Scaffold Public Documents – **SPD3**

Innovative strategies, methods and tools for occupational risks management of manufactured nanomaterials (MNMs) in the construction industry

ROADMAP FOR OCCUPATIONAL SAFETY IN RELATION WITH MANUFACTURED NANOMATERIALS (MNMs) IN THE CONSTRUCTION SECTOR

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Disclaimer

This document was prepared following extensive consultation with a range of stakeholders (via workshops, meetings, surveys, interviews and document reviews):

- Representatives of the construction sector, including:
  - European Construction Industry Federation (FIEC);
  - European Federation of Building and Wood Workers (EFBWW);
  - OHS Managers from several construction companies.
- Manufacturers of construction products;
- European and Spanish agencies for occupational safety;
- Manufacturers of personal protection equipment;
- Experts in nanosafety;
- Policy makers at European and national (Spain) levels.

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The views expressed herein are solely those of the authors.

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1. INTRODUCTION

Manufactured nanomaterials (**MNMs**) and nanocomposites are being considered for various uses in the construction industry and related infrastructure industries, not only for enhancing material properties and functions but also in the context of energy conservation. Despite the current relatively high cost of nano-enabled products, their use in construction materials is likely to increase because of highly valuable properties imparted at relatively low additive ratios, rapid development of new applications and decreasing cost of base MNMs as they are produced in larger quantities.

Thus the use of nano-products in the construction industry is a reality and can be expected to grow in the near future. Moreover, there is a general uncertainty with respect to health and safety risks and how to properly manage them to protect workers and be in compliance with OHS legislation.

According to a report by Broekhuizen and Broekhuizen (2009), the awareness of the different actors (including architects, construction engineers and those commissioning constructions) in the construction industry about the availability and performance of nano-materials is very limited. Only a limited number of nano-products make it to today's construction sites. According to a competitiveness report by Ecorys (2008), the key areas of application are in:

- Cement, concrete and wet mortar;
- Insulation materials;
- Infrastructure coatings;
- Coatings and paints for wood, glass and other materials as well as for self-cleaning purposes.

The limited use of nano-products is due to a lack of awareness and the fact that nanosized ingredients are often too expensive to result in competitive products. Intensive research and development is ongoing and future expectations are that the market share of nano-products and their diversity will grow because of the unique characteristics they provide (and are expected to provide). These same products might pose new health and safety risks to the worker onsite, of which science is only just starting to understand. This makes it extremely difficult for European construction companies to assess on what basis and involving what risks they should start using nano-based materials.

The present document has been produced in the context of the Work Package 1 of the SCAFFOLD project: *Profiling the European construction industry face the MNMs occupational exposure*. The goal of this WP was threefold:

- To develop a Life Cycle Analysis (LCA) for each of project selected MNMs (TiO_2, SiO_2, Cellulose Nanofibers, Carbon Nanofibers and Nanoclays).
- To collect and analyse sound available information on MNMs occupational exposure
- To develop a roadmap on occupational exposure to MNMs in the construction sector.

The two first objectives have been reached and reports have been produced (Galarza *et al*., 2012; Karjalainen *et al*., 2012).The present document contains some of the main outcomes of both reports and further develops a roadmap on occupational exposure to MNMs in the construction sector. The roadmap has been designed to support the identification of future product, service and technology needs for occupational MNMs risk management in the construction sector and the evaluation and selection of the technology alternatives to meet these needs. The roadmap –in its former intermediary versions-has been used as a guide all along the Scaffold project.

Besides the two reports mentioned above, this roadmap is based on:

- Review of the grey literature: reports from the sector, from the European Commission.
- A number of scientific and divulgation articles.
- Results of the other work packages of the Scaffold projects, especially the guides on Prevention, protection, risk assessment and risk management.
- Expertise of the authors.

2. THE CONSTRUCTION SECTOR

2.1. General situation of the construction sector

The overall construction sector is defined in the classification of economic activities as including the following subsectors (Ecorys, 2008):

- "*Manufacturing of construction materials: Suppliers of construction products and components (including wholesale);*
- *Onsite construction: Site preparation, construction of complete buildings, building installation, completion, and rental of construction machinery;*
- *Professional construction services (incl. architects, engineering services, cost controllers and building control bodies)*".

Importance of the sector

In 2011, the onsite construction subsector in Europe represented 14.5 Million jobs, 7% of the total amount of jobs and 30.7% of the industrial jobs. It produced a 1208 Bln € output, 8,8% of EU28 GDP (Table 1**,** FIEC, 2012).

The turnover of the European onsite construction construction subsector performed out of Europe during 2010 was 75.3 billion € (Figure 1).

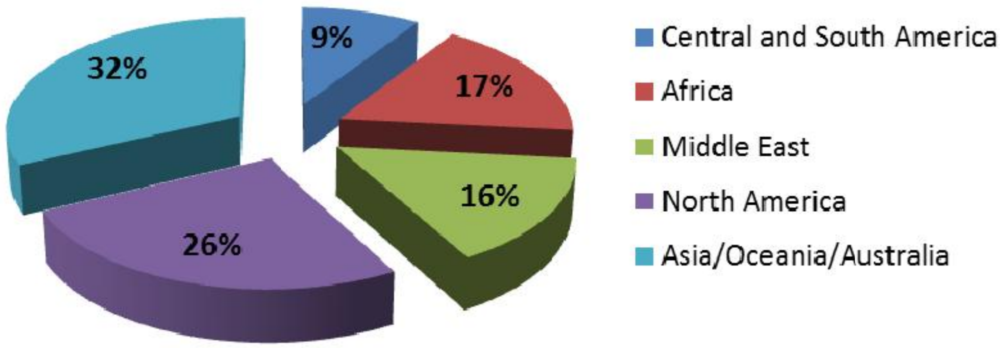


Figure 1. International activities by destination zone in 2010 (FIEC, 2012))

Table 1. Jobs in construction, total output and number of enterprises in the European construction sector in 2011 (FIEC, 2012)

Country	Jobs in Construction x1000	Total construction output (bln €)	Total number of enterprises x1000
Germany	2,428	256	390
France	1,753	169	355
United Kingdom	2,181	142	209
Spain	1,393	137	487
Italy	1,847	136	563
Netherlands	441	57	112
Poland	875	47	160
Sweden	312	46	77
Belgium	280	38	84
Finland	188	30	42
Austria	261	29	27
Denmark	146	26	30
Czech Republic	447	19	220
Portugal	440	16	61
Greece	242	10	95
Romania	339	9	25
Ireland	108	9	10
Bulgaria	203	6	21
Hungary	245	6	98
Slovakia	140	5	3
Luxembourg	38	4	2
Latvia	46	3	3
Cyprus	37	2	3
Lithuania	94	2	3
Slovenia	67	2	15
Estonia	37	2	4
Malta	11	0.5	6
Total EU	**14,559**	**1,208**	**3,105**
Switzerland	301	45	38
Turkey	1,676	38	200
Norway	191	41	50
USA	5,504	568	-
Japan	4,73	653	-

Manufacturing of construction materials

"The European Manufacturing of construction materials subsector is facing considerable competitiveness challenges with regard to the rising costs of energy and raw materials.

On one hand, the absence of a playing field at global level may result in a relocation of activities to countries outside Europe with a less strict regulatory environment.

On the other hand, the regulatory environment may drive competitiveness and innovation in the sector if non-EU manufacturers throughout the value chain are required to comply with EU regulations on markets inside the EU; also when functioning as sub-suppliers.

Standardization is a key issue for the manufacturing of construction materials subsector, and the different national standards and approval systems constitute a barrier to the realization of the internal market for construction materials. The development and implementation of European regulation and standards (e.g. the CPD [[Construction Products Directive] to be replaced by the CPR [Construction Products Regulation], the Eurocodes design standards, the ECOdesign directive, etc.) are vital for the future development and competitiveness of the sector. Equally, certification of products, professional construction services and key processes could become a driver for growth and increased internationalization of the sector" (Ecorys, 2008).

Trading of construction materials

"*In 2007, the distribution channels of manufactured construction products consisted of approximately 190,000 wholesale enterprises in the EU27 employing almost 1.5 million persons and generating a € 462bn turnover*" (Ecorys, 2008). These numbers have significantly decreased since 2007, due to the financial crisis.

Market structures

Consistent with the important role of SMEs (99.9% of all enterprises), and in particular micro enterprises (92%), in Onsite construction employment and output, market concentration in the subsector is relatively low. On average, the four largest enterprises in the EU accounted for no more than one third of total turnover in 2008. There are 3.1 million enterprises, among which 95% employ less than 20 workers.

In Manufacturing of construction materials, on the other hand, the four largest companies on average accounted for more than half of total turnover in 2008 implying considerable individual power to control the selling price of construction materials.

Investments

The value of investments amounted to 12% of value added in Onsite construction in the EU27 in 2007(Ecorys, 2008).

Research and Development

Business expenditures on research and development (BERD) amounted to less than 0.5% of turnover in Onsite construction and Manufacturing of construction materials in 2007. The share was lowest in Onsite construction and reached 0.05% of turnover in 2007, which appears to be a significant increase over 2001 levels. Shares were somewhat higher in the various sections of Manufacturing of construction materials but with decreases from 2001-2007. BERD approached almost 2% of turnover in Professional construction services in 2007 (Ecorys, 2008).

In a 2008 Community Innovation Survey, "*the share of enterprises which introduced a technological innovation during the previous two years was 20% of enterprises in Onsite construction, 30-40% of enterprises in manufacturing of construction materials and 42% of enterprises in Professional construction services. EU27 enterprises were responsible for more than half of all PCT/international patent applications for new processes and products registered at the European Patent Office in 2006*" (Ecorys, 2008).

Standards

Standardization is a key issue for the construction sector (construction materials and on-site activities): standards are omnipresent in the large public and private calls that often determine the state of the art in construction. Considering the predominance of SMEs in the construction sector, this effect is reinforced by the major importance of standards for SMEs when integrating new developments: due to their limited resources to watch and sort exploitable novelties in the overwhelming quantity of new knowledge or developments, these knowledge or developments that do not belong to the core business of SMEs are basically taken into account only when "enforced" as official references through regulation, Safety Data Sheets (SDS) and standards (Scaffold Conference, 2015).

Skills and Education

Most of the employees in Onsite construction have at least an upper secondary education, with large geographical variation: 61% in the EU15, 84% in EU12, but less than 40% in the Southern European countries, in 2007. *"Over time, the shares of employees in Onsite construction with an upper and post-secondary non-tertiary education or a tertiary education have increased although at a low annual rate in the EU27 from 2004-2008*" (Ecorys, 2008).

Environmental performance of the sector

"*Onsite construction and manufacturing of construction materials are characterized by the generation of large amounts of non-recyclable waste. Efforts started within the last decade (1997-2007) towards development of materials that are easier to salvage and reuse will not show their full pay-off in the waste statistics until 20 or 30 years from now.*

In the manufacturing subsector, there have been signs of a move towards a greener profile in recent years, especially in Manufacture of non-metallic mineral products" (Ecorys, 2008).

Occupational safety performance of the sector

The European construction sector is dominated by small firms with a bad image, high level of subcontracting (45% in 2013) and bad safety record. For instance, In the EU28 in 2013, the sector represented 6,4 % of total employment (and 29 % of industrial employment) and in 2012 22.2 % of fatal accidents at work (ENBRI, 2005; Eurostat, 2015). It is generally considered that the construction sector must improve its culture of safety, which is especially difficult to implement in very small companies (Delphi WS, 2014).

2020 vision for the future European construction sector

In 2005, the European Network of Building Research Institutes (ENBRI) published a document that discussed the technical, environmental and social issues facing the construction. In this document, some challenges that the construction sector has to face were identified.

The main action lines were identified to be:

- Raising environmental standards. The construction sector has a key role to play in preserving the natural environment and our cultural heritage, restoring polluted areas, and conserving natural resources such as water, energy and raw materials.
- Fulfilling user and stakeholder. Due to the high competitiveness, it is necessary to increase the level of customer satisfaction by understanding both the needs of clients and stakeholders.
- Changing construction processes and relationships. The construction sector is very fragmented and separated organizations take responsibility for the different phases of construction. Another factor is the price-based competition in this industry, which inhibits investment in training and increases hugely the accidents rate.
- Updating and improving the built environment. Due to the societal and demographic changes, there are new demands on built environment. It is impractical and unsustainable to demolish existing buildings and structures, therefore there is a need to modify and refurbish existing buildings and structures.
- Exploiting new materials and technologies. In order to improve performance and durability, traditional materials will be used in combination with novel technologies such as nanotechnology.
- Promoting education and training, knowledge transfer, quality employment and innovation.

The economic consultant Ecorys (2008) proposes a complementary vision in 2008: "*Given the challenges faced by the sector, the EU 2020 strategy and priorities, (...) by 2020 a sustainable and competitive European construction sector will:*

- *Conceptualize, design, build, operate and transform constructions based on life cycle performance (cost/benefit) and high quality models;*
- *Be an attractive sector to work within providing excellent opportunities for job quality, health and safety, remuneration and career development;*
- *Offer constructions (buildings & infrastructure) tailored to the changing social and economic needs of people, businesses and societies (incl. relevant special needs segments of populations);*
- *Offer new and innovative solutions that meet the demands associated with the global grand challenges (climate, security, etc.):*
  - *be instrumental in the EU reaching its 2050 targets for energy efficiency in buildings;*
  - *reach or go beyond the 70% target for waste recycling;*
  - *meet requirements for quality of inner climate in buildings;*
- *Be an attractive partner to clients in existing and emerging growth markets;*
- *Deliver outstanding economic performance*."

2.2. Activities of the onsite construction sector

According to the functions given to a construction element, traditionally the construction field has been divided in Building Construction and Civil Construction. The first type of construction is designed to host people and the second is designed to ease people´s activities. Note that this scheme is simplified; there are not two constructions alike and the needs of each construction depend on a number of factors such as budget, dimensions, geographic location, design or final use. This classification is shown in Figure 2. Figure 3 represents the distribution of construction activities in Europe in 2011 according to another classification in four main sectors.

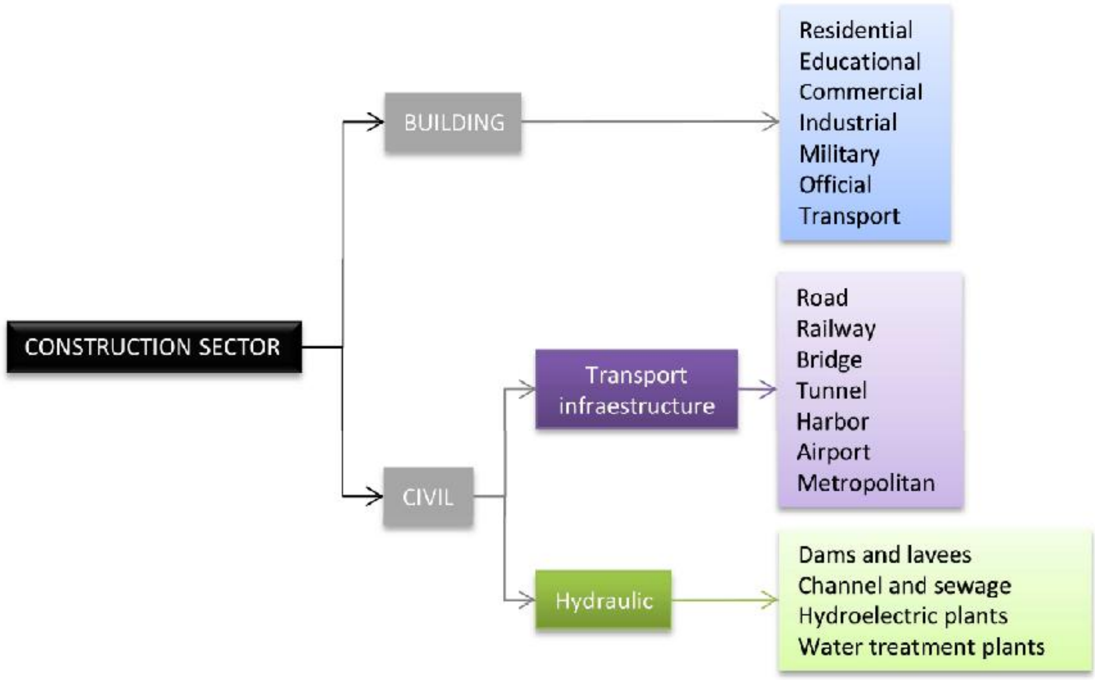


Figure 2. Diagram of the construction process

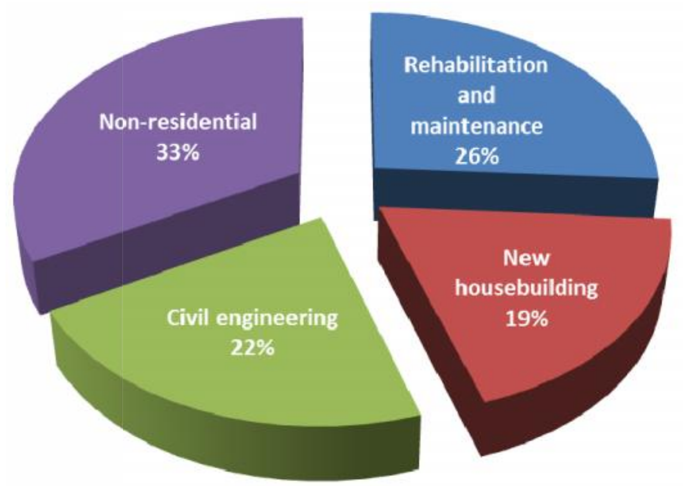


Figure 3.Main activities of the onsite construction sector during 2011 (FIEC, 2012).

Building Construction

Traditionally the buildings are classified according to their use; therefore there is a very large number of building types. Figure 2lists the most relevant ones: residential, educational, commercial, industrial, military, official, and those destined to sport activities.

The construction of a building is a long process that involves activities such as design or planning, promoting, sub-contractions, machinery, clearance, demolition, etc.

Nevertheless in the construction of all the mentioned buildings the most important steps in which workers might be exposed to MNM´s are relatively common and can be outlined as follows:
1-Clearance and demolition
2-Formwork and concrete
3-Foundation laying
4-Insulations and fire resisting panels
5-Iron works, walls and plumbing
6-Finishing, paint and polish (coatings)

Civil Construction

The civil constructions can be sub-classified in many ways. The different categories are described in **Appendix2** with their respective construction steps.

