DATA GAPS AND STAKEHOLDERS' NEEDS IN AVAILABLE EXPOSURE MEASUREMENT DATA AND RISK MANAGEMENT MEASURES

H2020 SbD4Nano Project Deliverable Report

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EXECUTIVE SUMMARY

The present deliverable D4.1 is a public report of the SbD4Nano project delivered in the context of WP4 (Safe by process design: exposure assessment and risk management). The main objective of WP4 is to **evaluate current gaps in exposure measurement data needed by regulators, industry and academics to support the risk assessment process**. The identification of data gaps is based on a complete review of data collected from available data repositories from different finished and ongoing EU projects and from the NECID-PEROSH exposure database.

To do that, templates regarding exposure measurement data, release, risk management and stakeholders' needs were established. Thanks to the analysis of results data gaps have been identified.

Regarding exposure data gaps, a lack in the characterization of ENMs was identified. This fact could present a big issue in the implementation of a safe-by-design approach considering that exposure plays a crucial role on the risk equation (Risk= exposure x hazard). Major gaps in exposure data were identified for industrial related processes, while pilot scale and small laboratory processes are well represented, especially under EU related projects.

With respect to release, the studies show an over-representation of dustiness test data compare to other release studies. It can be assumed that the reason for this is that dustiness testing is a standardized method (EN-17199) and a specific requirement in the REACH Guidance, which facilitates the transition to stakeholders and its widespread use.

Finally, concerning the effectiveness of risk management measures (RMMs), the level of information collected is lower than for the two other topics. This fact illustrates a gap and shows the need for conducting additional studies on the effectiveness of technical measures and organizational procedures when dealing with ENMs and nano-enabled products.

LIST OF ACRONYMS

ATMP: Advanced Therapy Medicinal Product
CHESAR: Chemical safety assessment reporting: the ECHA tool for developing CSAs/ESs under REACH
CES: contributing exposure scenarios
ECHA: European Chemicals Agency
EHS: Environmental, health and safety
ENM: Engineering nanomaterial
NEP: NanoEnabled Product
ES: Exposure scenario
IRM: Integrated Risk Management
LEV: Local Exhaust Ventilation
MD: Medical Device
NBM: Nanobiomaterial
NM: Nanomaterial
NP: Nanoparticle
OC: Operative conditions
RA: Risk Assessment
RMM: Risk management measures
REACH: Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
PPE: Personal Protective Equipment
CPE: Collective Protective Equipment
ACH: Air Change per Hour
SOP: Standard Operating Procedure
PSD: Particle Size Distribution

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1. Scope and goal of the deliverable

The present deliverable D4.1 is a public report of the SbD4Nano project delivered in the wider context of WP4 (Safe by process design: exposure assessment and risk management). The main objectives of WP4 are:

- To develop new strategies based on the safe by process design to reduce exposure and release
- To develop a newly tested and calibrated cost driven exposure model to predict the effectiveness of Risk Management Measures (RMM) to design a safe process.
- To support identification of all the relevant exposure/release hotspots along the life cycle for a given material/product scenario as provided by the actors/users in a safe by design scenario in the e-Infrastructure

The main goal of this document is to assess baseline knowledge on the levels of exposure of workers, effectiveness of risk management measures or release data, all of them of prime importance to understand current data gaps on the definition of safe by process design strategies. A first step on the development of such safe by process design strategies is to conduct a rigorous information gathering exercise to identify current gaps in exposure related data, risk management approaches and release data to support stakeholders in the risk assessment process.

A comprehensive overview and examination of existing knowledge retrieved from completed and on-going projects is presented in this document. A list of European projects included in the nanosafety cluster repository (i.e. SUN, GuideNano, NANOSH, NANEX, NANODEVICE, NanoNextNL, NanoMile, NanoFase, NanoRelease, caLIBRAte, CERASAFE, NanoLeap, INTEGRAL etc.), together with research projects funded under EU related calls, have been analysed to establish an overview of all available data that can be used in the framework project to define innovative safe by process design strategies.

This deliverable falls under the scope of the first step in task 4.1 “Collation of new data on dustiness, release and exposure on a life cycle basis”, and specifically, under subtask ST4.1.1 “Data gap analysis of available databases and exposure data libraries”, focused on the analysis of current gaps in exposure assessment data needed by stakeholders for regulatory risk assessment and risk management. Based on the data gap analysis in this deliverable report, new data can be collected in ST4.1.2.

The specific data included under the scope of D4.1 can be split as follows:

1. Exposure related data: robust information of the levels of exposure measured under the scope of relevant projects, including relevant metrics for the measurements of exposure to nanomaterials (nano-objects and nanostructured materials), such as mass concentration, number concentration and surface area concentration.

2. Release related data: robust information on the release of nanomaterials from powders, composites, suspensions or relevant nano-enabled products which can lead to an exposure of workers, consumers, public or the environment.
3. Risk management measures: information on the effectiveness of common risk management approaches when dealing with nanomaterials, including engineering controls, operation procedures, Collective Protective Equipment and personal protective equipment (i.e. respiratory, hand, eye and body protection).
4. Stakeholder's needs: information on the needs of the stakeholders to support regulatory compliance, highlighting the EC regulation REACH, where exposure related information is required under the registration procedure.

The work here has been divided into different phases, in which all the partners of ST4.1.1 have participated: the first step consisted of identifying the European projects related to the evaluation of exposure to nanomaterials developed in the last years, and in compiling the sources (websites, deliverables, reports, etc) from where to get the information of interest; the next task consisted of elaborating templates as tables with the necessary information requirements to be completed, so that the information collected would be homogeneous and comparable; then, the data collected in the previous templates have been transferred to .xslx format, forming a comprehensive database that collects all the information compiled from European projects; finally, the information contained in the database has been treated statistically and graphically represented, from which the data gap analysis has been performed.

The file in Excel® format used in the data analysis is available at *https://zenodo.org/record/4040988*.

2. Introduction

A wide range of projects have been working over the last 10 years on the generation of data on the potential exposure of workers to nanoscale particles. When looking at the information generated it can be noticed that much of the information available includes data on the potential levels of exposure in research facilities, pilot plants and small scale industrial facilities, mainly small companies manufacturing nanomaterials and nano-enabled products in quantities below 1 ton/year. A limited amount of information is available for large companies, which production ranges higher 20 – 30 kg/day.

An increase on the availability of data since 2000 can be observed analysing the number of publications on the field with more than 1,000 research papers addressing the potential exposure of workers to nano-objects, their agglomerates of aggregates. In addition, an increase of the number of studies is envisaged due to the expected growth of the industrial application of nanotechnology related products in areas such as medicine, cosmetics, polymer-based composites, electronics, and transport.

Available data published in research papers and technical reports from exposure related projects such as MARINA, GuideNano, NanoMICEX or NanoREG show concentrations ranging from 2,000 to 20,000 particles/cm^3 in activities involving handling nanomaterials such as weighing nanopowders, and higher concentrations in operations such as machining, where concentrations of up to 100,000 particles/cm^3 have been found. Lower exposures were reported for activities involving liquid applications and very small-scale R&D activities under controlled conditions. The analysis of the availability of data on the exposure potential for the wide range of existing processes and nanomaterials is of prime importance to detect current data gaps to cover the information requirements of stakeholders, specially regulatory bodies trying to regulate acceptable levels of exposure in workplaces , as well as occupational, health and safety professionals working in the nanosafety area. This data gap analysis forms a good basis for further data gathering during the project to fill these gaps.

Most of the measurements have been focused on measuring (personal) exposure and current data on the potential release of nanomaterials is still in its infancy, with exception of dustiness data that are required under REACH regulation, which means that all companies producing nanomaterial in quantities above 1 ton/year will have to provide information of the dustiness potential. In parallel, the number of publications and projects working on the analysis of the release of nano-objects during mechanical and thermal processes is rapidly increasing. A list of potential mechanisms of release have been identified in the literature, including diffusion, desorption, or matrix degradation, this last related with processes such as mechanical abrasion, thermal degradation, hydrolysis or UV exposure, which causes photodegradation (S. J. Froggett, et al., 2014). Mechanical abrasion plays a crucial role on industrial scenarios, where the nano-enabled products are subjected to machining operations, including cutting, grinding, shredding, sanding, or drilling processes. In contrast, photodegradation can be a consequence of weathering phenomena foster by solar irradiance.

A better understanding of the sources of release and operations involved in the release is of prime importance to define safe by design approaches that can be implemented to reduce the release of particles, and consequently reducing the likelihood of exposure to nanomaterials. Complementary data on the parameters with higher influence on the airborne behaviour and transport of the released material to the worker/consumer are starting to appear, being expected to play a key role in future projects focussed on safe by design approaches at workplace level.

In terms of risk management approaches, available data on the effectiveness of engineering controls and personal protective equipment (PPE) is still scarce, with a limited number of projects including experimental activities. In this specific topic, the EU projects Guidenano, NanoRISK and NanoREG concentrated much of the available experimental data over the past five years. In this regard, a Nano-specific Risk Management Library has been developed within the NanoReg research project to provide stakeholders with an easy to use tool to select proper measures for achieving a high level of protection of the human health and the environment. Similarly, an updated version of the Exposure Control Efficacy Library (ECEL) database developed by Fransman et al. and has now been updated to include nano-specific RMM data.

Evaluation of current gaps in exposure and release data, as well as risk management measures effectiveness is needed to identify critical areas where data is urgently needed for building exposure assessment models and risk assessment purposes on a regulatory basis, as well as to determine current gaps to define proven safe by process design strategies, mainly developed on the basis of robust data related with exposure-processes relationships, release-exposure relationships (source-receptor modifying / determinant factors), as well as removal / containment efficiency of risk management measures (RMMs) when dealing with ENMs.

Certain data gaps have already been identified in the eNanoMapper project, especially for human exposure from nano-enabled products at different life cycle stages, physical-chemical characterization of nano-enabled products, ENM functionality, product performance etc. The eNanoMapper database [doi:10.3762/bjnano.6.165, EU FP7 eNanoMapper], was adopted as a data management solution for nanomaterial safety data generated or compiled in projects dealing with environmental, health and safety issues, including the FP7 project NANoREG, and the H2020 projects NanoReg 2, caLIBRAte, PATROLS, BIORIMA, GRACIOUS, or NanoInformaTIX. This eNanoMapper database is an open source software developed by IDEA, member of the SbD4Nano Partnership (WP1), which could be freely downloaded and allowing installing it as multiple web applications and being populated with different sets of data. Currently, there are several eNanoMapper database installations hosting public and protected data on ENMs physical-chemical characterization, exposure, release/emission, biological and toxicological information assembled from past and ongoing EU nanosafety projects (e.g. NanoReg, NanoReg2, ENPRA, MARINA, SUN, Gov4Nano, NECID, NANOTEST, Nanogenotox). An aggregated search interface (both user friendly and API) provides various possibilities to search and explore information, and to download data which has been assembled from various projects and other databases.

The following chapters of the present document discuss and analyse the information currently available from FP7 and H2020 funded projects. Additionally, other European and National projects have been considered in the compilation of information, in order to integrate as much information as possible regarding studies related to release, exposure, and RMM. This information can be checked in the annex (*Project list and available resources*):

3. Methodology

The methodological approach to identify current data gaps on exposure, release and risk management is depicted in figure 1. In summary, experts from TNO, ITENE, CEA and IOM identified the main projects included in the nanosafety cluster compendium reporting data on the levels of exposure, release, and/or risk management measures. Additionally, those projects including information on the stakeholders´ needs were also identified.

A data compilation template for each type of data was developed to support a harmonized data collection and analysis process. The list of projects identified in the first instance are depicted in table 1. Only some of these projects were finally studied in detail as there are projects with limited access, and therefore, the analysis of the results was not possible.

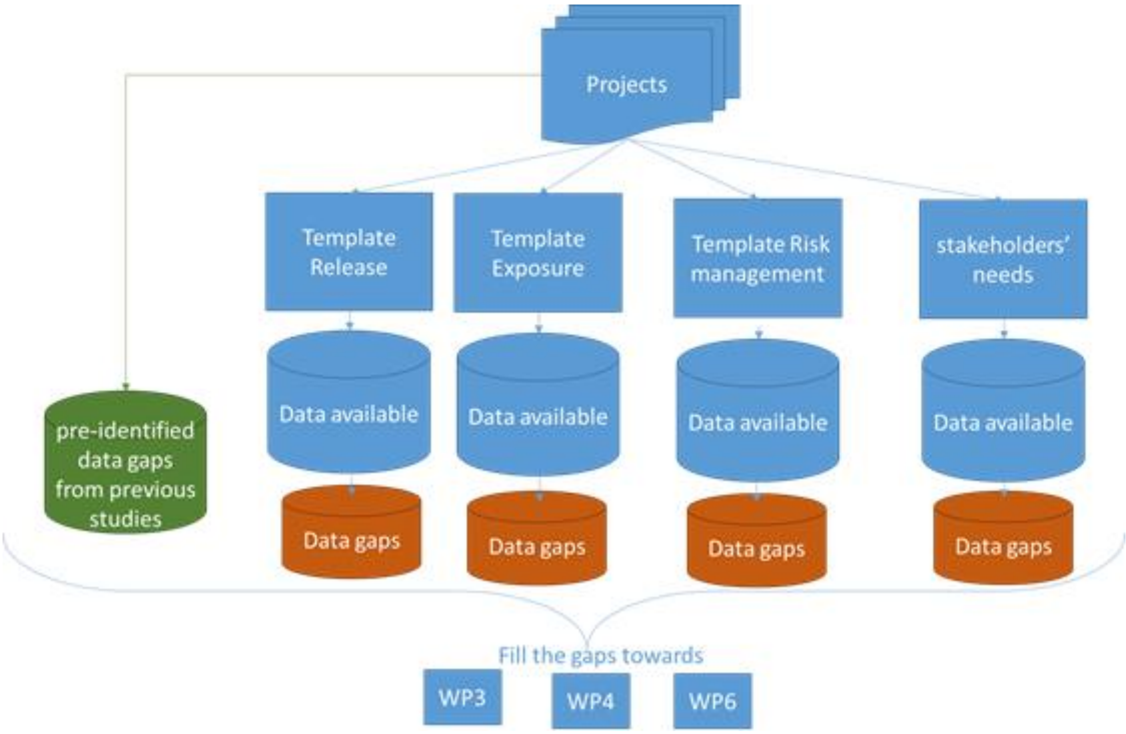

Figure 1. Methodology for identified data gaps

Currently available knowledge initially retrieved from the Compendium was supplemented and confirmed by further details from the project's website or other project-related articles, deliverables or papers. For sources not included in the Nanosafety cluster compendium, publicly available reports were analysed.

The data collected from each project was entered into an Excel® spreadsheet with appropriate look-up lists for the coding of information. The Excel® spreadsheet data was later analysed in detail to extract conclusions on the potential gaps on knowledge. A copy of the complete dataset is available as an Excel® spreadsheet file in the following repository: *https://zenodo.org/record/4040988*.

The list of projects mapped is summarized in the table below:

Available exposure measurement			
Ended Projects		**Ongoing projects**	
caLIBRAte	**FutureNanoNeeds**	ACEnano	nffa
cerasafe	**NanoLeap**	Evo nano	PATROLS
Dana2.0	**Integral**	**Gov4Nano**	RISKGONE
HISENTS	**NanoReg**	Gracious[1]	Sabyna
NANOFARM	**NanoNextNL**	LightMe	smartfan
NanoFase	**ENDURCRETE**	m3dloc	smartnanoTox
Nanogentools	**NanoMicex**	Modcomp	Bionanonet
nanostreem	**NanoSafePack**	NanoCommons	NIA
necomada	**GuideNano**	NanoFabNet	OASIS
npSCOPE	**NANOSH**	NanoInformaTIX	**Biorima**

[1] GRACIOUS data is confidential and not accessible when this deliverable was created.

OpenRiskNet	**MARINA**	NanoSolveIT	**Lee-Bed**
Pandora	**NANODEVICE**	n-track	
Skhincaps	**NanoCARE**		
SUN	**HINAMOX**		
Nanoreg2	**SERENADE**		
EC4SAFE nano	**Sanowork**		
NanoRisk	**Scaffold**		
Nanomonitor	**NanoImpulsa**		

Table 1: List of projects mapped. *Note: Table 2 depicts a non-exhaustive list of projects. The projects included in bold are the ones with access to release, exposure, RMM information and stakeholder's needs.

Up to 26 EU nanosafety projects from different sectors have been finally analysed during this task. The type of information available included both qualitative and quantitative information on the levels of exposure at different stages of the life cycle, release data and data on the effectiveness of risk management measures. It is suggested that the information compiled in this deliverable may be enhanced in the short term by updating the list of projects in the future, including additional collection exercises to include expanded and more structured information on exposure, release, risk management measures and stakeholder´s needs to be used in designing the exposure assessment model (Task 4.2) and the safe by design module (Task 4.3).

Figure 2: Representation of industrial sectors included in the analysis

Figure 2 shows the most represented sectors using the project description, and Figure 3 focused on the percentage of projects regarding their nanomaterial classification in SbD4Nano project (see table 2).

Functional	Structural ENMs	Coating	Cosmetics	Pharma and health
Avanzare	Applynano G.Antolin	Laurentia, Creativenano, Applynano	Ambrosialab Laurentia,Nanovector	AcZon, HiQnano, N-vector
• Graphene • Metal Oxides	• Carbon Nanofibers • Customized graphene oxide	• Core-shell SiO2-TiO_2 NPs • Functionalized SiO_2 NPs • ZnO NPs	• SiO_2 nanocapsule • Functionalized TiO2 • Functionalized ZnO • Antioxidant loaded lipid formulation	• Core-shell dye doped silica NPs • Fluorescent Silica nanobeads • Ophthalmic lipid colloidal formulations

Table 2: SbD4Nano ENMs and NEPs used in the case studies in WP6

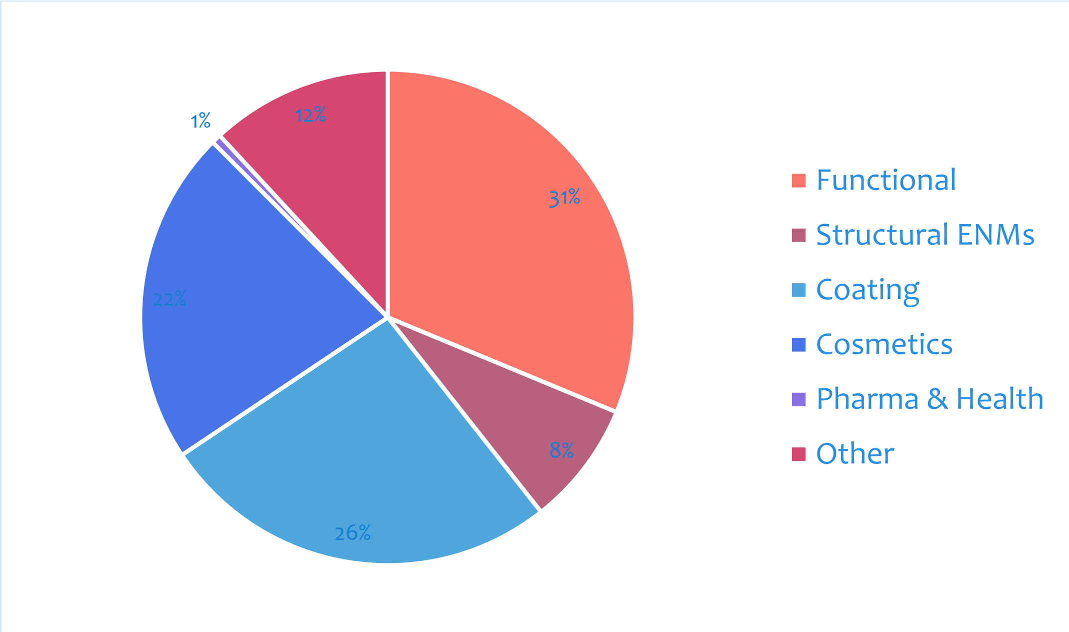

Figure 3: Sectors distribution using SbD4Nano nanomaterials classification in WP6

It is possible to see that the pharmaceutical and health sector is the lowest represented sector. Only BIORIMA project from the studied ones provides data for nanomaterials used in the medical sector. The most represented sector is the functional, with a 31% of the total.

The 26 projects have been subdivided into studies. Here, a study is defined as a subproject inside a project, which could include several measurements. A total of 85 different studies have been analysed, including the following information:

- 40 of them include release studies data (81 release measurements)
- 76 of them include exposure data (300 exposure scenarios)
- 7 of them include risk management data

For each project, the templates regarding exposure measurement data (section 4), release (section 5) and risk management (section 6) are used to list the data available and identify the data gaps. Concerning stakeholders' needs (section 7) the establishment of a template was not needed and data information are directly extracted from caLIBRAte and EC4SAFEnano. These templates are presented in the annex section.

4. Exposure measurement data

4.1. Available data

Projects that provide exposure measurement data are classified in 3 groups regarding their applicability: Workers, professional users and consumers. A total of 300 measurements have been analysed and Figure 4 shows the huge segregation of studies. It can be noticed that the majority of projects focused on the worker exposure.

