environmental exposure to engineered nanoparticles. Sand Hutton, UK, Central Science Laboratory.
[30] Mueller, N. C. and B. Nowack (2008). Exposure modeling of engineered nanoparticles in the environment. *Environ. Sci. Technol.* 42 (12): 4447-4453.
[31] Gottschalk et al (2009). Modeled environmental concentrations of engineered nanomaterials (TiO2, ZnO, Ag, CNT, fullerenes) for different regions. *Environ. Sci. Technol.* 43: 9216-9222.
[32] Gottschalk, F., T. Sonderer, R. W. Scholz and B. Nowack (2010). Possibilities and Limitations of Modeling Environmental Exposure to Engineered Nanomaterials by Probabilistic Material Flow Analysis. *Environ. Toxicol. Chem.* 29 (5): 1036-1048.

including sampling strategy, use conditions/contextual information (e.g., operational conditions and risk management measures), and data handling.

Contextual information is essential for qualitatively understanding the situation under study and interpretation of the results. As noted previously, basic information about MNM use and release volumes (and rates) from a site could contribute significantly to the limited existing body of information on environmental release. Further, contextual information is necessary for identifying how factors such as operational conditions or risk management measures can affect aerosol properties (e.g., agglomeration and transmission). Ideally, it will eventually be possible to estimate the impact of operational conditions and risk management measures on measurement results and exposure estimates. This level of understanding of MNM exposure is needed to build models, compare studies, understand the relevance of information collected in one situation for another situation, and, thus, to build exposure. Thus, we propose a minimum set of items that should be reported for all MNM exposure studies, which includes both nano-specific and non-nano-specific items.

Minimum data items

Nano-specific information:

- Description of physical and chemical form of the MNMs used (i.e., at source);
    - Chemical composition
    - Size distribution (including dimensions for fibres)
    - Whether MNM is bound in a matrix. If so, describe:
        - The matrix itself (e.g., plastic, rubber, concrete, paint)
        - Form of matrix (e.g., powder, liquid, solid, granules)
        - Amount of MNMs used in the matrix
- Description of physical and chemical form of released/detected particles;
    - Embedded in a matrix, agglomerated, single particle
    - Elemental composition by EDX/EDS or chemical analysis
- Potential other sources of ultrafine and other particles; and
- Exposure characterized using a combination of metrics and measurements, which could include, but are not limited to, mass, particle number, and particle size distribution.

Information that is not nano-specific:

- Information on process
    - Description of the process and all activities included in the process;
    - Typical duration and frequency of these activities; and
    - Type of enclosure of process: if enclosed, provide frequency and duration of opening for maintenance, quality control and/or other manual operations.

- Description of site
    - Room size, windows and other features that may affect exposure.

- Risk management measures (RMM)
    - For occupational studies, standardized description of types of RMM (e.g. ventilation) and personal protective equipment present (Fransman et al. 2009)[33];
    - For consumer studies, product design that affects the release (e.g., maximum volume released from one use of a spray) and description of other types other RMM applied during the measurement; and
    - Other measures (e.g., administrative controls, additional engineering controls).

- Environmental release information
    - Total volume of MNMs used on site;
    - Amounts and processes for disposal and/or recycling;
    - Volume of air flow and MNM concentrations in outlet air (emission to air after filters); and
    - Volume of waste water flow and MNM concentrations in effluent (after treatment) (emission to surface waters).

[33] Fransman, W., J. Cherrie, M. van Tongeren, T. Schneider, M. Tischer, J. Schinkel, H. Marquart, N. Warren, H. Kromhout and E. Tielemans (2009). Development of a mechanistic model for the Advanced REACH Tool (ART). Zeist, The Netherlands, TNO Quality of Life.

- Sampling and data analysis strategy:
  - Location of samples/measurements relative to source and receptor (e.g., workers);
  - Number of samples/measurements taken;
  - Description of activities associated with each sample/measurement;
  - Qualitative assessment describing how representative the measurements are for personal exposure;
  - Description of data analysis, including the difference between background and activity, and how this was calculated, whether and how peaks were addressed, whether and how data were averaged.

This list represents the minimum amount of data that we currently believe exposure scientists should report when describing the results of an exposure assessment study. We encourage scientists to also include the following information:

- Description of activities or use of RMMs in a standardized format, such as that in the Advanced REACH Tool (Fransman et al. 2009)[33].
- More detailed description of MNM physicochemical properties, including surface area, functional surface groups, surface reactivity, and solubility/biopersistance.

Additionally, it is dependent upon the expert judgment of the exposure assessor to include additional information when possible or deemed necessary (e.g., additional sources of environmental release or exceptions to standard operating procedures on the day of the study).