As an example, the steps to build a road are:
1-Clearance and demolition
2-Excavation, filling and compacting
3a-Bitumen application followed by 4-Compacting
3b-Pavement by grouting application

2.3. Actors of the construction sector in Europe

Key actors of the construction sector in Europe are:

- Managers, OSH managers and employees of the construction companies
- Construction companies associations, such as FIEC (European Construction Industry Federation) and ENCORD (European Network of Construction Companies for Research and Development)
- Trade-Unions, and their European federation EFBWW (European Federation of Building and Wood Workers)
- OHS consultants, including safety and health coordinators, who can disseminate best safety practices to SMEs
- Professional training organizations
- Architects´ Associations such as ACE (Architects Council of Europe)
- Manufacturers of construction products;
- Manufacturers of personal protection equipment;
- European Technology Platforms such as European Construction Technology Platform (ECTP) and other related platforms such as the PV Platform, RHC (RES for Heating and Cooling), SUSCHEM

- Local authorities & National/Regional Public Bodies (like Municipalities), as policy clients with strong power to influence the practices.
- Public promoters such as the European Federation of Social Housing (CECODHAS) and private promoters (European Real Estate Association)
- Standardization and certification bodies
- OSH European and national agencies
- Policy makers at European and national levels

2.4. Materials in the construction sector

In this chapter, three types of materials are briefly presented as the most representative matrixes in the industrial sector, due to the large volumes in which they are produced: cement and concrete, bituminous asphalts and polymers and polymeric composites. A more detailed presentation of cement and concrete and of bituminous asphalts can be found in **Appendix 3**.

2.4.1. Cement and concrete

Concrete is the most common and widely used construction material in the world. 6.3 billion tons were produced worldwide in 2011 (CEMBUREAU, 2012). China accounted for 57.3% of the world´s total cement production. The EU 27 production in 2011 was 195.3 million tonnes.

2.4.2. Bituminous asphalts

Bituminous asphalt concrete is a composite material commonly used in construction projects such as road surfaces, parking lots, and airports. It consists of asphalt (used as a binder) mixed with mineral aggregate and then laid down in layers and compacted.

The total production of hot and warm mix asphalt was of 324.3 million tonnes in Europe in 2011 (EAPA, 2012). Asphalt is typically a mixture of approximately 95% aggregate particles and sand, and 5% bitumen, which acts as the binder, or glue. It means that 16.21 Mtonnes of bitumen and 308 Mtonnes of aggregates were consumed in 2011.85% of all bitumen produced world-wide is used in asphalt pavements, 10% is used for roofing, and the remaining 5% is used in other ways.

2.4.3. Polymers and polymeric composites

Polymers have become increasingly important as engineering materials in the past decade and applications in the construction industry are expanding. In Europe, around 20% of plastic consumption is in the civil engineering and building industries. According to Plastics Europe, in 2010, the building and construction sector consumed 9.54 million tonnes of plastics (21% of total European plastics consumption), making it the second largest plastic application after packaging. Plastic pipes, for instance, command the majority of all new pipe installations, with well over 50% of the annual tonnage. Table 2 collects a series of polymers and their applications in the building sector.

Polymers offer many advantages over conventional materials including lightness, resilience to corrosion and ease of processing, moreover, polymers can be combined with fibers to form composites which have enhanced properties, enabling them to be used as structural members and units.

Materials used in construction applications must possess critical properties, depending on the exact use. In general the important property requirements are mechanical, weathering, permeability, flammability and thermal conductivity properties. Bulk polymers are used in applications such as pipes and conduit, wire and cable, foundations, fittings, roofing, flooring and insulation, the major use of polymers in the European construction sector is in rigid PVC window profiles. Fiber-reinforced plastics have recently been introduced for this application and have the advantage over PVC of not requiring additional reinforcement. Polymer foams are extensively used for insulation, primarily polystyrene, PVC, phenol-formaldehyde and polyurethane. Structural foams have also been developed from materials such as polyolefins, polycarbonate and Acrylonitrile Butadiene Styrene (ABS). Adhesives and sealants are used extensively in the construction sector and high performance levels are demanded.

Fiber-reinforced polymeric materials are gaining market share from traditional construction materials due to their low weight combined with high strength. Mechanical properties can be tailor-made by careful selection of fiber and direction of reinforcement.

Table 2. Polymers and their use in the building sector

Application		**Polymer**
Worksite and construction materials	Concrete protection Foundation layer	PE film
Channeling	Drinking water and gas Sewage	Polyolefins PVC
Walls	Sandwich panel Waterproofing Thermal insulation Acoustic insulation Decorative and protective covering	PS PE film PS foam Expanded PVC panel PE, PS
Roof/Ceiling	Thermal insulation Waterproofing	Expanded PS panels PE panel, PMMA, PC, PEI, glass fibers
Metal joinery	Windows, doors, blinds	Acrylic panels, PVC, PE
Floor, stairs		PVC covering
Various	Kitchen furniture, switches, bathroom complements, wiring	PMMA, PE, glass fiber, melamine laminated, PVC, ABS, phenolic resin

Applications of fiber reinforced materials include bridge construction, wind turbine beams, offshore platforms pipes, load bearing and infill panels, tank liners, roofs, column reinforcing wraps and reinforcing bars for concrete.[1] They can also offer better fire resistance than most other materials, for example, phenolics are used in firewalls. In contrast to the design procedures used for the more traditional construction materials, those for polymer composite materials in structural applications require greater development effort and a wider understanding of the material.

[1] Application of modern polymeric composite materials in industrial construction. Oprisan, G. *et al*, **2010**

Figure 4.46 m long carbon fiber pre-preg primary beams for a road bridge in Spain (left) and a composite wind turbine beam (right).

2.5. Nanomaterials in the construction sector

There are two "official" definitions for nanomaterials:

- The International Organization for Standards in ISO/TS 27687 defines 'nanomaterial'as "*nano-objects with at least one of their three dimensions in the range of 1-100 nm and nano-structured materials comprised of such nano-objects*". Structures which are intentionally produced are **manufactured nanomaterials (MNMs)**.
- The 2011 Commission Recommendation on the definition of nanomaterials (COM, 2011) defines 'nanomaterial' as *"a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. […]"*

Nanotechnology is a scientific-technological area relatively new, which represents a revolution in the field of the materials due to two facts:

- the behavior of a material in the nanometric scale might be radically different to expected by the extrapolation of its properties at the micrometric scale
- the multidisciplinary character.

Nanomaterials are being applied in a wide variety of industrial sectors such as: textile, packaging, automotive, biomedicine or telecommunications. Construction materials are also experiencing the incorporation of nanomaterials, in order to change the properties of the matrixes in which they are added. For instance, SiO_2 nanoparticles are incorporated to concrete in order to increase its self-compacting behavior and improve its surface properties reducing the honey-comb effect.

Indeed, the use of Manufactured Nanomaterials (MNMs) and nanocomposites in the construction industry and related infrastructure industries is already a reality, mostly in cement or concrete products, coatings or insulation materials and to a lesser extent in road-pavement products, flame retardant materials or textiles. Despite the current relatively high cost of nano-enabled products, their use in construction materials is likely to increase because of highly valuable properties imparted at relatively low additive ratios, rapid development of new applications and decreasing cost as MNMs are produced in larger quantities (Broekhuizen and Broekhuizen, 2009).

Commonly, the incorporation of the nanomaterials is in form of nanoadditives (powder, solutions, suspensions, etc.) into traditional matrixes, for instance, the addition of carbon nanotubes into a polymeric matrix by melt blending.

One of the key factors that influence so much the behavior of a traditional matrix by incorporating a nanomaterial instead of a microsized material is the dramatic increase of the interphase between both components. In an ideal scenario, the nanoparticles incorporated into a material would be in form of individual units interacting with the matrix around.

Nevertheless, the use of matter at the nanoscale presents challenges:

- the separation of the nanostructures into individual units (layers, tubes, particles, etc.) for a complete reinforcement often requires post-treatments such as chemical modification, mechanical or ultrasound treatments, or even the combination of several treatments. This is due to the very high energy surface between the nanostructures.
- the compatibilization between the nanostructures and the matrix; in many applications, mineral type nanostructures, such as SiO2or nano-clays are incorporated into polymeric matrixes that possess an organic composition, very different from the inorganic (hydrophilic) nature of the nanoparticles. In those cases, the surfaces of the nanoparticles need to be modified.

The use of nanomaterials in construction products is not always well known. Whereas it is well identified for some products, there is some confusion for many others (van Broekhuizen and van Broekhuizen 2009):

- Nano-products are sometimes sold as non-nano-products, while non-nano-products are sometimes sold as nano-products[2].
- Only a very small part of nano-enabled construction products are notified as such to their users through the technical data sheets or the Safety Data sheets (SDS), and then often only with unclear statements such as "*achieved with nanotechnology*"[3].

The coexistence of two "official" definitions for nanomaterials does not contribute to clarity.

Scaffold's review "*Available information on MNMs occupational exposure in the construction sector*" (Karjalainen *et al*., 2012) describes as follows the current knowledge about the use of MNMs in the construction sector:

[2] "*Also quite standard products containing enzymes (that have typical sizes in the nano-regime) or oily dispersions (containing small oil-droplets of nano-size diameter) have been typed nano-. Or products that can be seen as borderline cases, which precursor materials are produced using nano-materials or nano-production processes, but which actual ingredients are no nano-materials anymore*" (van Broekhuizen and van Broekhuizen 2009).

[3] For example, the BASF company PCI sells the mortar "PCI Nanofug" with "Nanotechnology". But here the technical data sheet precises that this Nanotechnology consists in the good knowledge and exploitation of nanostructures within the mortar, and adds that the company "*uses nanoparticles in none of* [its] *products*" (PCI, 2014).

“*Compared to the nanoproduct development in total, the market share of nano-products in the* construction *industry is small and considered to be applied in niche markets (van Broekhuizen and van Broekhuizen 2009). Costs and the present uncertainty regarding long-term technical performance of nanoproducts are factors that have limited the use of nanoproducts in the European construction industry (van Broekhuizen et al. 2011). However, the number of consumer products containing ENPs is increasing rapidly (Green and Ndegwa 2011) and NPs are expected to play an important role in material design, development and production for the construction industry (van Broekhuizen and van Broekhuizen 2009). Consequently, the potential for exposure to humans and the environment is also likely to increase rapidly (NANEX 2010).*

The most common MNMs in construction industry are carbon-based nanomaterials (e.g., carbon nanotubes/fibers and C60 fullerene), metal oxide NPs (e.g., SiO2, Fe2O3 and TiO2) and metal NPs (e.g., Cu and Ag NPs) (Zhu et al. 2004; van Broekhuizen and van Broekhuizen 2009; Lee et al. 2010). Nanoproducts in the construction industry are currently mainly concentrated into four sectors: (1) cement-bound construction materials, (2) noise reduction and thermal insulation or temperature regulation, (3) surface-coatings to improve the functionality of various materials, and (4) fire protection (Greßler and Gazsó 2012). In 2009, coating products were identified to dominate the market, covering 68% of the total number of the identified nanoproducts. Concrete and cement products and insulation products made up for 12% and 7% of all the identified products, respectively (van Broekhuizen and van Broekhuizen 2009).

Selected current and potential uses of MNMs in construction are presented in Table 3.

Table 3. *Examples of MNMs used in construction (Lee et al. 2010)*

MNMs	*Architectural/construction materials*	*Expected benefits*
Carbon nanotubes	*Concrete*	*Mechanical durability, crack prevention*
	Ceramics	*Enhanced mechanical and thermal properties*
	NEMS/MEMS	*Real-time structural health monitoring*
	Solar cell	*Effective electron mediation*
SiO_2 NPs	*Concrete*	*Reinforcement in mechanical strength*
	Ceramics	*Coolant, light transmission, fire resistant*
	Window	*Flame-proofing, anti-reflection*
TiO_2 NPs	*Cement*	*Rapid hydration, increased degree of hydration, self-cleaning*
	Window	*Superhydrophilicity, anti-fogging, fouling-resistance*
	Solar cell	*Non-utility electricity generation*
Fe_2O_3 NPs	*Concrete*	*Increased compressive strength, abrasion-resistant*
Cu NPs	*Steel*	*Weldability, corrosion resistance, formability*
Ag NPs	*Coating/painting*	*Biocidal activity”*

Besides, van Broekhuizen and van Broekhuizen (2009) conclude that "*in the construction sector, only a limited group of nanoparticles are actually identified as being used in products*". Those particles encountered most often are described as follows:

- "***Carbon-fluoride polymers*** *(CF-polymers) are Teflon like molecules that are brought onto a surface to make this surface water* and *oil repellent. Applications are typically found on glass.*
- ***Titanium dioxide (TiO_2)*** *absorbs UV* light *and is used as a protective layer against UV degradation. Some forms of TiO2 are photo-catalytic and catalyze the degradation of organic pollutants like algae, PAHs, formaldehyde and NOx under the influence of UV light. Applications are found for practically every surface type that has to be UV-protected, made self-cleaning or should assist in the reduction of air pollution.*
- ***Zink oxide*** *(ZnO) knows* similar *photo-active characteristics to TiO2 and can be used for similar applications.*
- ***Silica fume*** *(amorphous SiO_2) compacts concrete,* making *it more strong and more durable under alkaline conditions like marine environments. It can also be added to concrete to stabilize fillers like fly-ash, to a coating material resulting in a very strong matrix, or used as fire retardant agent. Typical applications are UHPC (Ultra High Performance Concrete), scratch resistant coatings and fire resistant glass.*
- ***Silver*** *(Ag) acts as a bactericide and can be added to all sorts of materials. In construction it is mostly found in coatings. In fact, it is the silver-ion, formed when Ag dissolves in water that is responsible for the anti-bacterial activity.*
- ***Aluminium oxide*** *(Al_2O_3) is used in coatings to interact with the binder material and to add high scratch resistance to this coating".*

In terms of volume, the highest use of nanomaterials the **Silica fume, with** EU wide **"***a total amount of about 3.6 Mtons of silica fume concentrated in few special construction projects*" in 2009. In comparison, van Broekhuizen and van Broekhuizen estimate the market of TiO_2 cement in the order of 1 kton per year EU-wide in 2009.

The SCAFFOLD partners have identified three further applications of MNMs in construction, among the five studied in the project (Table 4). Table 5 compares the physical characteristics of the MNMs selected for the SCAFFOLD project to those of the conventional homologous. These five nanomaterials are further described in Appendix 4 in terms of use in the construction sector and of hazards.

Table 4. MNMs used in the SCAFFOLD project.

MNM	**Application/matrix**	**Expected benefit**
AmorphousNano-SiO_2	Concrete	Improvement of rheology and mechanical properties
Nano-TiO_2	Mortar	Self-cleaning and decontamination
Nano-clay (organically modified)	Fire resistance panels	Improvement of creep resistance and thermal stability
Cellulose nanofibers	Insulation panels	Improvement of mechanical and thermal properties
Carbon nanofibers (modified surface)	Coating/paint	Improvement of mechanical, thermal and electrical properties

Table 5. Comparison of the additives in their micro and nano scale

Nanoadditive	**Size**	**Nanostructure**	**Traditional additive**	**Structure**	**Size**
Nano-SiO_2	3-150 nm	0D-Spheres	Micro-SiO_2	Spheres	Range of µm
Nano-TiO_2	20 nm	0D-Spheres	Micro-TiO_2	Spheres	Range of µm
Nano-clay (organically modified)	10-1000 nm	2D-Platelets	Clay	Stacks or micro-aggregates	Up to 10 µm
Carbon nanofibers (modified surface)	Diameter range=10-100 nm Length range=100nm-few microns	1D-Fibers	Carbon fibers	Fibers	5–10 µm diameter
Cellulose nanofibers	Aspect ratio=15:1 Length=30-250 nm Diameter=2-10 nm	1D-Fibers	Cellulose fibers	Wood pulp/Cellulose fibers	Around 50 µm

To our knowledge, due to Nano-SiO_2, the five nanomaterials account for more than 90% of the total volume of nano-enabled constructions products currently used and also for a large part of the onsite works with nano-enabled constructions products.

3. OCCUPATIONAL SAFETY RELATED TO NANOMATERIALS IN CONSTRUCTION

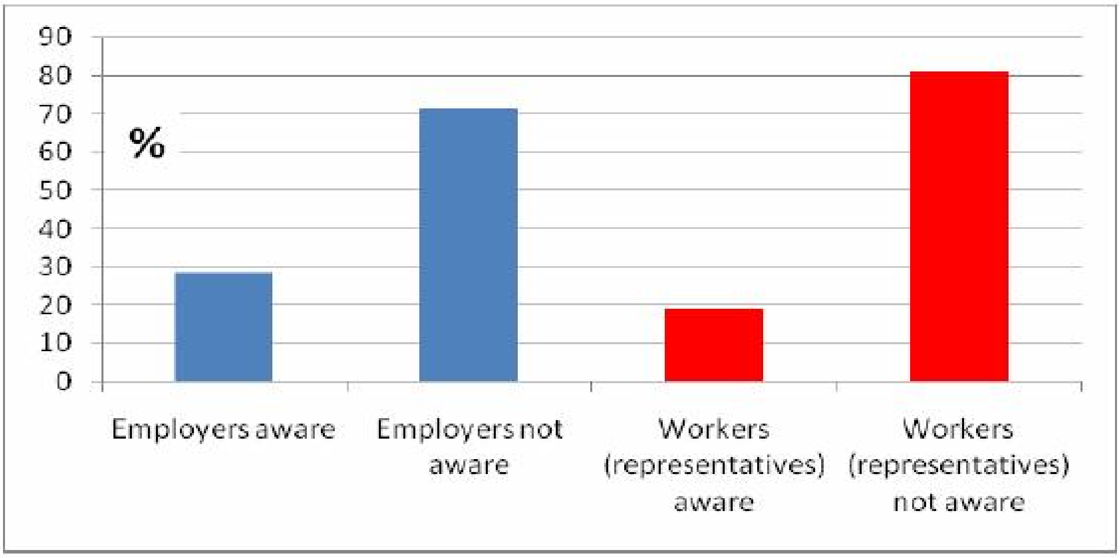
In this chapter, we describe the current situation and praxis concerning occupational safety related to nanomaterials in the construction sector. After an introduction about the awareness of MNMs in construction products and the Identification of exposure scenarios, the different components of risk management are successively discussed:

- Prevention
- Protection
- Risk assessment, incl. hazard assessment and exposure assessment
- Risk management

3.1. Awareness of MNMs in construction products

Due to the loss of information down the user chain about the presence of nanomaterials in the different construction products (see § 2.5), a majority of workers and their employers in the construction sector (~75%) are not aware that they may work with nano-products (Figure 5). When the information about the presence of MNMs is available, then with the mention that they represent no risk in the normal use of the product, and the safety measures are not changed in comparison with previous non-nano products (van Broekhuizen and van Broekhuizen, 2009).

Figure 5: Low awareness of workers and employers of the construction sector regarding the use of MNMs in construction products



Source: van Broekhuizen and van Broekhuizen, 2009

Considering the structure of the sector, dominated by SMEs with limited OSH resources and access to up-to-date information, this means that nanomaterials are almost never considered or managed as an occupational safety issue in construction companies.

In the same way, nanomaterials are not primarily mentioned as key issues for the construction sector in the communication of the OSH agencies (e.g. EU-OSHA, 2015a at European level, INRS (2015) in France, BG Bau in Germany), which rather list tangible and certain concerns such as: Working at height, Vehicle accidents in the workplace, Asbestos, Musculoskeletal disorders, Exposure to loud noises, Vibration at work.

