LICARA Guidelines for the sustainable competitiveness of nanoproducts

Citation

Som C., Zondervan-van den Beuken E., Van Harmelen T., Güttinger J., Bodmer M., Brouwer D., Buist H.E., Carroll R., Coll C., Fransman W., Hartmanis A., Hincapie I., Hischier R., Karachalios T., Kouravelou K., Kuijpers E., Ligthart T., Notter D., Nowack B., Seibold U., Schneider G.: LICARA Guidelines for the sustainable competitiveness of nanoproducts, Dübendorf, St. Gallen, Zeist, 2014.

Layout and print at Empa, version 29.09.2014

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement Number 315494.

Preface
The LICARA Concept

Great expectations surround the potential for engineered nanoparticles and nanomaterials to be key elements in the development of innovative materials, products and applications. Yet there are still numerous unanswered questions about these types of products:

- What are their nano-specific benefits?
- What are the nano-specific risks to humans and the environment?
- How sustainable are these products?
- What are the legal issues?

These Guidelines were designed to help small and medium-sized enterprises (SMEs) deal with these questions.

What is the added value for an SME?

LICARA is the acronym for an EU FP7 project named 'Life Cycle Assessment and Risk Assessment of Nanoproducts'. It has developed the **LICARA concept** which helps SMEs to:

1. Make decisions about developing and producing safe, sustainable products by gathering relevant information to answer the pertinent questions;
2. Learn from best practices;
3. Build a coherent argument about nano-products for suppliers, clients, consumer groups, authorities and other stakeholders (a comprehensive guide to the nanoproduct).

The **LICARA guidelines** help to implement the concept itself and are directed at SMEs that:

- Produce nanoparticles for wide or narrow fields of application;
- Produce intermediate products using nano-particles;
- Produce end products with nanoparticles and nanomaterials.

The guidelines are accompanied by a first version of an analytical tool in Excel, the **LICARA nanoSCAN**, that facilitates the implementation of the guidelines themselves.

The guidelines are based on the scientific work of three research institutes – TNO, Empa and RAS – and the experiences of private sector companies (NCB, SNT, Freso, Nanothinx and AGPYME) which were partners in the LICARA project.

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Scope and limits

The **LICARA guidelines** and their accompanying tool – known as **LICARA nanoSCAN** – should be used to assess the benefits and risks of engineered nanoparticles, nanomaterials and nanoproducts. However, it is also possible to use the guidelines and tool for incidental nanoparticles (nanoscale particles produced by anthropogenic processes such as combustion) provided that their composition and physicochemical properties are known.

Nanoproduct developers should be aware that a regulatory risk assessment of the nanomaterial or nanoproduct may also be necessary, as may a detailed business case.

Furthermore, strong sectorial knowledge is needed to make robust decisions. As the **LICARA guidelines** and the **LICARA nanoSCAN** tool are generic, we do not claim completeness (for instance food and medical applications are excluded from the **LICARA nanoSCAN** due to strict regulations in the use phase).

Outline

Part one of this brochure, structured in seven steps, provides background information and lists the relevant questions which need to be answered to develop competitive and sustainable nanoproducts. Part two describes the modular **LICARA nanoSCAN** tool which enables SMEs to answer these relevant questions and to evaluate the results in a semi-quantitative way. Part three and the annex present further information.

The **LICARA guidelines'** seven steps can be followed from the start of new product development using a qualitative approach. Or, the **LICARA nanoSCAN** tool can be used in order to evaluate benefits and risks of a new nanomaterial or product in a semi-quantitative way. Both the **LICARA guidelines** and the **LICARA nanoSCAN** tool are structured in modules: the guidelines in 'steps' and the tool in 'boxes'. Any module can be looked at first and only the modules of interest need to be selected or applied. Furthermore, results can be updated and re-evaluated by applying the guidelines and the tool (see Figure 1, next page).

