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NANoREG

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Assessment of value chain case studies

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1 Description of task

Task 1.6: Working Groups (addressing Value Chain Case Studies and other R&D related activities)

Value chain case studies (VCCS) and other R&D related activities will be established to support and test the development of answers to the regulatory issues/questions. This may range from testing proposed risk reduction strategies to more detailed aspects of a risk/safety assessment. It is suggested that the case studies are established at an early stage to ensure an iterative development of answers to the regulatory question.

Depending on the available information and relevance, case studies should consider the entire value chain, from R&D and design over production/manufacturing, to use and disposal/recycling. The outcome of the case studies is manifold:

1. Testing the feasibility of suggested answers from WPs 2-6,
2. Gaining insight in remaining bottlenecks in performing safety assessment and management, including knowledge gaps for risk assessment along the value-chain,
3. Contributing to development of the framework to be defined in Task 1.4.

The establishment of case studies and evaluation of their outcome is done to support Task 1.3 and in parallel with Task 1.2 and, thus, in close cooperation with WP2-6. The case studies will inform the work of WPs 2 to 6 and, vice versa, will receive input from these WPs.

In the case studies, an integrated analysis of data as obtained especially in WP2 and WP5 will be made. The case studies will be based on the MNMs tested in WP4. In addition, as an extension of the case studies, a few selected NMs will also be subjected to life-cycle analyses.

This task requires input from risk assessors, EHS researchers from industry, specialists in value-chain analysis. A specific activity in this task is a re-evaluation and ranking of existing toxicity testing data, which will be of use in completing the value chain case studies.

VCCS will be performed initially on already decided materials, and if relevant on materials as suggested based on input from regulators to Task 1.1. In the case of TEKNIKER, case studies will focus on the use of nanoparticles in lubricants. SINTEF will contribute in particular to the CNT VCCS and other case studies as well. ENEA will produce an integrated analysis of a value chain case study on nano silver and could expand these activities to the interesting NMs for the project purposes.

(Lead: AIT, contributors: RIVM, IOM, ENEA, TEKNIKER, SINTEF, NILU, TEMAS)

2 Description of work & main achievements

2.1 Summary

The aims of this Deliverable are to:

- Provide an overview of what value chain case studies (VCCS) are, and how they are performed in general.
- Describe how VCCS are defined and perfomed within the framework of the NANoREG project.
- Provide selected examples of VCCS in related areas and overview the conclusions that can be drawn from those.

A value chain includes the complete set of value-adding activities/business functions: R&D, design, production, logistics, marketing, services, etc. that is connected to a product and/or a service. The NANoREG Project aims to add value to the normal linear process of describing the fate of a material/product and how its value increases or decreases along the value chain by integrating aspects related to safety, performing risk assessment when appropriate. Within NANoREG this is called Safety Value Chain Case Studies (SVCCS).

Assessment of potential human / environmental risks along the value chain, and solutions (development and implementation) for their management are a key element of the NANoREG studies. In order to perform relevant SVCCS, NANoREG has developed acquisition and approval procedures for the studies. This deliverable explains these procedures and outlines the different aspects that are needed to include in a SVCCS. Furthermore, examples are given of previous value chain case studies (both with and without any aspects of nanomaterials) that are published in the professional literature. The importance and usefulness of SVCCS for risk assessment of nanomaterials is furthermore highlighted in the document.

To the best of our knowledge, there are few real value chain case studies of nanomaterials, and possibly no ones that are performed from a safety perspective. The NANoREG Project would thus be pioneering this field of activities, with potential benefits for the concerned stakeholders, including legislators, industries, and NGOs.

2.2 Background of the task

Task 1.6 Working Groups (addressing Value Chain Case Studies and other R&D related activities) aims to provide case-specific information on how a specific nanomaterial is used along a given value chain. Furthermore, by employing expertise from within the NANoREG project, data will be produced that show the fate and behaviour of the specific nanomaterial at given stages of the appropriate value chain.

The fate and behaviour data are especially important for assessment of whether release of a nanomaterial can occur, and if so, for whom the release is important (i.e. if occupational exposure or exposure to consumers or to the environment can take place).

Based on the specific results, the task will identify if there are critical knowledge gaps regarding safety assessments that need to be covered, and by which means in such a case.

Knowledge generated in work with Task 1.6 can feed into especially Tasks 1.3, 1.4, and 1.7.

2.3 Description of the work carried out

2.3.1 Aims of the deliverable

Deliverable D1.6 Assessment of value chain case studies aims to:

- Provide an overview of what value chain case studies (VCCS) are, and how they are performed in general.
- Describe how VCCS are defined and perfomed within the framework of the NANoREG project.