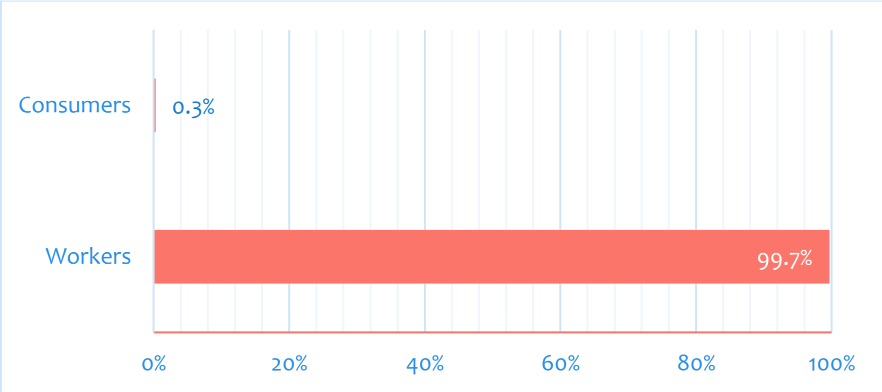

Figure 4: Exposure measurement classification

Among the studied nanomaterials, almost one half of the known nanomaterials are silicon dioxide (SiO_2), titanium dioxide (TiO_2) or zinc oxide (ZnO) nanoparticles. Silver (Ag) and aluminium oxide (Al2O3) nanoparticles are also high represented. Category "Other" groups nanomaterials with very low (1) appearance (Quatum Dots (CdSe/ZnS), powder MnSi-powder Mg2SiSn-Ti/Au (metallization), Lipid nanoparticles, Ceramic and metallic dentures, Bi2O3, CaCO3, Ce2O3, CoAl2O4, Mixture of ZnO and TiO2, MnO2, Nanocelullose, Nanoclays and WO3), while not available represents unknown nanomaterials. Figure 5 represents the total number of nanomaterials in this study.

It can be seen **that there is a 12% of the studies that not provide the nanomaterial** (not available), but almost all of them are outdoor environmental and urban monitoring campaigns, so it cannot be consider a data gap.

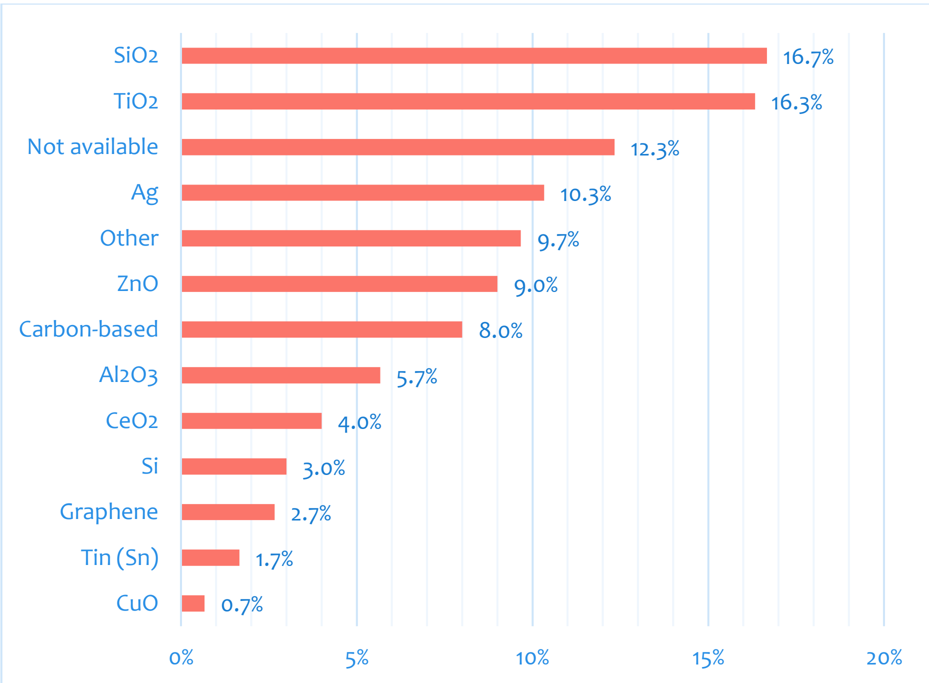

Figure 5: Nanomaterials representation

Figure 6 shows the distribution of the life cycle stages, production scale, morphology and the physical state of the studied nanomaterials. Different stages from the life cycle of the nanomaterials have been analysed. Manufacture, use and formulation of nanomaterials covers more than a half of the total stages. Implementation and end-of-life are the less represented stages of the life cycle. Pilot and industry production scales represent almost all the studies. Small R&D production scales in laboratory only covers 15 exposure data entries. Spherical nanoparticles in powder physical state are the most represented. Only a few studies provide information about fibres, high aspect ratio, platelet or other morphology. Liquid state is also well represented. Not available correspond to the number of studies where the specific property is not provided in the study.

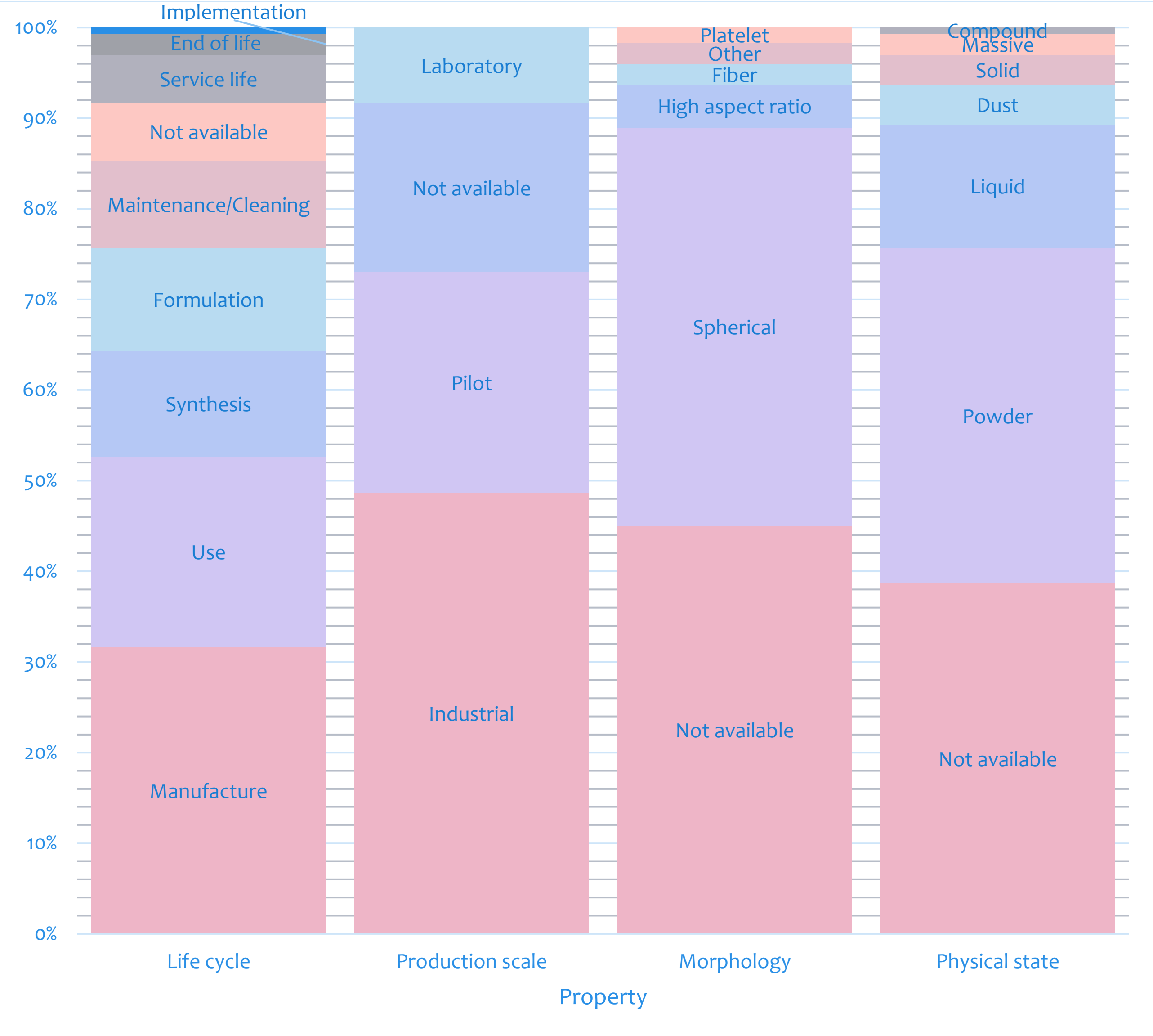

Figure 6: Nanomaterials properties representing studied exposure measurements

In terms of exposure characteristics, companies with a low number of exposed workers (1-3) represent the majority of the studies, and only 12 studies represent medium (3-5) or high (5-10) number of exposed workers. Exposure levels have been grouped by frequency level (See Table 3:

Exposure measurement template). For example, Daily (D1), weekly (W1), monthly (M1) and annual (A1) frequency 1, has been assigned level of exposure 1. There is a well balance of levels of exposure 1, 2 and 3 representation in the studies. Only a few level 4 studies have been found. Almost all the studies where the information is available, contain intermittent release mode. Only a few represent information about constant or instantaneous releases of nanomaterials. Figure 7 represents graphically these distributions, while Figure 8 shows the availability of other exposure characteristics analysed. In this last graph, it is possible to see that the use or not use of PPEs and ventilation is normally taken into account in exposure measurements, while other characteristics such as worker segregation, ACH and the source domain are not so easily findable.

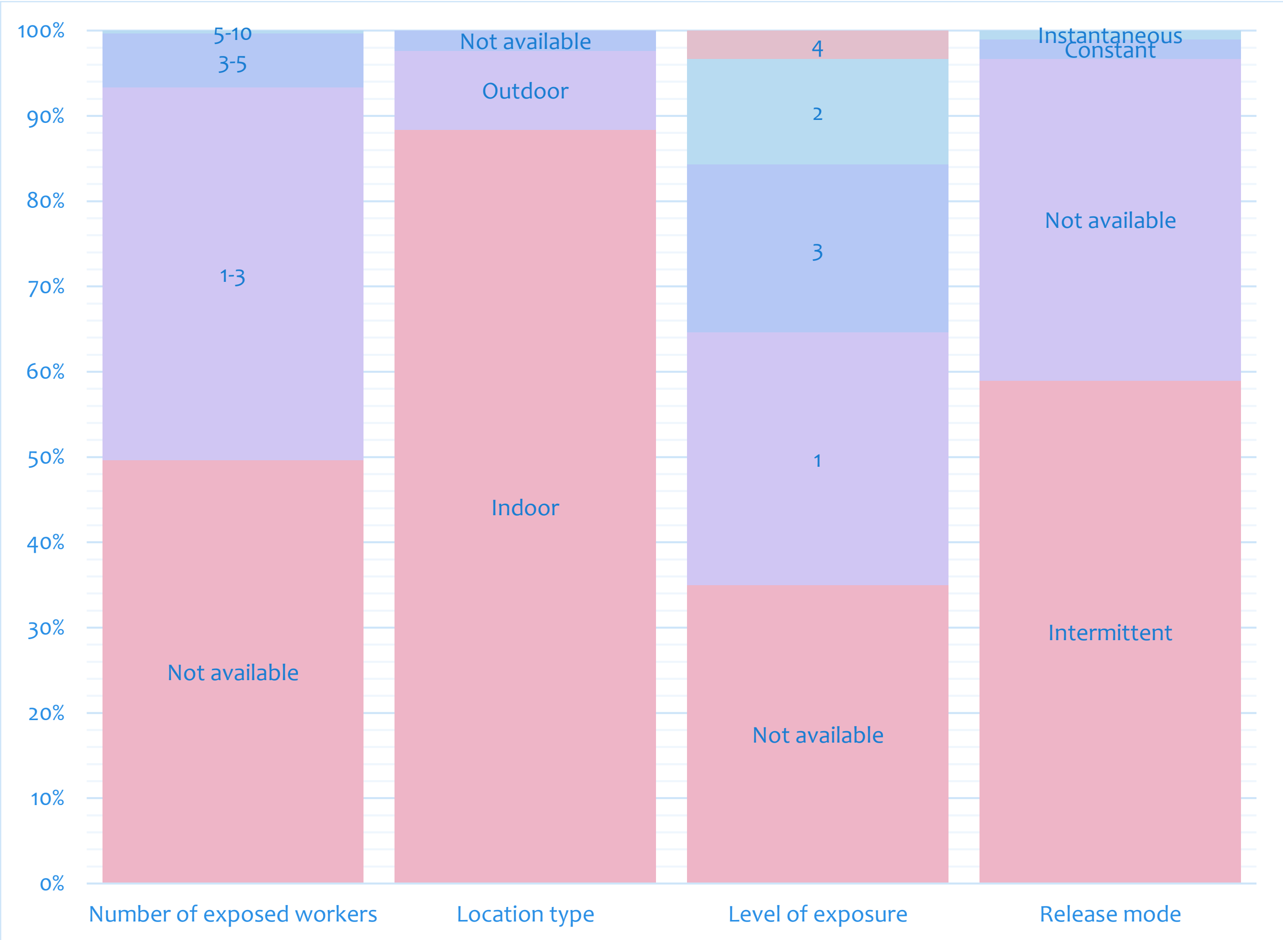

Figure 7: Exposure characteristics

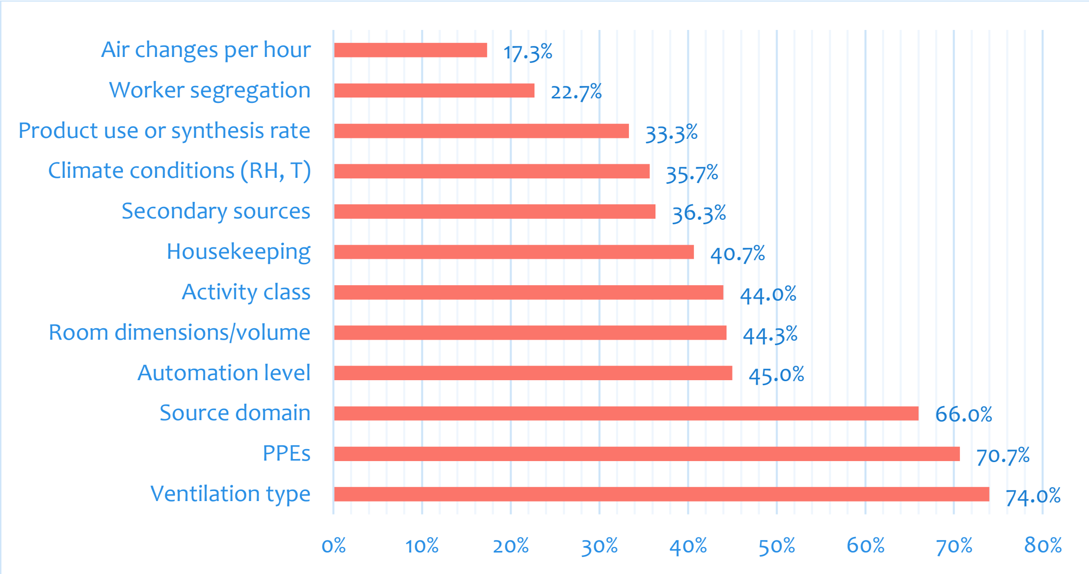

Figure 8: Availability of other exposure characteristics

Source domain also provides a good picture regarding the type of nanomaterial and the step of the life cycle:

- **Source Domain 1:** Synthesis of NMs, e.g. Gas phase synthesis/flame pyrolysis/laser ablation/electro-spraying, mechanical reduction (grinding and cutting), chemical vapor condensation, wet chemistry
- **Source Domain 2:** Handling/transfer of bulk nanopowders, e.g. powder harvesting, dumping, mixing, transfer, cleaning of a reactor
- **Source Domain 3:** Handling of liquid intermediates/ready-to-use products, e.g. liquid spray, dipping, stirring, ultrasound, pouring, brushing
- **Source Domain 4:** Handling of nano-enabled products, e.g. abrasion, cutting, grinding, crushing of nano-enabled products.

This information is available in 2 out of three studies, and there are more information in source domains 1 and 2, than in 3 and 4. Figure 9 represents the availability of this information.

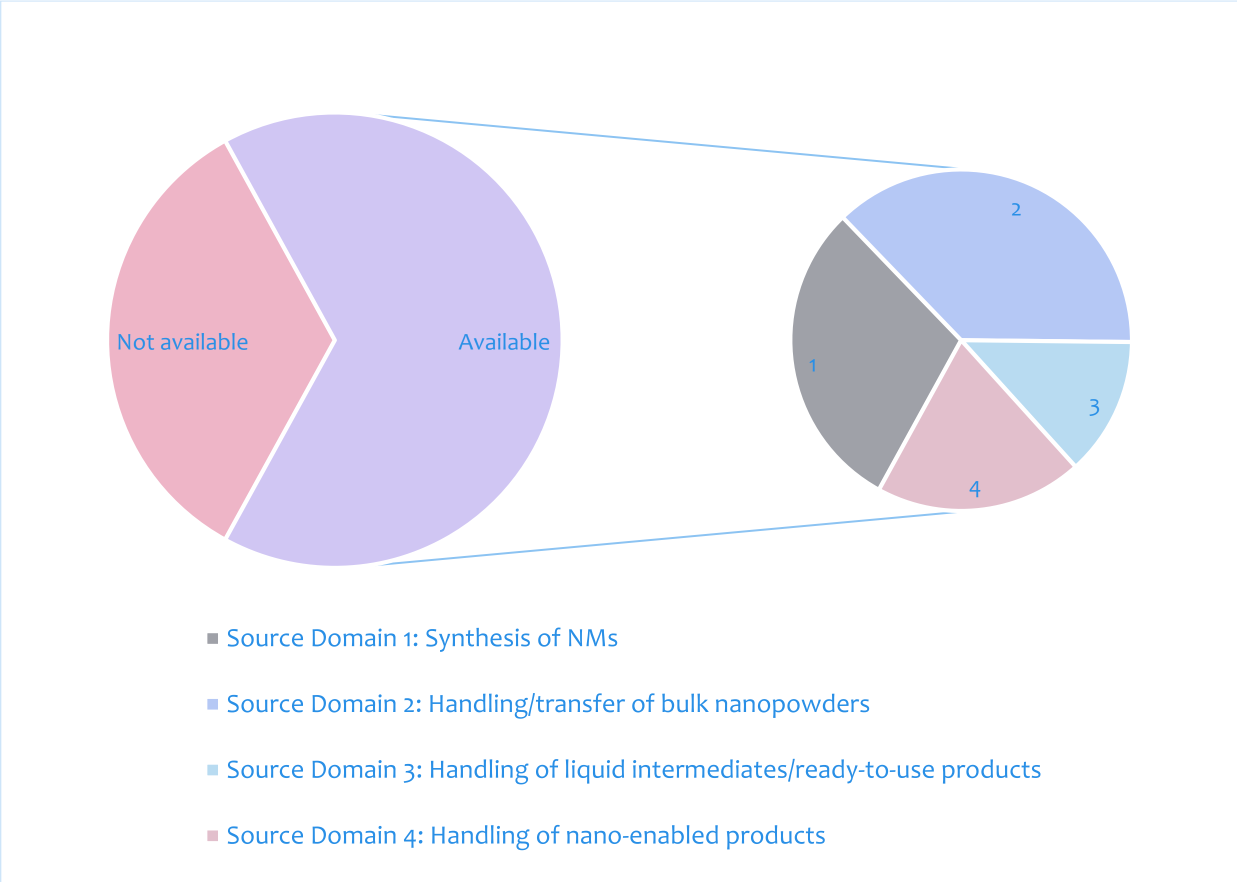

Figure 9: Source domain availability

4.1.1. Available data for functional ENMs and NEPs

Figure 10 represents the availability of data for functional ENMs and NEPs. Apart from viscosity data, it is possible to find information for all the studied properties, with more or less representation for functional ENMs and NEPs. Different conclusions can be obtained from this analysis:

- Regarding diversity: Concentration or wt% (8), primary particle size/range (7), purity (6) and coating or doping (6) are the most diverse properties in terms of representation of different nanomaterials. Moisture content (1) and Molecular mass (3) are the less diverse.
- Regarding amount: CAS number (54) and concentration or wt% (48) are the most represented properties in term of total amount of nanomaterials. Moisture content (5) and Density (6) are the less represented.