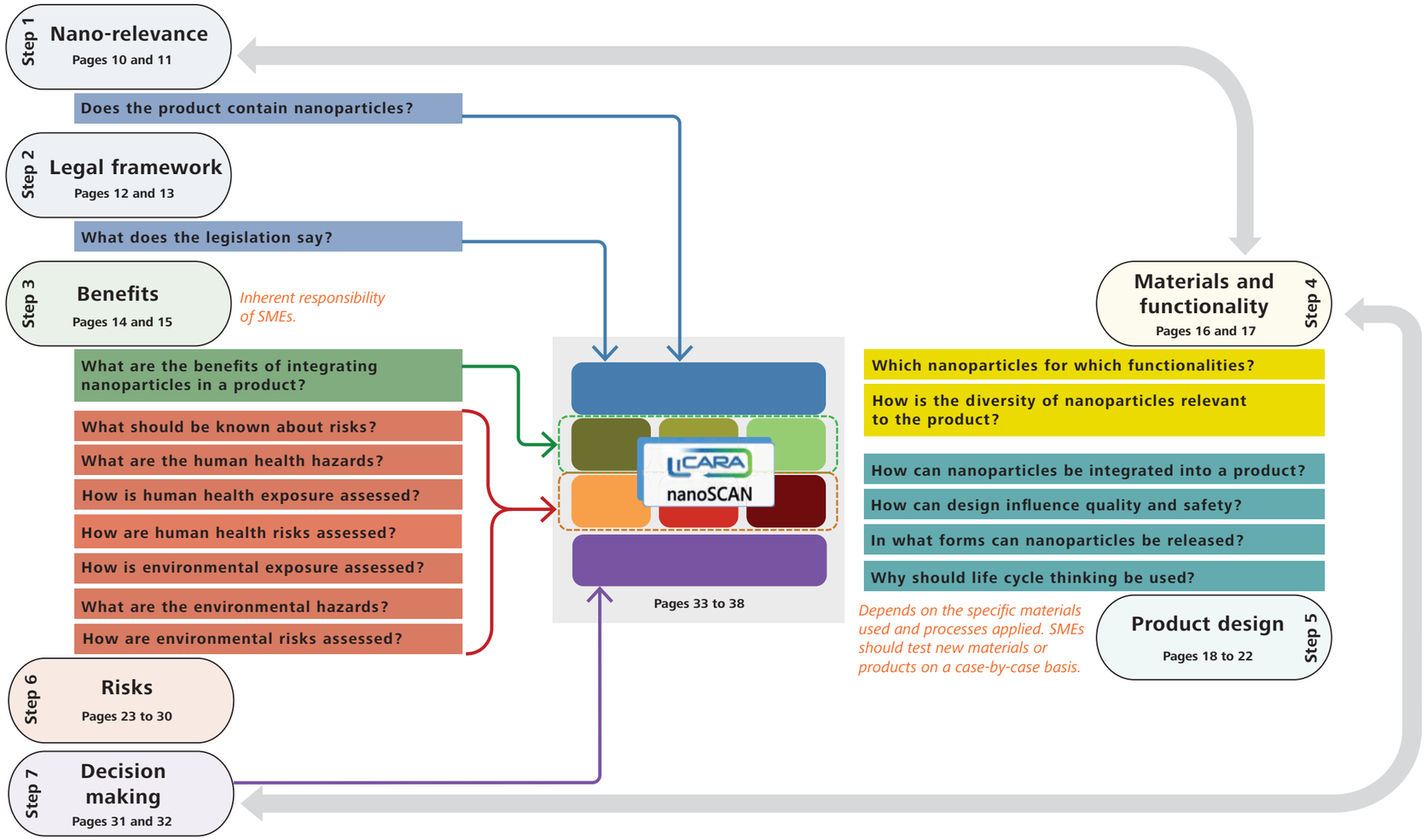

Figure 1. Illustration of the LICARA concept, and the interfaces between the guidelines and the tool.

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Step 1. Nano-relevance
Does the product contain nanoparticles?

'Nano' is the Greek term meaning 'dwarf'. Like other prefixes, it stands for a certain size scale. The term 'nanotechnologies' embraces technologies to analyse and to manipulate nanoscale structures and these nanomaterials themselves.

In these guidelines, we will use the terms: '**nanomaterials**', '**nanoparticles**' and '**nanoproducts**'. The term '**nanomaterials**' includes:

- Nanoparticles, i.e. single nanoscale particles (spheres, fibres, plates);
- Nanostructured material, such as agglomerates and aggregates of nanoparticles and nanocomposites containing nanoparticles (see Figure 2).

Nanoparticles have various shapes and sizes with one to three dimensions between 1–100 nm: spherical (3 nano-dimensions), fibre (2 nano-dimensions) or plate (1 nano-dimension).

Currently, there are several alternative international definitions of nanomaterials and nanoparticles (e.g. EU, ISO[1], see Figure 3). Some of these definitions are still in development.

In some cases, therefore, it may be difficult to assess whether a given product contains nanomaterials or not. It is important to know whether one is dealing with nanoparticles in relation to:

- Taking responsibility for risk assessment and management;
- Legal compliance and accountability;
- Relevance of the LICARA concept and LICARA nanoSCAN.