Most of the information listed above is not specific for MNM exposure assessment, yet this information is necessary to maximize the value of exposure studies, both in terms of information available (e.g., on environmental release), and to ensure that results of studies can be interpreted and compared with other exposure studies and results used for similar exposure scenarios.

The minimum dataset does not include a prescribed list of measurements needed in an exposure assessment. This is because there is still significant uncertainty on this issue, and it was not within the NANEX scope to determine the best choice of metrics or measurements (as these also heavily depend on toxicological considerations). It was clear within the NANEX project, however, that a single measurement or metric is generally not sufficient to characterise and quantify MNM exposure for all types of MNMs (although it may be appropriate for individual cases/types of MNMs). Rather, it seems that exposure is best characterized by many factors and thus should be described by a set of numbers/information. In the interim, until there are harmonized recommendations for presenting such data, we suggest that exposure studies include as much information as possible in terms of measurements, recognizing that not all may be appropriate in every situations. Size distribution is important for understanding the likelihood of deposition of particles in certain parts of the airways and both particle size and surface area concentration are associated with potential toxicity of an MNM. The mass concentration is important because there is already a large body of research on exposure to and toxicity of particles in the mass-based metric. Finally, particle (or fibre) number concentration is important as this metric may, in some cases, be more relevant than mass in determining potential risk from exposure to MNMs and because the mass of airborne nanoparticles will usually be very small and therefore can be much more difficult to measure than particle number.

The importance of harmonizing the metrics/measurements used to describe exposure, so that data can be compared, pooled, and used for broader research (e.g., epidemiology studies and development of nano-specific models), cannot be overstated. This lack of harmonization made it impossible to compare measurement data in the NANEX project. It is imperative that harmonized basic guidelines, preferably internationally agreed, for measurements collection and reporting be developed in the near future. Much of the contextual information requested above is easily observed and assembled. This level of detail can become burdensome to publish in peer reviewed journal articles due to space limitations; thus, we recommend making this information available in appendices or online supplementary information for articles and reports.

4.2 Use and dissemination of foreground

Seven types of relevant stakeholders previously were identified and have now the opportunity to be clearly informed on developing exposure scenarios for MNMs and estimating occupational, consumer and environmental exposures issues.

S1. REGULATION : ISO/CEN/BSI, Regulators EU/National, ECHA
S2. UNIONS and NGOs : Trade Unions, Environmental NGOs
S3. INDUSTRY: Technology platforms (safety, chemical), Industry associations (manufacturers, downstream users), Individual companies, multinationals, SMEs
S4. NANO: FP6/7 Nano projects with an exposure element, ObservatoryNANO, and projects developing novel nanomaterials and applications
S5. OHS: Occupational Hygiene/Health Safety Professionals
S6. INSTITUTION: Academia, materials science, Exposure/Risk/Epidemiology/Health
S7. PUBLIC: General Public, Consumer organisations,

In order to assure coherence in project communication, a Dissemination Report was produced. In addition, a public website was in order to promote external communication on project objectives, support workshop announcement information, disseminate technical results: make science sexy in order to facilitate basic understanding, and provide efficiently support academic teaching & training activities.

A workshop organised by IST-P5 on **M3** in collaboration with NanoImpactNet and with project team and invited experts gathered information on exposure scenarios and disseminated the project plan to the stakeholders. A specific NANEX session was been organized by during NanoSafe Conference 2010 in Minatec Grenoble in order to offer a large dissemination workshop with stakeholders including world wide standardisation organizations.

NANEX results will respectively:

- contribute to feed standards definition process,
- facilitate social stakeholders contributions to the governance issues,
- contribute to make industrial aware of the specific need for emerging risk management
- highlight respective research needs and orient strategy
- support academic and professional training activities on MNMs exposure estimation,
- facilitate MNMs exposure population understanding.

Future dissemination activities include presentations at several international conferences, including
- NANOIMPACTNET 2011,
- SES-SETAC EU Joint Special Session “Integrating the Sciences and Development of Methods, Approaches and Tools to Meet Emerging Exposure Needs in Chemical Regulation”, and
- 5th International Conference on Nanotechnology – Occupational and Environmental Health
9-12 August 2011

One publication from NANEX has been accepted for publication by the Journal of Environmental Monitoring, while several manuscripts for submission to peer-reviewed journals are currently in preparation

1) Development of exposure scenarios using publicly available information
2) Evaluation of the exposure models for estimating exposure to nanomaterials
3) Simulation to determine particle deposition in the workers' respiratory system using available exposure information.

Furthermore we are planning to submit a number of editorials to exposure assessment journals such as the Annals of Occupational Hygiene, to explain the need for collecting and reporting exposure and contextual information in a harmonized manner and making detailed contextual exposure information available, using electronic appendices.

Finally, we are currently preparing a White Paper describing the research needs that have been identified during the NANEX project. When completed we will distribute this White Paper to all relevant stakeholders, including the EU and national governments.