For those actors who are aware of this issue, a concern often expressed (and especially by trade-unions) is a repetition of the case of asbestos, with ignorance of possible hazards during exposure and effects occurring at large scale ca. 30 years after exposure. This concern is encouraged by the lack of awareness among the employees and managers, the strong lack of knowledge about possible exposure and hazards, and the fact that products are nevertheless released on the market before this knowledge is available and (due to small volumes) often without going through the REACH procedure (FIEC-EFBWW, 2013-2015; ETUI, 2013). This concern is particularly strong for long nanofibers (e.g., certain carbon nanotubes) for which a behaviour similar to asbestos may be suspected.

3.2. Identification of exposure scenarios and exposure routes

Scaffold's review "*Available information on MNMs occupational exposure in the construction sector*" (D1.2; Karjalainen *et al*., 2012) summarizes as follows the current knowledge about the exposure routes:

"*MNMs may be accidentally or incidentally released to the environment at different stages of their life cycle. Once in the environment, MNMs may undergo diverse physical, chemical, and biological transformations that change their properties, impact, and fate. (Lee et al. 2010)*

Workers' exposure to NPs may occur during production, handling and refinement, bagging and shipping, production and processing of materials containing NPs (Hristozov and Malsch 2009; Kuhlbusch 2011). When a worker inhales dust containing NPs, the actual exposure depends on the structure and solubility of the dust. If the dust is insoluble, part of the NPs will remain embedded in the matrix and exposure will only be to the NPs of the surface of the dust grain. If the dust itself is soluble, there will be systematic exposure to the whole number of NPs contained by the dust grain. (van Broekhuizen and van Broekhuizen 2009)

In general, it is likely that processes generating nanomaterials in the gas phase (after removal of the nanomaterial from an enclosed generation system), or using or producing nanomaterials as powders or slurries/suspensions/solutions (i.e., in liquid media), pose the greatest risk for releasing nanoparticles. In addition, maintenance of production systems (including cleaning and disposal of materials from dust collection systems) is likely to result in exposure to NPs. Exposures associated with waste streams containing nanomaterials may also occur. (NIOSH 2009)

An exposure to ENMs predominantly can occur via inhalation, dermal, oral and ocular routes. The major possible portals of ENM entry are lung, skin, gastrointestinal tract, nasal cavity and eyes. (Yokel and MacPhail 2011) Exposure through inhalation of dust generated when processing materials (e.g., from cutting, sanding, drilling or machining) or aerosols from paint-spraying are the scenarios most likely to pose health risks (van Broekhuizen and van Broekhuizen 2009). Skin penetration may in theory play a role as well, but most studies have shown little to no transdermal absorption through healthy skin. However, the uptake via damaged skin cannot be ruled out. Oral (gastrointestinal) exposure can occur from intentional ingestion, unintentional hand-to-mouth transfer, from inhaled particles (>5 µm) that are *cleared via the mucociliary escalator, and of drainage from the eye socket via the nasal cavity following ocular exposure. (Yokel and MacPhail 2011)*

Critical factors affecting exposure to ENMs include the amount of material being used, the ability of the material to be dispersed (in the case of a powder) or form airborne sprays or droplets (in the case of suspensions), the degree of containment, and duration of use. In the case of airborne material, the particle or droplet size will determine the deposition of material. Respirable particles may deposit in the alveolar (gas exchange) region of the lungs, which includes particles smaller than ca. 10 µm in diameter. Approximately 30%–90% of inhaled nanoparticles are likely to deposit in any region of the human respiratory tract depending on, e.g., breathing rate and particle size. Even 50% of nanoparticles in the 10–100 nm size range may deposit in the alveolar region, while nanoparticles smaller than 10 nm are more likely to deposit in the head and thoracic regions. (NIOSH 2009)

Jobs and operations that may increase the likelihood of exposure to nanoparticles include for example (Schulte et al. 2008):

- *Generating nanoparticles in the gas phase in non-enclosed systems increases the chance of aerosol release to the workplace.*
- *Handling nanostructured powders can result in aerosolization.*
- *Working with nanomaterials in liquid media without adequate protection (e.g., gloves) increases the probability of skin exposure.*
- *Working with nanomaterials in liquid during pouring or mixing operations or where a high degree of agitation is involved can cause the formation of airborne, inhalable, and respirable droplets.*
- *Conducting maintenance on equipment and processes used to produce or fabricate nanomaterials, or the cleanup of spills or waste material, pose a potential for exposure to workers performing these tasks.*
- *Cleaning of dust collection systems used to capture nanoparticles increases the potential for both skin and inhalation exposure.*
- *Machining, sanding, drilling, or other mechanical disruptions of materials containing nanoparticles can lead to aerosolization of nanomaterials."*

The life cycle analysis of the nano-enabled construction product all along its value chain (see Appendix 5**)** helps identify the potential occupational exposure during the life cycle of this construction product.

As an example, Table 6, Figure 6 and Table 7 represent a global vision of the results obtained in the Life Cycle Analysis of Construction Processes (LCA-CP) carried out in the Scaffold project. Table 6 displays the relation between the construction processes and the steps of the Life Cycle (except the "step 1: design", that is out of the scope of the project). For each process, potential occupational Exposure Scenarios (ES) have been identified at task level. Notice that in some tasks no ES have been identified, because it is not expected a potential worker exposure to MNMs.

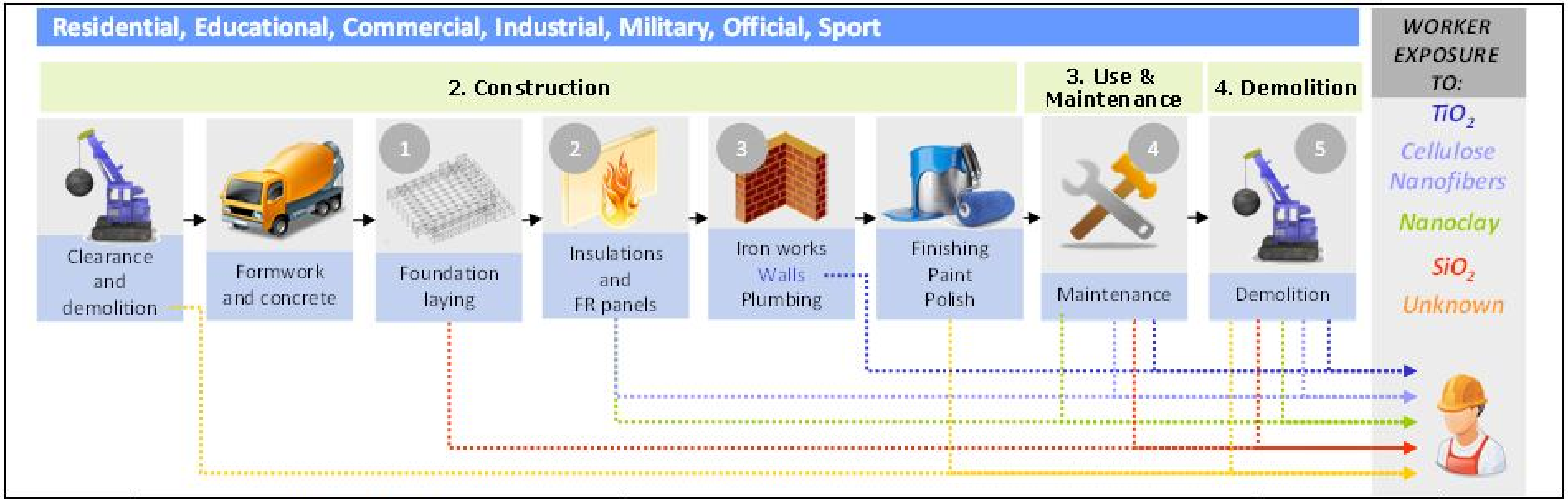
This LCA highlights that the potential highest level of exposure is related, in one hand to the scenarios where NMs are synthesized and there is the potentiality to exposure to Nano-objects, and their aggregates and agglomerates (NOAA; e.g. cleaning / maintenance tasks) and, in the other hand, to the scenarios where NOAA are mixed with other components to fabricate for instance, products like mortar, concrete or composites that are afterwards applied in the construction site.

The scenarios that have been classified with a preliminary potential level of exposure medium are: 1) scenarios that involve materials with NOAA embedded in a solid matrix to which high energy is applied (e.g. machining, sawing, demolition, etc.) and can generate a release of powders embedded with NOAA; 2) scenarios that involve combustion (accidental fire) of materials with NOAA embedded in a solid matrix, where fumes containing NOAA can be released; and finally 3) scenarios where NOAA in a suspension are highly dispersed (e.g. spraying tasks, grouting).

The lowest potential level of exposure is expected for tasks where the NOAA are embedded in a solid or dispersed in liquids (and no energy is applied). It is important to note again that these levels of exposure assigned to the ES are quite preliminary and are only based on the state of the nanomaterial and the energy applied to it and that they will be the real conditions which will determine the actual workers exposure: the life cycle analysis only brings the basis for future risk limitation and management steps as presented in the next chapters.

Table 6. Classification of occupational Exposure scenarios in construction processes

ES (ISO/DTS 12901-2)	Life Cycle Analysis of Construction Processes (LCA-CP) and occupational Exposure Scenarios (ES)	Potential exposure	LEVEL of exposure
STEP 2: CONSTRUCION WORKS			
Synthesis of NOAA	ES related to cleaning/maintenance tasks	Potential exposure to NOAA	High
Material in powder form	ES related to Tasks that involve the manipulation of nanopowders	Potential exposure to NOAA	High
Material dispersed in a solid matrix	ES related to machining, assembly tasks of materials with NOAA embedded in a solid matrix	Potential exposure to NOAA embedded in the matrix.	Medium
Material in suspension in a liquid	ES related to the manipulation of NOAA in a suspension	Potential exposure to liquid embedded with NOAA	Low
	ES related to the manipulation of NOAA in a suspension providing energy (ej. spraying tasks, grouting)	Potential exposure to liquid embedded with NOAA	Medium
STEP 3: MAINTENANCE			
Material dispersed in a solid matrix	ES related to accidental fire of materials with NOAA embedded in a solid matrix.	Potential exposure to NOAA embedded in the matrix.	Medium
STEP 4: DEMOLITION			
Material dispersed in a solid matrix	ES related to the end of life/demolition of materials with NOAA embedded in a solid matrix.	Potential exposure to NOAA embedded in the matrix.	Medium



LIFE CYCLE STEPS		EXPOSURE SCENARIO	MNM
Operation or construction	1. Grouting	ES15:Preparation, dosification and application	TiO_2
		ES16: Superficial machining	
	2. Bituminous road	ES11/ES11:Manufacture in-site of the pavements	NC[1] CNF
		ES12/ES12:Machining for superficial fitting of other elements	
3. **Maintenance**		ES18/ES14/ES14:Accidental fire: MNM combustion	TiO_2 NC CNF
4. **Demolition or dismantle**		ES17/ES13/ES13:Demolition, end of life	

Figure 6. Life Cycle Analysis of construction processes. Example in building construction.

Table 7. Exposure Scenarios (ES) identified in construction processes for TiO2, SiO2, CNF, Cellulose NF and nanoclays.

	LIFE CYCLE STEPS OF THE CONSTRUCTION PROCESSES *(NOTE: the first step "design" is out of the scope)*																										
	2. CONSTRUCTION WORKS																									3. USE & MAINTENANCE	4. DEMOLITION
	Precursors mixing	Reaction in a spark ignition chamber	Deposition of MNMs in filters	Packaging	Clearance and demolition	Excavation, demolition, explosion	Drainage	Foundation laying	Elements assembling	Formwork and concrete	Excavation, filling, compacting	Iron work	Grouting	Shotcrete or anchorage	Bituminous road	Formwork	Concrete	Raylway installation	Intallations: ventilation, wiring, accesses	Electrical installation	Compacting	Finishing, paint, polish	Insulations and FR panels	Iron Works, Wall, plumbing	Upside infrastructure		
1.- MANUFACTURING NMs	NI	NI	NI	**ES1$^{(H)}$** **ES6$^{(H)}$**																						**ES1$^{(H)}$** **ES6$^{(H)}$**	
2.- BUILDING CONSTRUCTION					NI			**ES7$^{(H)}$** ES8$^{(M)}$		NI												NI	ES19 ES23 ES20$^{(M)}$ ES24$^{(M)}$	ES2$^{(L)}$ ES3$^{(M)}$		ES10$^{(M)}$ ES5$^{(M)}$ ES22$^{(M)}$ ES26$^{(M)}$	ES9$^{(M)}$ ES4$^{(M)}$ ES21$^{(M)}$ ES25$^{(M)}$
3.- CIVIL CONSTRUCTION																											
3.1.- Transport-infrastructure																											
Road					NI						NI		**ES15$^{(H)}$** ES16$^{(M)}$		**ES11$^{(H)}$** ES12$^{(M)}$						NI					ES18$^{(M)}$ ES14$^{(M)}$	ES17$^{(M)}$ ES13$^{(M)}$
Railway					NI						NI						ES7$^{(H)}$	ES8$^{(M)}$		NI						ES10$^{(M)}$	ES9$^{(M)}$
Bridge							NI					NI					**ES7$^{(H)}$** ES8$^{(M)}$					NI				ES10$^{(M)}$	ES9$^{(M)}$
Tunnel						NI	NI							**ES11$^{(H)}$**					ES12$^{(M)}$						NI	ES14$^{(M)}$	ES13$^{(M)}$
Harbor								**ES7$^{(H)}$**	ES8$^{(M)}$							NI	**ES7$^{(H)}$**				NI					ES10$^{(M)}$	ES9$^{(M)}$
Airport					NI			**ES7$^{(H)}$** ES8$^{(M)}$		NI	NI		**ES15$^{(H)}$** ES16$^{(M)}$		**ES11$^{(H)}$** ES12$^{(M)}$						NI	NI	ES19 ES23 ES20$^{(M)}$ ES24$^{(M)}$	ES2$^{(L)}$ ES3$^{(M)}$		ES5$^{(M)}$ ES10$^{(M)}$ ES14$^{(M)}$ ES18$^{(M)}$ ES22$^{(M)}$ ES26$^{(M)}$	ES4$^{(M)}$ ES9$^{(M)}$ ES13$^{(M)}$ ES17$^{(M)}$ ES21$^{(M)}$ ES25$^{(M)}$
Metropolitan					NI	NI	NI				NI			**ES11$^{(H)}$**			**ES7$^{(H)}$**	ES8$^{(M)}$	ES12$^{(M)}$	NI					NI	ES10$^{(M)}$ ES14$^{(M)}$	ES9$^{(M)}$ ES13$^{(M)}$
3.2.- Hydraulic																											
Dams and levees								**ES7$^{(H)}$**	ES8$^{(M)}$							NI	ES7$^{(H)}$				NI					ES10$^{(M)}$	ES9$^{(M)}$
Channel and sewage						NI	NI							**ES11$^{(H)}$**					ES12$^{(M)}$						NI	ES14$^{(M)}$	ES13$^{(M)}$
Hydroelectric plants					NI			**ES7$^{(H)}$** ES8$^{(M)}$		NI												NI	ES19 ES23 ES20$^{(M)}$ ES24$^{(M)}$	ES2$^{(L)}$ ES3$^{(M)}$		ES10$^{(M)}$ ES5$^{(M)}$ ES22$^{(M)}$ ES26$^{(M)}$	ES9$^{(M)}$ ES4$^{(M)}$ ES21$^{(M)}$ ES25$^{(M)}$
Water Treatment plants					NI			**ES7$^{(H)}$** ES8$^{(M)}$		NI												NI	ES19 ES23 ES20$^{(M)}$ ES24$^{(M)}$	ES2$^{(L)}$ ES3$^{(M)}$		ES10$^{(M)}$ ES5 $^{(M)}$ ES22$^{(M)}$ ES26$^{(M)}$	ES9$^{(M)}$ ES4$^{(M)}$ ES21$^{(M)}$ ES25$^{(M)}$

Legend: NI - Task where NOAA are not used; ESX(H) - ES where high potential level of exposure is expected; ESX(M) - ES where Medium level of exposure is expected; ESX(L) - ES where Low level of exposure is expected. In grey, operations not involved in the process.

3.3. Risk Prevention

Risk Prevention tends to avoid "upstream" the possibility of exposure to the potentially hazardous compounds, by avoiding the very presence of these compounds in exposure media, e.g. through:

- Substitution of MNMs by conventional particles or by MNMs known as non-hazardous
- Confinement of MNMs in the process, in the product, or in a stable matrix.
- Isolation of potentially hazardous tasks and materials.

The most traditional way is to observe the Safety Data Sheet (SDS) provided by the supplier and use the specified collective and personal protective equipment indicated in each case. This is generally supervised by the OSH staff. However, SDSs very seldom contain information about MNMs (see § 2.5).

NIOSH (2009) proposes prevention measures with respect to nanomaterials (not specifically for the construction sector), such as:

- "Educating workers on the safe handling of engineered nano-objects or nano-object-containing materials to minimize the likelihood of inhalation exposure and skin contact.
- Storing dispersible nanomaterials, whether suspended in liquids or in a dry particle form in closed (tightly sealed) containers whenever possible.
- Avoiding storing and consuming food or beverages in workplaces where nanomaterials are handled"

These measure proposed by NIOSH (2009) do not differ fundamentally from those proposed by potentially toxic dust in general.

Other usual dust prevention measures at a construction site also fully apply to MNMs such as spraying water on the construction place, confining dust to the solid matrices.

Therefore, nano-specific prevention measures for the construction sector will essentially concern the steps where MNMs are introduced into the future construction products:

- During the manufacturing of construction products (off site);
- During the preparation of the final construction material from a conventional construction material and a MNM-containing additive (off site on site).

In the Scaffold project, the work on risk prevention was focused on developing and using nanoadditives that are safer-by-design (Table 8), i.e. which will reduce the risk in the following steps of the life cycle (incorporation into the construction material; construction, maintenance and aging of the constructions including accidents; demolition and disposal). This work led to a set of recommendations provided in Scaffold's Guide for Risk prevention (SPDS 2.7; Larraza *et al.*, 2015).

Table 8.Summary of safer-by-design strategies developed in the Scaffold project

Nanoparticle	Associated problem	Strategy
TiO_2	Very low density, powdery nature. Possible chemical modifications of uncertain nature	Use concentrated and stable dispersions Use n-TiO_2 supported on sepiolite microfibers
SiO_2		Use concentrated and stable dispersions
Nanoclay		Reduction of energy in agitation processes to reduce potential splits Safer-by-design process approach: nanoadditives less likelihood to release smoke in case of fire
Cellulose nanofibers	Fibrous and powdery nature. It is necessary to ensure that no problems similar to those caused by asbestos might occur	Achieve good dispersions-NOAA bounded to the matrix (to reduce the likelihood to release free NOAAs from solid matrix)

Most of those recommended prevention measures can also be applied for the preparation of the final construction material from a conventional construction material and a MNM-containing additive (off site on site), e.g.:

- Use nanoparticles supported on larger structures (confinement of the MNMs, substitution of the additive).
- Use highly concentrated aqueous suspensions, instead of powdery products (confinement of the MNMs, substitution of the additive).
- Use low energy mixing processes (confinement of the process; but care must be taken to ensure that the additive is well incorporated).
- Carry out an effective dispersion and compatibilization of nanofibers in polymeric matrixes (confinement of the MNMs): "*a good dispersion and compatibilization of these types of MNMs in polymeric matrixes reduces the formation of agglomerates and poorly attached particles and the likelihood to release free NOAAs from solid matrix*".