More information on the definition of a nanomaterial can be found in sector specific regulations, e.g. for food, food additives, food contact materials, and biocides (see Step 2. The legal framework).

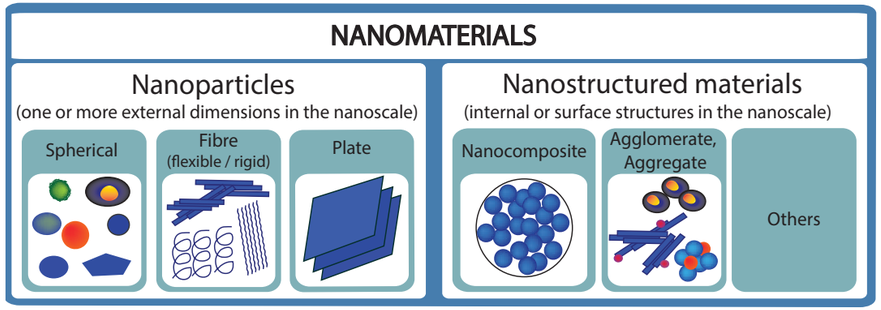


Figure 2. Explanation of the terms 'nanomaterials' and 'nanoparticles' as used in these guidelines.

1 International Organization for Standardization

Nanomaterial definitions

European Commission 2011/696/EU	Natural, incidental or manufactured material containing particles in an unbound state, as aggregate or as agglomerate. Where 50 % or more of the particles in the number size distribution have one or more external dimensions is in the size range 1 - 100 nm.
International Organization for Standardization ISO/TS 80004-1:2010	Material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale (size range from approximately 1 to 100 nm). See also engineered nanomaterial, manufactured nanomaterial and incidental nanomaterial.

Figure 3. Current, 2014, EU and ISO definitions. The term 'nanoparticles' as used in these guidelines approaches the term 'nano-objects' used by the ISO and the term 'nanomaterial' used by the EU. The ISO differentiates the term 'nano-objects' into 'nanoparticles', 'nanofibres' and 'nanoplates'. The EU uses the term 'nanomaterial' if 50% or more of the particles with one or more external dimension is in the size range 1–100 nm; it also includes incidental and natural materials[2]. (Disclaimer: these definitions may adapt over time).

Apply Box 0 in the LICARA nanoSCAN to assess whether the product contains nanoparticles.

[2] For more information please see also JRC 2014: Towards a review of the EC Recommendation for a definition of the term "nanomaterial", Part 1: Compilation of information concerning the experience with the definition, © European Union, (2014).

Step 2. The legal framework
What does the legislation say?

The following background information helps to provide an initial estimation of the relevance of different regulatory issues to nanoproducts. If particular legislation is indeed relevant to a product in development, we recommend contacting the competent national authorities or a member of the LICARA consortium (contact details are at the end of this compendium).

Nanomaterials are chemical compounds for which the following legislation exists:

Generic legislation: REACH, CAD, CLP, GPSD.

Legislation for specific products: cosmetics, biocides, food, etc.

REACH
REACH is the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It came into force on 1 June 2007. REACH's main aims are to ensure a high level of protection from the risks posed by chemicals. REACH makes industry responsible for assessing and managing those risks and for providing appropriate safety information to chemical users.

As of 31 May 2013, any substances for which 100 tonnes or more per year are manufactured or imported must be registered. Nanomaterials can be registered either as a nano-form of the compound in the bulk substance's dossier or as distinct substances with their own dossiers. Specific guidance for nanomaterials registration under REACH has been issued by ECHA. However, no nano-specific requirements exist as yet. A safety data sheet should be prepared for all substances, including any nanomaterial classified as hazardous.

It is not currently clear whether or not it is obligatory to register a nano-form of a substance separately. Only four substances have been registered as nanomaterials since the 2013 deadline. In September 2013, ECHA updated a document entitled 'Human health and environmental exposure assessment and risk characterisation of nanomaterials – Best practice for REACH registrants'. According to this document, dossiers should contain a "comprehensive" physico-chemical characterisation of any registered nano-form(s).

The next deadline for registration is 31 May 2018. As of this date any substances produced or imported in quantities between 1 and 100 tonnes per year must be registered.

CAD
The EU's Chemical Agent Directive (CAD) states that it is the employers' responsibility to ensure the safety and health of workers related to chemical exposure (98/24/EC).

CLP
The regulation on Classification, Labelling and Packaging of substances and mixtures (CLP) ensures that the hazards posed by chemicals are clearly communicated to workers and consumers in the EU through the classification and labelling of those chemicals.