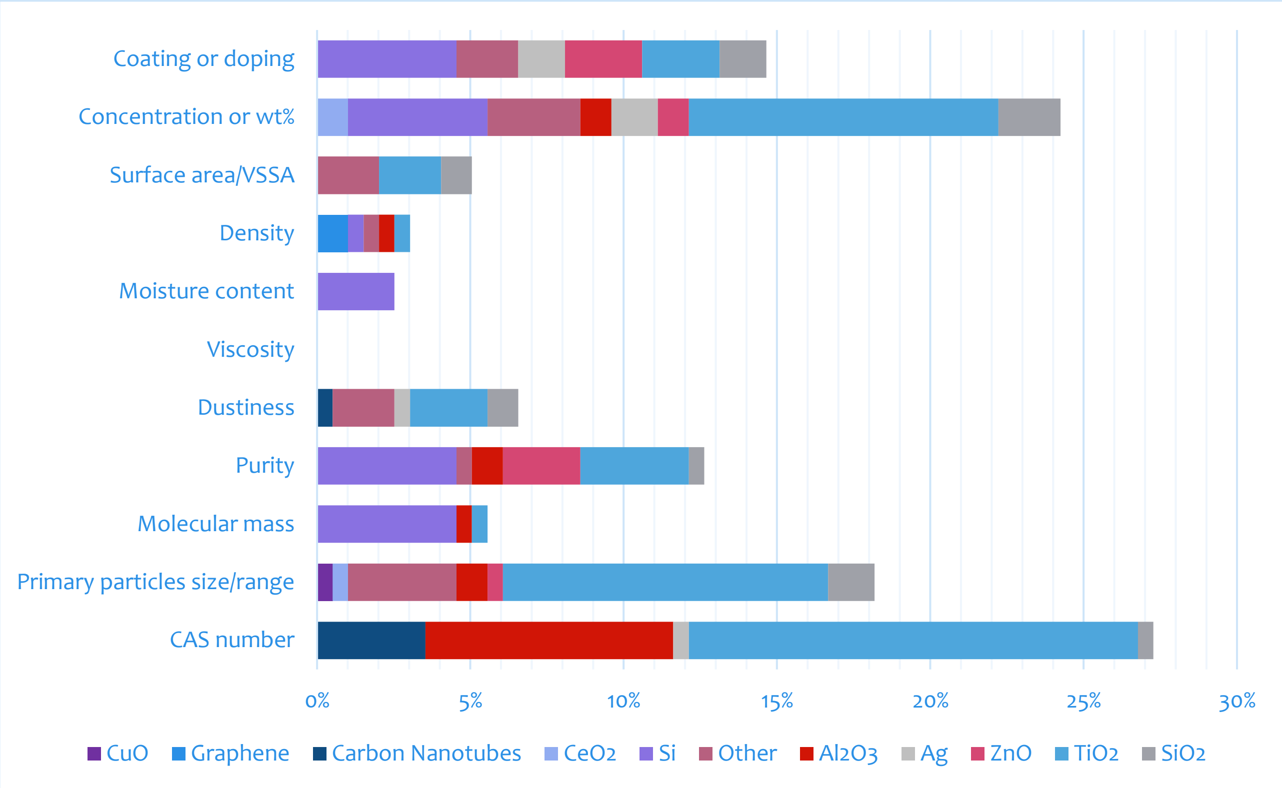

Figure 10: Available contextual information for functional ENMs and NEPs

4.1.2. Available data for structural ENMs

A similar approach as used in point 4.2.1 can be followed for structural ENMs:

- Regarding diversity: Concentration or wt% (8), CAS number (5) and coating or doping (5) are the most diverse properties in terms of representation of different nanomaterials. Primary particle size (1), Molecular mass (1), Moisture content (1) and density (1) are the less diverse.
- Regarding amount: Again, CAS number (70) and concentration or wt% (35) are the most represented properties in term of total amount of nanomaterials. Surface area (3) and dustiness (4) are the less represented.

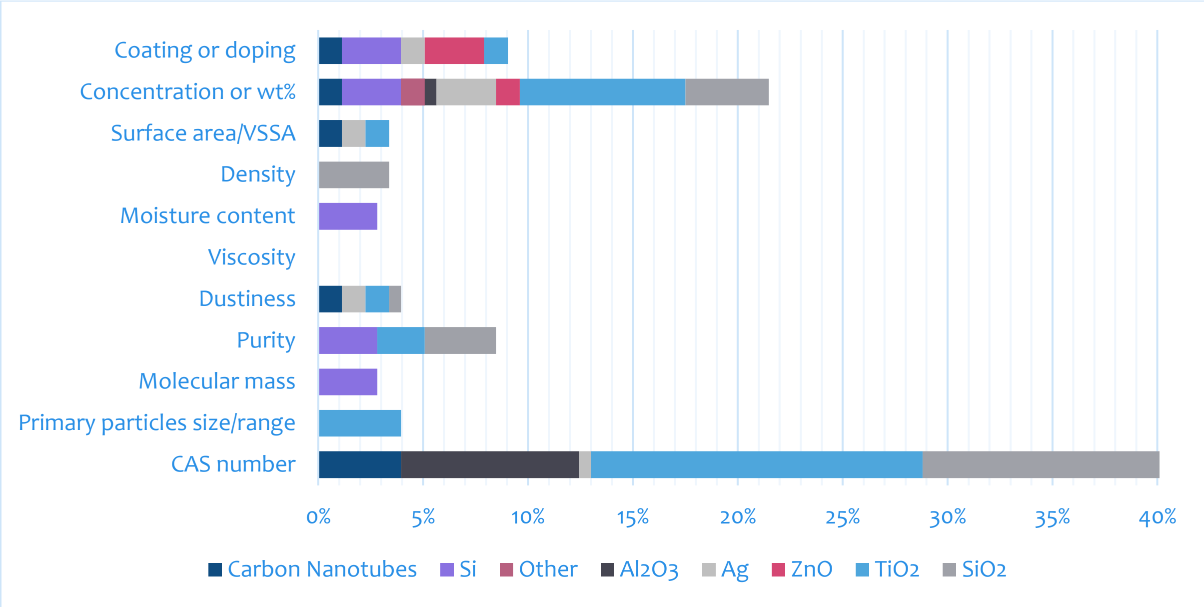

Figure 11: Available contextual information for structural ENMs

4.1.3. Available data for coating ENMs

Although there is some information missing for certain properties (dustiness, viscosity, moisture content and surface area) in the available data for coating ENMs, it is still possible to find interesting information in exposure measurements about the CAS number, the particle size, the purity the concentration and the presence or not of coating or doping.

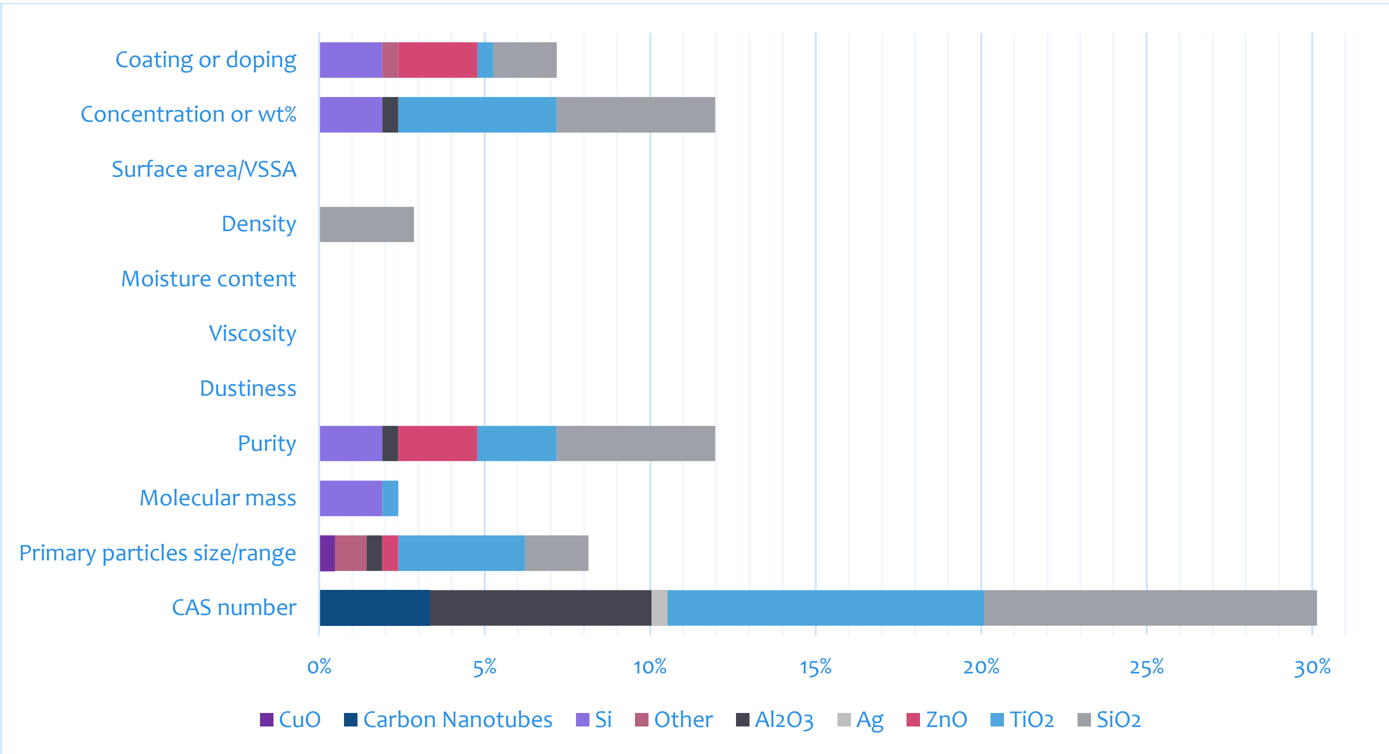

Figure 12: Available contextual information for coating ENMs

4.1.4. Available data for cosmetics ENMs and NEPs

Something similar happens for the available data for cosmetics ENMs and NEPs in relation to the point 5.2.3. There is no information about dustiness, viscosity, moisture content, density and surface area of cosmetic ENMs and NEPs, while some information is still available about the remaining properties. There are only five types of nanomaterials (including the category "Other").

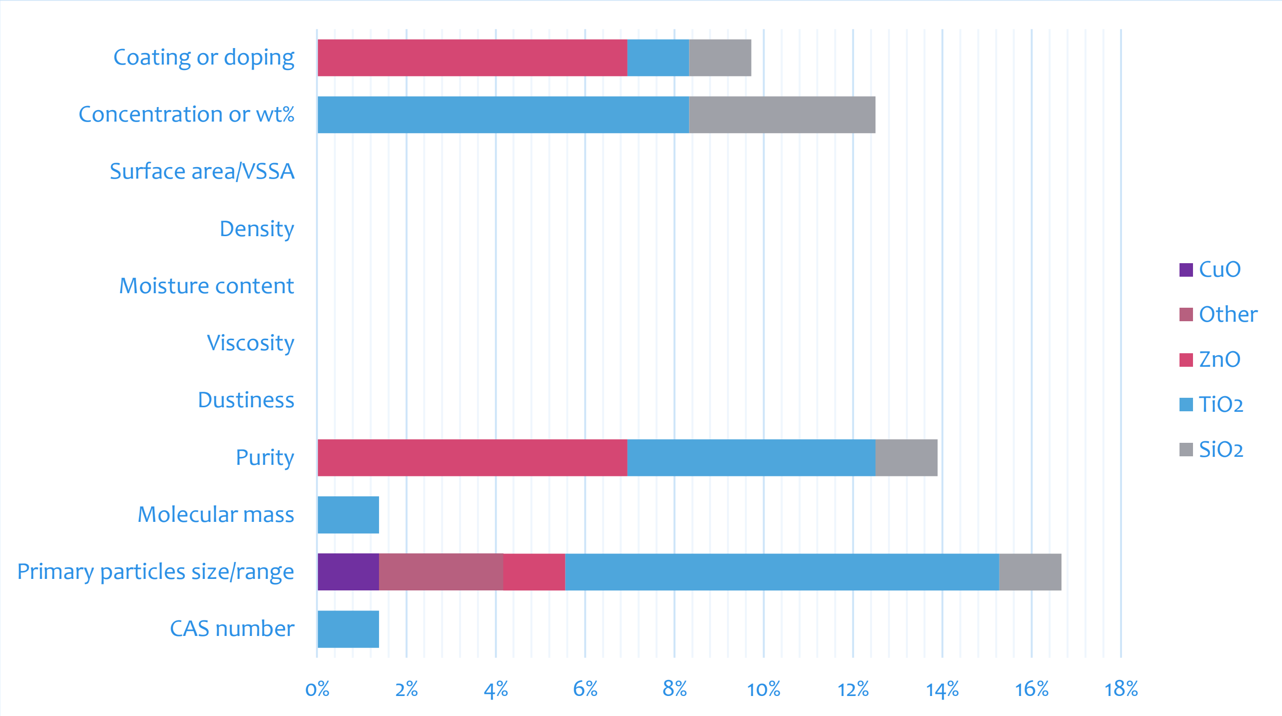

Figure 13: Available contextual information for cosmetics ENMs and NEPs

4.1.5. Pharma and health ENMs and NEPs

As there is only one project about ENMs and NEPs into the medical sector, it is not possible to perform an analysis. This can be identified as a clear data gap.

4.1.6. Other ENMs and NEPs

In this subsection, nanomaterials that could not be classified within the project categories (see Table 2) are included. Figure 14 shows the availability of different properties for these materials in the exposure measurement data. There is no information about surface area, molecular mass and CAS number. On the other hand, information regarding purity, the usage of a coating or the concentration is quite common.

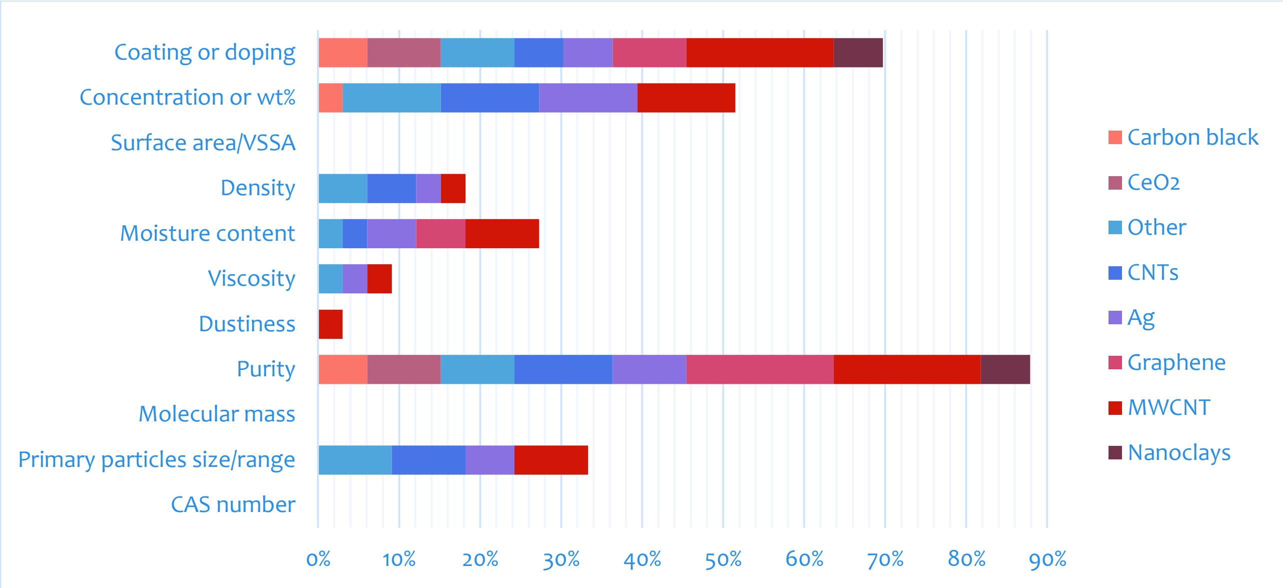

Figure 14: Available contextual information for the exposure data for other ENMs and NEPs

4.2. Data gaps

4.2.1. Pre-identified data gaps

Physio-chemical properties

To identify some data gaps related to the physio-chemical properties, Vílchez et al. (2018) considered compulsory input parameters of human risk assessment tools (e.g. LICARA nanoSCAN, NanoSafer CB, ConsExpo nano etc.) and determined whether their corresponding values can be found in existing databases which are enlisted in the annex (*Online databases with data on physio-chemical properties of nanomaterials and/or their human exposure*) as well as in selected literature, wherever necessary. Some of these databases also contain human exposure data and are available online or can be accessed by arrangement with their respective owners. For others, working with or for a particular project is necessary for database access. Some databases are entirely confidential and only available via an intranet, on a specific computer or to certain subscribers and paying users.

The available data were mapped by Shandilya et al. (2018) against the corresponding physio-chemical properties to which they belong, as shown in Table 3. Each property is shown to be colour coded and reflects the number of data points for which a measurement of the property is present. Out of 18 properties, only 3 properties, i.e. agglomeration/aggregation, chemical composition and morphology, were found to have plenty of data (or data rich) available in these databases. Another 6 properties, i.e. crystal structure, moisture content, primary size/size distribution, surface area, surface chemistry and water solubility, were observed to have limited number of data available. The remaining 9 properties have scarce data available. The data richness or limited data availability for certain properties was mainly found for only JRC-supplied nanomaterials (ZnO: NM-110, TiO_2: NM-101, SiO_2: NM-200, Ag: NM-300 etc.) or certain other metal oxides (e.g. Al_2O_3), metals, CNTs and fullerenes C60. For the rest of the nanomaterials (graphene, Au, Cu, Fe or Ce and their oxides, quantum dots, Cellulose nanofibers or nanofibrils, (1,4)-β-D-glucan, Barium Sulfate, Nickel Ferrite, Zinc Ferrite, Nickel-Zinc Ferrite, Lipopolysacharide, Calcium Carbonate, Graphite, Polyacrylamide macromolecule, Mitomycin C, Methyl methanesulfonate (MMS), 60 µM H2O2, Saline Bovine Serum Albumin solution and Nanoclay), the situation of data availability was observed to be even worse as the data for the same aforementioned 9 properties lied in the third category of scarce data.

1	Aggregation/Agglomeration	
2	Crystal structure/Crystallinity	
3	Chemical composition	
4	Dissolution rate	
5	Dustiness/mistiness	
6	Moisture content	
7	Morphology/Particle shape	
8	Purity	
9	Primary size/size distribution	
10	Specific density	
11	Stability (half-life) in phys. matrix	
12	Surface area	
13	Surface charge	
14	Surface chemistry	
15	Reactivity: Redox act.	
16	Reactivity: Catalytic and photocatalytic activity	
17	Viscosity	
18	Water Solubility	

Table 3: General overview of the data on different types of NMs for the parameters needed by the selected human risk assessment tools; number of data points found for each parameter is colour coded Green: plenty of data (>150 datapoints); Yellow: limited amount of data (<150 and >50 datapoints); Red: scarce data (<50 datapoints)

In addition, Shandilya et al. (2018) observed the information on the physio-chemical properties of nanomaterials in these aforementioned databases to be exclusively focused on pristine nanomaterials. They tend to include little or no information on transformed nanomaterials and matrix in different life cycle stages. The situation further deteriorated in case of nano-enabled products where almost no information on the relevant physio-chemical properties like fraction of NM in the matrix, composite hardness, NM dispersion state etc. is available. Moreover, there is also no information or data available on the nanomaterials or nano-enabled products in different innovation stages (or TRLs/MRLs) in the stage-gate process.

Exposure-related parameters

Occupational exposure limits

The mutually accepted regulatory Occupational exposure limits (OEL) for nanomaterials have been reported to be not yet set in caLIBRAte. However, the National Institute for Occupational Safety and Health (NIOSH) in USA have proposed Recommended Exposure Limits (REL) for TiO_2 nanoparticles (NIOSH, 2011) and for respirable carbon nanotubes and carbon nanofibres (NIOSH, 2013). Furthermore, the British Standard Institution developed benchmark levels for four group classes of nanomaterials (British Standard Institution, 2007): 1) insoluble, 2) fibrous, 3) highly soluble and 4) carcinogenic, mutagenic, asthmagenic or reprotoxic NMs. For that, multiplying factors are applied on corresponding OEL values[2] for bulk materials (1, 3 and 4) and on asbestos (2). A systematic review on OEL for manufactured nanomaterials found 56 OEL proposals for nanomaterials in 20 publications (Mihalache et al., 2017). However, any specific OEL value could not be recommended because of the huge variabilities in the proposed OEL values which varied by factors up to 300.

Exposure frequency

For exposure frequency, there are some studies that make use of available databases on application frequencies (e.g. cosmetics) to derive exposure level contributions resulting from different behaviour patterns (Lorenz et al., 2011). However, exposure frequencies were observed to be seldom reported in the databases or publications, due to which worst case scenario (i.e. maximum possible frequency) estimations are frequently used in human risk assessment tools when assuming the exposure frequency in a scenario.

Process-related contextual information, Workplace-related contextual information and Characterization of control measures

The process-related contextual information includes information on activity handling energy factor[3], frequency of the task /use in the room, duration of the process, peak concentration and long-term concentration. Workplace-related contextual information includes information on room dimensions, distance between source and worker, ventilation rate in room, emission controls, activity level in room, humidity in room, number of workers, body weight of workers/consumers, total working years of workers/consumers, workweeks a year of workers, workdays a week of workers/days a week consumer usage, working hours a day of workers/hours per day of use by consumers, total timespan of worker presence, worker presence frequency, average duration of worker presence in zone. And finally, characterization of control measures is done by information on cleaning frequency of workplace, equipment maintenance frequency and personal protective equipments. In the examined databases and relevant publications within Vílchez et al. (2018), all this information was observed to be covered, especially by NECID. Nevertheless, it was not on a regular basis. Moreover, relevant contextual information for estimating short-term and long-term personal exposure has been observed to reported in limited number of datasets. The parameters

[2] EU indicative occupational exposure limit values (EU-OSHA) (Directive 2000/39/EC) can be found in https://osha.europa.eu/en/legislation/directives/directive-2000-39-ec-indicative-occupationalexposure limit-values. Worldwide chemical exposure limits (ILO) can be found in http://www.ilo.org/safework/info/publications/WCMS_151534/lang--en/index.htm

[3] This factor modifies the emission potential according the dustiness method and the type/characteristics of the powder handling activity

like room dimension, ventilation rates, climate conditions (relative humidity), exposure frequency or description of secondary sources can be provided by the owner of the exposure scenario if not recorded during the measurements. Obviously, some like room dimensions will be easier to be provided than ventilation rates for instance.