Title	Main Author	Title of the periodical/the series	Number, date or frequency	Publisher	Place of publication	Date of publication (dd/mm/yyyy
Release of engineered nanomaterials to the environment	Gottschalk, F. and Nowack, B.	Journal of Environmental Monitoring	in press	Royal Society	London	anticipated April 2011

NO.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
1	NanoSafe2010 conference: full satellite meeting dedicated to NANEX	B. Nowack, M. Van Tongeren, D. Brouwer, K. Clark	Satellite session	18.11.2010	Grenoble, France	Scientific Community, Industry, Civil Society, Policy makers	50	worldwide
2	ENPRA harvesting workshop	Martie van Tongeren	NANEX and Exposure modelling	14.04.2010	Ispra, Italy	Scientific community, Policy makers	100-200	Europe
3	IOHA conference	Riediker / Clark	Gap analysis of existing data concerning occupational exposure to engineered nanomaterials	Sept. 29, 2010	Rome, Italy	Scientific community, industry	100	worldwide
4	Measurement of Health Risk and Exposure to CNT and other ENP	Muir, R.B. Lecloux, A	Workplace aerosols 2010, Karlsruhe	28-29.06.2010	Karlsruhe Institute of Technology, Germany	Scientific community, industry	ca.70	worldwide
5	Measurement of Health Risk and Exposure to CNT	RB Muir, B Gorbunov	Nanomaterials 2010	8th june 2010	London, UK	Scientific community, industry, policy makers	ca. 100	worldwide
6	NANOIMPACTNET conference, poster presentation	Riediker / Clark	Integration and Analysis of Available Information for Building Exposure Scenarios for Nanomaterials.	14 - 17 February 2011	Lausanne, Switzerland	Scientific community, industry, policy makers	-	worldwide

NO.	**Type of activities**	**Main leader**	**Title**	**Date**	**Place**	**Type of audience**	**Size of audience**	**Countries addressed**
7	conference	Riediker / Clark	Analysis of Existing Information Available for Building REACH-Compatible Exposure Scenarios for Nanomaterials	5.15.2011	Portland, OR, USA	Scientific community, industry, policy makers	-	USA
8	NANOIMPACTNET conference, poster presentation	Marika Pilou	“Deposition of CNTs in the Respiratory Tract for two Industrial Exposure Scenarios	14 - 17 February 2011	Lausanne, Switzerland	Scientific community, industry, policy makers	-	worldwide

Section B (Confidential[34] or public: confidential information to be marked clearly)
Part B1

Not applicable

[34] Note to be confused with the "EU CONFIDENTIAL" classification for some security research projects.

Part B2

Not applicable

4.3 Report on societal implications

A. Ethics

1. Did your project undergo an Ethics Review (and/or Screening)?	No
If Yes: have you described the progress of compliance with the relevant Ethics Review/Screening Requirements in the frame of the periodic/final reports?	

2. Please indicate whether your project involved any of the following issues :

RESEARCH ON HUMANS	
Did the project involve children?	No
Did the project involve patients?	No
Did the project involve persons not able to consent?	No
Did the project involve adult healthy volunteers?	No
Did the project involve Human genetic material?	No
Did the project involve Human biological samples?	No
Did the project involve Human data collection?	No
RESEARCH ON HUMAN EMBRYO/FOETUS	
Did the project involve Human Embryos?	No
Did the project involve Human Foetal Tissue / Cells?	No
Did the project involve Human Embryonic Stem Cells (hESCs)?	No
Did the project on human Embryonic Stem Cells involve cells in culture?	No
Did the project on human Embryonic Stem Cells involve the derivation of cells from Embryos?	No
PRIVACY	
Did the project involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	No
Did the project involve tracking the location or observation of people?	No
RESEARCH ON ANIMALS	
Did the project involve research on animals?	No

Were those animals transgenic small laboratory animals?	No
Were those animals transgenic farm animals?	No
Were those animals cloned farm animals?	No
Were those animals non-human primates?	No
RESEARCH INVOLVING DEVELOPING COUNTRIES	
Did the project involve the use of local resources (genetic, animal, plant etc)?	No
Was the project of benefit to local community (capacity building, access to healthcare, education etc)?	No
DUAL USE	
Research having direct military use	No
Research having potential for terrorist abuse	No

B. Workforce Statistics

3. Workforce statistics for the project: Please indicate in the table below the number of people who worked on the project (on a headcount basis).