- Provide selected examples of VCCS in related areas and overview the conclusions that can be drawn from those.

2.3.2 Methodological approach

The work relating to this deliverable is based on literature sources (peer reviewed scientific studies in primarily English language journals and other scholarly documents obtained from Internet sources and handbooks).

In Table 1 below is an overview of Internet-based databases that have been searched for terms including but not restricted to:

- Value chain
- Value chain analysis
- Value chain case study
- Supply chain
- Search terms above + “nano*”

Table 1. Internet-based databases that have been investigated for documents relevant for Deliverable D1.6.

Data base	Web address	Comments
Web of Science	http://thomsonreuters.com/en/products-services/scholarly-scientific-research/scholarly-search-and-discovery/web-of-science-core-collection.html	User fees applicable
IDEAS	https://ideas.repec.org	The largest bibliographic database dedicated to Economics. User fees applicable
Google Scholar	https://scholar.google.at	
PubMed	http://www.ncbi.nlm.nih.gov/pubmed	Does not contain many references useful for the present topic
EBSCOhost databases for research	https://www.ebscohost.com/academic/subjects/category/economics	User fees applicable

2.4 Results

2.4.1 Definitions

Initially the concept of a **value chain** (VC) was described as a chain of activities that a firm operating in a specific industry performs in order to deliver a valuable product or service for the market (Porter 1985). In the field of economics, a value chain is understood as a structure that can be used to categorize and organize factors related to industrial organization; the activities, places and firms involved in making a product or service. It includes the full range of activities that companies and workers do to bring a product or service from its conception to its end use and beyond. This includes the activities related to producing and transporting the product (**supply chain**) as well as other value-adding activities such as research, design, marketing, and support services (see Fig. 1 below). Thus this can be described as:

- The **full range** of value-adding activities/business functions: R&D, design, production, logistics, marketing, services
- **Supply chain**/product life cycle stages: inputs, components, final products, distribution/sales, disposal/recycling.

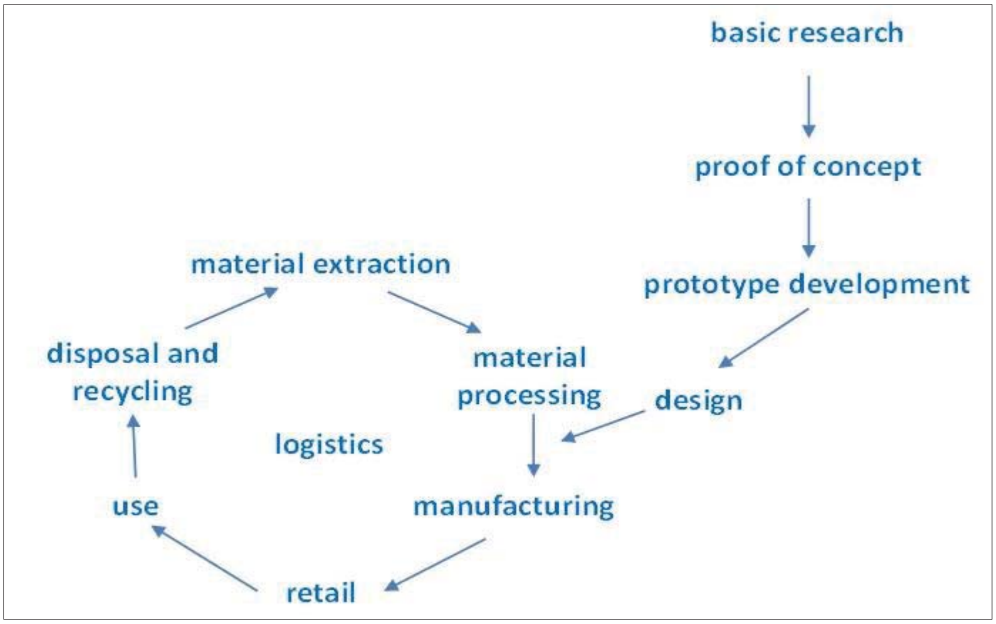

Figure 1. Schematic representation of the steps that constitute a value chain, from generation of knowledge to end-of-life.

This description of a complete value chain is both generic as well as perfectly appropriate when describing a value chain that includes the production and further use of products that contain engineered nanomaterials.