GPSD
The General Product Safety Directive (GPSD) is intended to ensure a high level of safety throughout the EU for consumer products that are not covered by specific sectorial legislation (e.g. toys, chemicals, cosmetics, machinery). The Directive also complements the provisions of sectorial legislation which do not cover certain matters, for instance in relation to manufacturers' obligations and authorities' powers and tasks.

Cosmetics, food, food additives, food contact materials and biocides
When using nanomaterials in products in one of these categories, these substances must be explicitly authorized. If they have not been, then an application for authorization, including a safety assessment, must be submitted to the relevant European authority.

For cosmetics, nanomaterials must be labelled in the list of ingredients with the word 'nano' in brackets following the name of the substance, e.g. titanium dioxide (nano).

Registration of nanomaterials
In 2009, the European Commission was asked by the European Parliament to set up a publicly accessible inventory of the different types and uses of nanomaterials on the European market.

To date, the European Commission has not started creating the inventory and, because of this, national level initiatives are in development for the registration of the use of nanomaterials in products.

France has already started setting up a national database. Its Ministry of Ecology, Sustainable Development and Energy published an overview of the mandatory nanomaterial reporting scheme which came into effect on 1 January 2013. It provides a website[3] to which reports must be submitted, questions and answers on the scheme itself, and gives an annual submission deadline of 1 May.

In Belgium, nanosubstances have to be registered by 1 January 2016, while mixtures will have to be registered by 1 January 2017.

The registration of nanomaterials is also being discussed in other EU countries such as Norway, Sweden, Denmark and the Netherlands.

These legislative aspects are dealt with in a very simple way in LICARA nanoSCAN Box 0.

For more detailed information, see also the relevant links on the LICARA website.

[3] *www.r-nano.fr*

Step 3. Evaluate the benefits

What are the benefits of integrating nanoparticles in a product?

In principal, nanoscale materials have explicit properties which make them different from bulk materials made of the same compounds:

- High surface reactivity due to greater surface area available in the nano-form than in the traditional bulk form;
- Improved or completely new properties caused by quantum effects;
- Structural specificities, such as size, shapes, structures in the nanoscale or the thickness of coatings (e.g. transparency of the nano-particles due to their size, improvement of materials' chemical properties by adding nanostructure – lotus effect);
- Reduced costs because lower amounts of materials are needed for the same functionality (e.g. catalysts).

However, the integration of nanomaterials into products in order to benefit from these properties has to be investigated on a case-by-case basis. Below, we describe some relevant examples, however, it must be noted that many other examples may exist too.

The integration of nanomaterials can enable:

1. Improved functionality
The nano-form of the clay mineral, Attapulgite, for example, is known for its effectiveness in swiftly tailoring the rheology of drilling fluids in order to reduce friction. This discourages the use of other more expensive additives, and improves functionality.

2. Novel functions
A highly absorbent sponge made of nanofibrillated cellulose can suck up engine oil, silicone oil, ethanol, acetone or chloroform within seconds. Because it floats so reliably on water, it can be used to absorb oil spills and is recoverable even when fully saturated. A further desirable property is that it is biodegradable.

Nano-cellulose sponge is a light material made from recycled paper, wood or agricultural by-products. By adding water and pressing the aqueous pulp through very narrow nozzles at high pressure, a suspension with gel-like properties is created, containing long, interconnected cellulose nanofibres. The nano-cellulose sponge is then formed by replacing the water in the gel with air using freeze-drying.

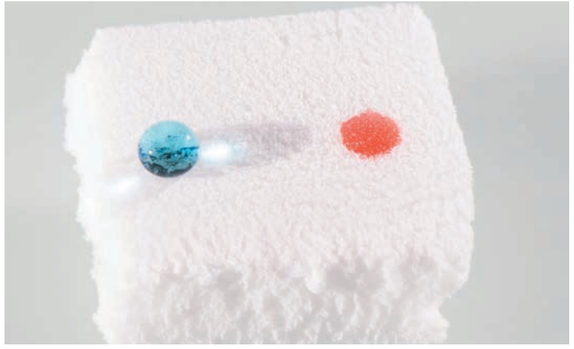


Figure 4. Chemically modified nano-cellulose: This new, absorbent material could be very useful in oil spill accidents (a blue-dyed drop of water runs off, while a drop of red-coloured oil is absorbed).© Empa, Applied Wood Materials.

3. Multifunctional products
New properties/functionalities may be added to a material without influencing its existing properties, e.g. polymers can be made flame resistant by adding nanoscale layered aluminosilicates.