Type of Position	Number of Women	Number of Men
Scientific manager	1	
Work package leader	6	
Experienced researcher (i.e. PhD holders)	8	
PhD student	1	
Other	2	

4. How many additional researchers (in companies and universities) were recruited specifically for this project?	1
Of which, indicate the number of men:	0

C. Gender Aspects

5. Did you carry out specific Gender Equality Actions under the project ?	No

6. Which of the following actions did you carry out and how effective were they?	
Design and implement an equal opportunity policy	Not Applicable
Set targets to achieve a gender balance in the workforce	Not Applicable
Organise conferences and workshops on gender	Not Applicable
Actions to improve work-life balance	Not Applicable
Other:	

7. Was there a gender dimension associated with the research content - i.e. wherever people were the focus of the research as, for example, consumers, users, patients or in trials, was the issue of gender considered and addressed?	No
If yes, please specify:	

D. Synergies with Science Education

8. Did your project involve working with students and/or school pupils (e.g. open days, participation in science festivals and events, prizes/competitions or joint projects)?	No
If yes, please specify:	

9. Did the project generate any science education material (e.g. kits, websites, explanatory booklets, DVDs)?	No

E. Interdisciplinarity

10. Which disciplines (see list below) are involved in your project?	
Main discipline:	2.3 Other engineering sciences (such as chemical, aeronautical and space, mechanical, metallurgical and materials engineering, and their specialised subdivisions; forest products; applied sciences such as geodesy, industrial chemistry, etc.; the science and technology of food production; specialised technologies of interdisciplinary fields, e.g. systems analysis, metallurgy, mining, textile technology and other applied subjects)
Associated discipline:	
Associated discipline:	3.3 Health sciences (public health services, social

	medicine, hygiene, nursing, epidemiology)

F. Engaging with Civil society and policy makers

11a. Did your project engage with societal actors beyond the research community? (if 'No', go to Question 14)	No
11b. If yes, did you engage with citizens (citizens' panels / juries) or organised civil society (NGOs, patients' groups etc.)?	
11c. In doing so, did your project involve actors whose role is mainly to organise the dialogue with citizens and organised civil society (e.g. professional mediator; communication company, science museums)?	
12. Did you engage with government / public bodies or policy makers (including international organisations)	
13a. Will the project generate outputs (expertise or scientific advice) which could be used by policy makers?	
13b. If Yes, in which fields?	
Agriculture	
Audiovisual and Media	
Budget	
Competition	
Consumers	
Culture	
Customs	
Development Economic and Monetary Affairs	
Education, Training, Youth	
Employment and Social Affairs	
Energy	
Enlargement	
Enterprise	
Environment	
External Relations	
External Trade	
Fisheries and Maritime Affairs	
Food Safety	
Foreign and Security Policy	

Fraud	
Humanitarian aid	
Human rightsd	
Information Society	
Institutional affairs	
Internal Market	
Justice, freedom and security	
Public Health	
Regional Policy	
Research and Innovation	
Space	
Taxation	
Transport	
13c. If Yes, at which level?	

G. Use and dissemination

14. How many Articles were published/accepted for publication in peer-reviewed journals?	0
To how many of these is open access provided?	0
How many of these are published in open access journals?	0
How many of these are published in open repositories?	0
To how many of these is open access not provided?	0
Please check all applicable reasons for not providing open access:	
publisher's licensing agreement would not permit publishing in a repository	No
no suitable repository available	No
no suitable open access journal available	No
no funds available to publish in an open access journal	No
lack of time and resources	No
lack of information on open access	No
other	
If other - please specify	
15. How many new patent applications ('priority filings') have been made?	0

("Technologically unique": multiple applications for the same invention in different jurisdictions should be counted as just one application of grant).	

16. Indicate how many of the following Intellectual Property Rights were applied for (give number in each box).	
Trademark	0
Registered design	0
Other	0

17. How many spin-off companies were created / are planned as a direct result of the project?	0
Indicate the approximate number of additional jobs in these companies:	0

18. Please indicate whether your project has a potential impact on employment, in comparison with the situation before your project:	Safeguard employment, In large companies

19. For your project partnership please estimate the employment effect resulting directly from your participation in Full Time Equivalent (FTE = one person working fulltime for a year) jobs:	0Difficult to estimate / not possible to quantify

H. Media and Communication to the general public

20. As part of the project, were any of the beneficiaries professionals in communication or media relations?	No

21. As part of the project, have any beneficiaries received professional media / communication training / advice to improve communication with the general public?	No

22. Which of the following have been used to communicate information about your project to the general public, or have resulted from your project?	
Press Release	No
Media briefing	No
TV coverage / report	No
Radio coverage / report	No
Brochures /posters / flyers	Yes
DVD /Film /Multimedia	No
Coverage in specialist press	Yes
Coverage in general (non-specialist) press	No

Coverage in national press	No
Coverage in international press	No
Website for the general public / internet	Yes
Event targeting general public (festival, conference, exhibition, science café)	No

23. In which languages are the information products for the general public produced?	
Language of the coordinator	No
Other language(s)	No
English	Yes