These recommendations can be broadened and completed as follows:

- Increase the size of your particles: rather big than small ENMs, rather micro- than nano-particles (substitution);
- When using a powder additive, keep it confined through all the addition and mixing process. For instance, van Broekhuizen and van Broekhuizen (2009) mention, in the case of silica fume (powders) for high performance and self-compacting concrete, "*a packaging material (large bags) that dissolve in water and which material does not affect the foreseen product characteristics (concrete)*".

3.4. Risk Protection

Three components of Risk Protection are considered in the project Scaffold:

- Collective protection
- Personal protection
- Medical surveillance

3.4.1. Collective protection

Collective protection consists for instance in: general ventilation, operating at negative pressure (room, glove box...); worker isolation; separated rooms; use of robots (instead of persons); and local exhaust ventilation (LEV).

Scaffold's review "*Available information on MNMs occupational exposure in the construction sector*" (D1.2; Karjalainen *et al*., 2012) concludes that these "*techniques should be effective for capturing airborne nanomaterials, based on what is known of nanomaterial motion and behaviour in air*". The review provides successful examples (from the construction sector or not) collective protection through available (non-nano-specific) measures such as LEV combined with HEPA (high efficiency particulate air) filter, covering of possible emission sources, "*thorough cleaning by washing the floor, and water-based removal of residual dust on all equipment*", NP handling in fume hoods.

In the frame of the Scaffold project, during experimental campaigns, investigations were carried out in nine rooms with different ventilation systems. It was confirmed that only in the room with positive pressure ventilation and when works were conducted in the glove box, particles from the processes were not transferring to the room air (Scaffold Report D4.2, Jankowska et al., 2014).

Except for the natural ventilation and LEV, the mainly used collective protection techniques are applicable only in closed buildings with permanent equipment (e.g. production or preparation of nano-enables construction products), not at onsite construction work (work outdoor or in a non-equipped building). Natural ventilation cannot be controlled, and may be insufficient in some cases, e.g. for some demolitions (outdoor), for sanding surfaces (indoor) or cutting materials with an electric circular saw (outdoor or indoor). Concerning LEV, Lippy Bruce and Gavin West (2015), from the Center for Construction Research and Training (USA), confirmed through lab and real-site experiments the efficiency of a LEV to reduce exposure during construction works except for cutting materials with an electric circular saw.

These possibilities and limits of available collective protection techniques for MNMs are not specific to nanoparticles: they concern dusts at construction in general. As a conclusion, Scaffold does not identify nano-specific gaps and needs concerning collective protection in construction. Scaffold's Guide on risk protection (D4.13; Boutry *et al*., 2015) provides a complete set of recommendations for collective protection in relation with manufactured nanomaterials (MNMs) in the construction industry.

3.4.2. Personal protection

"*Use of personal protective equipment (PPE) such as respirators, gloves, and protective clothing is the least preferred method for preventing worker exposure to a hazard, as it places the responsibility for preventing injury or illness on the worker. Given the uncertainties about the health risks for ENPs and limited data for determining the effectiveness of controlling workplace exposures, the supplemental use of PPE may be warranted for some job tasks where engineering controls (prevention) cannot be used or where they are only partially effective in preventing airborne or dermal exposure*. (Schulte et al. 2008, in Karjalainen *et al*., 2012)"

Scaffold's review "*Available information on MNMs occupational exposure in the construction sector*" (D1.2; Karjalainen *et al*., 2012) concludes:

- "*Until further results are obtained from clinical laboratory or workplace studies, traditional respirator selection guidelines should be used. Evaluation of commercial filter media under harsh conditions, for example, high-face velocity, is needed. However, there is currently no evidence that the assigned protection factors for respirators deviate for nanoparticles compared with conventional particles*".
- "*There are no generally accepted guidelines available based on scientific data for the selection of protective clothing or other apparel against exposure to nanomaterials. This is due in part to minimal data being available on the efficacy of existing protective clothing, including gloves. A challenge to making appropriate recommendations for dermal protection against nanoparticles is the need to strike a balance between comfort and protection. Garments that provide the highest level of protection are also the least comfortable to wear for longs periods of time, while garments that are probably the least protective are the most breathable and comfortable for employees to wear*".

In Scaffold, the efficiency of different types of personal protection equipments (respirators, protective gloves, protective clothing) used in or intended for the construction sector were characterized. The aim was to determine if NPs can diffuse or leak through PPEs and clothes in different states (liquid, powder, solid and aerosolized NPs) during different steps of their life cycle (synthesis, handling, manufacturing, using and end of life. The three main routes of exposure to nanomaterials at the workplace were considered: inhalation, dermal penetration and ingestion. For each type of PPEs, the current materials were found efficient against penetration of the MNMs tested (Brochocka *et al*., 2014; Boutry and Damlencourt, 2014). The main concern is the leakage through gaps, seams, defects, and interface closure areas. For respirators, filters for smaller particles (P3) are correlated with increased resistance to air of the material, therefore increased under-pressure when breathing and finally an increased risk of leakage. For instance, in Scaffold's testing of respirators with a breathing manikin simulating natural human movements and speech, the highest Total Inward Leakage (TIL) levels were found for speech simulation and simulation of up and down head movement (Brochocka *et al*., 2014). This concern about leakage is not specific to nanoparticles. But, based upon the uncertainty of the health effects of dermal exposure to nanoparticles, special attention should be paid that the PPEs used fit particularly well with the individual morphological characteristics (size; shape of the face;...).

Finally, Scaffold observation of PPEs involved in real scenarios at industrial partners' workplace showed that the actual gloves, masks and Tyvek clothes are efficient towards NPs incorporated at realistic concentrations (between 0,4 and 1,7%) in a material. Whether in powder form (synthesis of NPs, manufacturing of the mortar) or in solid state (mortar with water, applying on a wall) or in sol-gel state (liquid mortar), we never observed SiO2, TiO2, nanoclay or nanocellulose inside PPEs.

As a conclusion, <u>Scaffold does not identify nano-specific gaps and needs concerning personal protection equipment in construction</u>. Scaffold's Guide on risk protection (D4.13; Boutry *et al*., 2015) provides a complete set of recommendations for personal protection in relation with manufactured nanomaterials (MNMs) in the construction industry.

3.4.3. Medical surveillance

In the frame of the Scaffold project, FIOH has proposed a complete Guidance on health surveillance for workers in the construction industry (Hyytinen *et al*., 2014). A key difficulty here is the identification of construction products containing nanomaterials, due to the lack of information in the SDSs. FIOH recommends to search for more information in the national databases or registries on nanomaterial-containing products.

3.5. Risk assessment

Risk assessment compares information on hazards with information on exposure. A management orientated risk-management also uses science-based conventional reference values to appreciate the acceptability of the exposure measured and then characterize the risk. These components are described in the following sections.

3.5.1. Hazard assessment

Scaffold's Guide on risk assessment (SPD3.13; Vaquero *et al*., 2015) summarizes as follows the current situation about the hazard assessment of MNMs:

"*There are indications that nanomaterials are more biologically active than larger-sized particles of the same chemistry, due to their greater surface area per mass. Additional characteristics that may influence their toxicity include shape, surface functionalization or coating, solubility, surface reactivity, association with biological proteins, binding to receptors, and their tendency to agglomerate.*

Soluble or partly soluble nanomaterials may induce hazardous effects mainly due to the toxicological profile of the dissolved ions. However, the majority of nanomaterials being used in the construction sector is consisting of poorly soluble or insoluble nanomaterials, where some of the toxicological effects may be a result of so-called particle effects.

The main concerns regarding occupational exposure to nanomaterials are related to local pulmonary effects. Due to their small size, inhaled nanomaterials can be deposited in the lung cells in high amounts. This may consequently cause a significant local inflammation, as the immunological defence system is not cable of removing all particles. The ability of the particles to travel from the lung to the systemic blood circulation and further to other organs, is in theory possible, as the small particles might pass through membranes.

The potential hazardous effects of many nanomaterials are currently being studied in numerous research projects. A few of the materials have already now been investigated in large numbers of toxicological tests, whereas for other materials there is almost no data available yet. What is clear is that the nanomaterials cannot be considered as one homogenous group, as the hazardous effects are likely to be very different. One of the main concerns at the moment is related to the hazardous effects of fibrous nanomaterials. However, the effects may be very different for different types of fibrous materials. According to the current knowledge, long, rigid fibrous nanomaterials (e.g., certain carbon nanotubes) seem to be significantly more harmful than other types of fibrous materials. The concerns are based on findings of animal studies, indicating a behaviour similar to asbestos, meaning that repeated exposure might in the worst case cause carcinogenic effects.

As various nanomaterials may have different toxicological profiles, it is important to identify the nanomaterial in use, in order to be able to make a hazard and risk assessment. Making a risk assessment is complicated as, so far, the majority of nanomaterials has not been classified as harmful, and the safety data sheets seldom contain any nano-specific information on the hazardous effects.

In the hazard assessment it is highly important to consider all chemicals in use, and not only the nanomaterials. In many cases, other components of the products (for example organic solvents) are likely to be much more harmful than the nanomaterials".

As an illustration, the results of the hazard assessment of the nanoparticles studied in the Scaffold Project are briefly described in Appendix 4.

3.5.2. Occupational Exposure Limit values (OELs) and reference values

Scaffold's report "Formulating occupational exposure limits values (OELs) (inhalation & dermal)" (SPD3.11; Stockmann-Juvala *et al*., 2014b) summarizes as follows the current situation about Occupational Exposure Limit values (OELs):

"*Occupational Exposure Limit values (OELs) are binding or guideline limit values for the concentrations of impurities, such as chemical substances, in the workplace air. Their primary purpose is to protect the workers from the adverse health effects of the impurities. OELs are set both at the EU level and at national level. Depending on the type of the OEL, the value may be strictly health-based, include socio-economic and/or technical feasibility considerations, or it may be based solely on technical feasibility.*

So far, no regulatory OELs specifically addressing nanomaterials have been given by the EU or by any national authority (Gordon et al. 2014). However, recommended limit or reference values for the concentration of nanomaterials in the workplace air have been proposed, for example, by the Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) in Germany, by the British Standards Institution (BSI) in the UK, and by the National Institute for Occupational Safety and Health (NIOSH) in the US (IFA 2014a; BSI 2007; NIOSH 2011; 2013). A general framework for the development of OELs for nano-objects and their aggregates and agglomerates is under development in the International Organization for Standardization (ISO 2014).

The applicable approaches for setting OELs, or other reference values, for nanomaterials depend mainly on the availability of toxicological data on the material (Schulte et al. 2010; Kumpel et al. 2012). When adequate data is available, traditional quantitative risk assessment, based on the dose-response data on the critical health effects, may be applied for setting a substance-specific OEL. However, when the toxicity data is limited, alternative approaches, often including grouping of the materials on the basis of their physico-chemical properties, need to be applied".

Based on these considerations, Scaffold proposes the following OELs and reference values for the NOAAs in the scope of the project:

Table 9: OELs and reference values recommended by Scaffold project.

Nano-object	**OEL** mg/m3 or fibers/cm3 (1)	**Reference Values** particles/cm3 or fibers/cm3(1)
nano-TiO2	0.1	40.000
nano-SiO2	0.3	40.000
nano-clay	(2)	40.000
Low toxicity dust	0.3 (respirable) 4 (inhalable)	
nano-cellulose	0.01 (1)	0.01 (1)
Carbon nano-fiber	0.01 (1)	0.01 (1)

(1) OELs in fibers/cm3; (2) The OEL for low toxicity dust can be temporarily applied to nanoclays, as long as no valid substance-specific data is available.

Notes:

1) "*TiO_2 is included in the current work-list of the EU Scientific Committee on Occupational Exposure Limit Values (SCOEL), meaning that the committee is evaluating the available data and might, based on the evaluation, give recommendations for TiO_2 OEL-values to be included in the EU list of Indicative Occupational Exposure Limits*" (Stockmann-Juvala *et al*., 2014b).
2) "*There is an on-going debate in the scientific literature about what are the relevant parameters to evaluate an exposure to nanoparticles. At the moment, there are no generally agreed parameters which should be measured to define the nanoparticle concentration in the workplace air. Nor is there an agreement on which instruments should be used to carry out these measurements. (Leskinen et al. 2012). Number, mass and surface area exposure concentrations have been suggested as metrics for exposures to ENPs (van Broekhuizen et al. 2012). Particle number concentrations and particle number size distributions are the most commonly used metrics within the reviewed workplace and laboratory studies*". (Karjalainen *et al*., 2012). However, some OELs expressed in mass concentrations (mg/m^3) correspond to original OELs expressed in surface concentrations (m^2/m^3) and converted to mass concentrations (Schulte *et al*., 2015), but with the strong limitation that this conversion is made for one particular nanoparticle of a given size and may be inexact for other nanoparticles of other sizes.

3.5.3. Exposure assessment

Exposure data can be obtained from two sources:

- Own exposure measurements, either on the real site or in controlled simulated conditions (see Karjalainen *et al*., 2012, § 8.2 for advantages and limits), possibly combined with modelling.
- Exposure databases or emission data combined with modelling, with data reported from similar construction activities. This information can help organize and optimize own measurement, indicating what priority compounds and what range of concentrations should be expected. This information can also help to plan appropriate protection equipment at an early stage, without delaying the works on site.

These two options are discussed below.

Exposure or emission databases

Scaffold's review "*Available information on MNMs occupational exposure in the construction sector*" (D1.2; Karjalainen *et al*., 2012) concludes with the NANEX (2010) project, for the general situation of exposure to nanoparticle (i.e. not specifically in the construction sector), that there is not sufficient data for a reliable use in a pre-assessment of potential occupational exposure:

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

For the specific case of the construction sector:

- Karjalainen et al. (2012) consider that "*there are very limited amounts of data available on exposure to ENMs within the construction sector. Van Broekhuizen et al. (2011) measured exposure to dispersed NPs during use of nanoproducts on two different companies for the following working situations: spraying a liquid window coating, applying a cement repair mortar and nano-concrete filling. Personal exposure assessment and source identification measurements were carried out during all these activities. All the calculated 8-h TWA exposures remained well below the [Dutch limit values]. The background concentration, the use of electrical equipment, heaters, diesel aggregates and smoking were identified as potential confounding factors in ENP measurement*".
- The Scaffold project has measured exposure to MNMs in 3 construction scenarios in real case studies (application of coatings, construction of a concrete slab, demolition of fire-resistant panels) and in 5 scenarios at pilot scale (manufacturing self-cleaning mortar filled with n-TiO2 and n-SiO2, application of self-cleaning mortar, application of self-cleaning coatings, demolition of structures (cabs) covered with mortar, machining mortar/concretes/polymers filled with MNMs).
- PEROSH, the European network of 12 Occupational Safety and Health (OSH) institutes, is building a database of occupational exposure. From the contacts established

between Scaffold and PEROSH, it comes out that very few PEROSH data concern the construction sector and that PEROSH's database can be used by OSH institutes and possibly by researchers under strict confidentiality conditions, but is not available or exploitable for site-specific risk assessment.

- The Nanosafety Cluster's Working Group 3 on exposure also has the ambition to build an exposure database gathering the information produced in the FP7 and H2020 EU research programmes.

Exploitable emission data for construction scenarios appear even rarer. Besides, "*predictive exposure models are mass-based and this parameter might be less appropriate in cases where one wishes to evaluate the risks associated with a nanomaterial*" (Savolainen et al., 2013).

The Scaffold project performed a review of the operational information about exposure data, it did not perform an exhaustive review of exposure data (whether in real or in simulated situations). Other data may exist that could further be gathered in a directly exploitable way. For example, INERIS has performed over years MNM exposure measurements in simulated conditions (e.g. for drilling), but these data do not seem to be integrated in the sources mentioned.

Exposure measurements

Scaffold's review "*Available information on MNMs occupational exposure in the construction sector*" (Karjalainen *et al.*, 2012) summarizes as follows the current state of exposure measurement for MNMs at the workplace:

"*Although many organizations in the world have researched various methods for the workplace exposure assessment of nanomaterials, and different approaches for strategies to workplace measurements have been proposed (e.g., by NIOSH, ECHA, IUTA/BAuA/BG RCI/VCI/IFA/TUD and nanoGEM), a standard or an agreeable methodology has not yet been established. The main reason is the difficulty in precise analysis of airborne particles in workplace, due to the fact that nanomaterials have unique physico-chemical properties, different from those of bulk materials (Park et al. 2009). Since there is no generally established and validated method for nanoparticle occupational hygiene measurements, it is essential for scientists to produce data about the suitability of the aerosol measurement instruments for real-time nanoparticle exposure estimation (Leskinen et al. 2012).*

The current measuring methodology recommended by research organizations mostly is a modified form of conventional measuring methods for micro-sized materials. Importantly, it is a key point whether the equipment precisely and accurately can measure nano-sized materials (Park et al. 2009). ENPs can be measured in the workplace using a variety of instrumentation, including: condensation particle counter (CPC); optical particle counter (OPC); scanning mobility particle sizer (SMPS); electric low pressure impactor (ELPI); aerosol diffusion charger; and tapered element oscillating microbalance (TOEM), which vary in complexity and field portability. Unfortunately, relatively few of the instruments are readily applicable to routine exposure monitoring due to non-specificity, lack of portability, difficulty of use, and high cost. (NIOSH 2009) (...)

Personal exposure approaches are either based on personal devices and samples or real measurements combined with the recording of personal activity patterns, to allow the calculation of personal exposure (Kuhlbusch et al. 2011). A large number of equipment able to *measure nanoaerosols is available on the market. The majority is designed for laboratory use, but newly developed equipment are easily transportable and easy to use (Nanosafe-June 2008). A major drawback of current state of the art measurement devices is their lack of differentiation of background from nanomaterial related particles (Kuhlbusch et al. 2011). (...)*

Synthetic nanoparticles usually exist as agglomerates, which are made up of a varying number of small primary particles. The size, shape, and morphology can vary between different nanoparticles. This poses a significant challenge for the measurement methods as the particle properties affect the behaviour of the particles within the measurement instruments and human body. As the particle diameter decreases, the specific surface area increases exponentially. Therefore, the physico-chemical properties of these particles, or materials containing them, are substantially different from those of bulk materials. (Leskinen et al. 2012). For ENPs, more profound investigation is needed and different properties, such as particle size distribution, surface area/volume ratio, shape, electronic properties, surface characteristics, state of dispersion/agglomeration, and conductivity need to be studied. The high complexity and great diversity of ENPs, however, make their characterization very difficult. (Hristozov and Malsch 2009)

According to Savolainen et al. (2010), some of the real challenges ahead for ENM monitoring and health risk assessment are as follows: (a) to redesign "ENM-capable" instruments already in laboratory use into portable and affordable devices, (b) to expand the sensing technology available for ENM detection by adopting new options with realistic potential for real-time measurement and compact design; and (c) to extend the metrics into new areas such as CNT shape identification and catalytic properties. In the future, it will be increasingly important to have devices providing real-time, on-line data".

In addition: new portable devices have been developed during the last years, e.g. within the FP7 project Nanodevice.