Miscellaneous parameters

Within Shandilya et al. (2018), several other parameters like product application & use conditions (use frequency, temperature while using etc.), product functionality (hydrophobicity/hydrophilicity, anti-bacterial, photocatalysis etc.), economic & societal benefits (e.g. highly qualified labour force, expected purchase price etc.) were also analysed in aforementioned databases and relevant publications. However, no information or data could be retrieved, signifying a complete absence of the data to these parameters.

Occupational exposure

In a review study which analyzed the publications reporting occupational exposure to engineered nanomaterials (carbonaceous, metals or metal oxides, and nanoclays) during the period from January 2000 to January 2015, it was found that high-quality data exist for MWCNTs, SWCNTs, CNFs, Al_2O_3, TiO_2, and Ag nanoparticles; moderate-quality data for non-classified CNTs, nanoclays, and Fe and SiO_2 nanoparticles; low to no quality data for fullerenes C60, double-walled CNTs, ZnO and Ce_2O_3 nanoparticles, and for rest of the nanomaterials (Debia et al., 2016). The data quality in the study was evaluated using predetermined criteria which determined the level of contextual and technical information related to the exposure measurement. There were no studies on potential occupational exposure to dendrimers and Au nanomaterials that are listed by OECD 2010 as among the most frequently produced/used engineered nanomaterials. Moreover, some nanomaterials were over-represented given that the number of investigated exposure situations per nanomaterial ranged from 74 for MWCNTs to 6 for nanoclays and only 1 for ZnO nanoparticles.

The potential exposure was found to be most frequently due to handling tasks, that workers are mostly exposed to micro-sized agglomerated nanoparticles, and that engineering controls considerably reduce workers' exposure. There was moderate-quality evidence that workers are exposed in secondary manufacturing industrial-scale plants (e.g. electronics and plastics industries). The workers were rarely exposed to airborne particles with a size <100 nm.

Sampling of the breathing zone and specific off-line quantitative analysis have been found to be a real challenge as there is no harmonized measurement strategy for this. Several off-line analysis methods cannot discriminate between background nanomaterials and engineered nanomaterials resulting from production or handling. There is also no generally accepted valid method for electron microscopy analysis.

Most of the data correspond to short-term evaluations mainly related to a variety of handling tasks. This limits their comparability and the results cannot be generalized to other exposure situations. More than 60% of the data correspond to small-scale units. Operating conditions in small-scale units such as research laboratories or pilot-scale plants are considerably different than in large-scale industries. A situation without potential exposure on a small scale could have a substantial potential of exposure in large-scale operations. Moreover, industrial-scale units were mainly primary manufacturers. Although reports on secondary manufacturing were found, these did not represent all applications of nanotechnology. Huge data scarcity was found on exposure for other producers and users of manufactured nanomaterial-enabled end products such as the automotive industry, construction, glass industry, tire industry, or paint industry.

All workplaces which have been reported in the publications were in high-income countries such as the USA, South Korea, Japan, Belgium, Finland, France, and Sweden. None of the studies were from low- or middle-income countries. Therefore, the study findings cannot be probably directly extrapolated to low- or medium-income countries because work conditions, work practices, and prevention measures are expected to differ there.

In addition, very few authors returned to the investigated sites to repeat the measurements, which could have validated the first outcomes. It could have also allowed evaluating the day-to-day, season-to-season, and year-to-year variability for assessing the cumulative damage to chronic toxicants.

4.2.2. Additional data gaps identified in this study

This study has found several data gaps on nanomaterial related information regarding exposure. First of all, almost all the studies focus on worker exposure, while only some of them provide exposure data on consumers and/or professional users. Also, it has been found that the nanomaterial exposure to a small number of workers (1-5) is much more common than to a large number of workers (>5). It is very difficult to find exposure studies on outdoor or open locations. Bibliographic review shows a data gap regarding large-scale industries. However, the templates collected in this task show a data gap regarding laboratory scale. The release mode is normally intermittent, so there is a gap in the number of studies that provide information on constant or instantaneous release.

Regarding nanomaterial types, there is a huge gap on advanced and multi-component materials, being most of the information about metal oxides (such as SiO_2, TiO_2 and ZnO). There is only one project (BIORIMA) that contains information about pharmaceutical and medical nanomaterials. The information about the end-of-life stage is quite limited, as same as data about non-spherical non-powdered nanomaterials. Although less common, it is also possible to find some exposure studies using liquids.

The information provided on different types of nanomaterials, following SbD4Nano classification (see Table 2), follows a similar trend. Some properties such as viscosity, moisture content, density, dustiness or surface are not normally provided on exposure studies. On the other hand, properties such as concentration, particle size/range, the presence or not of certain coating or doping, and the purity of a nanomaterial is usually provided.

It has been found that some exposure-related parameters are easier to find than others. For example, the air changes per hour (ACH) in an indoor location and the worker segregation is not normally provided in an exposure study (see Figure 8). The source domain is provided in two out of three studies, and there is less information on the source domain 3 (Handling of liquid intermediates/ready-to-use products) and source domain 4 (Handling of nano-enabled products).

Table 4 shows a summary that compares pre-identified data gaps and identified data gaps in exposure studies, that provides a complete picture on exposure data gaps.

		Pre-identified data gaps	Identified data gaps
Physio-chemical properties	Dissolution	X	
	Dustiness	X	X
	Purity	X	
	Density	X	X
	Stability	X	
	Surface charge	X	
	Reactivity	X	
	Viscosity	X	X
	Moisture content		X
Exposure-related parameters	Occupational exposure limits	X	
	Exposure frequency	X	
	Process-related contextual information	X	
	Air Change per Hour		X
	Worker segregation		X
Other parameters	Product application & use conditions	X	
	Product functionality	X	
	Economic & societal benefits	X	
	Advanced and multicomponent materials		X

Table 4: Exposure data gaps

5. Release and dustiness studies data

5.1. Available data for release and dustiness

A total number of 12 projects include release or dustiness studies. With a total number of 81 measurements, the distribution in dustiness, mechanical release, release to water or other type is represented in Figure 15. It can be seen that the vast majority of release studies (more than 81 %) are focused on the study of the dustiness of the nanomaterials.

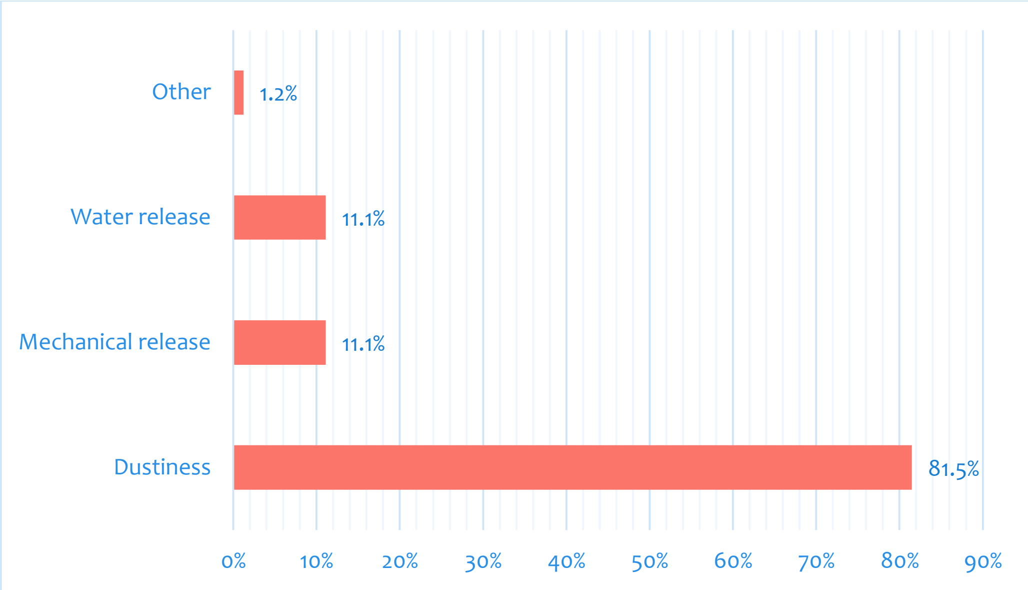

Figure 15: Release and dustiness studies grouped by type

Nanomaterials analysed in these release studies are represented in Figure 16. As same as in the exposure measurements (see paragraph 4), the most common nanomaterials are TiO_2 (24), SiO_2 (12), ZnO (9) and Al_2O_3 (8). The group "Other" includes nanomaterials with a very low (1) appearance, such as carbon black, graphene and nanomodified clay.

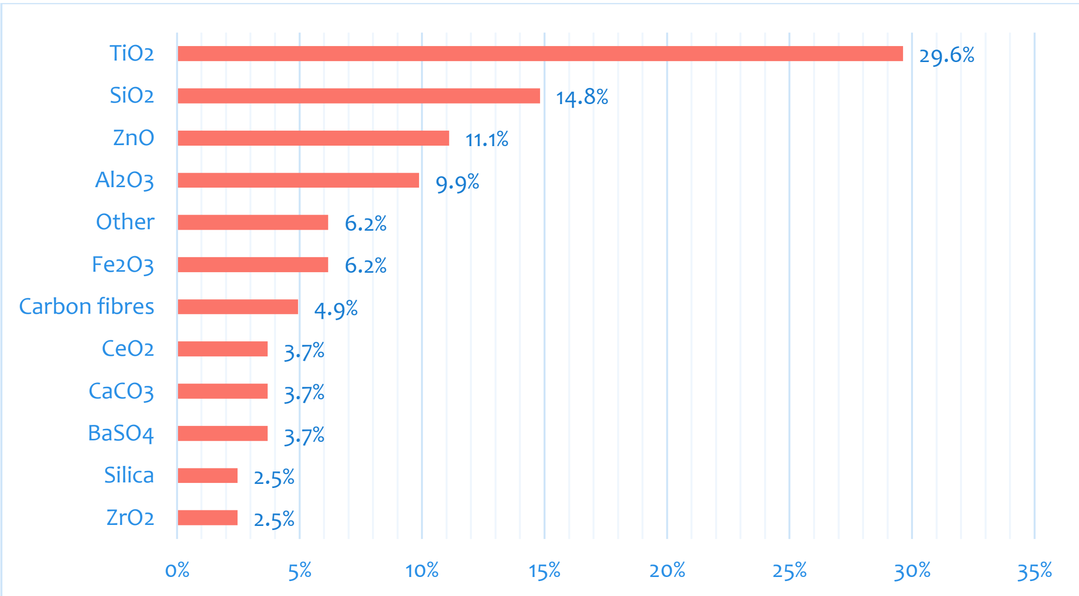

Figure 16: Available nanomaterials for the release studies

A similar characteristics distribution to the exposure measurements appears in the release and dustiness studies. The only big difference is the low production scale (laboratory) predominance. These characteristics are showed in Figure 17.

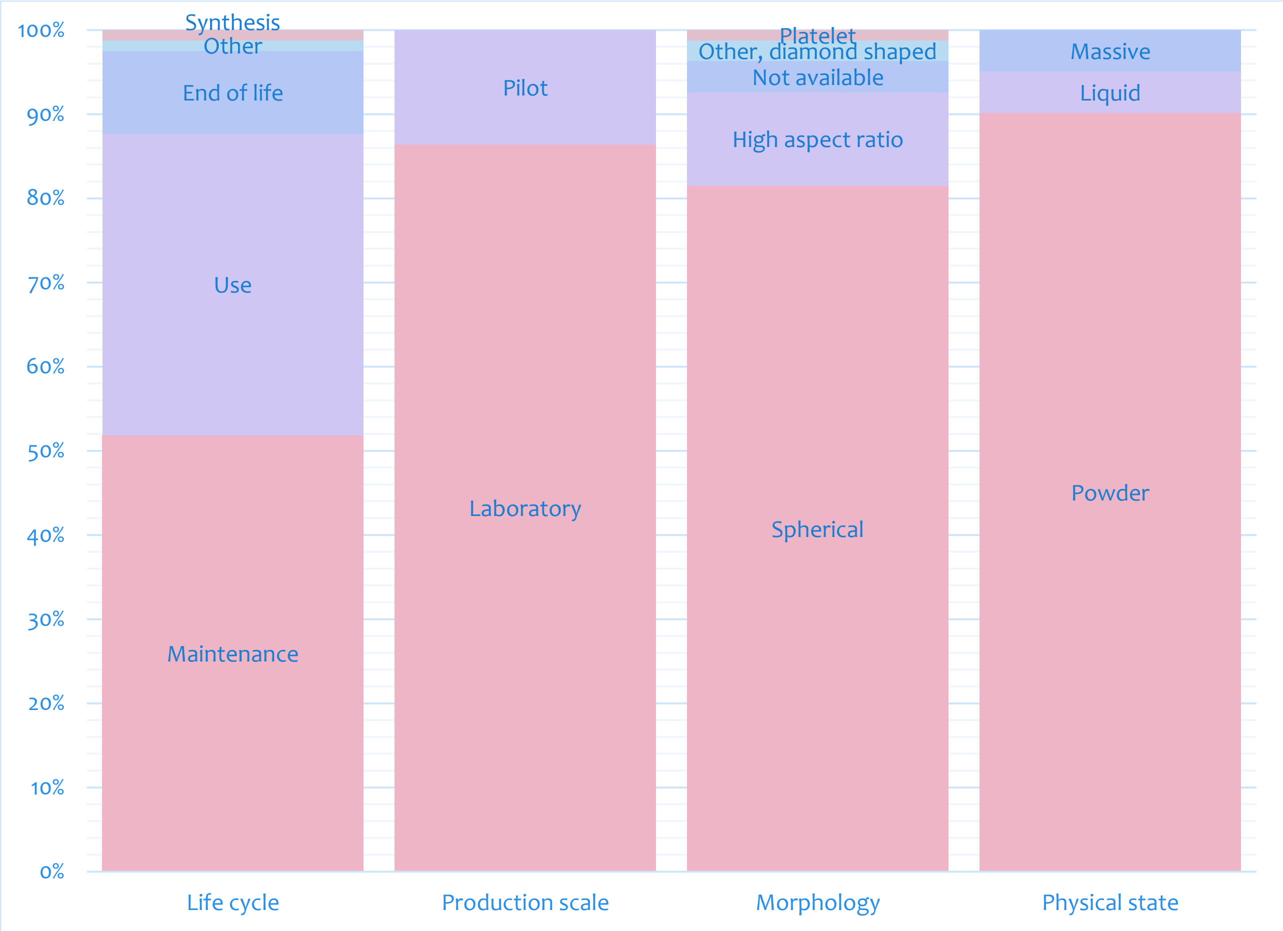

Figure 17. Nanomaterial characteristics distribution across projects

Other nanomaterial properties analysed in these projects are shown in Figure 18. Here, a smoother distribution across nanomaterials and projects can be observed, and all the properties are covered with any nanomaterial.

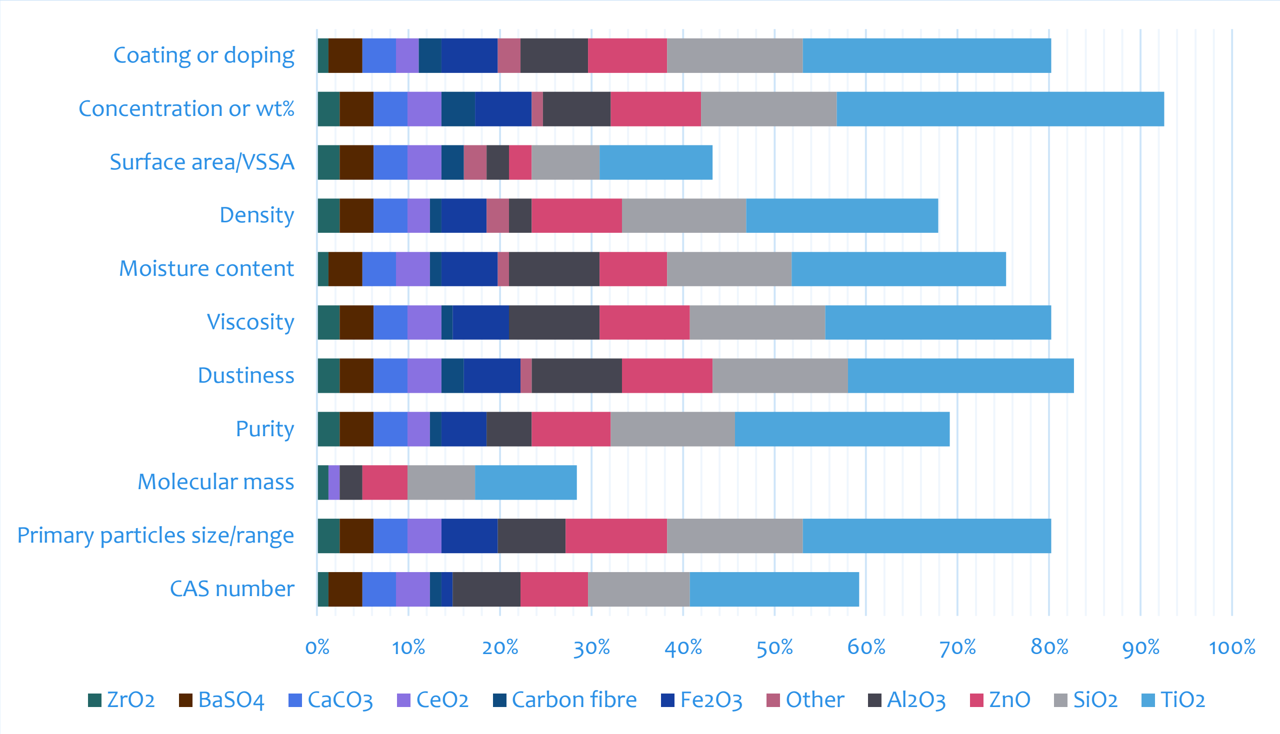

Figure 18: Availability of nanomaterial properties

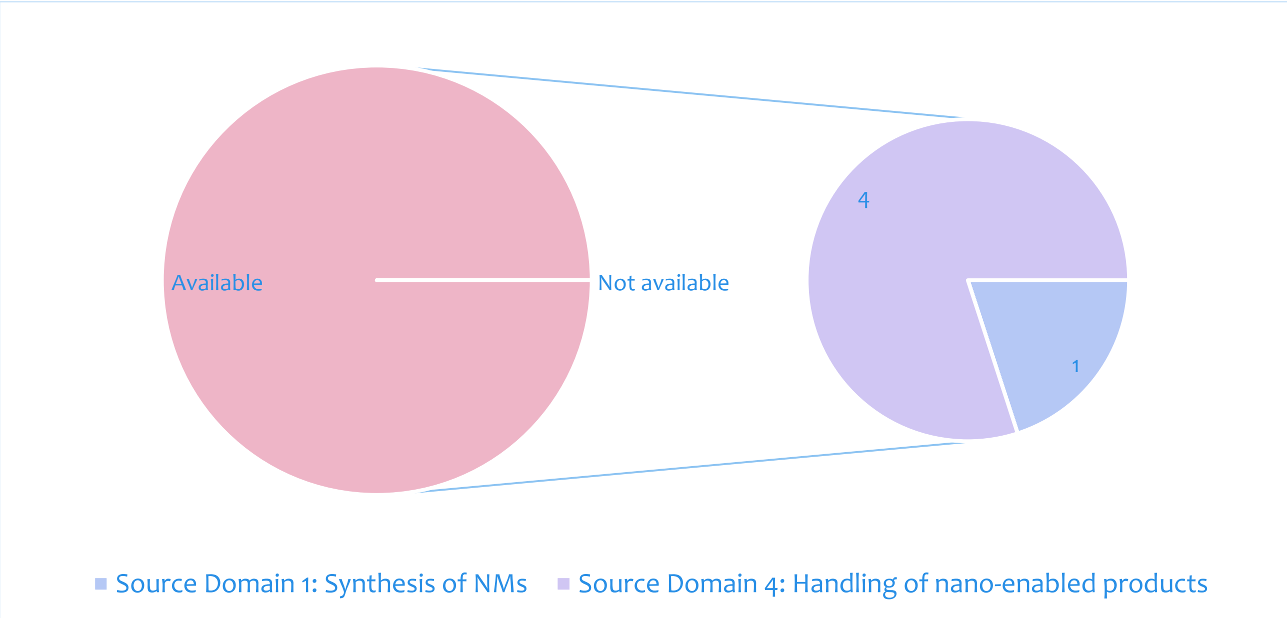

Figure 19: Source domain availability

Also, the applied energy level for the release studies has been analysed. High-energy processes are the most abundant (30), followed by medium-energy processes (28) and low-energy processes (18). There are no studies where no energy is applied. This information can be checked in Figure 20.