Substantial time has been devoted within NANoREG to agree on an appropriate definition of the term value chain case study, and especially what this term connotes in the context of safety evaluations (**Safety Value Chain Case Studies, SVCCS**). Accordingly, in the NANoREG document "Annex I. Towards a harmonised terminology in NANoREG Collection of existing definitions for the key terms used in the NANoREG Framework (Task 1.4)" these terms are defined, and also contrasted to another relevant term, viz. "value chain". The referred document thus contains the following paragraphs (ibid, pp 99-100) which are quoted verbatim here (italics provided by the authors):

"The 'value chain' describes the full range of activities which are required to bring a product or service from conception, through the different phases of production (involving a combination of physical transformation and the input of various producer services), delivery to final consumers, and final disposal after use (Kaplinsky and Morris 2001). "

"While the 'life cycle' is a series of ordered phases through which an object and its different forms passes, the 'value chain' begins with an intellectual process and focuses on the activities to bring that object from conception to use and disposal (including e.g. design, production, marketing, distribution). "

“Within NANoREG, 'safety value chain case studies' for some nanomaterials are performed. These case studies add value to the normal linear process of describing the fate of a material/product and how its value increases or decreases along the value chain by integrating aspects related to safety and performing risk assessment when appropriate. “

A natural conclusion from inspecting Figure 1 above is that the depicted activities and processes can have a large spatial as well as temporal spread. Consequently, a more or less comprehensive mapping of an entire value chain will be very informative, although it may be very difficult to perform such an activity. Because of the large scope of a value chain, there are many different players that can have an interest at least in part of the value chain (see Table 2 below). Safety aspects pertain to virtually all included steps, possibly to a lesser extent in steps that are upstream of market introduction.

Table 2. Value chain stakeholders,and examples of their different roles.

Stakeholder/ Role	Producers	Processors	Distributors	Consumers	Government/NGOs/ regulators
	mining	material processing	distributing	shopping	public health and safety
	R&D	manufacturing		consuming	environmental health
	design			disposing	food and feed product safety
					policy and support

The specific interest for NANoREG in VCCS implies that one has to include nanomaterials characterised by different degrees of sophistication into the relevant value chains. Even prior to outlining and mapping a complete value chain, it is clear that value is added to nanomaterials as the materials are used in ever more sophisticated products (see Table 3 below).

Table 3. From nanomaterials to nano-enabled products. Steps and processes where nanomaterials are adding value to goods and services along the value chain. (Adapted from Lux Research 2004)

	Nanomaterials	Nano intermediates	Nano-enabled products
Stage along a value chain	Nanoscale structures in unprocessed forms	Intermediate products with nanoscale features	Finished goods incorporating nanotechnology
Applications	Nanoparticles, nanotubes, quantum dots, fullerenes, dendrimers, nanoclays, etc.	Coatings, fabrics, ships, contrast media, optical components, orhtopedic materials, superconducting wires …	Cars, clothing, airplanes, sports goods, consumer electronics, pharmaceuticals, food and feed, plastic containers, appliances

2.4.2 Value chain characteristics within the NANoREG project

According to the NANoREG DoW, the VCs are “cross-cutting, horizontal activities that take output from all of the WPs, from regulatory questions through scientific answers to questions on characterisation, dosimetry, sampling, exposure, and toxicity testing through to integrating safe(r) design criteria and consumer confidence”.

In other words; NANoREG wants to add value to the normal linear process of describing the fate of a material/product and how its value increases or decreases along the VC by integrating aspects related to **safety**, performing risk assessment when appropriate. Another important aspect of the Safety VCCS is that they should provide essential input to the NANoREG **Framework** (Task number 1.4) which is the topic of another task and the fundament in turn for the final output, the NANoREG **Toolbox** (Task 1.7) (see Fig. 2).

Value chains describe and link the steps in the process which takes a high-level model of how companies receive raw materials as input, add value to the raw materials through various processes, and sell finished products to customers.

Assessment of potential human / environmental risks along the VC, and solutions (development and implementation) for their management are a key element of the NANoREG studies. This includes consideration of parts of the value chain which are already elaborated and those which are under consideration or in development.