Scaffold's partner Tecnalia tested and combined available measurement equipment in controlled and real situations, among others in the 5 case studies of the project. Together with other metrology experts within the consortium such as INERIS, Tecnalia came to a more precise analysis of the current technical gaps and needs for exposure measurement:

- The current priority needs do not concern the equipment itself, but the measurement strategy for the different nanoparticles and the relevant parameter (mass concentration, surface concentration, particle concentration, which is determined by the applicable reference values).
- Typically, such strategies combine concentration measure (mass concentration or particle concentration) and, behind, chemical characterization/identification of the nanoparticles trapped in the first step. Or, for fibers (as carbon nanofibers or nanocellulose), there is no consensus (a standard) about how to collect and analyze the samples in electron microscopy to count the fibers for comparison with the OEL of 0.01 fibers/cm^3.
- A large effort would be necessary to establish comprehensive harmonized, goal-focused, particle-specific protocols that can be used in a typical professional context (as opposed to research), and to standardize them as references[4].

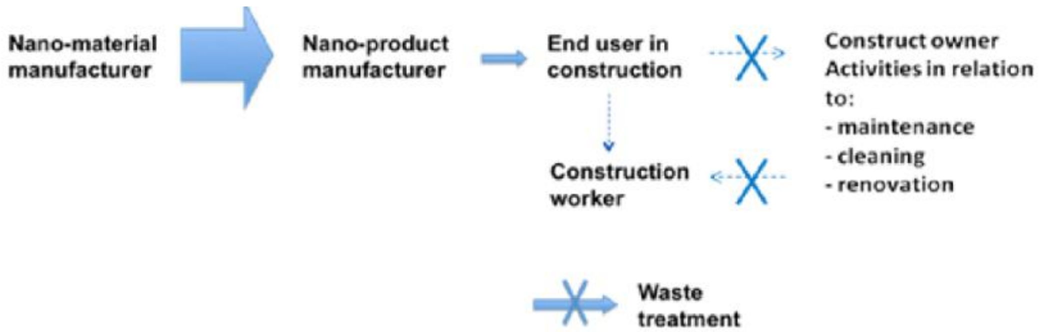
[4] As an exception, for nano-TIO2, there is a standardized analytical method which allows to specifically measure the target MNM down to the proposed OEL level.

- For the 5 MNMs in the scope of the project, the Scaffold consortium provided the best recommendations identified within the limited resources of the project (see the Guide on risk assessment: Vaquero *et al*., 2015), but a larger effort would be necessary to establish comprehensive harmonized, goal-focused, particle-specific protocols that can be used in a typical professional context (as opposed to research), and to standardize them as references.
- For n-TIO2, there is a standardized analytical method which allows to specifically measure the target MNM down to the proposed OEL level.

A prerequisite: knowing which nanoparticles to look for

The discussion above makes clear the importance to know what nanoparticles to look for when launching measurement campaigns. Two major hurdles are identified here.

1) For new constructions: given the high MNM-specificity of measurement techniques, the lack of information about nano-materials actually used in construction products (see § 2.5) makes a relevant exposure assessment more difficult;
2) For maintenance in or demolition of existing structures: the difficulty is increased by the poor documentation of the construction products in existing buildings. And generic data about typical MNMs emitted from these activities is missing or not organized in operational databases (see the section about "Exposure databases" above in this chapter).



Source: van Broekhuizen and van Broekhuizen, 2009. The thickness of the arrow represents roughly the amount of nano-specific information supplied to the next user down the chain.

Figure 7. Intensity of nano-specific information supply down the user chain from the raw material supplier to those who have to deal with the waste material

3.5.4. Risk characterization

Risk characterization itself does not present new difficulties *per se*, but is strongly impacted by the difficulties in the former steps: the major challenge here is to organize and describe rigorously the limits of and uncertainties of the assessment.

3.6. Risk Management

3.6.1. Risk Management model and implementation toolkit

The only Risk Management (RM) tools mentioned in the state of the art of the Nanosafety Strategic Research Agenda (Savolainen *et al*., 2013) are risk/control banding tools. "*Control banding is a qualitative or semi-quantitative risk assessment and management approach to promoting occupational safety and health (OSH). It is intended to minimise the exposure of workers to hazardous chemicals and other risk factors in the workplace, particularly in work situations in which information on hazards, exposure levels and risks are limited*" (EU-OSHA, 2013). "*The outcomes of the tool is not risk levels, but risk priority levels, meaning that in these cases one should be very careful with the substances and check that the control measures are working properly and the best practices are applied at the workplace*" (Väänänen *et al*., 2014). The Strategic Research Agenda notes (Savolainen *et al*., 2013): "*only a few of the exposure assessment components of these tools have been calibrated, and none of them have been extensively tested or validated. (...) Uncertainty by virtue of sufficient data can then be the driver for very conservative risk assessment approaches*."

In the frame of the Scaffold project, Väänänen *et al*. (2014) applied the control banding tool Stoffenmanager Nano in the construction work area. They concluded that Stoffenmanager Nanotool was applicable in some of the studied industrial workplaces, but was difficult to apply in other cases especially because of the lack of information about the presence, identity and then hazard potential of nanomaterial in the products.

Neither Risk Management Models (RMM) nor implementation toolkits specifically dedicated to occupational nanosafety in the construction sector already existed at the start of the Scaffold project.

The Scaffold project designed the first Risk Management Model (RMM) for nanosafety in construction, using requirements of OHSAS 18001 (structure, elements, etc.) with additional requirements derived from the guidelines established in ISO 31000. It integrates all results from Scaffold, including a control banding tool specifically customized for the construction sector (Marcoulaki *et al*., 2015). This RMM and further recommendations are presented in Scaffold's Guide for Risk Management (Contreras *et al*., 2015). The recommendations are applicable to companies of the construction sector, regardless of the size or type of organization. Every subsector involved in construction cycle could apply the MNMs RMM but with different necessities, perceptions and criteria (manufacture, building and civil construction and demolition). Scaffold's RMM is the starting point of a European technical Specification under preparation (Manufactured nanomaterials (MNMs) in the construction industry - Guidelines for occupational risk management; CEN TC 352/WG 3/PG 5 "Scaffold").

The Scaffold project designed the related toolkit (Table 10), a software tool to be used by OHS professionals to manage nano-risks in construction. The application has two operation modes:

- Learning mode. This mode is provided to help the user get familiar with the tool using dummy data and browsing the contents.
- Risk management mode. This is the production mode, where the tool manages real data and provides information about NMN risk management for the company.

Table 10. Main features of Scaffold's Risk Management toolkit

MODULE	DESCRIPTION
1. Library	It provides a library with documentation for managing nano-risks in construction (RP, RA, RPo, RM)
2. Customization	It allows companies to customize the application to their processes, tasks, scenarios and size. It uses the Module 1 to facilitate data input and generate the company profile.
3. Risk Management	It enables the initial assessment, implementation and audit of RMM guided by a step-by-step dialog. This module deploys two different setups, depending on the company profile (Large company or SME).
4. Tools	It contains the toolbox for nanosafety management: Risk management (scored checklist for diagnostic, implementation or audit), Risk assessment (Qualitative and quantitative approaches), Planning, KPIs, Documents and templates.
5. Help	It gives access to miscellaneous options: file management, configuration, and help (User manuals).

3.6.2. Training

Training programmes for occupational nanosafety already existed at the start of the Scaffold project, e.g. at INERIS in France (coupled with certification) or at TNO in The Netherlands. These programmes are generally multi-sectorial. To our knowledge, no training program specifically dedicated to occupational nanosafety in the construction sector already existed.

The Scaffold consortium translated the guidelines developed by Scaffold - previously reviewed by FIEC and EFBWW - in 6 training modules (Power Point presentations) for companies of the construction sector:
1.- General overview of nano-risks in construction
2.- Risk prevention
3.- Risk assessment
4.- Risk protection
5.- Risk management
6.- Using Scaffold Toolkit
These modules have been implemented in the Toolkit and are also available from the project website.

A further development would be an EU-wide system for the certification of competencies (esp. for company managers and OSH managers) based on Scaffold's guides and training modules and when necessary on larger multi-sectorial training programs.

4. ROADMAP

The description of the construction sector and of its occupational safety issues related to nanomaterials (§ 2 and § 3) leads to propose the roadmap described in Table 11 below. This roadmap is further developed into a European Strategy in a separate report (Hazebrouck *et al.*, 2015).

Table 11.Roadmap for occupational safety in the construction sector

RM step[5]				**Issue**	**Strategic objective**	**Challenge with respect to the state of the art**	**Specific to**		**Operational objectives**	**Timing**[6]		
Pr	**Pt**	**A**	**M**				**MNMs**	**Constr.**		**S**	**M**	**L**
X	X	X	X	Awareness, infor-mation	Raise awareness, disseminate information on MNMs in construction products	The information about MNMs in the construction products and about specific risk management measures is rare and inappropriate. It does not reach OSH managers and workers.	Yes	No	• Improve the information on MNMs in Safety Data Sheets, labels and Technical Sheets of construction products. • Disseminate Information to stakeholders. • Improve the information on MNM-containing products in construction calls for tenders and contracts.		X	X
X	X	X	X	Safe work culture and practices	Disseminate and implement best practices regarding MNMs in construction	Have the best practices recommended in Scaffold's guides and handbook implemented. Propose Scaffold's RMM and toolkit. This objective goes along with a general objective to increase the culture of safety in construction.	Partly	Partly	• Improve the quality of Safety Data Sheets and labels of construction products regarding MNMs. • Disseminate actively Scaffold's guides and tools within the construction sector: large & small companies, relevant OSH actors... • Ensure the link with standards and regulatory guidance.	X	X	X
		X	X	Exposure limit values	Establish OELs and other reference values for MNMs relevant in construction	No official MNM-specific health-based OELs have been set by European or national authorities. Only indicative reference values are available. This complicates the interpretation of exposure measurement and the subsequent risk assessment.	Yes	Little (NPs con-cer-rned)	• Promote needs and priorities from construction on MNMs towards actors in charge of OELs. • Support on-going works on OELs for priority MNMs, incl. background research.		X	X

[5] Pr: Risk prevention; Pt: Risk protection; A: Risk assessment; M : Risk management. X: mainly concerned; x: secondarily concerned.
[6] S: short term; M: mid-term; L: long term.

RM step[5]				Issue	Strategic objective	Challenge with respect to the state of the art	Specific to		Operational objectives	Timing[6]		
Pr	Pt	A	M				MNMs	Constr.		S	M	L
		X	x	Exposure measure-ment	Ensure better adequacy of measurement capacities with assessment needs	Harmonized or even consensual reference methods are missing to optimize and secure the combination of techniques needed to obtain a measurement enough selective and precise.	Yes	Little (NPs con-cer-rned)	• Develop strategies and standards to measure the different MNMs with the relevant metrics (number, mass or surface concentration) and at relevant levels for comparison with available occupational limits. • For some MNMs, develop R&D to design more accurate devices.		X	X
x	x	X	x	Exposure data	Make available typical exposure data for key construction activities	Very few -if any- exploitable exposure data are available in operational databases to inform about risks to be expected and to help focus the exposure protection and measurement.	Yes	Yes	• Develop an operational public database on emission of and exposure to MNMs in construction. • Feed this database with data from the literature and/or with new experimental data.		X	X

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Appendix 1: Glossary and definitions

Agglomerate	Collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components[ISO/TS 27687:2008, 3.2]
Aggregate	Particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components. [ISO/TS 27687:2008, 3.3]
Exposure	Contact with a chemical, physical or biological agent by swallowing, breathing, or touching the skin or eyes. (ISO 12901-1:2011).
Health hazard	Potential source of harm to health [ISO 10993-17:2002, 3.7]
Health risk	Combination of the likelihood of occurrence of harm to health and the severity of that harm [ISO 10993-17:2002, 3.8]
(M)SDS	(Material) Safety Data sheets. SDS is the current denomination (ECHA, 2014)
Nanomaterial	Material with any external dimension in the nanoscale (2.1) or having internal or surface structure in the nanoscale (ISO/TS 80004-1).
Nano-object	Material with one, two or three external dimensions in the nano-scale [ISO/TS 27687:2008]
NOAA	**N**ano-objects, and their aggregates and agglomerates greater than 100 nm (ISO/TS 12901-2
Nanoscale	Size range from approximately 1 nm to 100 nm. [ISO/TS 27687:2008]
Particle	Minute piece of matter with defined physical boundaries [ISO/TS 27687:2008, 3.1]

Appendix2: Details of the civil construction activities

The civil constructions can be classified in many ways; in this case we have taken into account whether they are transport infrastructures, or hydraulic constructions.

Within the transport infrastructures, one can find at least the following types:

-Roads. A road is a thoroughfare, route, or way on land between two places, which typically has been paved or otherwise improved to allow travel by some conveyance, including a horse, cart, or motor vehicle. Roads consist of one, or sometimes two, roadways each with one or more lanes and also any associated sidewalks and road verges. Roads that are available for use by the public may be referred to as public roads or highways.

The steps to build a road are:
1-Clearance and demolition
2-Excavation, filling and compacting
3a-Bitumen application followed by 4-Compacting
3b-Pavement by grouting application

-Railways. Rail transport is a means of conveyance of passengers and goods by way of wheeled vehicles running on rail tracks. In contrast to road transport, where vehicles merely run on a prepared surface, rail vehicles are also directionally guided by the tracks on which they run. Track usually consists of steel rails installed on sleepers/ties and ballast, on which the rolling stock, usually fitted with metal wheels, moves. However, other variations are also possible, such as slab track where the rails are fastened to a concrete foundation resting on a prepared subsurface.

The steps to build a railway are:
1-Clearance and demolition
2-Excavation, filling and compacting
3-Concrete
4-Railway installation
5-Electrical installation

-Bridges. A bridge is a structure built to span physical obstacles such as a body of water, valley, or road, for the purpose of providing passage over the obstacle. Designs of bridges vary depending on the function of the bridge, the nature of the terrain where the bridge is constructed, the material used to make it and the funds available to build it.

The first activity in the construction of a bridge is the drainage. A bridge is basically composed of 4 elements: foundation laying, column, span and support. Each of these elements is built in three steps:
1-Ironwork
2-Concrete
3-Finishing

-Tunnels. A tunnel is an underground passageway, completely enclosed except for openings for ingress and egress, commonly at each end. A tunnel may be for foot or vehicular road traffic, for rail traffic, or for a canal. Some tunnels are aqueducts to supply water for consumption or for hydroelectric stations or are sewers. Other uses include routing power or telecommunication cables, some are to permit wildlife such as European badgers to cross highways.

The steps to build a tunnel are:
1-Drainage
2-Excavation, demolition or explosion
3-Shotcrete or anchorage
4-Installations: ventilation, wiring and accesses
5-Construction of the upside infrastructure

-Harbors. A harbor is a place where ships, boats, and barges can seek shelter through stormy weather, or else are stored for future use. Harbors can be natural or artificial. An artificial harbor has deliberately-constructed breakwaters, sea walls, or jetties, or otherwise, they could have been constructed by dredging, and these require maintenance by further periodic dredging.

The steps to build a harbor are:
1-Foundation laying
2-Elements assembling
3-Formwork
4-Concrete
5-Compacting

-Airports. An airport is a location where aircraft such as fixed-wing aircraft, helicopters, and blimps take off and land. Aircraft may be stored or maintained at an airport. An airport consists of at least one surface such as a runway for a plane to take off and land, a helipad, or water for takeoffs and landings, and often includes buildings such as control towers, hangars and terminal buildings.

The steps to build an airport could be summarized as the combination of those to build a road plus those to build a building.

-Metropolitans. A metropolitan railway system is an electric passenger railway in an urban area with a high capacity and frequency, and grade separation from other traffic.[1][2] Rapid transit systems are typically located either in underground tunnels or on elevated rails above street level. Outside urban centers, rapid transit lines may run on grade separated ground level tracks.

The steps to build a metropolitan could be summarized as the combination of those to build a tunnel plus those to build a railway.

Within the hydraulic constructions, one can find at least the following types:

-Dams and levees. A dam is a barrier that impounds water or underground streams. Dams generally serve the primary purpose of retaining water, while other structures such as floodgates or levees (also known as dikes) are used to manage or prevent water flow into specific land regions. A levee is an elongated naturally occurring ridge or artificially constructed fill or wall, which regulates water levels. It is usually earthen and often parallel to the course of a river in its floodplain or along low-lying coastlines.

The construction steps to build these elements are similar to those for a harbor.

-Channels and sewages. A channel or water supply canals are used for the conveyance and delivery of potable water for human consumption, municipal uses, and agriculture irrigation. Sewage is water-carried waste, in solution or suspension that is intended to be removed from a community.

The construction steps to build these elements are similar to those for a tunnel.

-Hydroelectric plants. It is a plant where hydroelectricity is produced. Hydroelectricity is the term referring to electricity generated by hydropower; the production of electrical power through the use of the gravitational force of falling or flowing water.

The construction steps to build these elements are similar to those for an industrial building.

-Water treatment plants. Water treatment describes those processes used to make water more acceptable for a desired end-use. These can include use as drinking water, industrial processes, medical and many other uses. The goal of all water treatment process is to remove existing contaminants in the water, or reduce the concentration of such contaminants so the water becomes fit for its desired end-use. One such use is returning water that has been used back into the natural environment without adverse ecological impact.

The construction steps to build these elements are similar to those for an industrial building plus a further exploitation. Note that in some water treatment plants, nanotechnology has started to be used.

According to the descriptions presented above, there are some similarities between different processes which can be analyzed as if they were the same process or as a combination of two processes. Figure 8 summarizes the combinations between all the infrastructures studied in the project.

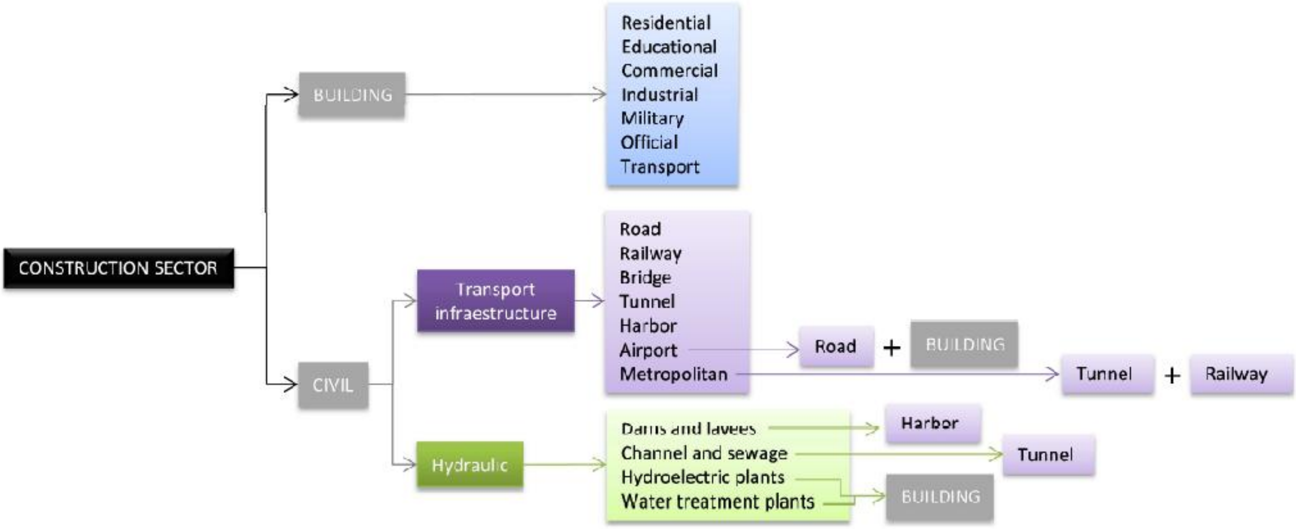


Figure 8. Combination of the different infrastructures

Appendix 3: Details about cement, concrete and bituminous asphalts

In this Appendix, three types of materials are presented as the most representative matrixes in the present industrial sector, due to the large volumes in which they are produced: cement and concrete, bituminous asphalts and polymers and polymeric composites.