Benefits
Thanks to such improvements in the functionality of conventional products, nanomaterials can improve:

- **Environmental performance**
  - through lighter materials reducing the energy needed to transport products;
  - through more robust surfaces extending product life spans;
  - through safer materials replacing hazardous substances;
  - through better structured materials saving energy and resources during production, e.g. fuel cells that are not only lighter, but require smaller amounts of rare metals.
- **Economic performance**
  - through improved marketability or profitability.
- **Social performance**
  - through technological breakthroughs that provide substantial improvements in efficiency, opportunities to develop new energy technology and Information and Communication Technologies;
  - through stimulating the need for a skilled and highly qualified labour force;
  - through the benefits of increased agricultural yields or food products with improved nutritional values;
  - through supporting human health, e.g. cleaner water, better sanitation or cures for diseases.

Apply Boxes 1–3 in the LICARA nanoSCAN to assess whether the nanoparticles bring benefits to the product.

Which nanoparticles can be used for which functionalities?

The integration of nanoparticles with specific theoretical qualities into materials and products may improve or enable a wide variety of functionalities. However, there is no guarantee that the intended functionality appears in the end product. It is therefore necessary to know both the specific physicochemical properties of the nanoparticle itself and its interactions with the product's matrix material.

Table 1 shows a selection of relationships between nanoparticles and functionalities in order to give a first understanding of which nanomaterials might have the potential to enable a specific functionality in materials and products.

Table 1. Selection of potential functions of nanoparticles investigated and integrated in products (e.g. composites, coatings, textiles, energy production; though excluding food and medical applications). Functionalization or coating of nanoparticles may influence their functionality. There is no guarantee that the intended functionality appears in the end product.

Nanoparticle type / Potential functional effects	Ag	ZnO	SiO_2	TiO_2		Al_2O_3	"nanoclay"	CB	CNT	MWCNT	SWCNT	Fe_2O_3	ZrO_2	CeO_2	CuO	MgO/ Mg(OH)
				Anatase	Rutile											
Abrasion resistance		✔	✔			✔	✔		✔							
Antimicrobial activity	✔	✔		✔	✔										✔	✔
Antistatic	✔							✔	✔	✔	✔					
Carrier of active agents			✔				✔									
Catalyst															✔	✔
Dirt repellent		✔	✔	✔												
Easy to clean				✔												
Electrical conductivity	✔							✔	✔							
Flame retardant		✔	✔	✔	✔	✔	✔		✔	✔	✔					✔
High chemical resistance						✔										
Hydrophobic (water repellent)		✔	✔	✔	✔											
Hydrophillic			✔													
Magnetic												✔				
Mechanical (stiffness and hardness)			✔			✔			✔	✔	✔		✔	✔		
Optical (UV reflection)		✔			✔							✔		✔		
Photo catalytic activity		✔		✔	✔											
Pigment		✔		✔		✔		✔				✔				
Scratch resistance		✔				✔							✔	✔		
Self-cleaning	✔	✔	✔	✔	✔											
Thermal conductivity	✔								✔	✔	✔					
Thermal insulation		✔	✔	✔	✔				✔	✔	✔					

Nanoparticles can be produced in different sizes, shapes and densities. Furthermore, they can be functionalized using coatings, by binding other functional compounds to their surfaces or by the substitution of single atoms. These various methods change the nanoparticles' physicochemical properties, resulting in a great diversity of forms, even if they are all originally made from the same element or compound (Figure 5).

Thus each different type of nanoparticle may interact with its surroundings (product matrix, biological media in organisms, environmental compartments such as soil, air, water) and the technosphere (i.e. waste water treatment facilities, incineration, etc.) in a complex and unpredictable way.

When developing a new nano-enhanced product it is important to:

- Evaluate and test the functional benefits of the nanoparticles or nanomaterials in the product on a case-by-case basis;
- Critically evaluate nanomaterials' environmental, technical and economic performance along the whole product life cycle.