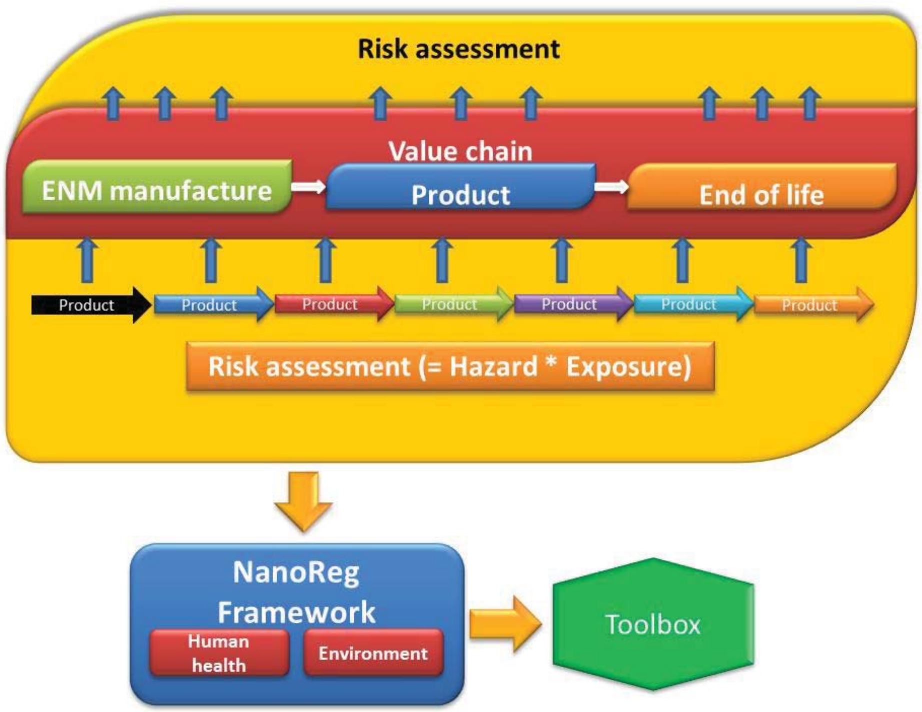

Figure 2. The NANoREG VCCS approach and its´ connection to the NANoREG Framework and the NANoREG Toolbox.

2.4.3 The NANoREG SVCCS process

The formal procedure for the initiation of VCCS in NANoREG has previously been decided upon prior to the work on SVCCS themselves. The process starts with initiatives from NCs or other participants where industrial partners with „interesting“ products and/or materials are brought into a discussion of appropriateness. According to NANoREGs **Guideline** for Value Chain Project Proposals (Fig. 3), the appropriateness of the proposal is decided by the Task 1.6 leader, after which the NANoREG MC decides upon approval/rejection of the proposal. In case of approval, a suitable project leader is assigned from the partners available for Task 1.6.

The work with the VC will basically adhere to the following scheme:

Initially an engagement process with the industry partner(s) is needed to understand the elements of the value chain. This mapping step should include the:

- Understanding of the scope of the value chain, the key steps and possible options
- Identification of the materials used or produced, (phys-chem characteristics, forms, quantities etc.) and how these change along the value chain
- Identification of potential exposure scenarios in current and near future life cycles and industry knowledge of how these can be controlled
- Collection of all relevant industrial information on the points above

This is followed by a hazard profile development (using tools such as grouping, QSAR, and available data); exposure profile development (based on knowledge of the scenarios, exposure data from similar scenarios, exposure tools and models, and existing exposure data); assessment of current and future exposures of concern and identification of exposure hotspots (preliminary risk assessment where feasible); assessment of opportunities for risk management (including safe(r)-by-design of materials, products and processes; control measures in the work place, etc.); cost-benefit analysis arising from human/environmental risk; and recommendations for actions (taking uncertainty into account).

Obviously, the VCCS working groups need competence from various areas in order to address the different aspects of both the mapping and analysis parts of the studies. The competence matrix developed within Task 1.3 could here provide a valuable support.

2.4.4 VCCS on nanomaterials and other emerging technologies

Value chain analysis is used to improve a product or a service so that it is commercially more valuable. This can be done on the level of the individual company, but also on a higher level of organisation such as an industry sector or a geographical region or even a country. It is also possible to construct global value chains and thus make analyses of individual components or the entire value chain. In short, the value chain analyses, which more or less equal the case studies, can be performed from a micro- or a macro-economic perspective. (See e.g. Kaplinsky 2000; Briones 2014; Rieple and Singh 2010; Oikawa 2008; Chiwaula et al. 2012, for examples of published case studies focusing on sectors, countries, or global actors.)

A sector where value chain case studies are common is agriculture, in a broad sense. There are thus several published studies available, of which the papers by Kumar and Kapoor 2010, Waldron et al 2014, and Gordon et al 2011, are good examples of simultaneously broad and penetrating analyses.

Value chains representing novel and emerging technologies have also appeared in the scientific literature in recent years. Thus, Funcke (2012) investigated the added value of renewable energy systems (primarily introduction of solar panels) in a German city (Freiburg). Other examples of value adding activities related to solar energy have also been published (e.g. Charles 2014; Chan and Reiner 2011).

Value chain case studies of nanomaterials are far and few between in the available literature. There are some reports that deal with limited parts of a value chain, and in many cases without a value chain perspective. There are also a limited number of reports that employ a life cycle perspective of a nanomaterial or a nano-enabled product. However, in summary, there seems to be a limited number of studies that are truly value chain analyses/case studies.