1. Cement and concrete

Concrete is the most common and widely used construction material in the world. According to CEMBUREAU (2012), 6.3 billion tons were produced worldwide in 2011. China accounted for 57.3% of the world´s total cement production (Figure 9). The EU 27 production in 2011 was 195.3 million tonnes, and the clinker and cement exports was 45million tonnes, compared to 23 million tonnes of imports.

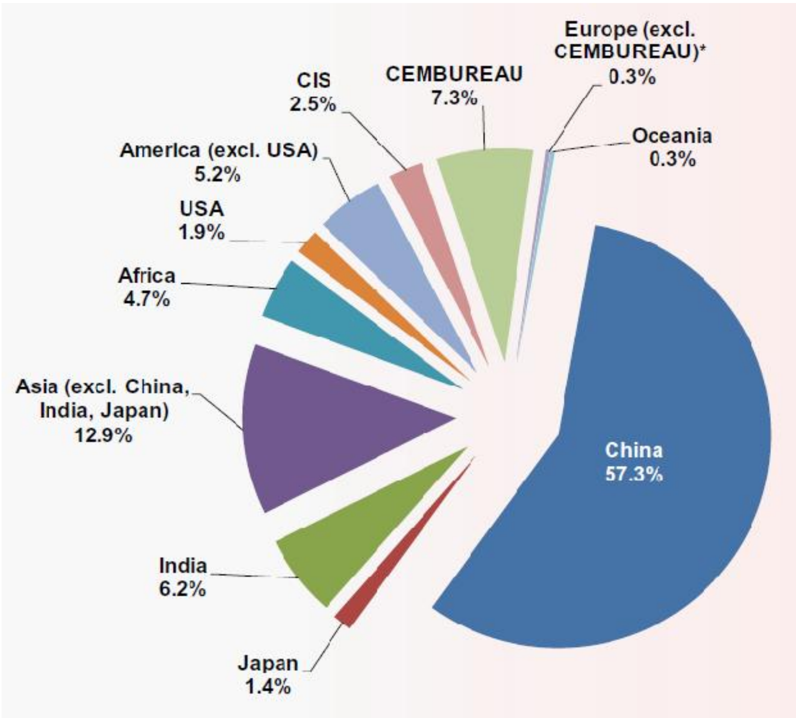


Figure 9.World cement production 2011, by regions and countries (CEMBUREAU, 2012)

2. Bituminous asphalts

Bituminous asphalt concrete is a composite material commonly used in construction projects such as road surfaces, parking lots, and airports. It consists of asphalt (used as a binder) mixed with mineral aggregate and then laid down in layers and compacted.

According to EAPA (2012; European industry association which represents the manufacturers of bituminous mixtures and companies engaged in asphalt road construction and maintenance) the total production of hot and warm mix asphalt was of 324.3 million tonnes in Europe in 2011. Asphalt is typically a mixture of approximately 95% aggregate particles and sand, and 5% bitumen, which acts as the binder, or glue. It means that 16.21 Mtonnes of bitumen and 308 Mtonnes of aggregates were consumed in 2011.

Table 12: Consumption of bitumen in the road industry in million tonnes in 2011

Country	**Tonnage in 2011**	**% Modified bitumen (of total)**			**Emulsions in 2011**
		In 2009	**In 2010**	**In 2011**	
Austria	0,55	30	35	25	0,004
Belgium	0,25	23	24,4	25,5	
Czech Republic	0,35	20	16	18	0,03
Denmark	0,2	5	5	5	0,021
Finland	0,29	0	0	0	0,009
France	3,06	<10	<10	<10	0,96
Germany	2,2	23			
Great Britain	1,35	8	8	8	0,105
Greece	0,12	2,9	2	2	0,003
Hungary	0,12	21	12	11	0,005
Iceland	0,02	0			0,005
Ireland	0,1	10	25		
Italy	1,45	12,5	13,3	14	0,06
Lithuania	0,09	13	18	14	0,01
Luxembourg	0,04	15	20		
Netherland	0,34				
Norway	0,37	10	13	15	0,001
Poland	1,75	24	22	21	0,105
Portugal	0,29	15	1,5	0,024	
Romania	0,21	74	45	74	0,28
Slovakia	0,13			60	0,01
Slovenia	0,05	17	10	0,002	
Spain	1,41	12,6	14,3	13,1	0,12
Sweden	0,4	5	6	6	0,04
Switzerland	0,27	11	12	10	
Turkey	2,6	2	4	8	0,067
Japan	1,75		19,6	22,1	0,091
Ontario-Canada	1		15	25	
South Africa	0,43				0,15

Source: EAPA, Asphalt in Figures, 2011.

85 percent of all bitumen produced world-wide is used in asphalt pavements, 10 percent is used for roofing, and the remaining 5 percent is used in other ways, Figure 10.

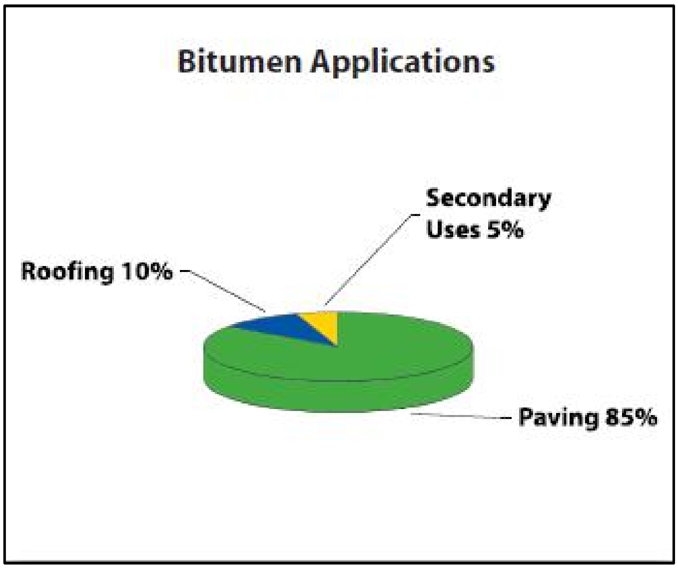


Figure 10. Uses of bitumen

Mixing of asphalt and aggregate is accomplished in one of several ways:

Hot mix asphalt concrete (commonly abbreviated as HMA) is produced by heating the asphalt binder to decrease its viscosity, and drying the aggregate to 150 °C. Paving and compaction must be performed while the asphalt is sufficiently hot. In many countries paving is restricted to summer months because in winter the compacted base will cool the asphalt too much before it is able to be packed to the required density. HMA is the form of asphalt concrete most commonly used on high traffic pavements such as those on major highways, racetracks and airfields.

Warm mix asphalt concrete (commonly abbreviated as WMA) is produced by adding zeolites, waxes, asphalt emulsions, or sometimes even water to the asphalt binder prior to mixing. This allows significantly lower mixing and laying temperatures and results in lower consumption of fossil fuels, thus releasing less carbon dioxide, aerosols and vapors. Not only are working conditions improved, but the lower laying-temperature also leads to more rapid availability of the surface for use, which is important for construction sites with critical time schedules. The usage of these additives in hot mixed asphalt (above) may afford easier compaction and allow cold weather paving or longer hauls.

While conventional asphalt mixes are produced at 160-180ºC and compaction should be finished at 120ºC, WMA are produced at 130-150ºC and compaction is possible even below 100ºC.

Cold mix asphalt concrete is produced by emulsifying the asphalt in water with (essentially) soap prior to mixing with the aggregate. While in its emulsified state the asphalt is less viscous and the mixture is easy to work and compact. The emulsion will break after enough water evaporates and the cold mix will, ideally, take on the properties of cold HMA. Cold mix is commonly used as a patching material and on lesser trafficked service roads.

Table 13. Total production of hot and warm mix asphalt between 2006 and 2011, in million tonnes (EAPA, 2012)

Country	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Austria	10	9,5	9,5	9	8,2	8
Belgium	5	4,5	4,9	4,7	4,8	5,9
Croatia	3,7	3,7*	4,2	3,2	2,7	2,6
Czech Republic	7,4	7	7,3	7	6,2	5,8
Denmark	3,4	3,3	3,1	2,7	3,2	4
Estonia	1,5	1,5	1,5	1,2	1,1	1,3
Finland	5,5	5,9	6	5,2	4,9	5
France	41,5	42,3	41,8	40,1	38,8	39,2
Germany	57	51	51	55	45	50
Great Britain	25,7	25,7	25	20,5	21,5	22,4
Greece	7,8	8	8,1	8,7	5,2	2,3
Hungary	4,4	3,3	2,5	1,6	3,4	2,3
Iceland	0,3	0,3	0,4	0,3	0,2	0,2
Ireland	3,5	3,3	2,8	3,3	2,3	1,8
Italy	44,3	39,9	36,5	34,9	29	28
Latvia	0,6*	0,6*	0,6*	0,6*	0,6*	0,6*
Lithuania	1,7	2,2	1,5	1,6	1,6	
Luxembourg	0,6	0,6	0,6*	0,6	0,7	0,7
Netherlands	9,8	10,2	9,3	9,8	9,5	9,6
Norway	5,1	5,9	5,7	6,5	5,9	6,7
Poland	18	18,0*	15	18	18	26,5
Portugal	8,9	9	9,0*	9,0*	6,7	6,4
Romania	2.8*	3,2	3,3	3,6	3,2	3,6
Slovakia	2,2	2,2*	2,2*	2,2	1,9	2,2
Slovenia	2,2	2,1	2,6	2,3	1,8	1,3
Spain	43,4	49,9	42,3	39	34,4	29,3
Sweden	7,3	7,7	8,7	8,1	7,9	8,1
Switzerland	5,4	5,2	5,3	5,4	5,3	5,4
Turkey	18,9	22,2	26,6	23,1	35,3	43,5
Europe	346,1	347,7	338	317,3	309,3	324,3
Australia	7,7	9	9,5	9,5*	7,52	8,7
Japan	56,6	54,9	49,6	49,6	44,7	45,6
Ontario-Canada	13	13,2	13,2*	13,2*	14	13,5
U.S.A.	500	500	440	324	326	332
South Africa	5,7					
South Korea	35,6	20,7				

*Figure not provided

Table 14.Cold Bituminous Mixes (annual tonnage; EAPA, 2012)

Country	2009 tonnes	2010 tonnes	2011 tonnes
Austria	20.000	10.000	20.000
Belgium	33.000	30.000	33.000
Croatia	0	30.000	21.000
Czech Republic	8.100	11.620	9.907
Denmark	0	≈ 0	≈ 0
France	> 1500000	>1500000	1.600.000
Great Britain		<	1.000.000
Hungary	0	0	40.000
Iceland	6.000		
Lithuania	0	61.936	59.950
Norway	5.000	9.000	37.000
Poland	60.000	61.000	
Portugal		130	110
Romania	13.000	22.000	13.000
Slovakia			3.000
Slovenia	5.000		
Spain	275.000	185.000	200.000
Sweden	90.000	70.000	60.000
Switzerland	560.000	630.000	740.000
Turkey	1.404.000	2.370.000	1.020.000
Japan		104000	95.000
Mexico	3.000.000	3300000	

Appendix 4: Description of the selected MNMs

In this appendix, the nanomaterials selected for the SCAFFOLD project are briefly described according to the previous deliverables produced within the **Work Package 1:** *Profiling the European construction industry face the MNMs occupational exposure*.

The potential adverse effects and toxicity mechanisms for the MNMs are part of the literature review performed in Scaffold on Background information on exposure, use, and hazard (Karjalainen *et al*., 2012) and on toxicity (Stockmann-Juvala *et al*., 2014a). They are summarized in tables in order to facilitate the reading of this document.

Nano-SiO2 (amorphous silica)

There are several different forms of silica. A common CAS number for all silicas is 7631-86- 9. However, each different polymorph of silica has its own polymorph specific CAS number. Amorphous silica can be divided into synthetic amorphous silicas, natural amorphous silicas (like diatomaceous earth) and by-products metal industry (silica fume). Natural forms of amorphous silica may contain impurities, particularly crystalline silica. The physico-chemical properties and particle characteristics differ between different amorphous silica polymorphs.

Cementitious materials such as concrete experience changes in their properties by the incorporation of nano-SiO_2; nano-particles of SiO_2 can fill the spaces between particles of gel of Calcium Silicate Hydrate (C–S–H), acting as a nano-filler. Furthermore, by the pozzolanic reaction with calcium hydroxide, the amount of C–S–H increases, resulting a higher densification of the matrix, which improves the strength and durability of the material. Literature data indicates that the inclusion of nano-particles modifies fresh and hardened state properties, even when compared with conventional mineral additions of silica. Colloidal particles of amorphous silica appear to considerably impact the process of C3S hydration. Nano-silica decreased the setting time of mortar when compared with silica fume and reduced bleeding water and segregation, while improving the cohesiveness of the mixtures in the fresh state. When combined with ultra-fine fly ash it assures better performance than that achieved by the use of silica fume alone. Besides, the compressive strength of mortar or concrete with silica fume is improved when compared with formulations without addition.[7]

[7]Senff*et al*. Construction and Building Materials, 23 (7), 2487–2491, **2009**

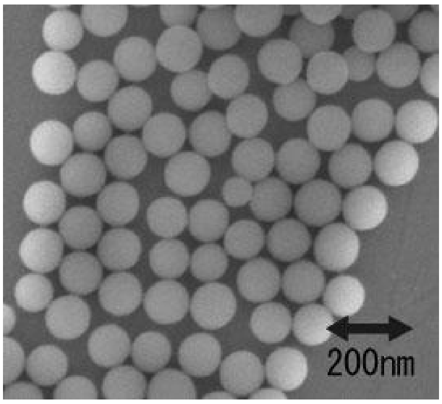


Figure 11. TEM micrograph of SiO_2 nanoparticles[8]

Table 15. Summarized information regarding the toxicity of (amorphous) nano-SiO_2

Toxicokinetics	Greater lung accumulation of nano-sized compared to micro-sized
Acute toxicity	No adverse effects after the acute exposure
Irritation and sensitization	No eye or skin irritation has been observed
Repeated dose toxicity	Inflammation, epithelial damage and morphological alterations in the lungs. Effects more severe with nano-sized than micro-sized TiO_2
Reproductive toxicity	Animal studies indicate a potential of causing developmental effects in offspring
Genotoxicity	Inconclusive results. Genotoxicity may be driven via an indirect threshold mechanism.
Carcinogenicity	Inconclusive data.
Conclusions	A lot of toxicity data available. Nano-TiO_2 is considerably more toxic than micro-TiO_2.

The main concerns related to amorphous silica nanoparticles are their possible lung effects. In repeated dose inhalation toxicity studies, chronic inflammation and fibrotic lesions have been seen. These have, however, been reversible after the cessation of exposure, which differs from the lesions caused by crystalline silica.

Limited data is available on the carcinogenicity of nanosized amorphous silica particles. In a recent study, a statistically significant tumor response was observed after repeated intra-tracheal administration of amorphous silica particles in rats. Tumor responses correlated with inflammatory responses in lungs and mechanisms like lung overloading may have played a role in tumor response. The data on the genotoxicity of amorphous silica particles is inconclusive.

Nano-TiO_2

[8] http://www.furukawa.co.jp/english/what/2007/070618_nano.htm.

Titanium dioxide is the naturally occurring oxide of titanium. Often distinction is made by TiO_2manufacturers between pigmentary and ultrafine grade. The primary crystal size typically ranges from 150 to 300 nm for TiO_2 of pigmentary grade and the surface area from 6 to 60 m^2/g. The ultrafine grade typically has a primary crystal size from 10 to 150 nm, and surface area between 50 and 200 m^2/g. The pigmentary TiO_2 has a white color and is therefore widely used in paints etc. The ultrafine, including nano-sized, TiO_2 is transparent.

In contrast to the bulk TiO_2 (>100 nm) that is considered chemically inert, nano-scale TiO_2 can act as a photo-catalyst, and can generate reactive oxygen species upon illumination. A wide range of applications exist, exploiting the various properties of TiO_2 nanomaterials. In paints and for water treatment nano-sized TiO_2 is used as a photocatalyst producing reactive oxygen that may degrade other organics. Adding nano-TiO_2 into concrete aims to enhance its durability and to maintain whiteness throughout the lifetime of the construct. The addition of TiO2 to the common mortar implies the improvement of barrier properties of the material. These MNMs add to the mortar the capacity to maintain the surface of the product clean more time than the common mortar, therefore the maintenance tasks of the product will be reduced during the use of the product.

In glass nano-TiO_2 is used for heat and fire protection and for its self-clean properties. A number of other very diverse areas of application exist such as catalysts, toothpaste, sunscreens and other cosmetics, air filtration devices, semiconductors, etc.

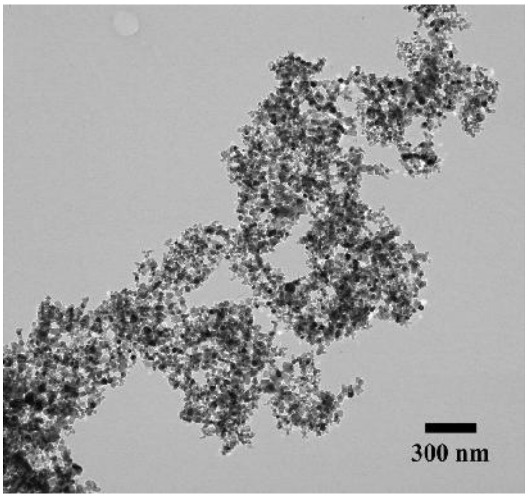


Figure 12. TEM micrograph of TiO_2 nanoparticles

Table 16. Summarized information regarding the toxicity of nano-TiO_2

Toxicokinetics	Greater lung accumulation of nano-sized compared to micro-sized
Acute toxicity	No adverse effects after the acute exposure
Irritation and sensitization	No eye or skin irritation has been observed
Repeated dose toxicity	Inflammation, epithelial damage and morphological alterations in the lungs. Effects more severe with nano-sized than micro-sized TiO_2
Reproductive toxicity	Animal studies indicate a potential of causing developmental effects in offspring
Genotoxicity	Inconclusive results. Genotoxicity may be driven via an indirect threshold mechanism.
Carcinogenicity	Classified as possibly carcinogenic to humans, acting through a secondary genotoxicity mechanism related to chronic pulmonary inflammation
Conclusions	A lot of toxicity data available. Nano-TiO_2 is considerably more toxic than micro-TiO_2.