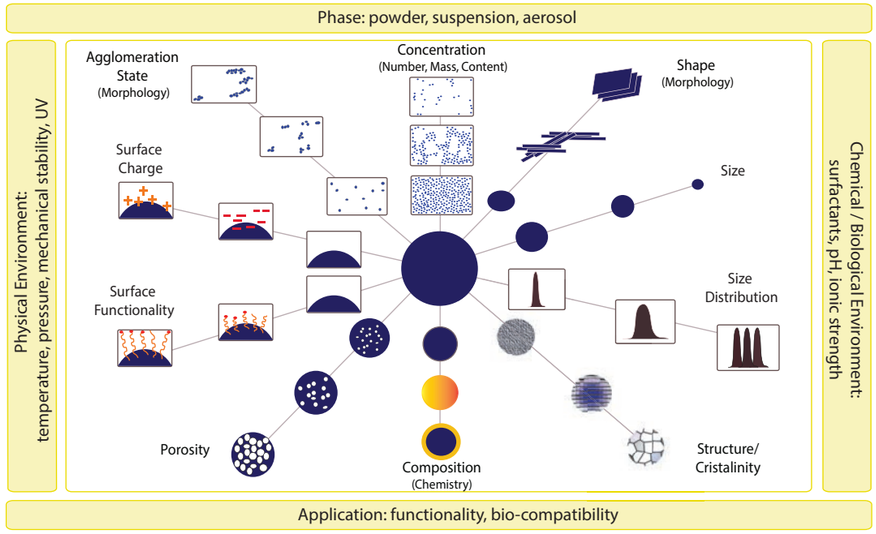


Figure 5. Diversity of nanoparticles. Adapted after M. Hassellov, et al. 2008.

In what forms can nanoparticles be integrated into products?

Depending on the type of product and the desired functionality, nanoparticles can be integrated:

- As free powders, stabilized particles in a dispersion/suspension, or incorporated into masterbatches/granulates in polymers (e.g. in paints, facade coatings, textile fibres, see Figure 6);
- By a dispersion/suspension on the surface of a material (e.g. on textile fibres);
- *In situ*, i.e. produced during the process (e.g. plasma coating of surfaces) or nanoparticles grown on a defined surface (e.g. carbon nanotubes grown on electronic devices, see Figure 7);
- As distinct nanoparticles fixed in a sol gel. These nanoparticles may build large networks during the sol-gel process and thus no longer exist as single nanoparticles in the end product.

A nanomaterial can be produced:

- By embedding nanoparticles in a matrix or on the surface of the material;
- By producing nanostructures such as nanostructured surfaces or nanoporous materials (these do not fall within these guidelines; they do not contain nanoparticles and thus pose no nano-specific risks to humans or the environment).

Figure 6. Masterbatches:
1. Nano-Ag form of AgPURE W10 is incorporated into a polymer (e.g. PA, PET or PP) to form a masterbatch;
2. A certain amount of this masterbatch is added to polymer fibres via extrusion;
3. The fibre containing nano-Ag is then knitted to become a cleaning cloth, for example. Source: RAS Materials.

Figure 7. Nanoparticle integration into products:
1. CNT from Nanothinx;
2. Nanoparticle suspension;
3. Integration in a product.

Conclusion: The quality and functionality of a final product will greatly depend upon the process knowledge and process control during the integration of nanoparticles. The up and downstream processes are also relevant to the final product quality and go hand in hand with the product's safety and its success on the market. This step requires sector-specific knowledge and is therefore the responsibility of the SME rather than a part of the LICARA NanoSCAN.

How can design influence quality and safety?

The quality and safety of nanoproducts depends on the stable embedding of nanoparticles and nanomaterials. The stability, and thus the durability of the functionality, mainly depends on the affinity between the surface of the nanoparticles and the matrix. When the nanoparticle surfaces are fine-tuned to the matrix then product stability will be higher.

To improve the embedding of nanoparticles dispersed in the matrix, their surfaces should be functionalized with groups which match with the matrix. For this purpose, surfactants can be used which have a high affinity to both the matrix and the nanoparticles. Table 2 shows other factors that can influence stability.

High product quality and functionality go hand in hand with safety and sustainability. Stable embedding of nanoparticles prevents their unintended release and thus reduces the risks to human health and the environment. It also positively influences the durability (life expectancy) of a product and thus its sustainability[4].

Table 2. Factors that can influence the stability of nanoparticle integration in a product.

'Factors for stability'	Stability of nanoparticle integration in the product's solid matrix[5],	
	tends to be higher when:	tends to be lower when:
1. Compatibility between nanoparticles and their matrix material (fibre polymer, coating)	Nanoparticles exhibit high wettability	Nanoparticles exhibit low wettability
2. Location of nanoparticles in the product	Nanoparticles are fully embedded in the matrix	Nanoparticles are partly or completely exposed on the material surface
3. Bond between nanoparticles and the matrix	Bonds are covalent	Bonds are non-covalent
4. Intrinsic properties of the nanoparticles: • photocatalytic activity of nanoparticles • stability of nanoparticles against aging	 Nanoparticles are not photocatalytic Nanoparticles exhibit high stability	 Nanoparticles are photocatalytic (in organic substances) Nanoparticles exhibit low stability
5. Resistance of matrix material to abrasion or chemical attack	Matrix is resistant	Matrix is not resistant
6. Mechanical properties of the matrix material	Matrix material is flexible	Matrix material is brittle
7. Functional barrier	Functional barrier is present (e.g. coating, plastic layer)	Functional barrier is absent
8. Closed systems, if applicable, e.g. fuel cells, batteries, solar cells, other electronic components	System is fully contained	System is not contained

[4] However, all production processes (see Step 6. Risks) and the end-of-life must also be considered; shredding processes may cause the release of nanoparticles from closed product systems.
[5] Coatings can be seen as extremely thin matrices, thus the table is also valid for nanoparticles in coatings.