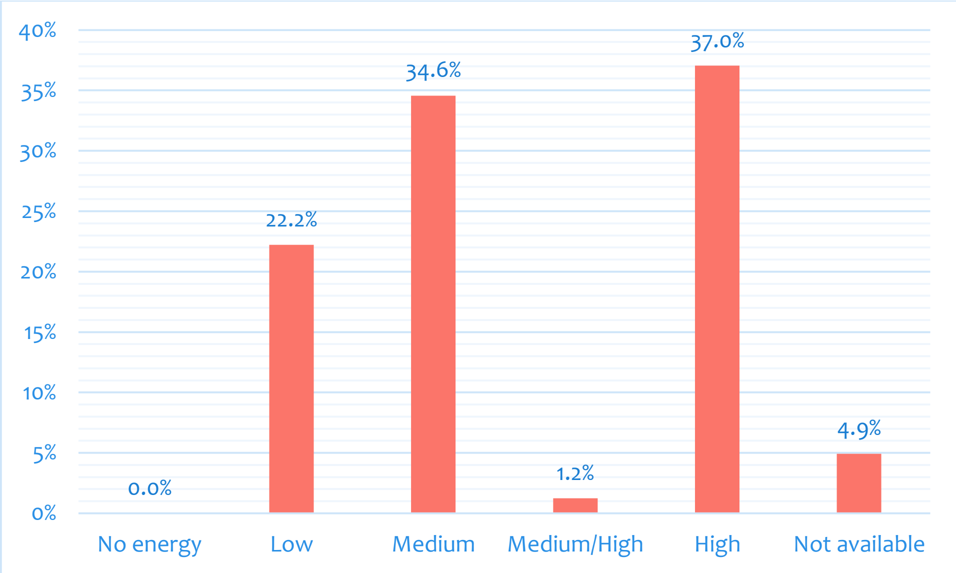

Figure 20: Applied energy level

5.1.1. Available data for release

In release studies, the information is mainly represented in Particle Size Distribution (PSD) or in particle number concentration. It is rather common to find information in mass or in total concentration, while information in volume or in specific surface area is more difficult to find. These results are shown in Figure 21.

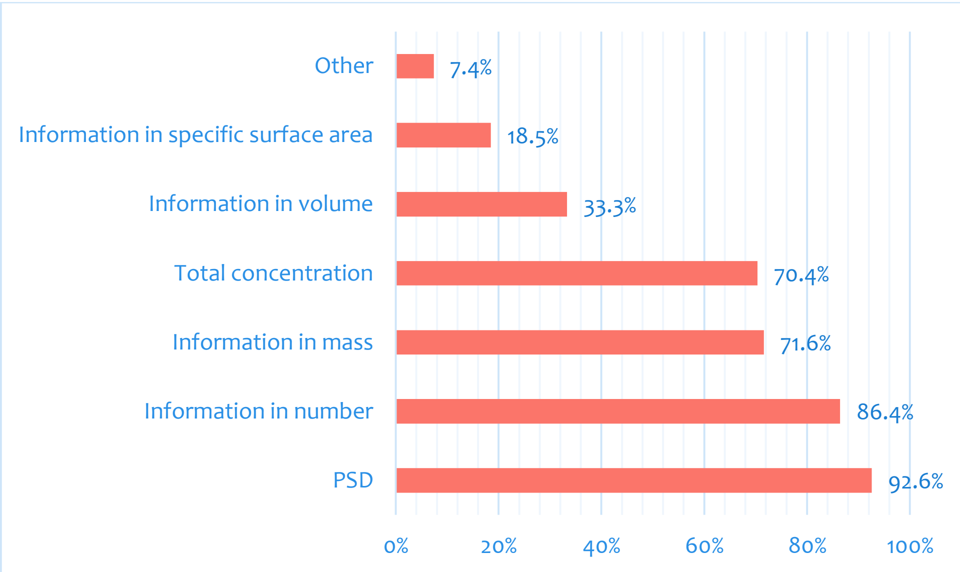

Figure 21: Available data on different metrics for release

5.1.2. Available dustiness data

Dustiness studies information is quite homogeneous, being possible to find information about the bulk density, the moisture content and the test procedure and test method used. More information is available in Figure 22.

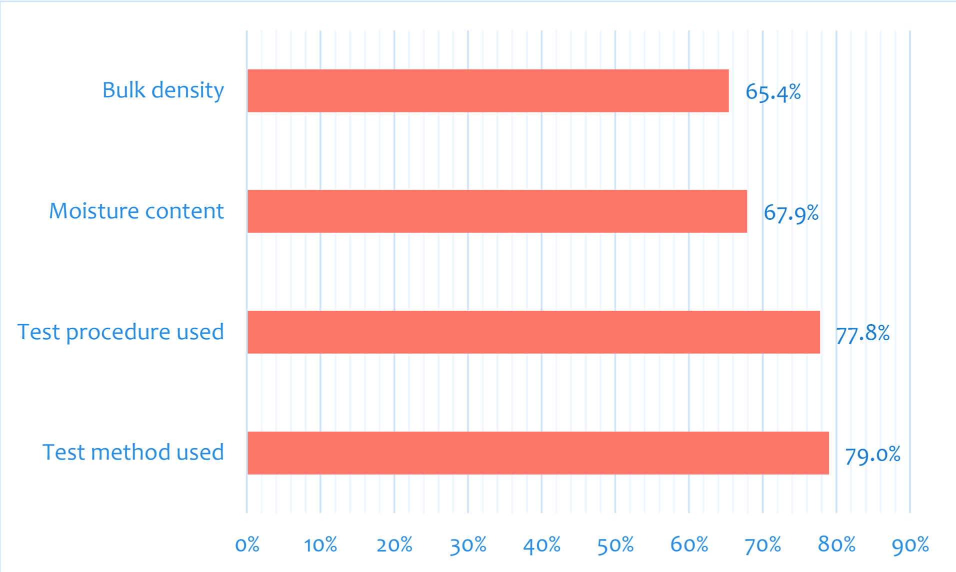

Figure 22: Available data for dustiness

5.2. Data gaps

5.2.1. Pre-identified data gaps

A recent review study investigated several studies which focused on nanomaterial release and release rates from various consumer products in the form of solid nanocomposites (Mackevica and Hansen 2016). They found that such studies are limited in number and, therefore, there is a great need to conduct and publish more studies to improve the understanding of rates and forms of ENM release. So far, the research has been focused on a very small set of possible products (such as paints, textiles, and coatings), and the conclusions drawn from the obtained data cannot be extrapolated to other consumer product groups. Also, there are very few nanomaterial types tested (mainly Ag, TiO_2, and CNT), even though there are many others used in various consumer products (e.g. ZnO, Au, and SiO_2) (The Nanodatabase, 2015). To get a better overview of ENM released from consumer products, more product groups and different ENM types have to be investigated.

The research done so far has furthermore been attempting to illustrate ENM release rates in relatively short time frames (short relative to the real-life use of the product) and imitating only few usage scenarios that are characterizing the possible emissions. The experimental setups are often far from the real-life conditions, which makes it difficult to interpret the data in the context of environmental and consumer risk of exposure. For example, washing of textiles without detergent cannot provide characterization of real-life emissions of ENM. As it is very time consuming and expensive to attempt to imitate the whole use phase of the life cycle of a certain product, it is necessary to find a method that would be representative enough for describing the ENM release rates over a longer period of time.

Even though it is well recognized that the release of ENMs from consumer products is a relevant factor for risk assessment, there is a distinct lack of analytical information available regarding the potential release (Gottschalk & Nowack, 2011). Majority of the publications focus on mass-based release rather than particle-based. A number of studies indicate whether or not there were any actual nanoparticles released, but with the current analytical techniques available, it is difficult to quantify the number of particles released. The particle release forms and kinetics are product specific and are highly dependent on the manufacturing process (Nowack et al., 2012), which makes it difficult to generalize the ENM release from different consumer product groups. Also, the experimental setups applied for determining the release rates are very different. For example, the ENM release from fabrics has been investigated using ultrapure water (Benn & Westerhoff, 2008; Pasricha et al., 2012), tap water (Benn et al., 2010), washing solutions (Windler et al., 2012), or artificial sweat (Kulthong et al., 2010; von Goetz et al., 2013; Yan et al., 2012), each giving different outcome. Therefore, there are a lot of variables that have to be taken into account when interpreting the results, such as exposure temperature, duration of the experiment, and pH.

Currently, the analytical methods for the characterization of ENM are very limited and mostly designed for detecting nanomaterials in pristine conditions. It is way more complicated to acquire data regarding the behaviour of ENM in complex media at realistic concentrations and conditions (Klaine et al., 2012). The behaviour of ENM in the matrix and in the environment will be affected by a wide range of factors, such as particle number and mass concentration, surface area, charge, chemistry, reactivity, size distribution, state of aggregation, elemental composition, as well as structure and shape (Chau et al., 2007). Therefore, the analysis of ENM is different from traditional chemical analysis because both chemical and physical forms must be considered. ENM exist in colloidal systems with a wide range of different properties, which is why it is equally important for detection and analysis to address not only chemical but also physical form (Hassellov et al., 2008).

Ideally, analytical methods should provide information on (i) whether the certain substance is in the sample (identity); (ii) how much of the substance is found in the sample (mass or number of particles); and (iii) in what physical form and size, the particles are present in the sample. A wide range of analytical tools is available for characterizing systems containing ENM to address the aforementioned questions, but they have a lot of limitations when it comes to analysing samples containing nanomaterials (von der Kammer et al., 2012).

Concerning nano-enabled products, despite that several nano-enabled product databases exist[4] which provide reliable sources of information about nanotechnology products, these only provide information about which products (might) contain nanomaterials with limited information about the wt% of the nanomaterial in the product, the lifespan of the product, and the position/location of NMs in the nano-enabled products. Considerable efforts have been devoted to estimate world

[4] Woodrow Wilson Centre for Scholars' Project on Emerging Nanotechnologies (http://www.nanotechproject.org/), The BUND inventory (https://www.bund.net/chemie/nanotechnologie/nanoprodukte-im-alltag/nanoproduktdatenbank/), Danish nanodatabase (http://nanodb.dk/), Nanotechnology Products Database in the USA (NPD, http://product.statnano.com).

/European production volumes of NMs, and how this amount is distributed among different product categories, but this is still very uncertain because the data is mainly based on reports or informal data (Keller et al., 2013; Piccinno et al., 2012). Thus, enough data can be obtained from literature with respect to the three aforementioned properties of nano-enabled products. This is essential when trying to predict environmental concentrations in the different environmental compartments, since release of NMs to the environment from products will differ depending on how particles are embedded into the product, intended use of the product or the disposable pathway of the product after its service life.

In Table 5, the most recognized and well accepted application sectors of nanomaterials (product categories), lifespan of the products and the estimative release fraction of nanomaterials during the service life of the product are identified, according to Sun et al. 2016. The release fraction is the fraction of the original content of NMs in the products that is released during the lifespan of the corresponding product category. This release is subsequently assigned to different environmental / technological compartments in mass-flow models. In addition, the wt% of NMs in the product, and the position or location of the nanomaterial in the product are indicated. The categories established are: a) embedded in a solid matrix, b) dispersed in a liquid matrix, c) adsorbed on a surface, keeping their individuality, d) adsorbed on a surface forming a coating (i.e. fused particles).

Product categories	Use duration (years)	Use release	Position/location of NM in the nano-enabled product
Cosmetics	2	0.95	b in the product, c once applied
Paints	7	0.01	a in the product, c once applied
Electronic & Appliances	8	0.30	a, d
Cleaning Agent	1	0.95	b in the product, c once applied
Filter	8	0.30	c
Plastics/ Composites	8	0.03	a
Coatings	10	0.35	d
Glass & ceramics	10	0.35	d
Sports goods	7	0.04	a
Waste water treatment plant	1	0.98	c
Batteries	NA	0	c, d
Food	1	0.90	a, b
Textiles	3	0.03	a, c
Light Bulbs	NA	0	d
Spray	1	0.95	b
Cement	80	0.01	a
Ink	NA	0	b in the product, c once applied
Metals	20	0.05	d
Woods	20	0.30	c
Paper	NA	0	a, c

Table 5: Product categories containing NMs, product lifespan and expected NMs release during use

One of the many ways to quantify the release of nanomaterials from consumer or nano-enabled products is through release rates which are also essential for improving modelling-based assessments of occupational and consumer exposure as well as the flow of nanomaterials into the environment along the material and product life-cycle (Koivisto et al., 2017). A library has been recently developed that contains release data from 374 nano-enabled products or scenarios (Koivisto et al., 2017). It considers all, occupational, consumer and environmental exposure scenarios and information about released materials (i.e. pure nanomaterials to fully matrix-embedded nanomaterials) is also provided for every scenario. Even though this is not a parameter requested by the human risk assessment yet, this information is of extremely importance to establish the hazard profile of the substance, and therefore to define the potential health and environmental risks. However, release rate or the required contextual information to estimate release rate has been found to be rarely reported by a separate review study of workplace exposure (Ding et al., 2017).

DTU Environment Database Library on Release from Consumer products has also been developed (Mackevica and Hansen, 2016). This library contains information extracted from published scientific literature on:

- Product: identification of the nanomaterial(s), product name, product type, Product or Article.
- Product Category according to REACH (PC1: Adhesives, sealants and PC35: Washing and cleaning products).
- Experimental setup: total content in product, results and information on release, techniques used for characterization of nanomaterials both in product matrix and in the released form.

Further information in the library includes information on inhalation, dermal and oral exposure as well as description of potential exposure scenarios and consumer exposure estimates from ECETOC TRA and ConsExpo Nano. However, the usability of the library is very limited. It does not include unpublished data and the information and data provided by each of the studies rarely contain all the requested information entries. Also, there is lack of information regarding the wt% of nanomaterials for too many products.

5.2.2. Additional data gaps identified in this study

As in the exposure studies, there is a huge gap on advanced materials. There is much more information about the more conventional nanomaterials like metal oxides (such as TiO_2, SiO_2, ZnO and Al_2O_3). For release studies, there is a lack of information regarding the end of life of the nanomaterial, but also for the synthesis step. Here, almost all the studies are developed at laboratory scale, and only a few of them provide information at pilot scale. None of the release studies were made at industrial scale.

Spherical morphology nanomaterials are the most studied, while less than the 20% of the release studies were made on non-spherical particles. There is also a gap on release information of non-powdered nanomaterials. Regarding available physicochemical properties with the release studies, it can be found that a better characterization is done, compared with exposure studies, reaching for example the 92% of availability in the case of concentration. Other properties are more difficult to find in release studies, such as surface area and molecular mass.

In release studies, there is a lack on information provided in surface area and in volume, and data regarding source domains 2 and 3 (Handling/transfer of bulk nanopowders and Handling of liquid intermediates/ready-to-use products respectively) has not found.

	Pre-identified data gaps	Identified data gaps
Reliability of exposure scenario	X	X
Limited set of tested products	X	X
Studies on complex or integrate NMS	X	X
Number-based release	X	
Analytical methods for characterization	X	
Re-usability of data	X	X
Data on end of life	X	X
Data from industry scale	X	X

Table 6: Release data gaps

6. Risk management measures

6.1. Available data

A total of 8 projects include information on risk management, with 7 different measures:

- EcotexNano
    - Field measurement campaign to assess the exposure to nanomaterials of workers of a textile company, with a Soil-release finished.
    - Field measurement campaign to assess the exposure to nanomaterials of workers of a textile company.

- NanoMicex
    - Field measurement campaign to assess the exposure to nanomaterials in common activities in the paint / ink sector
    - New data on the effectiveness of risk management measures against metal oxide nanoparticles used in the paint / ink sector

- NanoSafepack
    - Field measurement campaign to assess the exposure to nanomaterials in common activities in the packaging sector
    - New data on the effectiveness of risk management measures against metal oxide nanoparticles and layered clays used in the paint / ink sector

- SUN
    - Technological Alternatives and Risk Management Measures (TARMM) inventor

- NanoRISK
    - 4 Field measurement campaign to assess the exposure to nanomaterials in the nanocomposites life cycle, including NMs production, handling, packing and compounding
    - New data on the effectiveness of risk management measures against metal oxide nanoparticles and graphene, including ventilation, respiratory protection equipment, chemical protection gloves and protective clothes
    - New standard operating procedures (SOPs) to evaluate the effectiveness of risk management measures, including filtration efficiency (respiratory protection and protective clothes), permeation potential (protective gloves) and capture efficiency (ventilation).

- GuideNano
    - Field measurement campaign to assess the exposure to nanomaterials in different sectors, including building and paint related sectors, and nanocomposites. A wide range of activities were covered, including NMs production, handling, packing, compounding or spraying.
    - New data on the effectiveness of risk management measures against metal oxide nanoparticles and graphene, including ventilation, respiratory protection equipment (negative / positive pressure), chemical protection gloves and protective clothes
    - New data on the effectiveness of measures and technologies to reduce the environmental release of ENMs and nano-enabled products.

- Integral
    - The general ventilation of the hall is ensured by an air inlet with the opening of the hall door and an extraction with a fan at the upper side of the wall. Normally, the door of the hall must remain closed but when it is very hot outside, it is slightly open. All the process equipments are connected to the same air treatment station, except the bricking workstation. Most of the other process steps, especially cutting steps (bricking, wafering, wafer grinding, cleaning and leg dicing) are wet processes and most of them are enclosed (wafer grinding, cleaning and leg dicing). Both factors are favourable in terms of the limitation of worker's exposure to particulate aerosols.
    - Hazard information of powders are based on Material Safety Data Sheets (MSDS) provided. Except for the wet cleaning which takes place outside, all of the other process steps are dry processes. Design of some LEV does not seem optimal. Priority ranking was made following CPC emissions calculation. Personal Protective Equipment (PPE) can only be considered when all other risk mitigation measures are insufficient or impossible to implement.
- Nanoleap
    - Spray drying pilot plant for production of consolidated nanoparticles in microsized granules.
    - Pilot plant of nanoimprinting roll to roll to produce biomimetic hydrophobic and self-cleaning nanocomposites.

- BIORIMA
    - Field measurement campaign to assess the exposure to aerosols of workers of a SME, which manufactures dentures.
    - New data on the effectiveness of respiratory protective equipment when dealing with nanobiomaterials, including bioaerosols.

For each of the projects, data regarding different strategies has been analysed and the availability of these individual strategies are evaluated in the paragraphs from 6.2.1 to 6.2.4. Figure 23 represent the availability of these strategies.

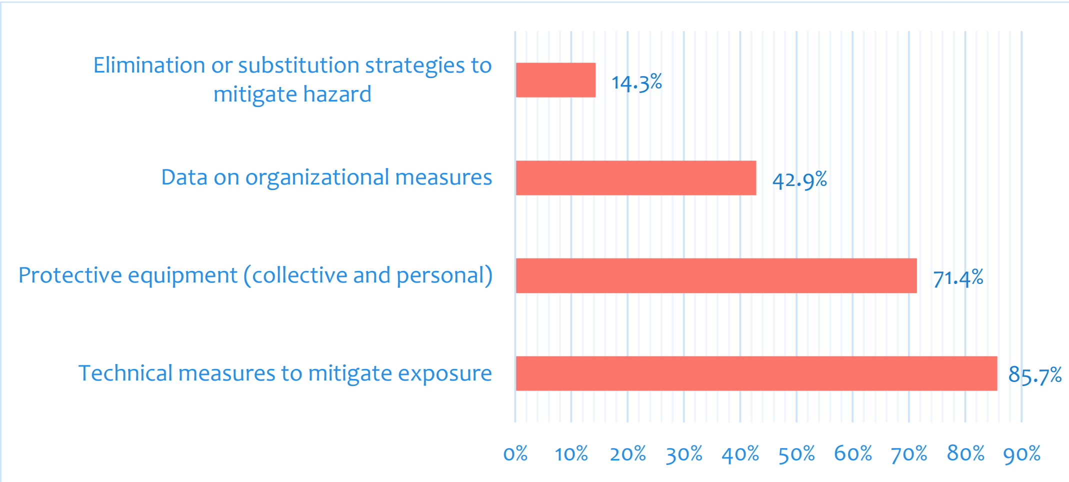

Figure 23: Availability of risk management measures

6.1.1. Available data regarding elimination or substitution strategies to mitigate risk

In Nanoleap project, changing the size of the nanomaterial is proposed as a strategy to mitigate the risk. This strategy was associated with the implementation of collective protective equipment (CPE) in the pilot line, based on static (containment chamber) and dynamic (extraction pipes connected to a fan at each floor) containment. This combination is very effective to mitigate the risk of exposure. But it is difficult to evaluate the contribution of each strategy. However, we were able to assess the impact of changing the emission during maintenance and cleaning activities that require breaking the containment. The results show that few emissions were recorded. Indeed, one short (below 10 seconds) significant emission occurred during the 2 hours of handling without static containment. Emission recorded is mainly composed of submicron and micron-sized particles. Nevertheless, some of them could be aggregate or agglomerate of nanoparticles. One way to assess the impact of the change in size to mitigate the hazard and reduce the risk would be to assess the release by dust testing before implementing the new nanomaterial formulation in plant.

6.1.2. Available data regarding technical measures to mitigate exposure

Technical measures are the most common response to mitigate exposure. One explanation could be that elimination or substitution strategies require a complete redesign of the process(es), as do organizational measures. The implementation of a technical measure provides a quick and effective response to exposure with a low level of investment.