Several studies have shown clear evidence that nano-sized TiO_2 is considerably more toxic than micro-sized TiO_2. Among the TiO_2-induced adverse effects, respiratory tract is considered as the most critical site. The pulmonary response to TiO_2 is inflammation, epithelial damage, increased permeability of the lung epithelium, oxidative stress and cytotoxicity, and morphological alteration within the lung.

The genotoxicity of TiO_2 nanoparticles is thought to be driven by particle mediated reactive oxygen species production. The particles themselves are not thought to be inherently genotoxic, but may trigger genotoxicity via an indirect threshold driven inflammatory mechanism involving oxidative stress.

In rodents, nano-TiO_2 has been shown to be able to translocate into the central nervous system via axons of sensory neurons in the upper respiratory tract. In the human body, the relevance of transfer via this route is however questionable. Some evidence exists of a neurotoxic potential ofnano-TiO_2.

A limited data suggest that TiO2 nanoparticles may affect the cardiovascular system. Dermal studies have shown little evidence for skin penetration after dermal applications of nano-TiO_2. However, there may be a risk associated with nano-TiO2 applied to damaged skin.Nano-TiO_2 has been classified as possibly carcinogenic to humans (Group 2B) (IARC 2006). The US National Institute of Safety and Health has determined that inhaled nano-TiO_2 is a potential occupational carcinogen and recommended an exposure limit of 0.3 mg/m^3.

Cellulose nano-fibers

Nanocrystalline cellulose derived from acid hydrolysis of native cellulose possesses different morphologies depending on the origin and hydrolysis conditions. Nanocrystalline cellulose structures are rigid rod-like crystals with diameter in the range of 10–20nm and lengths of a few hundred nanometers (Figure 13).

Cellulose fibers are extensively used in paper production, cotton textiles, and as insulation and structural strengtheners in construction products. Despite the large scale use of cellulose fibers their possible toxic properties have not been as rigorously tested as for asbestos and other man-made fibers.

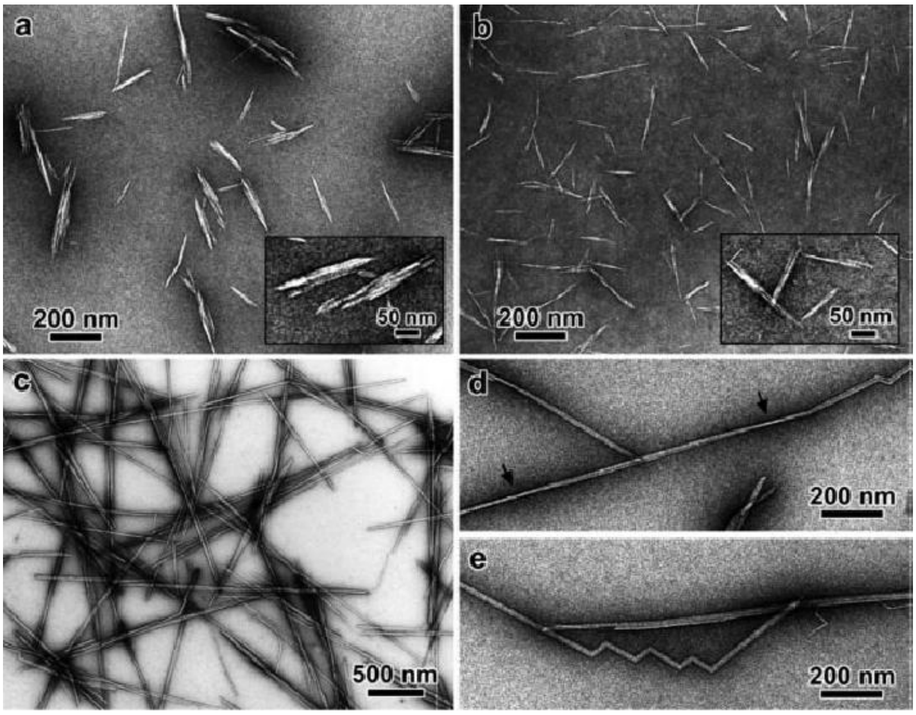


Figure 13.TEM micrographs of nanocrystals obtained by sulphuric acid hydrolysis of (a) cotton (b) avicel (c) tunicate cellulose[9]

Inhalation or instillation studies with cellulose fibers in rats and hamsters have shown that the fibers can cause different pathological changes like inflammation, granulomas, alveoltis, fibrosis and epithelial hyperplasia. It has also been shown that intraperitoneal injections (3 injections spaced at weekly intervals) of high doses of cellulose fibers can cause tumors (sarcomas) in the abdominal cavity of male Wistar rats. In another study, a similar induction of tumors was seen in rats after intraperitoneal injection of cellulose fibers for 7 h a day, 5 days/week for periods of 1 day - 3 weeks. The toxicological data on nanocellulose fibers is still very scarce because many of the new materials are still under development. There is no information about exposure to nanocellulose in industrial scale processes. In exposure scenarios, the most probable route for exposure of workers at workplaces would be via inhalation and skin. There is some concern that nanocellulose fibers could act similarly to other

[9]Elazzouzi-Hafraoui, S. et al. Biomacromolecules 9, 57–65, **2008.**

fibrous nanoscale structures such as carbon nanotubes and asbestos causing fibrosis and cancer. When generalizing the available toxicity data on nanocellulose fibers, it is important to remember that the physico-chemical properties vary between different materials and also the test systems used are different.

Table 17. Summarized information regarding the toxicity of cellulose nanofibers

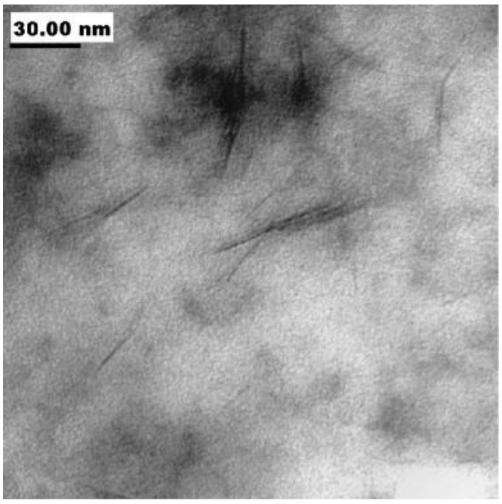
Acute toxicity	No data was found
Irritation and sensitization	No data was found
Repeated dose toxicity	No data was found
Reproductive toxicity	No data was found
Genotoxicity	Some indications of a genotoxic potential but the mechanism is unknown
Carcinogenicity	No data was found
Cytotoxicity	Some indications of cytotoxicity in vitro
Conclusions	Very few studies on nanocellulose toxicity conducted so far. Evaluation complicated by differences in/unclearness related to composition. Nanocellulose materials might be slightly toxic in vitro and in vivo, but the effect is milder than the one caused by MWCNTs and asbestos fibers.

In summary, the few studies on nanocellulose toxicity conducted so far suggest that the different types of nanocellulose materials can be slightly toxic in vitro and in vivo, but the effect is milder than the one caused by MWCNTs and asbestos fibers. Further studies, especially in vivo and in mammalian cells, are necessary in order to make it possible to draw more firm conclusions about the toxic potential of nanocellulose.

Nano-clays

The layered silicates commonly used in nanocomposites belong to the structural family known as the 2:1 phyllosilicates. Their crystal lattice consists of two-dimensional layers where a central octahedral sheet of alumina or magnesia is fused to two external silica tetrahedron by the tip so that the oxygen ions of the octahedral sheet do also belong to the tetrahedral sheets. The layer thickness is around 1 nm and the lateral dimensions of these layers may vary from 10 nm to several microns and even larger depending on the particular silicate.

These layers organize themselves to form stacks with a regular van der Walls gap in between them called the interlayer or the gallery. Between the layers inorganic cations exist, generally Na^+, K^+ and Li^+. As the forces that hold the stacks together are relatively weak, the intercalation of small molecules between the layers is easy. In order to render these hydrophilic phyllosilicates more organophilic, the hydrated cations of the interlayer can be exchanged with cationic surfactants such as alkylammonium or alkylphosphonium. The modified clay (or organoclay) being organophilic, its surface energy is lowered and is more compatible with organic polymers. These polymers may be able to intercalate within the galleries. Montmorillonite (Figure 14) hectorite and saponite are the most commonly used layered silicates. Their structure is given in Figure 15 and their chemical formulas are shown in Table 18.



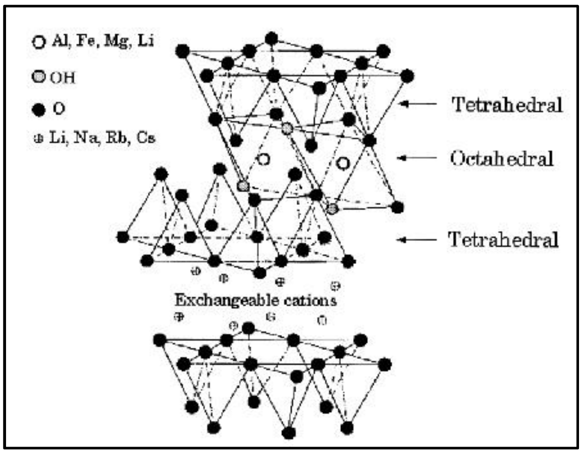


Figure 14. TEM micrograph of exfoliated MMT

Figure 15.Structure of 2:1 phyllosilicates.[10]

This type of clay is characterized by a moderate negative surface charge (known as the cation exchange capacity, CEC and expressed in meq/100 g). The charge of the layer is not locally constant as it varies from layer to layer and must rather be considered as an average value over the whole crystal. Proportionally, even if a small part of the charge balancing cations is located on the external crystallite surface, the majority of these exchangeable cations are located inside the galleries. When the hydrated cations are ion-exchanged with organic cations such as more bulky alkyammoniums, it usually results in a larger interlayer spacing.[11]

Table 18.Chemical structure of commonly used 2:1 phyllosilicates

2:1 Phyllosilicate	**General formula**
Montmorillonite	$M_x(Al_{4-x}Mg_x)Si_8O_{20}(OH)_4$
Hectorite	$M_x(Mg_{6-x}Li_x)Si_8O_{20}(OH)_4$
Saponite	$M_xMg_6(Si_{8-x}Al_x)O_{20}(OH)_4$

Nanoclays are usually incorporated into polymeric matrixes in order to improve or modify one or more characteristics of the material: improve their mechanical properties, increase their resistance to thermo-oxidative processes, modify their surface properties, increase their crystallinity, improve their creep behavior, reduce the gas permeability, give antibacterial properties, etc. This nano-filler is industrially used in the automotive and packaging sectors as

[10]Giannelis, E.P. *et al*. Adv. Polym. Sci, 118, 108-147, **1999.**
[11]Alexander, M. Materials Science and Engineering, 28, 1-63, **2000.**

well as in the construction for the preparation of materials and elements with improved fire resistance, since the clay layers reduce the gas permeation and act as protection to the polymeric matrix.

Fire resistance panels are prefabricated structural elements for use in building walls, ceilings, floors, and roofs. They provide superior and uniform insulation compared to more traditional construction methods. Different nano-powders are used as mass-ingredients in the technology of structural insulated panels at different dosages up to 20% by weight in order to enhance fire retardant properties. The main nanoclay reinforcements used are of hydrated sodium calcium aluminium silicate (Van Broekhuizen and van Broekhuizen, 2009).

The health effects of bentonite and kaolin clays, which are widely used in different industrial fields, have been fairly extensively examined. Bentonite is formed of highly colloidal and plastic clays composed mainly of montmorillonite. Kaolin is a mixture of different minerals with the main component being kaolinite. The large variability in composition of clay materials has, however been a challenge for the hazard characterization. The amount of crystalline silica, which is always present in clays, has often been the decisive factor in clay induced toxicity. As a summary, there is still very little information about the possible carcinogenicity or genotoxicity of bentonite and kaolin clays.

Based on the available studies it has been shown that long term exposure to kaolin may lead to pneumoconiosis but that the potency is at least one order of magnitude less than quartz. Bentonite is likely to be less dangerous to humans than kaolin.

Table 19. Summarized information regarding the toxicity of nanoclays

Introduction	Layered silicates 1 nm thick and 10-1000 nm side; micrometric aggregates
Acute toxicity	Low toxic potential
Irritation and sensitization	No data was found
Repeated dose toxicity	No repeated dose inhalation studies were found
Reproductive toxicity	No data was found
Genotoxicity	Few studies available; mainly negative results.
Carcinogenicity	No data was found
Cytotoxicity	Some in vitro studies indicate a cytotoxic potential.
Conclusions	Limited data available. Evaluation complicated by differences in/unclearness related to composition.

So far, there is only very limited data available on the potential toxicity of nanoclays. Concerning the available toxicological data on nanoclays it is of importance to take into account that the physico-chemical properties usually vary between different materials and also the test systems used(e.g. dosing, in vitro cell culture/in vivo mice/rats, treatment time) are usually different, which makes the comparison of results challenging. As many nanoclays are modified to form nanocomposites, it seems important to elucidate if the modifiers are causing the toxic events or if the nanoclay itself can induce harmful effects. Repeated dose inhalation studies are needed to confirm the possible pulmonary toxicity of nanoclays.

Carbon nanofibers

Carbon nanofibres (CNFs) typically have a diameter of 50-200 nm and structurally they resemble MWCNTs. The primary characteristic that makes them different from CNTs is the graphene alignment - if the graphene plane and fiber axis do not align, the structure is defined as a CNF. It is less expensive to produce CNFs as compared to carbon nanotubes and they are used, for example, in composite materials to improve strength, stiffness, electrical conductivity, or heat resistance. Despite the widespread use of CNFs, their toxicity has not been extensively studied.

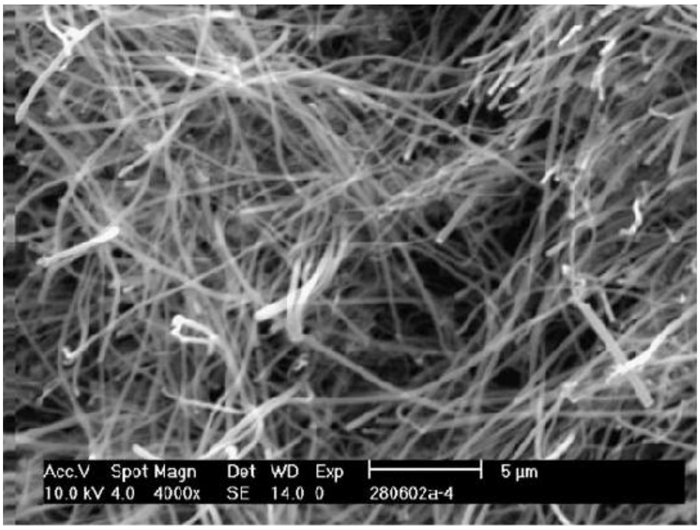


Figure 16. SEM image of Electrovac VGCF, ENF© 200 nm.[12]

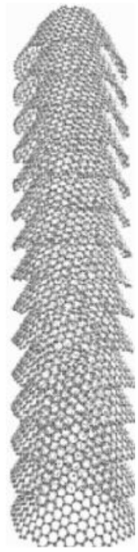


Figure 17. Ideal representation of a carbon nanofiber

[12]Hammel E. *et al*. Carbon 42, 1153–1158, **2004.**

Table 20. Summarized information regarding the toxicity of carbon nanofibers

Acute toxicity	No data was found
Irritation and sensitization	No data was found
Repeated dose toxicity	A few studies available, indicating local pulmonary inflammatory and systemic immunological effects
Reproductive toxicity	No data was found
Genotoxicity	One study found, indicating a genotoxic potential
Carcinogenicity	No data was found
Conclusions	Based on the very limited data, there are indications that these materials may cause pulmonary inflammation. Evaluation complicated by differences in/unclearness related to composition.

CNFs have been studied for their potential health hazards only in a limited amount of studies. Based on the available data, there are indications that these materials may cause pulmonary inflammation. One study also indicates a possible genotoxic potential of CNFs. Therefore it would be critical to carry out further studies on the toxic effects of these materials.

Appendix 5: The Value Chain

A value chain is a chain of activities that a firm operating in a specific industry perf**orms in order t**o deliver a valuable product or service for the market.[13]In order to define the needs and gaps that may exist in the occupational exposure to MNMs in the construction sector, it is essential to define the stages in which a worker could be exposed, in what way and how to attenuate the associated risks.

For the SCAFFOLD project we have designed a similar value chain for the MNMs exclusively focused on the construction sector, and more specifically, on the risk prevention aspect. Figure 18shows the different stages where workers might be exposed to MNMs.

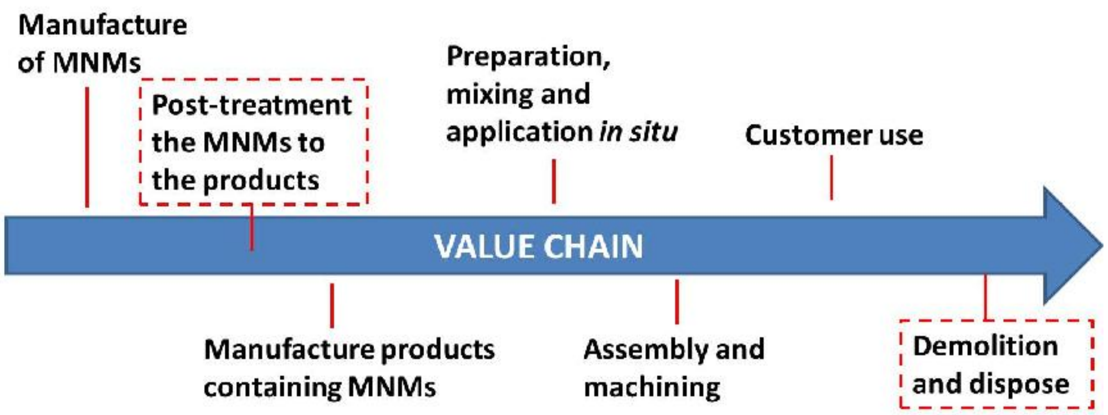


Figure 18. Value chain of MNMs in the SCAFFOLD project

In order to illustrate this concept, a real case has been chosen: the use of nano-TiO_2 in cement based matrixes for photo-catalytic application.

ACCIONA Infrastructure has developed along with Grupo Tolsa a photocatalytic additive based on TiO_2 nanoparticles supported on sepiolite nanofibers. The objective of supporting the nano-TiO_2 onto the sepiolite surface is threefold:

- Minimizing the aggregation degree of the TiO_2 nanoparticles by reducing their high surface energy
- Improving the photocatalytic efficiency of the TiO_2 nanoparticles; the clay surface possesses a polar nature and the pollutants in form of organic molecules tend to adhere to its surface, where their experience decomposition catalyzed by the TiO_2 nanoparticles.
- Reducing the risks associated to the manipulation of matter at the nanoscale, since the aggregates of TiO_2-sepiolite possess a structure in the micro-scale, Figure 19.