In what forms can nanoparticles be released?

In order to improve product design with regard to safety, it helps to understand which types of nanoparticles might be released from it.

During the product's whole life cycle (production, processing, use and disposal or recycling) different types of nanoparticles released could be:

- Pristine engineered nanoparticles: the form of nanoparticle that was originally embedded in the product;
- Aged nanoparticles: after a chemical transformation (e.g. degradation of the nanoparticle coating);
- New nanoscale particles of host matrix material formed by mechanical forces (e.g. grinding, milling);
- New nanoscale particles: composite particles of host matrix and embedded nanoparticles;
- Dissolved forms, and therefore no longer present as nanoparticles.

These different types of nanoparticles can be released from nanoproducts in different forms:

- Fully or partly embedded in solid nanoscale or larger matrix particles;
- Fully or partly immersed in liquid nanoscale or larger droplets;
- As free pristine nanoparticles;
- As agglomerated and/or aggregated particle.

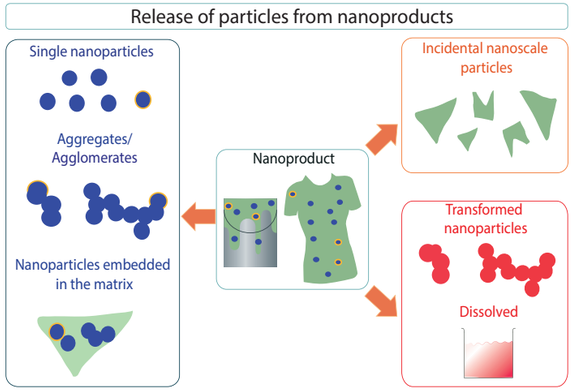


Figure 8. Release of particles from nanoproducts.

The risk of nanoparticles in a wider perspective:
Conventional products which do not contain nanoparticles can still release incidental nanoscale particles due to:

- **Chemical reactions (e.g. formation of nanoparticles from dissolved metals);**
- **Combustion processes;**
- **Mechanical stress;**
- **Heat.**

Why should life cycle thinking be used?

In life cycle thinking, a nanoproduct is examined along its complete life cycle, starting with the production of the nanoparticles and all other product components, continuing throughout its use and ending with disposal or recycling (see Figure 9, next page).

Good qualitative knowledge about a nanoproduct's life cycle may help to identify opportunities that lead to more sustainable products. Nanomaterials or nanoproducts can thus be optimally designed to improve environmental performance, society's image and/or their economic benefits.

More efficient production
Integrating nanomaterials may reduce the consumption of energy and resources and shorten production times, e.g. by accelerating drying times for coatings or improving the colourability of polymers. However, nanomaterials or nanoparticles production may also consume a lot of energy and produce substantial waste. The overall costs and benefits of producing and integrating nanomaterials into a product must be evaluated with care.

Good knowledge of up and downstream production processes may help to further reduce waste and nanoparticle emissions.

Use phase
Using nanomaterials may improve the self-cleaning effect of coatings, extend product life times or decrease the weight of transported products. These improvements clearly save time spent cleaning, cut resource use and reduce the energy consumed in transportation, but costs and benefits should still be evaluated with care. Product users' behaviours are very relevant: there is no need to add self-cleaning coatings if users continue normal cleaning regimes.

Knowing about a product's use phase may help to design it in a way adapted to its wearing processes and to sensitive environments, e.g. if a product is planned to be used in natural water bodies, no ecotoxic nanoparticles should be released.

Disposal or recycling
Authorities and recycling or disposal industries are increasing the pressure on manufacturing industry to take product or material end-of-life into account. It should be verified whether a product will be subject to recycling processes which disturb or release nanoparticles or nanomaterials. In the chapter "How can environmental exposure to nanomaterials be assessed?" there is more information on the behaviour of nanoparticles in waste water treatment and waste incineration plants.

This first findings can be confirmed by applying a quantitative in-depth assessment (see page 39).