Some studies should be mentioned however. Since nanomaterials are prominent parts of several approaches to renewable energies, there are studies that cover at least partly the value chains of energy-relevant applications (see e.g. Bandyopdyhag et al 2015; Zhang et al. 2013; Wamankar and Murugan 2015). Other "environmental" applications of engineered nanomaterials are also included in studies that have some value chain perspectives (Struwe and Schindler 2015; Cariola and Manello 2013).

Some studies have relevance for safety assessment relevant for human health and the environment, without explicitly addressing a specific value chain or parts thereof. However, reading the studies, it is clear that certain aspects of specific value chains are parts of the studies in question. Some of

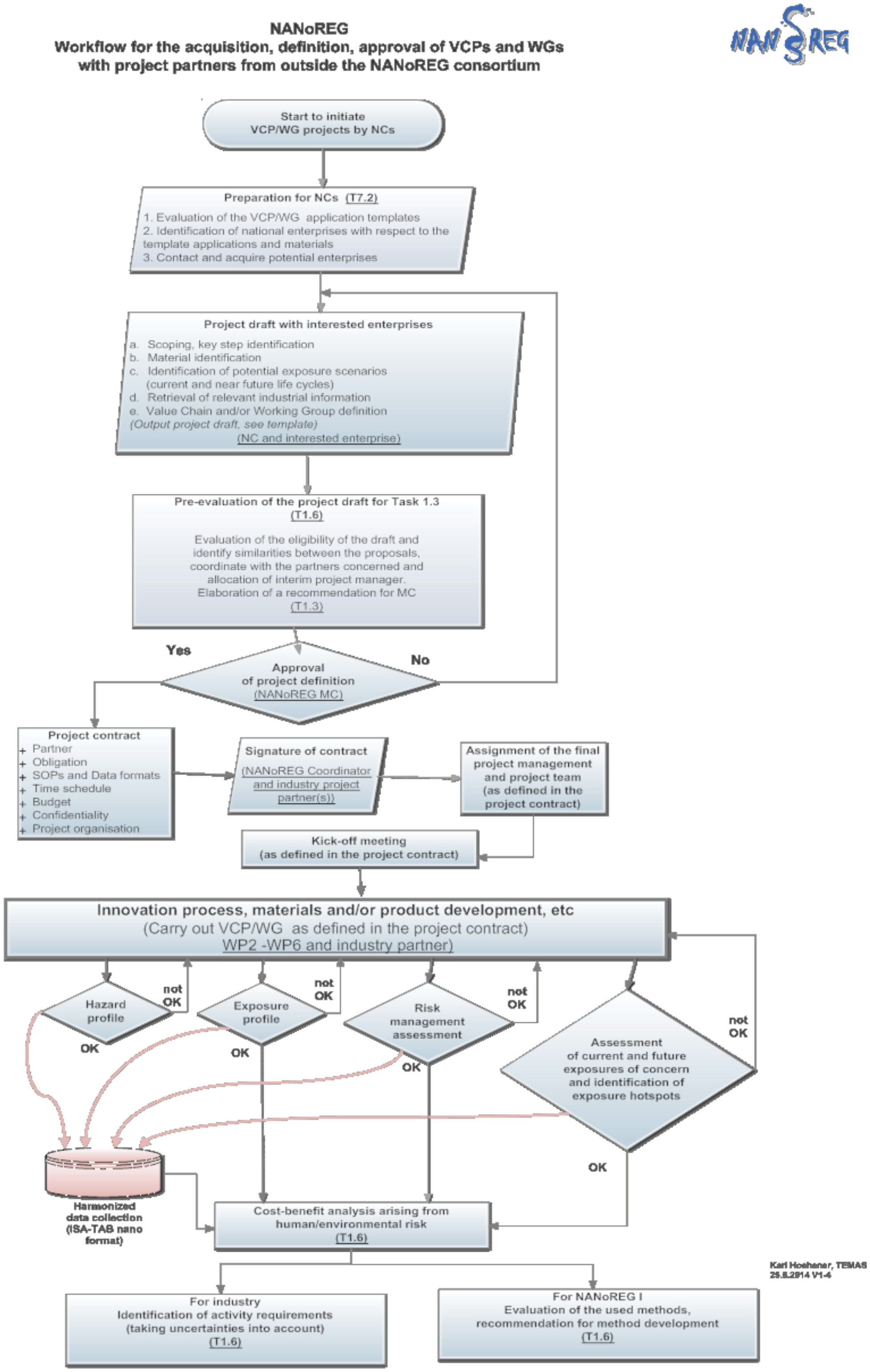

Figure 3. NANoREGs Guideline for Value Chain Project Proposals.

the studies have their focus on release of nanomaterials, the environmental fate of the materials, and possibly aspects of exposure assessment. These studies include the work by Köhler et al 2011; Ostertag and Hüsing 2007; Laury and Casman 2009; Cuddy et al. 2016; Pirela et al 2015; and Praetorius et al. 2012.