Scientists agree that if engineering controls (ECs) are well designed, they will be effective in limiting environmental release and workplace exposure. However, these controls need to be supplemented by good practices and the use of appropriate personal protective equipment (PPE), especially relevant when other approaches such as elimination, substitution or modification of is not possible, as could be the case of ENMs.

There is limited information on the effectiveness of these engineering controls. Currently available controls are designed to capture inhalable particles, with a size range from less than 0.01 µm up to 100 µm aerodynamic diameter, clouds of respirable particles that can penetrate deeply into the lungs, with an upper size limit of about 10 µm.

Particles above 100 µm have been demonstrated to be “non-inhalable” as they are too large to be breathed in. They fall out of the air and settle on the floor and surfaces near the process

6.1.3. Available data on organizational measures

Standard Operating Procedures (SOPs) are selected in NanoRISK, EcotexNano and Integral projects as organizational measures. Neither repartition of work, nor schedule are chosen for any of the projects.

6.1.4. Available data regarding protective equipment (collective and personal)

Protective equipment efficiency was addressed in several projects, including Nanoleap, NanoRISK, NanoMICEX, GuideNano and BIORIMA. Used protective equipment is stated below in Table 7:

Project	Integral	Nanoleap		BIORIMA	NanoRISK NanoMICEX	Guidenano	SUN
PPE Type	Safety shoes, Nitrile gloves, P1 mask,	Chemical non-woven coveralls, Loose-fitting powered-air-purifying respirators	UV protection glasses, Closed-toe shoes	Mask (P1)	P1-P3 Mask Protective Suits Gloves	P1-P3 Mask Protective Suits Gloves	P1-P3 Mask

Table 7: Available data regarding protective equipment

6.2. Data gaps

6.2.1. Pre-identified data gaps

Current knowledge on the effectiveness of personal protective equipment and technical measures against nanomaterials is still scarce. However, a number of initiatives, including EU funded research projects and studies from research organizations across the scientific community were identified during this data gap analysis.

The EU funded projects NanoMICEX, NanoREG, NanoRISK and GUIDEnano are the most relevant sources of information concerning the performance of risk management measures against nanomaterials. On the other hand, institutions such as IRSN (Institut de Radioprotection et de Sûreté Nucléaire) and INRS (Institut National de Recherche et de Sécurité) in France are very active on the publication on new data on the effectiveness of personal protective equipment.

Knowledge on the measures that concern waste management are far less advanced, with few references in peer reviewed publications.

Concerning personal protective equipment, the protection of the respiratory track has been prioritized due to the relevance of the inhalatory route in the workplace. Data on the performance of chemical protective gloves and protective clothing is available to a limited number of fabrics, mainly nitrile and polyethylene for chemical protective gloves and protective clothes respectively.

Technical measures

Goede et al. (2018) collated nano-specific data on workplace RMM. A total of 770 data points from 41 studies were retrieved, out of which one third of data points corresponded to technical measures or engineering controls. Although the number of data for technical measures was limited, the analyzed studies generally showed that localized ventilation systems are effective for particle sizes between 200 and 300 nm due to their minimal diffusion and small inertia that results in increased capturing efficiencies (Schulte et al., 2008; Schneider et al., 2011). When particle motion is dominated by diffusion for particle diameters smaller than 200 nm, and suction is sufficiently high, the particles follow the streamlines into the ventilation device with only minor random zig-zag deviation, resulting in high capture efficiencies. Localized ventilation controls appeared to be in the same order of magnitude of their efficacy as to that of conventional substances.

Manufactured nanomaterials that are emitted during synthesis are known to coagulate rapidly during the emission from the source and transport to the receptor (Schneider and Jensen, 2009). Considering the data evaluated by Goede et al. (2018), particles at the source typically ranged between 10 and 400 nm. Since nanoparticles agglomerate and aggregate and increase in size over time, the effectiveness of different types of engineering controls vary accordingly. An option can be to differentiate between effectiveness of ventilation systems based on the expected particle size distribution. However, since an estimation of the coagulation rate is complex (Schneider and Jensen, 2009) and time and concentration dependent, and with the current scarcity of efficacy data, it is not yet possible to do a distinction between particle size distributions of different expected nano forms (e.g. pristine versus fragmented, or synthesis versus end of life) and determine their capture efficiencies.

Protective equipment

An approximately two-thirds of 770 datapoints of Goede et al. (2018) corresponded to the respiratory equipment and skin protective equipment: gloves and clothing which can be combined as protective equipment. The available studies established that nanoparticle sizes ranging between 4 and 20 nm can be captured very efficiently by respirator filter media (Rengasamy et al., 2008). Theoretically, a combination of both diffusion and interception mechanisms results in a minimal efficiency or maximum penetration at a given particle size, typically between 100 and 500 nm and normally peaking at 300 nm. Filtering face respirators typically provide the lowest protection factors for particles between 80 and 200 nm (Rengasamy et al., 2007). Worst case conditions in the workplace such as the removal of electrostatic charges on filter media can result in much less effective protection (Rengasamy et al., 2009), in addition to factors such as respirator fit, reduced leakages (Reponen et al.,2011), breathing rates, and airflow (Balazy et al., 2006; He et al., 2014). Testing of permeation, penetration, and degradation associated with the potential migration of nanoparticles through different skin protective equipments such as coveralls and gloves was observed to be complex. Although, the available data was found to be scarce, some studies indicated that the type of nanoparticles (e.g. TiO_2), their physical state (solid, solid-in-liquid), garment thickness, and textile type and composition (woven, non-woven, coated) are important factors (Boutry and Damlencourt, 2014; Vinches et al., 2014). Overall, data indicated that the nanoparticles could penetrate through textiles and materials, with high density materials (e.g. polyethylene, polyamide, polyurethane) performing better as a protection barrier than woven materials such as cotton. The available data also suggested that the thickness of gloves could be an important factor that affects protection from nanomaterials.

Another issue of concern identified Goede et al. (2018) was the large number of experimental studies, with some exceptions of (simulated) tests of human subjects or workplace measurements. Although some workplace studies in the review have confirmed that workers received the expected levels of protection when compared with experimental studies (Balazy et al., 2006), experimental data should be interpreted with caution because of the different test methods and test conditions applied. In addition, datasets were observed to be generally too small or not representative enough to extract, for example, a meaningful value based on percentiles (e.g. 5th percentile for RPE). This is of particular interest when proposing efficacy values for the modelling of nanomaterials where level of conservatism is an important consideration.

For each RMM type, technical measure or protective equipment, the review emphasized to have realistic assumptions about the technical specifications, conditions of use and maintenance of RMM. ECHA (2012) has proposed that RMM effectiveness could be best described by considering both typical default values (as used) and maximum achievable values (as built) of RMM. It was mentioned that these descriptors should ideally be used to develop a viable approach to estimate efficiency values that represent and incorporate RMM during typical conditions of use in practice. Therefore, in event of sufficient data in the future, the review proposed to have a clear and structured method to effectively disseminate information on the efficiency of RMM (e.g. time series of nano-specific data). It also recognizes the need for a suitable and robust data analysis to derive reliable efficiency values based on percentiles and/or confidence levels.

6.2.2. Additional data gaps identified in this study

There is a clear data gap on risk management measures studies, being less common to find projects with this kind of data. Apart from this difficulty, within these projects it is very difficult to find elimination or substitution strategies to mitigate hazard, as same as data on organizational measures. On the other hand, information regarding used PPE and technical measures can be usually found.

	Pre-identified data gaps	Identified data gaps
Elimination or substitution strategies		X
Technical measures		
Protective equipment	X	
Organizational measures		X

Table 8: RMM data gaps

7. Stakeholders' needs

7.1. Results from previous initiatives regarding stakeholder engagement

To identify the needs of the stakeholders in the context of exposure assessment and risk management, we provide results from previous EU H2020 projects like EC4SafeNano and caLIBRAte which carried out surveys and workshop respectively to identify and make an inventory of the needs. More details are provided in the subsequent sections.

7.1.1. Nanosafety

van Duuren-Stuurman et al. (2019) implemented a survey to identify the needs of different stakeholder groups that include EU member states, European Commission and its agencies, Industry and Civil society (NGOs, citizen groups). This survey collected information about all responding persons and their organization, their needs for access to expertise, knowledge and services regarding nanosafety.

EU member states and European Commission (EC) and EC Agencies

A total of 32 responses were received collectively from EU member states and EU agencies in 13 countries (Austria, Belgium, Finland, France, Ireland, Italy, Germany, Great Britain, Greece, Portugal, Spain and Sweden and The Netherlands). The respondents were mostly involved in different areas of science, policy or regulation. These included scientists (toxicological tests for nanomaterials, environmental analysis for nanomaterials, public and occupational health, genotoxicology, occupational hygiene and exposure), policy advisors (policies for the environment public, occupational health, and national science policies), technical project managers (national and international projects on safety of nanomaterials for workers, health and safety initiatives, and medical devices), regulatory specialists (implementation of REACH, CLP, BPR, Belgian registry for nanomaterials and authorization for market safety of chemicals), risk assessment specialists (risk of exposure to chemicals including risk for contamination of food and use of nanomaterials in agriculture) and committee workers (specialist advisory expert committees for safety of chemicals and nanomaterials).

More than 80% of the 32 aforementioned respondents were concerned about the potential risk to human health presented by nanotechnology. Concerns about other areas such as general safety, the environment, risk perception and regulations remained high (>65%). There were >60% concerned about the potential hazardous properties of nanomaterials, the risk for acute and chronic ill health. Approximately one third had specific concerns about the use of nanomaterials in manufacturing processes, consumer products, medical products and devices, the environment and in relation to chemical and physical hazards. Approximately a fifth expressed concern about safety and risk perception of nanomaterials in the environment. A larger proportion (approximately a third) were concerned about regulations that may in future be applied to nanomaterials.

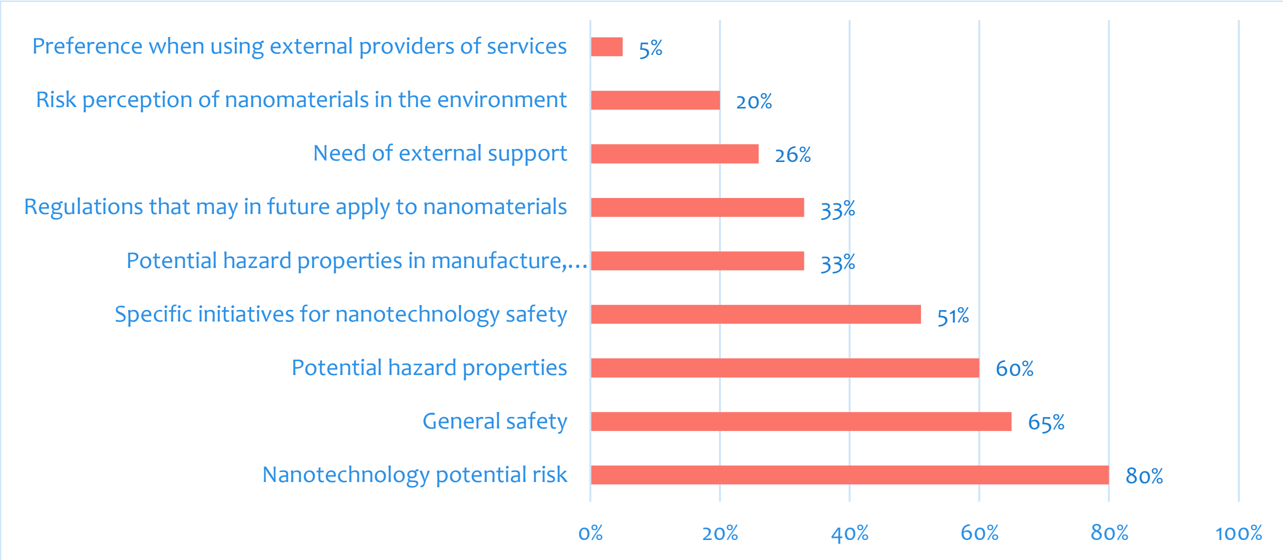

Figure 24: EU member states, European Commission (EC) and EC Agencies needs

Within the organisational requirements, it was observed that more than half of the respondents were undertaking specific initiatives in relation to the safety of nanotechnology and nanomaterials, but under half considered that external support is needed to address their requirements. Only a quarter of the respondents currently used external providers to help them deliver their work in this area. A very small percentage (~5%) had expressed a specific preference when using external providers of services, whether these be nationally based, based within the EU or based internationally.

The respondents also made some additional comments on their main concerns for nanosafety. With respect to human health, concerns were expressed about the unknown hazardous properties of novel nanomaterials. This included risks for chronic toxicity and whether biomarkers of exposure could be developed to anticipate risks for future disease. In addition to concerns about acute toxicity, specific issues of immunotoxicity, genotoxicity and mutagenicity of nanoparticles were raised. Several respondents raised a specific concern to better understand the risk for inhalation of nanoparticles and whether concerns about granular bio-persistent particles (GBP) and fibres (WHO fibres, High aspect ratio nanoparticles (HARN)) would apply to some materials. Others raised concerns about occupational and consumer safety with respect to how individuals become exposed to nanomaterials. To better understand this exposure, there was a need to improve sampling methods and methods to quantify and characterise airborne nanoparticles by metrics of number, surface area, and mass. Some respondents noted the lack of specific exposure limits for nanoparticles and the need to standardise protocols for working safely with nanomaterials. The risk of food contamination through direct contact with packaging containing nanomaterials was raised.

With respect to health effects in humans there was a need for clear, validated and standardised methods to characterise hazardous nanomaterials and to appraise their critical properties e.g. fibrous materials and platelets. These tests should consider both acute and chronic exposure circumstances and the migration of nanoparticles throughout the body. To assess human exposure (occupational or consumer) there was a need for improved methods for sampling nanomaterials and monitoring emissions from different processes. This included the development of safe limits for occupational/consumer/ environmental exposure.

Data requirements were considered important and several respondents identified the need for access to databases that contain information about occupational exposure to nanomaterials. An EU web portal could provide a means for sharing information about nanomaterials and nanotechnology with access to relevant occupational exposure data studies, epidemiological and toxicological data, proposed exposure limit values and suitable sampling methods. There is a need for an EU wide consumer database of products for human use that contain nanomaterials. There was a need to develop evidence-based policy and provide access to data that could help duty holders undertake suitable risk management. An expert group was needed to evaluate consumer safety from products containing nanomaterials. The requirement for specific EU legislation about Health and Safety for nanomaterials should be considered. Support for communicating knowledge and good practice across the entire life cycle of the nanomaterial was proposed along with the need to raise awareness and develop tools for training end users in good practise methods.

Organisational priorities for safe use of nanomaterials for some organisations were to recognise risks for enhanced flammability, explosivity and chemical reactivity of some nanomaterials. Concerns were expressed ensuring the traceability of nanomaterials along the supply chain with safety-data sheets of good quality providing relevant information on form and characterisation of the nanomaterial. “Safe-by-design” was proposed as an important principle to ensure that early stages of developing technology, or products, the risks to employees, consumers or patients were considered and minimised. The risk to workers is a priority particularly for inhalation exposure. Improved characterisation by toxicity tests (in vitro and in vivo) was required considering all relevant endpoints including genotoxicity, mutagenicity, epigenetic and immunotoxic effects and physico-chemical characterisation of the materials. The potential for bioaccumulation and persistence of nanomaterials in the wider environment was considered important.

In the context of support needed to best help the responding organisations, most of the points raised were similar to those summarised for the organisational priorities. Some additional points included the need for funding and innovation hubs that support nanosafety research.

For the regulatory issues which organizations considered important, most of the points raised corresponded with issues previously summarized. They focused on the need to improve the definition of nanomaterials; for improvements in standardized methods for toxicology and exposure assessments; and for considering how best to deal with the nanomaterials whose properties may increase the risk for serious health consequences (e.g., rigid high aspect ratio nanofibers). The essential requirements for regulations may include the need for occupational exposure limits for the more toxic nanomaterials. Regulations should be up to date and transparent on how current EU regulatory process should be applied. Exemptions for labelling substances and mixtures with a low potential for release of nanomaterials was suggested.

Industry

A total of 91 responses were received from the target group of Industry that consisted of small, medium sized and large companies as well as their associations. The respondents were active in all sectors, but mainly in chemical industry, electronics industry, energy industry, paint industry, agriculture/agrochemical industry, construction industry and plastics/synthetics industry. All stages of the life cycle were represented, but the majority was R&D and manufacturing of nanomaterials enabled products/articles. Manufacturers of nanomaterials and users of nanomaterial enabled products/articles were also represented, but to a lesser extent. The waste stage was represented only by one respondent.

The industry holds human health issue at the topmost priority, followed by risk perception, safety, regulations and environment. The respondents were more interested in solutions than in quantification of the problem. Their main concerns were for their company/organization. Possible life cycle problems of their products were of less interest, while environment issues received even less interest. Issues in relation to risk perception were "how to assess risk perception" rather than "how to influence risk perception". In relation to regulation, the industry expressed the need for a tool that would help them know which regulation applied to ensure their compliance. National law appeared to be more important than international law.

Two out of three respondents undertook initiatives to solve these issues; the majority used their internal resources (<50kEuro; occasionally up to >500kEuro), while some used external resources to the same order of magnitude. EU service providers were preferred followed by worldwide providers and then national providers of services. Just a limited number of the respondents used specific tools. About a third of the respondents have needs in relation to nanosafety, but about half of the respondents did not answer this question.

The types of services mostly considered as essential were guidance followed by testing & measurement. Particularly for tests related to measuring concentrations and characteristics for nanoparticles including their physical/chemical properties like size, shape, solubility, surface chemistry, dustiness etc. Exposure assessments and risk assessment for workers were also requirements. In relation to keep their knowledge up to date, the respondents indicated that a website, newsletters and workshops could assist.

General public

A total of 28 responses were collected from the general public including NGOs, citizen groups from different domains of environment and health (75%), consumer protection (11%), trade union (11%) and miscellaneous (3%). Approximately 89% of the respondents were actively involved in the nanotechnology field. Like Industry, general public also give their highest priority to human health issues. They are followed by other issue like risk perception, regulation, accidental risks and impacts on ecosystems.

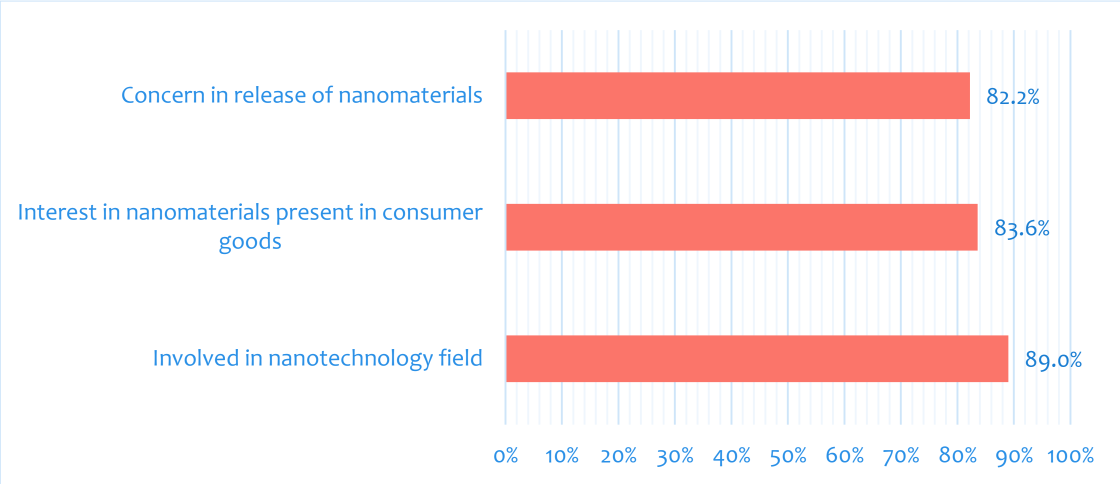

Figure 25: General public needs

The respondents concerns about the use of nanoparticles in consumer products were also observed during this survey. Most interest was shown about recognizing what the kind of nanomaterials are present in consumer goods (average of 4.18 in the scale of 1-5). Additionally, an average Likert scale of 4.11 was observed in their concerns about whether nanomaterials were released during production, storage and transportation, and how they can be produced safely. The properties of the nanoparticles that are contributing to safety risks, physical hazards and general safety of workers were also a concern for these respondents. With regard to environmental safety, the survey results suggested that ecotoxicity, and the concentration of nanomaterials in the environment and their impacts on ecosystems, were significant points of concern.

Overall, the survey results suggest that the civil societies showed most interest in understanding the risk and possible prevention to risk related to nanomaterials.

7.1.2. Requirements over product innovation stages

Bakker et al. (2017) reported the outcomes of a stakeholder's workshop to design a risk governance framework or system for manufactured nanomaterials which is suited for the "Cooper Stage-Gate" product innovation model. The aim was to identify certain requirements and objective performance criteria which are considered to be critical for the system among different stakeholder groups. These requirements and criteria can have implications on a risk modelling framework and e-infrastructure, as being developed in SbD4Nano project (WP4 and WP5 respectively).

A total of 29 people participated in the workshop who belonged to the stakeholder groups of regulators, industry associations, large industries, SMEs and consultants. Their responses were collectively treated and processed by Bakker et al. (2017). It was observed that it matters to the stakeholders under which regulation a nanomaterial or nano-enabled product falls. This should therefore be built in, in the system. SMEs will benefit most from a simple to use system, that has all the risk assessment expertise hidden inside the system, as they lack this expertise. It is also important that the system can be run as a stand-alone model, to warrant data security and confidentiality, although some stakeholders have indicated to desire a web-based system.