[13] Porter, M. E. (1996). What is strategy? Harvard Business Review, November–December, 61-78.The value chain.

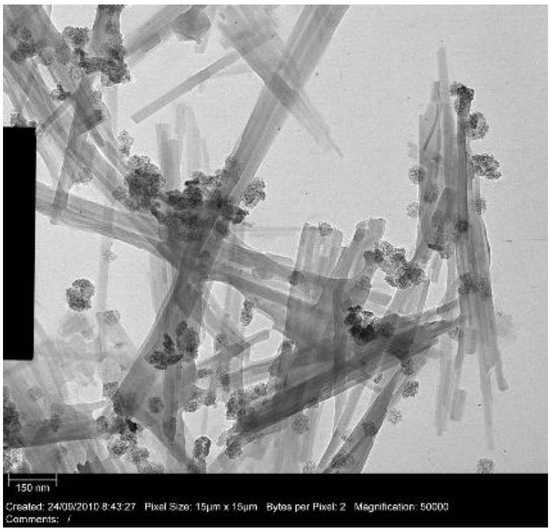


Figure 19. TiO_2-sepiolite additive developed by ACCIONA Infrastructure and Grupo Tolsa

Stages in the value chain:

- Manufacture of the MNMs. This is a key stage in the design of MNMs in a safe way. As explained above, the MNMs can be designed and synthesized in such a way that is potentially less harmful for the human health.
- Post-treatment or adaptation of the MNMs to the products. After their synthesis, nano-additives can be prepared for delivery and use in safe forms such as stable suspensions or embedded in pellets or polymeric matrixes.
- Manufacture of products containing MNMs. This stage consists in the preparation of a product containing the MNMs. In Figure 20 a paving stone and in Figure 21 façade panels containing TiO_2-sepiolite are shown.

Figure 20. Paving stone with TiO_2-sepiolite

Figure 21. Façade panels containing photocatalytic TiO_2-sepiolite

- Preparation, mixing and application in situ/Assembly and machining. These activities consist in the use of the products containing MNMs in the worksite for its use. Figure 22 and Figure 23 show the assembly of the paving stones and the paving of a bus station with concrete containing the mentioned additive.

Figure 22**.** Assembly of paving stones at ACCIONA´s parking lots in Madrid

Figure 23. In situ preparation, mixing and application of photocatalytic concrete in a bus station in Ávila, Spain

- Customer use. The product, regardless its form and shape is ready for being used by the customers. Figure 24 shows the ground in the bus station ready to drive on it.

Figure 24**.** Bus station in Ávila

- Demolition and disposal (Figure 25). This stage is critical, since during this step, multiple nature MNMs can be released without control and moreover.

Figure 25. Exposure measurement during demolition activity

Appendix 6: European Commission's 2012 position on safety and transparency aspects of nanomaterials

Source: Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. Second Regulatory Review on Nanomaterials. 2012.

4. SAFETY ASPECTS

4.1 Nanomaterials in the workplace, in consumer products and in the environment

Natural and incidental man-made nanoparticles are ubiquitous in the human environment and their presence and behaviour is generally known and understood. However, limited data exist on manufactured nanoparticles in the workplace and the environment. There are major technical challenges to monitor their presence, including those pertaining to their small size and low concentration levels and to distinguishing particles of manufactured nanomaterials from natural or incidental nanoparticles. Detecting nanomaterials in complex matrices such as cosmetics, food, waste, soil, water or sludge is even more challenging. While some monitoring methods exist, these often remain to be validated, which hampers comparability of data.

4.2. Safety, risk assessment, and risk/benefit assessment

Since 2004, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Scientific Committee on Consumer Safety (SCCS), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) have been working on the risk assessment of nanomaterials.

In 2009, SCENIHR concluded that *"while risk assessment methodologies for the evaluation of potential risks of substances and conventional materials to man and the environment are widely used and are generally applicable to nanomaterials, specific aspects related to nanomaterials still require further development. This will remain so until there is sufficient scientific information available to characterise the harmful effects of nanomaterials on humans and the environment."*

It further asserted that "*health and environmental hazards have been demonstrated for a variety of manufactured nanomaterials. The identified hazards indicate potential toxic effects of nanomaterials for man and the environment. However, it should be noted that not all nanomaterials induce toxic effects. Some manufactured nanomaterials have already been in use for a long time (e.g., carbon black, TiO_2) showing low toxicity. Therefore, the hypothesis that smaller means more reactive, and thus more toxic, cannot be substantiated by the published data. In this respect nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case-by-case approach for the risk assessment of nanomaterials is still warranted."*[14]

[14] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf, p. 52 and p. 56.

EFSA in its 2011 scientific opinion[15] confirmed that the risk assessment paradigm used for the evaluation of standard food products is also appropriate for nanomaterial applications in the food and feed chain and the need for a case by case approach. Such a case-by-case approach is in place through the pre-market approval system in food and feed legislation (such as novel foods, food additives, feed additives, plastic food contact materials). A similar approach was adopted by the EMA for medicinal products.[16]

Despite certain limitations as mentioned by the Scientific Committees and Agencies, in particular the need for a case-by-case scientific approach when assessing differences between bulk and various nanoforms of the same chemical substance, it is possible to perform risk assessments of nanomaterials today.

Several risk assessments and risk/benefit assessments have been completed and various products in different sectors have been authorised (such as 20 medicines and three food contact materials[17]). The SCCS has assessed and approved the safety of one nanomaterial used as a UV filter and is completing the assessment of three other nanomaterials. Other substances will be assessed as the case arises (e.g. UV filters, food and feed ingredients).

Harmonization and standardization of measurement and test methods in support of risk assessment of nanomaterials is being promoted through the OECD and by a Commission Mandate to the European Standards Organisations.[18]

A study launched by the Commission in 2011 on occupational risks of nanomaterials, and other relevant research, including on the fate of nanomaterials in the environment and in waste, will provide more insight for further legislative guidance and risk assessment work.

Research concerning safety and the development of reliable test methods will also remain a key priority under the EU Framework Programmes and for the Commission's Joint Research Centre.

5. REACH AND CLP

Pursuant to REACH[19], chemical substances imported or manufactured in the EU must in most cases be registered with ECHA, demonstrating their safe use. The registration dossier or

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15 Scientific opinion on "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain" (2011), 9(5):2140.

16 http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000345.jsp&mid=WC0b01ac05800baed9

17 Namely silicon dioxide, carbon black and titanium nitride. Silicon dioxide has also been authorised as food additive.

18 M/461 EN of 2.2.2010

19 Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 136, 29.5.2007, p.3. Unofficial consolidated version see: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20110505:en:PDF

substance may be subject to evaluation. Depending on its characteristics, any substance may be subject to authorisation or restrictions. REACH applies equally to substances for which all or some forms are nanomaterials.[20]

The CLP Regulation[21] provides an obligation to notify to ECHA substances in the forms as placed on the market, including nanomaterials, which meet the criteria for classification as hazardous, independent of their tonnage.

The European Parliament called on the Commission to evaluate the need to review REACH concerning simplified registration for nanomaterials manufactured or imported below one tonne, consideration of all nanomaterials as new substances, and a chemical safety report with exposure assessment for all registered nanomaterials.

5.1. Coverage of nanomaterials in REACH registrations and CLP notifications

Many substances exist in different forms (solids, suspensions, powders, nanomaterials, etc.). Under REACH, different forms can be considered within a single registration of a substance. However, the registrant must ensure the safety of all included forms and provide adequate information to address the different forms in the registrations, including the chemical safety assessment and its conclusions (e.g. through different classifications where appropriate).

The information requirements of REACH registration apply to the total tonnage of substance, including all forms. There is no prescription to undertake specific tests for each different form, or to spell out the way in which the different forms have been addressed in the registrations, although the REACH dossier structure allows this and the technical advice from ECHA encourages it.

In close collaboration with ECHA, the Commission has assessed how nanomaterials have been addressed in REACH registrations and CLP notifications. As of February 2012, 7 substance registrations and 18 CLP notifications had selected "nanomaterial" as the form of the substance in voluntary fields. A further assessment identified additional substances with nanoforms.[22]

Many registrations for substances known to have nanomaterial forms do not mention clearly which forms are covered or how information relates to the nanoform. Only little information is specifically addressing safe use of the specific nanomaterials supposed to be covered by the registration dossiers. These findings can partly be explained by the absence of detailed guidance to registrants on registration for nanomaterials and the general wording of the REACH annexes.

The Commission Recommendation on a definition of nanomaterial will clarify terminology, but will in itself not provide the necessary clarity to the registrants on how to address nanomaterials in REACH registrations.

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20 For an explanation of terminology see http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanomaterials_en.pdf

21 Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labeling and packaging of substances and mixtures, OJ L353, 31.12.2008

22 For details see SWP, chapter 5.2 and appendix 3.

The Commission will therefore, based on available information on technical progress, including the REACH Implementation Projects on Nanomaterials and experience with the current registrations, in the upcoming REACH review assess relevant regulatory options, in particular possible amendments of REACH annexes, to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations.

5.2. Substance identification and registration timelines

Many substances exist as bulk and nanoforms. The nanoforms can be seen as forms of the same substance or as distinct substances. In the latter case, the question arises whether they are treated as "new" substances and whether they would be subject to immediate registration.[23]

When more experience from the evaluation of registrations is available, ECHA will provide guidance on treating nanomaterials as forms of a bulk substance or as distinct substances with the aim of enabling effective data sharing. The results of the REACH Implementation Project on Nanomaterials on Substance Identification (RIPoN1) suggest, however, that some flexibility will be needed. Whether nanoforms have been addressed in one or several registrations, for the Commission the key issue remains whether the registration provides clear information on the safe use for all forms of the substance.

5.3. Chemical safety assessment

RIPoN on Information Requirements (RIPoN2) and the RIPoN on Chemical Safety Assessment (RIPoN3)[24] address – inter alia - the question whether the existing REACH requirements and the relevant guidance are appropriate to assess nanomaterials. They contain a number of specific proposals.

RIPoN 2 concluded that, with a few caveats, the guidance at the time of the project and the information requirements were considered applicable for the assessment of nanomaterials. RIPoN3 concluded that known exposure assessment methods were generally applicable but may still experience methodological challenges.

The REACH approach to hazard assessment and risk characterisation, with its built-in flexibility, makes it overall suitable for nanomaterials. The key remaining question is to what extent data for one form of a substance can be used to demonstrate the safety of another form, due to still developing understanding of e.g. drivers of toxicity. In a case-by-case scientific approach:

- Clarity is required whether and which nanoforms of a substance are covered by a registration. These nanoforms should be adequately characterised, and the user should be able to identify which operational conditions and risk management measures apply to them.

[23] Any immediate registration requirement for nanomaterials treated as new substance could reasonably only apply from the moment that the interpretation of the REACH provisions was clear enough for registrants to exclude the interpretation that the nanomaterial is a form of an existing substance.

[24] http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon

- Information should be provided on which forms of a substance have been tested, with the test conditions adequately documented.
- Conclusions of a chemical safety assessment should cover all forms in a registration. Where data from one form of a substance are used in demonstration of the safe use of other forms, a scientific justification should be given on how, applying the rules for grouping and read-across[25], the data from a specific test or other information can be used for the other forms of the substance. Similar considerations apply to exposure scenarios and the risk management measures.

ECHA has updated guidance to take into account the final RIPoN Reports. ECHA has set up a Group Assessing Already Registered Nanomaterials (GAARN), who considers in co-operation with the Commission, Member States experts and stakeholders, a few key nanomaterial registrations. The purpose is to identify best practices for assessment and reporting of nanomaterials in REACH registrations and to develop recommendations on how to fill potential information gaps.In addition, ECHA has set up a Nanomaterials Working Group to give advice on scientific and technical issues in relation to nanomaterials under REACH.

5.4. Extension of REACH obligations to small volume nanomaterials

Most nanomaterials which are subject to a scientific debate are manufactured or imported in volumes of 1 tonne per year or more. Small volume nanomaterials are mostly used in technical applications such as catalysts or in applications where the nanomaterials are bound in a matrix or enclosed in equipment. Consumer and environmental exposure to those nanomaterials is likely to be limited.

In line with SCENIHR's conclusion that nanomaterials are similar to normal substances in that some may be toxic and some may not, the Commission does not consider appropriate at present to change the rules for when a chemicals safety assessment is required. As regards registration thresholds and timelines for registration based on volume, the Commission considers REACH appropriate, subject to actions outlined in chapter 7.

6. HEALTH, SAFETY AND ENVIRONMENT PROTECTION IN EU LEGISLATION

The Parliament called on the Commission to evaluate the need to review a number of areas of legislation, including air, water, waste, industrial emissions and worker protection legislation.

- As regards safety and health at work, the ongoing work can be summarized as follows:

In addition to the study on nanomaterials in the workplace[26], a Nano subgroup of the Chemicals working party set up under the Advisory Committee on Safety and Health at Work is working on a draft opinion on risk assessment and management of nanomaterials at the workplace, to be subsequently endorsed by the Advisory Committee. A final assessment on a review of occupational health and safety legislation will be made by 2014 in the light of these activities and respective conclusions.

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[25] REACH, Annex XI, section 1.5

[26] See section 4.2

- As regards consumer product safety legislation, work is under way on adapting the relevant legislation in order to transpose the horizontal definition and to introduce specific provisions on nanomaterials; on updating the relevant risk assessment processes; on strengthening market surveillance; and on improving information and labelling requirements:

The Commission is committed to implement the definition of nanomaterials in consumer product safety legislation, when appropriate. Specific provisions on nanomaterials have been introduced for biocides, cosmetics, food additives, food labelling and materials in contact with foodstuff.

At the same time, the Commission undertook a detailed analysis of how consumer product legislation is being implemented with reference to nanomaterials. The main challenge remains the implementation of a proper risk assessment, also in those areas where legislative change has been implemented.

Therefore, for instance, EFSA has at the request of the Commission adopted a guidance document[27] clarifying the data to be provided when submitting an application dossier for a nanomaterial to be incorporated in food and feed.

Similarly, guidance has recently been developed by the Scientific Committee on Consumer Safety for cosmetic products.

The Commission takes the view that current legislation on medicinal products allows an appropriate risk/benefit analysis and risk management of nanomaterials.

For legislation on medical devices, actions under consideration include a labelling requirement in a proposal foreseen for 2012. In addition, the Commission is considering to reclassify devices containing free nanomaterials under Class III, making them subject to the most severe conformity assessment procedure(s).

The Commission considers that New Approach and in general consumer product legislation allow nano-specific issues to be taken into consideration.

Market surveillance is a key element in effective consumer protection, and the Commission is facilitating a joint surveillance pilot project with various Member States on the presence of nanomaterials in cosmetic products.

A main issue in the debate on nanomaterials is consumer information and labelling of nanomaterials. Nano-ingredient labelling has been introduced in products of relevance to consumers, notably food and cosmetics.

Similar provisions can be envisaged for other regulatory schemes where ingredient labelling already exists, allowing consumers to make an informed choice.

- As regards environmental legislation, the evaluation[28] of this legislation identified and assessed environmental exposure pathways for nanomaterials relevant to each

[27] Scientific opinion on "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (2011)", 9(5):2140.

piece of legislation, the level of control afforded over possible releases of nanomaterials and the associated risks.

The evaluation showed that all environmental legislation reviewed could be considered to address nanomaterials in principle. Nevertheless, this might pose challenges and has not been tested in practice. Principal triggers of pollutant identification are hazard classification under CLP and exposure information. There is still a considerable lack of data on exposure to nanomaterials via the environment. Consequently, no specific provisions for nanomaterials have yet been established in EU environmental legislation, triggering measures to control such pollutants through monitoring, separate treatment or environmental quality standards. This applies also to the risk management responses explicitly identified by the European Parliament: new environmental quality standards, revision of emission limit values, a separate entry for nanomaterials in the list of waste and the revision of waste acceptance criteria in landfills. As risk characterisation may depend on particle size or surface functionalization, it is anticipated that setting the precise scope, dose metrics and value of any thresholds employed under environmental legislation, if necessary, would be more challenging than for conventional pollutants. REACH should generate relevant data in this respect.

Even when it is possible to show the presence of specific nanoparticles in environmental media or waste, it would be technically difficult to separate or eliminate them. Therefore 'end-of-pipe' measures would not be effective to prevent potential negative impacts on the environment or health, nor would they allow addressing any emerging recycling challenges or need for remediation in a cost-effective manner.

Although the Commission does not exclude specific provisions in downstream environmental legislation, potential risks are normally best addressed "upstream" by REACH and product legislation.Any CLP classification of a nanomaterial will automatically unlock some operative provisions across a range of environmental legislation that serve to control releases of hazardous substances into the environment.

The Commission is also taking steps to ensure that remaining implementation gaps of the legislation are addressed. For example, revisions of the selection process for priority substances under the water legislation and the relevant BREF[29] documents under industrial emissions legislation, incorporating various nanomaterial aspects, are already being pursued.

Developing capacity to monitor and model nanomaterials, e.g. in the environment is necessary. This will facilitate the evaluation of the efficiency of different tools of the environmental legislation and inform appropriate risk management strategies. Where necessary, this will be supported by targeted implementing environmental legislation.

7. NEED FOR BETTER ACCESSIBLE INFORMATION

Transparency of information on nanomaterials and products containing nanomaterials is essential. This has been recognised by the Parliament which has called on the Commission to

[28] http://ec.europa.eu/environment/chemicals/nanotech

[29] BREFs - Best available technique REFerence Documents define Best Available Technique (BAT) for individual industrial sectors under the Industrial Emission Directive

evaluate the need for notification requirements for all nanomaterials, including in mixtures and articles, and the Council, which invited the Commission to evaluate the need for the further development of a harmonized database for nanomaterials, while considering potential impacts.

Current knowledge about nanomaterials does not suggest risks which would require information about all products in which nanomaterials are used. Experience so far shows that, if risks were to be identified, they could be handled with the existing tools such as the General Product Safety Directive[30] and its RAPEX system[31], or more specific instruments under EU product legislation.

Currently available information (such as the information presented in the attached Staff Working Paper and the information generated by existing legislative tools such as REACH and the Cosmetics Regulation) is considered a good basis for policy making.

As a first step, the Commission will create a web platform with references to all relevant information sources, including registries on a national or sector level, where they exist. A first version mainly based on links to available information will be put on line as soon as possible. The Commission will assist in the elaboration of harmonised data formats, to improve exchange of information. In parallel, the Commission will be launching an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

8. CONCLUSIONS

In the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required.

The definition of nanomaterials will be integrated in EU legislation, where appropriate. The Commission is currently working on detection, measurement and monitoring methods for nanomaterials and their validation to ensure the proper implementation of the definition.

Important challenges relate primarily to establishing validated methods and instrumentation for detection, characterization, and analysis, completing information on hazards of nanomaterials and developing methods to assess exposure to nanomaterials.

30 Directive 2001/95/EC OJ L 11, 15.1.2002.
31 http://ec.europa.eu/consumers/safety/rapex/index_en.htm

Overall the Commission remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013.

The Commission will carefully follow developments, and report back to the Parliament, the Council and the European Economic and Social Committee within 3 years.