Still other studies on nanomaterials have a focus on risk assessment and safety aspects in case studies. In some of the cases, a clear life cycle perspective is present. These studies include Aschberger et al 2011; Lu et al. 2015; Gao et al. 2015; Voelker et al. 2015; Semenzin et al. 2015; Barberio et al 2014.

2.4.5 Risk assessment of nanomaterials and connections to SVCCS

One of the ambitions with the SVCCS in NANoREG is to try to use obtained knowledge for risk assessment of nanomaterials and nano-enabled products where appropriate. For that purpose, this section provides insights into risk assessment of nanomaterials and how this could relate to performing and using SVCCS.

The scientific literature contains a significant number of studies that have relevance for risk assessment (RA) of engineered nanomaterials, particularly in the form of hazard identification studies. However, there are very few articles that actually perform a proper and complete RA for a given nanomaterial, taking exposure, hazard identification and dose-response relationship studies, as well as uncertainty analysis into consideration.

van Kesteren et al. (2014) made a risk assessment of a specific material, synthetic amorphous silica in nano-form. This material is also known as food additive E551, which is present in a number of products including food, where it functions as an anticaking agent. The authors based the assessment on human kinetic studies (i.e. the exposure assessment) and on *in vivo* toxicity studies (both oral and i.v. administration studies; the hazard assessment). Importantly, this study considered sources of uncertainty and recommendations for improvement.

Another publication of nanomaterial risk assessment, with environmental focus in this case, was recently published by Civardi and co-authors (Civardi et al. 2015). The study describes the case of particulate ("micronized") Cu, which contains nano-sized Cu particles. The material is intended for wood preservation, acting as an anti-fungal agent. However, certain strains of fungi develop Cu-resistance, and the authors hypothesize that these fungi can produce Cu-loaded spores that can be inhaled by humans, and possibly cause health effects. The study provides data on global annual use of the Cu-based particles, as well as data from relevant studies on hazard identification and characterisation. On the other hand, there is no data on human or environmental exposure to Cu-based nanomaterials from treated wood. The conclusion is thus that the lack of exposure data precludes a risk assessment in this case.

A recent study from Hristozov et al. (2014) used a quantitative weight of evidence RA approach for hazard identification and analysis. This is the first time that expert evaluation of data quality is applied to RA of engineered nanomaterials according to the authors. However, the study focuses on hazard identification and does not include specific exposure assessment.

Risk assessment of occupational nanomaterial exposure is sparingly published in the scientific literature. However, one example is a study by Koivisto et al. (2014) who assessed possible risks of inhalation exposure to nano-diamonds in a laboratory setting. The authors determined nano-diamond emission rates during handling, and performed cytotoxicity studies in the human leukemia cell line THP-1. The conclusions of the study were that the exposure levels in this case were low (minute fractions of the total exposure to submicrometer urban air particles) and that the performed hazard assessment was insufficient for risk assessment.

Other examples of occupational RA were published by Liao et al. (2008) and Ling et al. (2011). The first of these studies focused on occupational TiO_2 exposures and inhalation, whereas the study from Ling and co-workers included both airborne TiO_2 as well as carbon black nanoparticles. The exposure assessment in the Liao study was complemented with experimental studies on the effects on the lungs. However, these studies have received substantial methodological criticism regarding exposure assessment (Morfeld et al. 2012) and are furthermore not covering more than limited aspects of the risk assessment procedures.

Hristozov and co-authors (Hristozov et al. 2012) pointed recently to that the available RA data is limited, and that especially studies on the exposure assessment part of RA are poorly characterised. Their conclusion was that most available studies serve as screening tools for hazard, and that the use for regulatory purposes is limited. Specific findings in the same directions were previously documented by Helland et al (2008). They studied 40 German and Swiss companies and reported that 65% of these did not consider RA at all, whereas the remaining fraction of companies at least sometimes performed some aspects of RA. A common theme among the companies was that they did not foresee any unintentional release during the life cycle of the nanomaterial in question.