The stakeholders deemed critical to have a good indication of high risk materials in stage 1 and 2 (red flag) and a clear (more quantitative and regulatory accepted) indication of risks within a specific regulatory framework in the later stages of the innovation process. As testing material is generally only available from stage 3 (R&D) onwards, earlier stages can only include QSARs and grouping approaches to obtain a hazard indication. The most important populations prone to nanomaterial risks were indicated to be workers and then consumers, with inhalation expected to be the most important exposure route. These deserve priority, therefore, in the setup of the system.

All stakeholders agreed that the hazard and exposure outcomes, and exposure outcomes per route, should be given. They wanted to know which information was used to get to the risk estimate and what approach that has been taken in case there were multiple data for one input parameter. A worst-case risk estimate was considered to be not useful, except whenever a potential occupational health risk is foreseen for their own employees that are involved in the R&D process.

7.2. Plans for survey and workshops to refine stakeholder needs

To refine the needs of industrial stakeholders, a survey on exposure assessment and risk management practices and barriers to implementing SbD approaches is being established. This work is carried out in collaboration with WP6 to reduce the demands on stakeholders as much as possible. The aim is to identify knowledge gaps and this survey is being prepared for this purpose. An extract of the survey template is available in the annex section.

8. Conclusion & Plan for the future

The aim of this deliverable was to identify current knowledge gaps in exposure, release and risk management measures when dealing with ENMs, highlight research gaps, and suggest future research directions under the framework of the project.

Recent research advances have improved particle monitoring technologies for conducting quantitative exposure assessment, and increased awareness of the potential exposure in industrial settings has promoted new studies on the effectiveness of risk management measures against ENMs of different forms and shapes.

The GAP analysis conducted has revealed an **evident lack of knowledge for large scale productions**, due probably to the domain of the sector by a high number of small and medium sized enterprises (SMEs) and start-up companies, much of them originated from research groups working in universities and public research organizations.

The data gathered from key EU project show that **data form multicomponent ENMs and high aspect ratio NMs (HARNs) are already scarce**, with a focus on commonly used materials such as SiO_2, ZnO, or TiO_2, which are used in large quantities. Meanwhile, for low production volume ENMs such as CNTs or graphene nanoparticles, there are limited data from production sites, which generates the need for new studies in view of the expected market volume.

Besides the above, current data covers short measurement times, ranging from seconds to several minutes, limiting decision making using similarity approaches.

It should be also highlighted that the exposure potential at consumer level has not been subject of systematic research projects. Some studies indicate that ENMs incorporated into nano-enabled products can be released during the use phase, but no approach for consumer exposure assessment has been widely accepted so far, limiting the availability of data.

Concerning release, dustiness data dominate this field. This endpoint has risen as a valuable tool for occupational safety, as it is a measure of a material's tendency to generate airborne dust during handling. As a result, dustiness testing is currently used as an input for occupational exposure assessment. On the other hand, despite that the potential release has gained importance on recent years, only a few studies related with processes such as mechanical abrasion (i.e. sanding) have been reported, which means that new studies are needed for identifying the nature and extent of nanoparticles and nanoparticle-containing fragments released from nano-enabled products as a consequence of relevant process.

Under SbD4Nano, new data on the release potential are anticipated, being key to support the development of the exposure models to be generated. In addition, new efforts for the definition of harmonized methods for release studies (in addition to dustiness testing) are urgently needed for decision making.

The last topic analysed focussed on the analysis of current data on the effectiveness of RMMs. In this specific topic, only a few projects were identified. Recent data show a proper effectiveness of PPEs and engineering controls against ENMs, with proven results for respiratory protection equipment. In terms of engineering controls, current data is limited to a few projects covering a very limited number of ENMs. Therefore, a strong effort on the analysis of the effectiveness of technical measures is urgently needed to protect workers following the hierarchy of controls.

Knowledge on the measures that concern waste management are far less advanced, with few references in peer reviewed publications. The project will also explore technical measures to avoid end-of-life related release, supporting the selection of proper measures to reduce the unintended emissions.

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10.Annex

Overview matrix of current projects including information on process safety

Acronym	Exposure data	Release data	Risk Management	Applicability to develop SbD approaches
ENPRA	√		√	
NANEX	√			
ITS-NANO				√
MARINA	√	√	√	√
NanoHouse	√	√		
NanoMIXEX	√		√	√
NanoSafepack	√	√	√	
NanoSustain		√		
Sanowork	√	√		√
NanoMaster	√			
EIROS	√			
ELECTROGRAPH	√			
Polygraph	√			
Scaffold	√		√	√
ACEnano				
Calibrate	√		√	√
CERASAFE	√		√	
FutureNanoNeeds	√	√	√	
Nancore	√			
GuideNano	√		√	
Hisents				√
Lorcenis				√
ModCOMP				√
NanoGenTools				√
NanoMILE			√	√
NANoREG	√	√	√	√
NanoREG2	√		√	√
SUN	√	√	√	√
NanoValid			√	
NanoRISK	√		√	
NanoIndex	√			
SIRENA		√		
NanoGEM	√			
NanoMonitor	√			
BIORIMA	√			
PATROLS	√			
GRACIOUS	√	√	√	√

Project list and available resources

The Table below provides an overview of completed and ongoing projects in which release, exposure and/or RMM data have been collected. The Table gives for each project a short description of the data and a link or name of the relevant information / deliverable report.

Project Acronym	name	Short description	Link or name of relevant deliverable
NANoREG	A common European approach to the regulatory testing of nanomaterials (II)	The interdisciplinary approach involving the three main stakeholders (Regulation, Industry and Science) contributed significantly to reducing the risks from MNMs in industrial and consumer products. NANoREG starts by analysing existing knowledge (from WPMN-, FP- and other projects). This is combined with a synthesis of the needs of the authorities and new knowledge covering the identified gaps, used to fill the validated NANoREG toolbox and data base, conform with ECHA's IUCLID DB structure.	NANoREG D3.1 Gap analysis report, identifying the critical exposure scenarios within the key value chains
NANoREG2	Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks	Within NanoReg2, eNanoMapper and NECID databases were analysed to determine the data gaps corresponding to various exposure, toxicology and ecotoxicology relevant parameters (classified in 15 categories of which 9 are applicable exposure) of NMs. There are 25 NMs for which information is available in both databases. In addition, the main concern with these databases are that they focus almost exclusively on phys-chem and exposure of pristine NMs but tend to include little or no information on transformed NMs and matrix in different life cycle stages. No information or data were available on the NMs in different innovation stages (or TRLs/MRLs) in the stage-gate process.	D2.3 Final comparative risk assessment and life Cycle assessment for candidate materials after SbD implementation in "hot spots" along the life cycle
EC4SafeNano	European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	A survey was carried out to identify the nanosafety relevant needs among different stakeholder groups that include Member States, EC and EC Agencies, Industry (large companies and SMEs) and others private actors, and Representatives of civil society (NGOs, citizen groups). The highest concerns were found for human health for all stakeholder groups. With respect to health effects in humans there is a need for clear, validated and standardised methods and guidelines to characterise hazardous nanomaterials and to appraise their critical properties. To assess human exposure (occupational or consumer) there was a need for improved methods for sampling nanomaterials and monitoring emissions from different processes. This included the development of safe limits for occupational/consumer/environmental	D1.1 Final description of current needs of member states, European Commission & EU agencies, private stakeholders and NGOs

		exposure. Civil society is mostly interested in understanding risks and prevention of possible risks. In terms of needed services, support services like newsletters, helpdesks, workshops, sector guidances etc. are the most sought-after services by the stakeholders. They are followed by training services, conformity assessment and certification services (e.g. standardization, metrology), consultancy services and finally testing and analysis. Media (electronic, printed and social) and various public events are the most preferred means for the stakeholders to gather relevant knowledge.	
NECID, NanoReg2 and Gov4Nano	Nano exposure & contextual information database – Implementation of Risk Governance: meeting the needs of nanotechnology	NECID database covers 60 occupational exposure datasets, consisting of around 250 datapoints, which have been targeted for integration within ongoing EU projects (Gov4Nano88). The data has been obtained from industrial exposure measurement campaigns at various NMs manufacturing and processing facilities of SMEs and large industries (EU funded projects NANOSH and NanoNextNL), and literature studies for testing and validation of risk assessment models (EU Horizon 2020 caLIBRAte project89). The datapoints cover exposure to a wide range of NMs, including nanoclay, Silicon dioxide, Carbon nanotubes, Silver, Cerium dioxide, Aluminum oxide, Carbon black, Titanium dioxide, Bismuth phosphate, Bismuth oxide, Zinc oxide, Zirconium dioxide, Carbon nanofibers and fullerenes. Exposure activities or scenarios include synthesis (via gas phase, mechanical reductions, carbon vapor deposition and wet chemistry), cleaning, powder dumping, mixing, spray, abrasion etc, and deal with several types of products like nanostructured powders, liquid dispersions, composites and coated surfaces in different occupational settings. The exposure levels are expressed in terms of time- and size-resolved number-based particle concentrations (i.e. number of particles present in per unit volume of air, particles/cm3). The accompanying metadata or contextual information generally includes the description of the activity (e.g. used method, amount of product used), frequency and duration of tasks, description of the work place (e.g. room dimensions, ventilation rate, air changes per hour) exposure controls (e.g. local or general exhaust ventilation), PPEs (e.g. masks, gloves), description of secondary sources (e.g. diesel engines, cigarette smoke, welding, busy road), background concentrations, indoor/outdoor information, cleaning frequency of the workplace, equipment maintenance frequency, number of workers, working hours a day of the workers, average duration and frequency of worker presence in the work zone and climate conditions (e.g. temperature, relative humidity). In addition, for the	NanoReg2 D3.2 Database/structural model and report describing the relationships between functionality, physicochemical properties and hazard, and allowing for integration in the safe innovation approach Gov4Nano WP1

		identity of the measured NMs, specific information on their physicochemical properties is also provided which generally include chemical composition, particle density, primary particle size and size distribution, particle shape, dustiness, moisture content, purity, type of product (i.e. 100% nano or intermediate/final product; incl. weight fraction of nanomaterial in the product), physical form of nanomaterial/product (i.e. liquid, powder, solid matrix), dustiness, viscosity and surface chemistry. In terms of quality of the data, 70% of all datapoints have a quality score of more than 0.7 (out of 1) in line with quality criteria defined within the caLIBRAte project for selecting and storing high-quality data in caLIBRAte database. At present, almost one fifth of the occupational exposure data from the NECID database has been integrated in eNanoMapper database. Ongoing efforts in Gov4Nano project aims to integrate rest of the data and also include determining the relevance (i.e. the extent to which the data are appropriate for a given purpose like their use in available risk assessment models), completeness (i.e. the availability of the necessary, non-redundant (meta)data for a given NM or exposure activity) and reliability (i.e. evidence of the clarity and plausibility of the findings in terms of Klimisch scores).	
caLIBRAte	Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	caLIBRAte establishes a versatile next-generation nano-risk governance framework for assessment and management of human and environmental risks of manufactured nanomaterials (MN) and MN-enabled products. The framework has been founded on thoroughly tested models and stakeholder needs. The goal is that the quality and trust in the caLIBRAte nano-risk governance framework models will exceed the current level of most existing REACH tools. An inventory of 69 databases has been developed which are (or can be) interesting for the assessment of NMs for their human and environmental risks (nanoEHS). These databases were developed in the framework of previous national, EU FP7 and EU H2020 projects and provide data on physicochemical, kinetic and toxicological properties and on exposure for wide range of NMs. The data from these nanoEHS databases has also been compared with the required data for testing of RA models in a data gap analysis.	D5.1 Report on data requirements and listing of available data collections D6.2 Gap Analysis
NanoRisk	Best practices effectiveness, prevention, and protection measures for control of risk posed by engineered nanomaterials	The LIFE nanoRISK project demonstrated the effectiveness of workplace controls to prevent or minimise exposure to engineered nanomaterials (ENMs), during specific workplace situations in the polymer nanocomposite industry. Recommended Risk Management Measures (RMMs) were implemented and evaluated in five case studies that covered the whole life cycle of relevant ENMs. This provided valuable data for determining whether RMMs are	DB5 Report on the reduction in exposure and release in industrial studies

		suitable for exposure scenarios, so making a positive contribution to the REACH Regulation and its RMM library. LIFE nanoRISK provided industry with science-based tools and data to guarantee a safe working environment and made a direct contribution to decreasing the exposure of employees and the environment to potentially dangerous substances. The project team designed a testing chamber prototype to support the evaluation of the effectiveness of RMMs against ENMs under controlled conditions, thus providing industry with a tool to simulate operative conditions involving the use of ENMs. Ten standardised protocols were used to evaluate the effectiveness of ventilation systems and personal protective equipment against particles and aerosols below 100 nm.	
NanoMonitor	Development of real-time information and monitoring system to support the risk assessment of nanomaterial under REACH	The overall objective of the project is to improve the use of environmental monitoring data to support the implementation of REACH regulation and promote the protection of human health and the environment when dealing with engineering nanomaterials (ENMs), a new class of emerging pollutants. To this end, the project takes the challenge of developing an innovative monitoring system to characterise the concentration of ENMs in indoor workplaces, urban areas, and relevant environmental compartments. Several pilot studies with the developed device were performed in different outdoor locations for the monitorization of PM0.1.	DB1. Report on determinants of exposure and exposure scenarios over NMs Life Cycle
Lee-Bed	Innovation test bed for development and production of nanomaterials for lightweight embedded electronics	LEE-BED brings together world leading European RTOs to establish an Open Innovation Test Bed to de-risk and accelerate the development and manufacturing of nanomaterials and lightweight embedded electronics for the benefit of European industry. For the time being, an occupational exposure measurement campaign has been carried out in a company dedicated to the synthesis of nanoparticles, which will later be used for the formulation of conductive inks. Quantitative data have been included in the analysis.	Interim Report of WP9
Biorima	Risk Management of Biomaterials	BIORIMA aims to develop an Integrated Risk Management (IRM) framework for NBM used in ATMP and MD. The BIORIMA IRM framework is a structure upon which the validated tools and methods for materials, exposure, hazard and risk identification/assessment and management are allocated plus a rationale for selecting and using them to manage and reduce the risk for specific NBM used in ATMP and MD.	Interim Report of WP5 and D3.4 about Biomonitoring of Wp3
NanoMicex	Mitigation of risk and control of exposure in nanotechnology-based inks and pigments	Exposure assessments were carried out at five companies involved in the manufacture and downstream use of engineered nanomaterials (ENM) in the pigments and inks sector using a tiered approach. This approach (Tier 1 Scoping Visit and Tier 2 Full Measurement Survey) was developed and	D4.2 Quantitative exposure and contextual data for key exposure scenarios

		implementedto:1.Characterisethe sector by exposure scenarios (ES) and determine 'key' (exposure significant)ES (Tier 1) and2.Monitor those 'key' ES (Tier 2).This approach was developed from published methodologies for systematic assessments exposure to nanomaterials (NMs) in the workplace. It is based on using an informed and efficient deployment of sophisticated instrumental techniques in the field in Tier 2. Tier 2 was a multi-instrument measurement survey for production and downstream use (preparation of an intermediate product for professional/industrial use, formulation of prototype paints and inkjet printing) of ENM in the pigments and inks industry. While the full measurement survey (Tier 2) is the main focus of this report, the results from Tier 1 are reported for completeness.	
NanoSafePack	Safe Handling and Use of Nanoparticles in Packaging	The main goal of the project is to develop a best practices guide to allow the safe handling and use of nanofillers, considering integrated strategies and best practices to control the exposure in industrial settings, and provide stakeholders with scientific data to minimize and control the release and migration of submicron sized particles from the polymer nanocomposites placed on the market. To achieve this aim, a complete hazard and exposure assessment has been conducted to obtain new scientific data about the safety of polymer nanocomposites. The work focuses on a selected set of relevant fillers and polymeric matrices to the packaging sector, including including layered nanoclays, silver (Ag), silicon dioxide (SiO_2), zinc oxide (ZnO), and calcium carbonate ($CaCO_3$) nanoparticles. The polymer matrices selected on the basis of market data and applicability in the packaging industry included polypropylene (PP), polyethylene (PE), polyethylene terephthalate (PET), as well as poly-lactic acid (PLA), a promising biodegradable polymer. The monitoring activities carried out in the laboratory consisted of a combination of aerosol sampling and use of real-time direct reading instruments to determine i) particle size concentrations, ii) particle size distribution profiles, and iii) particle morphology and composition.	D3.2 Quantitative exposure and contextual data for key exposure scenarios
GUIDEnano	Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance	The GUIDEnano project generates a risk assessment web-based tool, which incorporates as well guidance on the selection of risk management options. To reach these goals, the project is building upon the state-of-the-art on risk assessment and management by validating critical assumptions in the risk assessment process, generating new predictive models, and novel risk management solutions. Categorizes the possible processes that take place during the different stages of a NM-enabled product life cycle. Default worse-case release values are	D4.2 Interim report on refinement of exposure estimates to be incorporated in GUIDEnanoTool v2 based in generated data and harvested information

	tool for nanotech industries	assigned to these different processes that will be refined when specific models or experimental data are available for some of the processes. In order to generate release data during the use phase, methodologies will be identified or developed to simulate such types of processes in an accelerated manner. GUIDEnano will work on the adaptation of other standard methods or develop new aging devices to evaluate release and transformation of NM during other types of processes not yet considered in previous projects. During experimental release evaluation, released NMs or the residues of degradation of the nano-enabled products, e.g. paint debris containing NMs, will be collected and a thorough physical-chemical characterization will be conducted.	
EcotexNano	Innovative tool to improve risk assessment and promote the safe use of nanomaterials in the textile finishing industry	The LIFE_ECO-TEXNANO project aimed to improve the competitiveness of the EU textile sector by demonstrating the benefits of nanomaterials for producing high value, low cost textiles. It also aimed to improve the environmental performance of innovative textiles that incorporate nanoparticles. The project focused on the textile finishing industry, where it assessed the environmental and health and safety impacts from using nanomaterials during finishing. The overall aim was to help confirm and demonstrate their potential as 'green' technologies. Two pilot trials have provided evidence of best practice in the application of nano-based techniques and compare these with conventional finishing chemicals. The project also aimed to carry out Comprehensive Life Cycle Assessments on nanomaterials to inform the development and testing of robust risk assessment techniques, to be made available to EU textile companies.	DB.2 Risk Assessment Report
SanoWork	Safe Nano Worker Exposure Scenarios	The main goal of Sanowork project is to identify a safe occupational exposure scenario by exposure assessment in real conditions and at all stages of nanomaterials (NM) production, use and disposal. The proposed strategies are to be integrated within SANOWORK manufacturing companies (risk control extra-steps) and to be assessed on the basis of RISK and COST/BENEFIT.	PHD Thesis. Camilla Delpivo, 2015. Università di Bologna
NanoHouse	Life cycle of nanoparticle based façade coatings	NanoHOUSE intends to create a holistic and prospective view on the Environmental Health and Safety (EHS) impacts of nanoproducts used in house building, namely paints and coatings. The latter are using relatively high amounts of Engineered NanoParticles (ENPs) such as nano-Ag and nano-TiO2 which will be investigated. The integration of engineered nanoparticles (ENPs) in façade coatings may lead to improved or new functionalities during their life cycle and may bring several sustainable	WP2

		advantages; they may replace hazardous substances, prolong the life time of façade coatings and they can be advantageously used for air purification, thermal insulation, self-cleaning, and other. Nevertheless, the use of nanomaterials in this economic area can grow dynamically only if the safety of humans and the environment is satisfactorily resolved.	
Nanoimpulsa		The NanoIMPULSA project's main objective is to boost investment in nanotechnology in the Valencian Community by ensuring the technical feasibility and sustainable and safe use of processes and products based on the use of nanomaterials (NMs), understood as materials where at least one of its dimensions is less than 100 nm, thus providing the industrial fabric of the Community with tools to address the current challenges and barriers that limit investment in nanotechnology. To this end, the project proposes the development of an integrated system of tools to address the challenges posed by nanotechnology, and in particular, the use of nanomaterials, to SMEs that make up the traditional sectors of the Valencian community, including companies linked to the manufacture of packaging materials, ceramic pigments, inks, paints, building materials, textiles, and electronic components, thus providing them with new tools to meet their technological and training needs and contributing to improving their competitiveness.	D4.1 Detailed report of exposure levels in the Valencian Community
Integral	INitiative to bring the 2nd generation of ThermoElectric Generators into industrial ReALity	The aim of the INTEGRAL project is to upscale the GEN2 TE material technology using existing pilot lines and growing SMEs, in order to address mass markets TE needs (automotive, heavy duty trucks, autonomous sensors and industry waste heat recovery). The large-scale processes which will be developed for producing nanostructured materials within the INTEGRAL project will explore a wider range of applications.	INTEGRAL D7.3 Report on EHS issues on TEG production
NanoLeap	Nanocomposite for building constructions and civil infraestructures	NANOLEAP project aims at the development of a coordinated network of specialized pilot lines for the production of nanocomposite based products for different civil infrastructure and building applications.	Deliverable D8.3b Preliminary and general risk assessment due to nanopowders handling and processing

ENDURCRETE	New Environmental friendly and Durable conCrete, integrating industrial by-products and hybrid systems, for civil, industrial and offshore applications	The main goal of Endurcrete Project is to develop a new cost-effective sustainable reinforced concrete for long lasting and added value applications. The concept is based on the integration of novel low-clinker cement including high-value industrial by-products, new nano and micro technologies and hybrid systems ensuring enhanced durability of sustainable concrete structures with high mechanical properties, self-healing and self-monitoring capacities.	D7.6 Report on assessment of nanomaterial exposure likelihood

Literature	Short description
Debia et al., Ann. Occup. Hyg., 2016	Engineered nanomaterials (ENMs) have a large economic impact in a range of fields, but the concerns about health and safety of occupational activities involving nanomaterials have not yet been addressed. Monitoring exposure is an important step in risk management. Hence, the interest for reviewing studies that reported a potential for occupational exposure. We systematically searched for studies published between January 2000 and January 2015. We included studies that used a comprehensive method of exposure assessment. Studies were grouped by nanomaterial and categorized as carbonaceous, metallic, or nanoclays. We summarized data on task, monitoring strategy, exposure outcomes, and controls in a narrative way. For each study, the strength of the exposure assessment was evaluated using predetermined criteria. Then, we identified all exposure situations that reported potential occupational exposure based on qualitative or quantitative outcomes. Results were synthesized and general conclusion statements on exposure situations were formulated. The quality of evidence for the conclusion statements was rated as low, moderate, or high depending on the number of confirmed exposure situations, the strength of the exposure assessment, and the consistency of the results. Regarding the potential of exposure in the workplace, we found high quality evidence for multiwalled carbon nanotubes (CNTs), single-walled CNTs, CNFs, aluminium oxide, titanium dioxide, and silver NPs; moderate-quality evidence for non-classified CNTs, nanoclays, and iron and silicon dioxide NPs; low-quality evidence for fullerene C60, double walled CNTs, and zinc oxide NPs; and no evidence for cerium oxide NPs. We found high-quality evidence that potential exposure is most frequently due to handling tasks, that workers are mostly exposed to micro-sized agglomerated NPs, and that engineering controls considerably reduce workers' exposure. There was moderate-quality evidence that workers are exposed in secondary manufacturing industrial-scale plants. There was low quality evidence that workers are exposed to airborne particles with a size <100 nm. There were no studies conducted in low- and middle-income countries.
ECEL (Goede et al. 2018)	A literature review was conducted to collate nano-specific data on workplace RMM. In total 770 data points were retrieved from 41 studies for three general types of RMM (engineering controls, respiratory equipment and skin protective equipment: gloves and clothing). Data were found for various sub-categories of the different types of RMM although the number of data for each was generally limited. It is concluded that RMM efficacy data for nanomaterials are limited and often inconclusive to propose effectiveness values. This review also shed some light on the current knowledge gaps for nanomaterials related to RMM effectiveness (e.g. ventilated walk-in enclosures and clean rooms) and the challenges foreseen to derive reliable RMM efficacy values from aggregated data in the future.

Dustiness release potential (Shandilya et al. 2019)	It uses data generated during Marina, SUN, Nanodustiness and NanoNextNL projects on the influence of powder intrinsic properties on the dustiness. The converging results indicate that the powder physical properties can be used to model and estimate dustiness which can eventually be used in risk assessment tools for exposure estimation.

Templates for data gathering

Exposure measurement template

<table>
<tr><th colspan="6">Available exposure measurement</th></tr>
<tr><td>Project 1 relevant for D4.1</td><td colspan="5">Name one project</td></tr>
<tr><td>Industrial sector</td><td colspan="5">Industrial sector associated</td></tr>
<tr><td rowspan="2">Industrial sector related to table 5 of SBD4 * see below</td><td>Functional</td><td>Structural ENMS</td><td>Coating</td><td>Cosmetics</td><td>Pharma & Health</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Protocol used</td><td colspan="5">Protocol used (OECD, ISO, regulations …)</td></tr>
<tr><td>Data form</td><td colspan="5">Precise the data form (rapport, database, publication, tool, Necid template…)</td></tr>
<tr><td>Information concerning the other relevant topics</td><td>Release studies data</td><td colspan="2">Risk management measures</td><td colspan="2">Stakeholders' needs</td></tr>
<tr><td></td><td>Yes/No</td><td colspan="2">Yes/No</td><td colspan="2">Yes/No</td></tr>
<tr><td>Relevant link</td><td colspan="5">Paste the links towards relevant publications</td></tr>
<tr><td>Date of publication</td><td colspan="5"></td></tr>
</table>

<table>
<tr><th colspan="3">Exposure scenario 1</th></tr>
<tr><td>Workers</td><td>Professional Users</td><td>Consumers</td></tr>
<tr><td>X</td><td>X</td><td>X</td></tr>
<tr><td colspan="3">Describe in one sentence the exposure scenario you assessed:
for workers professional users, and consumers indicate if the information below are available:
In orange you find additional questions for consumers</td></tr>
<tr><td colspan="2">The Life cycle</td><td>(choose from this list: Synthesis, implementation, maintenance, cleaning, use, end of life) or not available (NAv)</td></tr>
<tr><td colspan="2">Production scale</td><td>(laboratory, pilot, industrial scale) or (NAv)</td></tr>
<tr><td colspan="2">Substance characteristics
(Indicate if data available (A) or not (NA) for each Item if there is no other indication)</td><td>Name: (name)
CAS number: (number)
Morphology: (S=Spherical/P=Platelet/H=High aspect ratio, O=Other)</td></tr>
</table>

<table>
<tr><td></td><td>Physical state: (P=Powder/L=liquid/M=Massive)
Molecular mass: Indicate if data available (A) or not (NAv) (A/NAv)
Purity: (A/NAv)*
Dustiness/Viscosity: (A/NAv)
Moisture content: (A/NAv)
Density: (A/NAv)
Surface area/VSSA: (A/NAv)
Concentration or wt%: (A/NAv)
Coating or doping: (A/NAv)</td></tr>
<tr><td>Product used or synthesis rate</td><td>Indicate if data available (A) or not (NAv)</td></tr>
<tr><td>Exposure (duration, frequency):
<table>
<tr><th>frequency level</th><th>Daily</th><th>Weekly</th><th>Monthly</th><th>Annual</th></tr>
<tr><td>1</td><td>< 30 min</td><td>< 2h</td><td>< 1 day</td><td>< 1 week</td></tr>
<tr><td>2</td><td>30 min to 2h</td><td>2 to 8h</td><td>1 to 6 days</td><td>15 days to 2 months</td></tr>
<tr><td>3</td><td>2 to 6 h</td><td>1 to 3 days</td><td>6 to 15 days</td><td>2 to 5 month</td></tr>
<tr><td>4</td><td>> 6h</td><td>> 3 days</td><td>> 15 days</td><td>> 5 months</td></tr>
</table></td><td>D1 (example Daily and <30min)
W2….

Or (NAv)</td></tr>
<tr><td>Activity class</td><td>Indicate if data available (A) or not (NAv)</td></tr>
<tr><td>Source domain</td><td>Indicate if data available (A) or not (NAv)</td></tr>
<tr><td>Automation level</td><td>A/Nav and y/n if yes give a %</td></tr>
<tr><td>Secondary sources</td><td>A/Nav and y/n</td></tr>
<tr><td>Number of exposed workers</td><td>choose from this list 1-3; 3-5 ; 5-10 ; >10 persons or (NAv)</td></tr>
<tr><td>Location type</td><td>(indoor/outdoor) or (NAv)</td></tr>
<tr><td>Release mode</td><td>(constant, intermittent, instantaneous) or (NAv)</td></tr>
<tr><td>Room dimensions/volume</td><td>Indicate if data available (A) or (NAv)</td></tr>
<tr><td>Housekeeping</td><td>y/n or (NAv)</td></tr>
<tr><td>Ventilation type</td><td>Indicate if data available (A) or (NAv)</td></tr>
<tr><td>Air changes per hour</td><td>Indicate if data available (A) or (NAv)</td></tr>
<tr><td>Worker segregation</td><td>y/no or (NAv)</td></tr>
<tr><td>PPEs</td><td>y/no or (NAv)</td></tr>
<tr><td>Climate conditions (RH, T)</td><td>Indicate if data available (A) or not (NAv)</td></tr>
</table>

Population type (for consumers only)	*Indicate if data available (A) or not (NAv)*
Use type (for consumers only)	*Indicate if data available (A) or not (NAv)*
Body weight (for consumers only)	*Indicate if data available (A) or not (NAv)*

Release studies template

Available Release studies					
Project 1 relevant for D4.1	*Name one project*				
Industrial sector	*Industrial sector associated*				
Industrial sector related to table 5 of SBD4	**Functional**	**Structural ENMS**	**Coating**	**Cosmetics**	**Pharma & Health**

Data form	*Precise the data form (rapport, database, publication, tool, Necid template…)*		
Information concerning the other relevant topics	**exposure measurement data**	**Risk management measures**	**Stakeholders' needs**
Precise the table number corresponding	*Table X*	*Table X*	*Table X*
Relevant link	*Paste the links towards relevant publications*		
Date of publication			

Release 1			
Dustiness	**Mechanical Release**	**Water Release**	**Other**
X	*X*	*X*	*X*
Describe in one sentence the several Release measures you assessed Indicate if the information below are available (or linked to the table concerning the release scenarios):			

***The Life cycle** (choose from this list: Synthesis, maintenance, use, end of life)*	
***Production scale** (laboratory, pilot, industrial scale)*	
Substance characteristics *(Indicate if data available (A) or not (NA) for each Item if there is no other indication)*	*Name: (name)* *CAS number: (number)* *Morphology: (S=Spherical/P=Platelet/H=Hight aspect ratio, O=Other)*

	Physical state: *(P=Powder/L=liquid/M=Massive)* *Molecular mass:* *(A/Nav)* *Purity:* *(A/Nav)* *Dustiness:* *(A/Nav)* *Viscosity:* *(A/Nav)* *Moisture content:* *(A/Nav)* *Density:* *(A/Nav)* *Surface area/VSSA:* *(A/Nav)* *Concentration or wt%:* *(A/Nav)* *coating or doping:* *(A/Nav)*
Product category	*Indicate if data available (A) or (Nav)*
Activity class	*Indicate if data available (A) or (Nav)*
Source domain	*Indicate if data available (A) or (Nav)*
Applied energy level	*(High/Medium/Low/No energy)*
***For release** indicate the type of information*	*Information in mass* *Information in number* *Information in volume* *PSD* *total concentration* *or (Nav)*
***For dustiness** indicate the type of information*	*Moisture content and bulk density* *Test procedure used* *Test method used* *or (Nav)*

Risk management measures template

<table>
<tr><th colspan="6">Available risk management measures</th></tr>
<tr><td>Project 1 relevant for D4.1</td><td colspan="5">Name one project</td></tr>
<tr><td>Industrial sector</td><td colspan="5">Industrial sector associated</td></tr>
<tr><td rowspan="2">Industrial sector related to table 5 of SBD4</td><td>Functional</td><td>Structural ENMS</td><td>Coating</td><td>Cosmetics</td><td>Pharma & Health</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Protocol used</td><td colspan="5">Protocol used (STOP, ISO, regulations, specific tools …)</td></tr>
<tr><td>Data from</td><td colspan="5">Precise the data form (rapport, database, publication, oral presentation, tool…)</td></tr>
<tr><td>Information concerning the other relevant topics</td><td>exposure measurement data</td><td colspan="2">Release studies data</td><td colspan="2">Stakeholders' needs</td></tr>
</table>

Precise the table number corresponding	*Table X*	*Table X*	*Table X*
Relevant link	*Paste the links towards relevant publications*		
Date of publication			
Risk management measures 1			
Workers	**Professional Users**	**Consumers**	
X	X	X	
Describe in one sentence the several Risk Management Measures you assessed and describe and/or give the table concerning the exposure scenarios ***indicate if the information below are available:***			
Elimination or substitution strategies to mitigate hazard	*Elimination* *Chemical substitution* *Changing form* *Changing size* *Or (NAv)*		
Technical measures to mitigate exposure	*Technical monitoring* *Exhaust ventilation* *Other* *Or (NAv)*		
Data on organizational measures	*SOP* *Repartition work* *Schedule* *Other* *Or (NAv)*		
protective equipment (collective and personal)	*Dynamic containment* *Static containment* *PEE (give the type if available)* *Other* *Or (NAv)*		

Online databases with data on physio-chemical properties of nanomaterials and/or their human exposure

#	Database/ information system	Nature of the data	Access conditions
1	NanoWiki	Aggregated data (averaged values)	Available online or by arrangement with the owners (e.g. downloads via a web database, or transferrable datasets)
2	eNanoMapper	Experimental raw data Aggregated data (averaged values) SOPs and other experimental documentation	Available online or by arrangement with the owners (e.g. downloads via a web database, or transferrable datasets)
3	NanoPUZZLES	Aggregated data (averaged values)	Available online or by arrangement with the owners (e.g. downloads via a web database, or transferrable datasets)
4	NANoREG	Experimental raw data Aggregated data (averaged values) SOPs and other experimental documentation	Available online or by arrangement with the owners (e.g. downloads via a web database, or transferrable datasets)
5	NanoFATE	Experimental raw data Aggregated data (averaged values) SOPs and other experimental documentation	Data are available online or by arrangement with the owners but only when working with or for a particular project
6	NanoMILE Knowledge Base	Experimental raw data Aggregated data (averaged values) SOPs and other experimental documentation Data and information on nano-enabled products and articles	Data are available online or by arrangement with the owners but only when working with or for a particular project
7	NERC Environmental Information Data Centre	Experimental raw data	Data are not currently available but are planned to be in a future and accessible for everyone
8	CERASAFE	Experimental raw data Aggregated data (averaged values) SOPs and other experimental documentation nanoEHS general help, advice and guidance information	Data are not currently available but are planned to be in a future and accessible for everyone
9	SERENADE database	Experimental raw data	Data are not currently available but are planned to be in a future and accessible for everyone
10	NANOSOLUTIO NS	Experimental raw data Aggregated data (averaged values)	Data are not currently available but are planned to be in a future when working with or for a particular project

11	S2NANO	Experimental raw data Aggregated data (averaged values)	Data are not currently available but are planned to be in a future when working with or for a particular project
12	NECID - Nano Exposure and Contextual Information Database	Experimental raw data SOPs, protocols and other experimental documentation Data and information on nano-enabled products and articles	Data are currently available to NECID partners and are planned to be freely available in a future when working with or for a particular project
13	SUN database	Experimental raw data Aggregated data (averaged values) SOPs, protocols and other experimental documentation	Data are not currently available but are planned to be in a future when working with or for a particular project
14	SANOWORK	Experimental raw data Aggregated data (averaged values)	Data are confidential and only available via an intranet, on a specific computer or to certain subscribers and paying users
15	Scaffold databases	Experimental raw data	Data are confidential and only available via an intranet, on a specific computer or to certain subscribers and paying users
16	NanoValid database	Experimental raw data Aggregated data (averaged values) SOPs, protocols and other experimental documentation nanoEHS general help, advice and guidance information	Data are confidential and only available via an intranet, on a specific computer or to certain subscribers and paying users

Extract of the survey on exposure assessment and risk management practices and barriers to implementing SbD approaches

1. Please specify what type of nanomaterials does your organisation manufacture, use, or commercialise?

   Fill in the following table by adding a new raw for each material and/or upload a safety data sheet.

Composition / Name / formulation	Type of material	Size	Shape	Stage and/or Annual production volume	Type of use	Type of surface modification
▪ TiO2 ▪ Ag ▪ ZnO ▪ CNTs ▪ Silicon dioxide ▪ Aluminium oxide ▪ Dendrimers ▪ Cerium oxide ▪ Fullerenes ▪ Iron oxide ▪ Nanoclay ▪ Carbon nanofibres ▪ Quantum dots ▪ Gold ▪ Carbon Black ▪ Others..	□ Liquid □ Powder □ Firm granules, flakes or pellets □ Coarse dust □ Fine dust □ Extremely fine and light powder □ Solid object/nanocomposite □ Fibers □ Paste □ Other ……	▪ 0-100 nm ▪ 100 - 300 nm ▪ 300 nm - 1µm ▪ >1µm ▪ Other…	- spherical - non spherical with aspect ratio l/d<3 - non spherical with aspect ratio l/d>3	□ Idea stage □Under development □ Testing & validation □ Market launch □< 1g / year □< 1kg / year □< 1t / year □< 10t / year □> 10t / year	☐ Dispersive ☐ Open ☐ Closed but open regularly ☐ Always closed	

2. Which of the following have you previously performed:
   □ Chemical risk assessment (specify the method used)
   □ Nano related risk assessment (specify the method used)
      □ Nanomaterials toxicity
      □ Nano exposure level
         □ Time
         □ Concentration
         □ Size
         □ others to be specified ...
   □ Nano risk assessment specific for maintenance/cleaning workers
   □ Prevention plan included nanorisk for external compagny

3. In case your company uses nanomaterials incorporated to formulation of coatings, paints, etc.., Have you evaluated migration under standards (UNE, ISO)?
   □ yes (explain)
   □ no (explain)

4. Please provide more information about the exposure assessment and risk management practices in your organisation

   Fill in the following table by adding a new raw for each each NM or NMP

	Activity Information	
	How do you handle Nanomaterials or NMPs in the workplace?	❑ Impaction on contaminated solid objects (e.g. scrubbing, scraping) ❑ Handling of contaminated solid objects or paste (e.g. assembly or sorting of objects, plastering of walls) ❑ Spray application of powders ❑ Movement and agitation of powders, granules, or pelletized material (e.g. cleaning with compressed air, brooming, sweeping, mixing powders, vacuum cleaning) ❑ Transfer of powders, granules, or pelletized material (e.g. bagging, dumping, scooping) ❑ Compressing of powders, granules, or pelletized material (e.g. making tablets from powder) ❑ Fracturing of powders, granules, or pelletized material (e.g. comminution/size reduction of powder particles) ❑ Spray application of liquids ❑ Activities with open liquid surfaces and open reservoirs (e.g. dip coating,

		electroplating, Cleaning using immersion techniques) ❑ Handling of contaminated objects (handling cleaned objects, handling equipment) ❑ Spreading of liquid products (e.g. paint rolling and brushing) ❑ Application of liquids in high speed processes (e.g. machining metal) ❑ Transfer of liquid products (e.g. loading, drumming) ❑ Fracturing and abrasion of solid objects (e.g. sanding, sawing) ❑ Abrasive blasting (e.g. sand blasting)
Release and exposure	Can the release of dust and/or aerosols into the workplace air be reasonably prevented?	□ yes (explain) □ no (explain)
	Can the ingestion of nanoscale particles by workers be reasonably prevented during production, handling, processing or maintenance and cleaning phases?	□ yes (explain) □ no (explain)
	Can the dermal contact of nanoscale particles by workers be reasonably prevented during production, handling, processing or maintenance and cleaning phases?"	□ yes (explain) □ no (explain)
Risks	Have you experienced incidental situations (spills, metal fire …)	□ yes (explain) □ no(explain)
	During which life cycle stage(s) release or emission occur?	□ production/maintenance of process equipment □ use/service life of NEPs □ waste/end of life/recycling
	In which categories do you need additional information to evaluate if a release can occur and what kind of information do you need?	□ production/maintenance of process equipment □ use/service life of NEPs □ waste/end of life/recycling □ Data/expert analysis
Risk manageme nt measures	What are the risk management measures implemented	□ Collective protective equipment (process related): Dynamic barrier ☐ Integrated exhaust ☐ Safety cabinet ☐ Extraction arms ☐ Hood ☐ Pouyes ring ☐ Others … Static barrier ☐ Closed system ☐ Disposal gloves tent ☐ Glove Box ☐ Provisional containment

		☐ Others ... □ Mitigate exposure duration □ PPE used for nano risk (Gloves, FPP3-half masks, safety goggles, lab coat) □ Worker's specific training about nano-risk □ Specific assessment of nano risk □ Dedicated person in nano risk management □ Safe by design product □ have safety procedures implemented (please describe)
	Have the implemented measures been tested and have they worked efficiently?	□ yes (explain) □ no (explain)
	Which key performance indicator are you using to monitor the efficiency of the implemented measures	(explain)
	In which categories do you need additional information to implement these risk management measures?	❏ Elimination: Designing out the hazard of nanomaterials (e.g. modifying size or surface properties of nanomaterial) ❏ Substitution: Replacing hazardous nanomaterials or processes with another that is less hazardous or safer (e.g. substitution of quantum dots with dye doped silica nanoparticles, using nanomaterial in liquid suspension instead of its dry powder) ❏ Engineering controls: Measures that prevent release/emission of nanomaterials into the (workplace) air or their transport through the air to the worker or systems (e.g. fume hoods, local exhaust ventilation, enclosed glove boxes) ❏ Administrative controls: Changes to workers' behaviour to mitigate exposure risk of nanomaterials (e.g. written safety policies, rules, supervision, training, reducing task duration/frequency) ❏ Personal Protective Equipments: Protective equipments worn by workers to protect themselves from exposure to nanomaterials (e.g. respirators, gloves, goggles) ❏ Other (please specify)
Do you have any other comments on the exposure assessment and risk management practices at your workplace? …..		

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