2.4.5.1 Challenges for ENM Risk Assessment

As noted, there are not many outcomes of nanomaterial RA that are available in the open scientific literature. This does not exclude that a substantial amount of such assessments have been performed, e.g. by competent authorities but also by the industry that manufactures, uses, or disposes of nanomaterials, nano-intermediates or nano-enabled products. The needs for proper RA are on the other hand stated in many documents (including *inter alia* Maynard et al. 2006; Borm et al. 2006; Savolainen et al. 2010; Simkó and Mattsson 2010, 2014; Klaine et al. 2012; Kuempel et al. 2012), as well as the challenges for ENM RA, whether they are specific or not.

In general, it is considered that the currently available toxicology tests and assays are appropriate also for hazard evaluation of ENM (e.g. Oberdörster et al. 2005; OECD 2008, 2012; Kuempel et al. 2012). However, certain factors may influence the toxicity of a nanomaterial relative to larger particles, or to the dissolved form of the chemicals in question. A major question mark concerns exposure assessment. Due to the often complicated value chains and life cycles of nanomaterials, especially since they can be expected to be integrated in nano-intermediates and nano-enabled products, knowledge about their specific forms, fate and behaviour, and concentrations are difficult to obtain.

There are a number of challenges that make RA of nanomaterials unique and possibly also to some extent more complicated than RA of traditional chemicals in solution and of particles of larger size than nanosized particles. Without prioritization, some of the major challenges include:

- Engineered nanomaterials are sophisticated materials that currently appear in many forms, made up of many different chemical elements, and sometimes in combination with other materials. It is likely that the development of new materials will proceed even faster, leading to that the repertoire of materials needing assessment becomes forbiddingly large. Thus, there is a need to find ways to perform predictive risk assessment, based on e.g. grouping principles that can include a number of materials.
- A given nanomaterial exists along a value chain with its specific life cycle, from the initial research stages to the final disposal. To what extent is the material existing at the nanoscale along this chain, and to what extent are humans and/or the environment actually exposed to the material?
- A number of physical-chemical properties characterize these materials. Although some knowledge has accumulated during the last years, the respective properties´ influence on the toxicity of an engineered nanomaterial needs further investigation.
- A nanomaterial in an environmental setting (water, soil and sediment, or air) or in an organism such as the human will be exposed to different kind of matrices (which can be both organic and inorganic). A significant challenge deals with understanding the effects of these matrices on the properties of the material.

Table 4 below expands on these considerations and give the most important challenges and corresponding needs and knowledge gaps.

Table 4. Overview of major RA challenges.

Challenge	Corresponding needs and knowledge gaps
Exposure assessment data for products entire life cycle	- Value chain characterization - Material behaviour during product manufacture, use, aging, disposal
Relevant detection and characterization	- Behaviour in complex media - Methods for determinations of realistic concentrations - Noise (background) levels - Behaviour in different organismal

	environments
Realistic hazard assessment	- Toxicokinetic modelling in organisms - Effects due to matrix interactions - Long term, low dose and persistency effects - High throughput and high content data for endpoint identification and mode of action - Relevant experimental controls - Relevant dose metrics
Risk assessment approach development	- Improved exposure assessment - Case-by-case vs grouping approaches - Quantified RA methods - Uncertainty analyses

2.4.6 Bringing SVCCS and risk assessment together

The possible effects of engineered nanomaterials on human health and the environment are sometimes ascribed to the „novelty“ of these materials. This could be interpreted in such a way that “novel” types of responses occur, and that novel approaches for RA are needed. However, there are no data available that support such assumptions. The responses in biological systems (which can be molecules, cells, tissues, or organisms) to nanomaterials are not unique, they are also appearing when chemicals in solution or larger particles are interacting with biological components. Furthermore, RA of nanomaterials requires knowledge about the exposure as well as of hazard potential and dose-response relationships. This is once again in line with what is required for conventional RA of chemicals.

The specific challenges for nanomaterial risk assessment are thus of another character. Central to all RA-related activities is the need for profile life cycles. For each stage along the value chain, the properties of the material or the product are needed to be known, as well as to what extent there is a real exposure at that stage, and if exposure at these levels, and with a nanomaterials in that specific form actually has hazard potential. Corresponding knowledge about the effects of the pristine form of the nanomaterials is thus having very limited, if any, value for risk assessment.

The present specific tools used in characterization of nanomaterials, in exposure assessment, in toxicological testing, and the risk assessment are appropriate, but not necessarily sufficient for RA. There is thus a considerable amount of work within NANoREG that is devoted to adaption and validation of methods and approaches for material characterization and detection, exposure assessment, and *in vivo* and *in vitro* experimental work.

In this context, the importance of SVCCS studies is imminent (see also Figure 4 below). The value chain analyses provide with identification of key steps in the “life” of a material or product, where potential for release can be pinpointed. Accordingly, necessary actions for characterisation, exposure determinations, and toxicity tests can be called upon, and a proper and relevant risk assessment is possible to perform

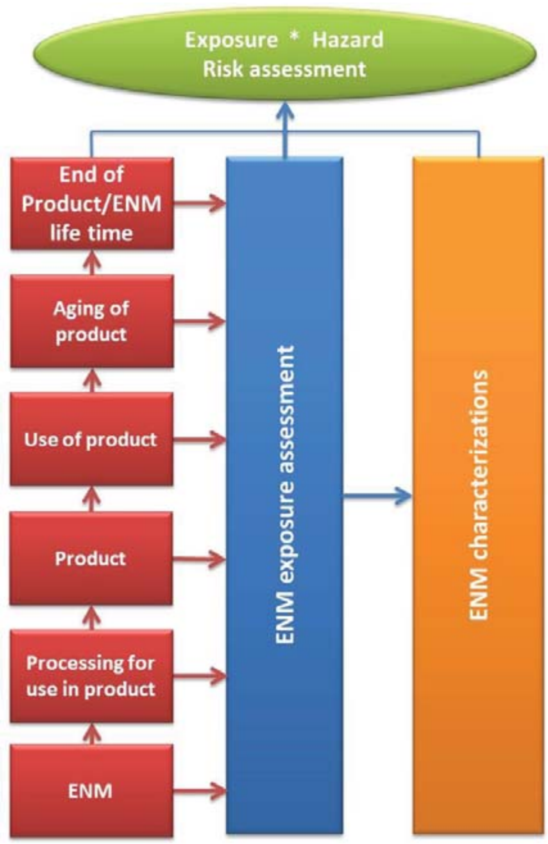

Figure 4. Risk assessment of ENM requires knowledge about the hazard potential and of the actual exposure, for each stage in the value chain of the given ENM-containing product. There is thus possibly not appropriate to perform one single RA for a given material, but multiple ones, characterising a specific stage along the value chain.

2.5 Evaluation and conclusions

There is a big discrepancy between the use of the concept of a value chain in economics disciplines and in the risk assessment for human health and the environment. In the former case, value chain case studies (or value chain analyses) have a clearly defined role, which is to find out which activities provide added value to a product or a service.

At a first glance, this seems to be far away from the activities related to risk assessment of engineered nanomaterials and products that contain nanomaterials. Risk in this context is per definition a function of exposure and hazard. If there is no exposure, even the most hazardous substances pose no risk. Likewise, the presence of a non-toxic agent is not causing risk. In other words, it is needed to know if the environment and/or humans are exposed to nanomaterials in the first place.

By elaborating the fate of a given nanomaterial from its production, via product incorporation, mercantile activities, consumer use, to end-of-life stages, one can establish or map the basic components of a value chain. A value chain also requires knowledge about goods volumes, logistics, investments etc. to be complete. This can thus be accomplished, at least in part, for most products.

The usefulness of a value chain case study for specific nanomaterials or nano-enabled products, when considering risk assessment and use by various stakeholders, thus becomes more pronounced. Such an assessment requires knowledge about what form the nanomaterial takes at the different stages. In addition, it is necessary to know if/when any material is released, and how it behaves in the environmental compartment where it is ending up. Finally, what are the amounts that are available for interactions with biological processes, and will these amounts cause adverse effects? If so, how grave are these effects?

This set of questions is possible to address from a value chain case study perspective. What´s more, risk assessment has another aspect to it as well for a risk manager, viz. if reduction of risk is worth its´ cost. Thus, the risk management has to operate with a risk-benefit perspective. In conclusion, the value chain perspective can bring about additional and very valuable aspects to risk assessment.

This deliverable has outlined value chains and value chain case studies and pointed to that NANoREG is trying to add a unique value to nanomaterial case studies by addressing the safety aspects that are essential for risk assessment. To the best of our knowledge, there are few real value chain case studies of nanomaterials, and possibly no ones that are performed from a safety perspective. The NANoREG Project would thus be pioneering this field of activities, with potential benefits for the concerned stakeholders, including legislators, industries, and NGOs.

2.6 Data management

Not applicable.

3 Deviations from the work plan

The work with D1.6 has been performed according to the outline provided by the DoW.

The Deliverable has been delayed. The main reason is the delay which Task 1.6 has experienced in general. That, in turn, has several reasons, including initial problems in receiving the national funding for NANoREG, subsequent delays in personnel recruitment, and more recently reorganization within the partner organization.

4 References / Selected sources of information (optional)

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5 List of abbreviations (optional)

Not applicable.

Annexes (optional)

Not applicable.