Sustainable competitiveness

Proper consideration of a product's life cycle may contribute to:

- Hedging against unwise investments at an early stage of product development;
- Improving product stewardship – stakeholder acceptance of nanomaterials and products;
- Identify opportunities that increase efficiency (material and energy savings) and innovation;
- Hedging against unintentional releases of substances that can lead to large external costs (e.g. long-term environmental effects);
- Helping SMEs understand and improve their environmental performance, while maintaining or improving profits;
- Better compliance with regulations and gaining competitive advantage.

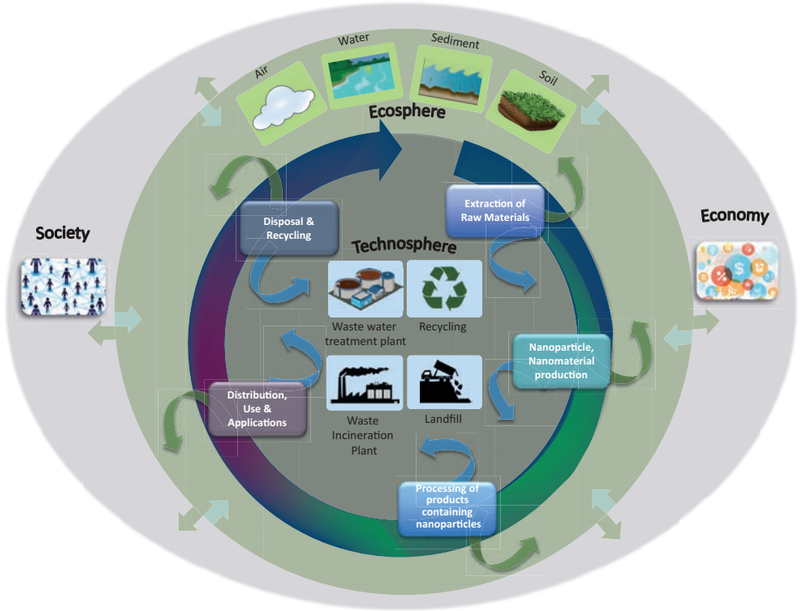


Figure 9. The qualitative life cycle of a product may be used to systematically analyse all its benefits and risks.

Step 6. Risks

What should be known about risks?

Nanomaterials may pose risks to human health and the environment. The degree of risk is determined by the nature and degree of: (1) the toxicological hazard of the nanomaterial, which is an intrinsic property; and (2) the exposure to it, which can be managed.
For the purpose of risk assessment, the released nanoparticles and their aggregates and agglomerates should be considered as a whole. All these forms fall under the term 'nanomaterial'.

Risk assessment of any chemical substance or of nanomaterials (including nanoparticles) consists of two main procedures: hazard assessment and exposure assessment. The hazardous properties of a substance are set against the potential for exposure to that substance, in order to evaluate to what extent exposure will constitute a health risk.

Nanomaterials are categorised into highly heterogeneous groups of materials with different physicochemical properties (i.e. size, charge, hydrophobicity, crystal structure). Their potential risks may vary considerably, even within groups. Furthermore, lots of data on hazardous properties and exposure are still lacking; long-term hazards, have not been extensively evaluated, as such evaluations are time consuming and costly.

The following chapters provide more detail on the potential risks which nanomaterials pose to human health and the environment. They represent the LICARA consortium's evaluation and are based on the current state of knowledge; the potential risks should thus be updated regularly.

Figure 10. The risk is defined by a combination of hazard and exposure:
1. Low risk: high exposure, low hazard;
2. Low risk: low exposure, high hazard; Source: http://www.dogster.com/files/post_images/d02b4a0e98dffae217b8f6e4dfc1008e.jpg
3. High risk: high exposure, high hazard. Source: http://animalpicture.ru/foto-nedeli/fotopodborka-nedeli-4-aprelya/

The hazard posed by a nanomaterial depends on its physical and chemical properties. Furthermore, that hazard may differ depending on the exposure route: inhalation, skin contact or ingestion.

Table 3 gives indications on the hazard potential of various nanomaterials based on their behaviour in toxicity tests.

Table 3. Hazard potential of various nanoparticles and nanofibres.

Hazard potential	Ag [a]	ZnO [c]	TiO_2 [a]	SiO_2 [a] amorphous	Al_2O_3 [# b]	Montmorillonite (nanoclay) [b]	CNT		CB [c]
							Rigid (with high aspect ratio) [b]	Flexible [b]	
Acute toxicity									
– via inhalation	-/+	–	–	-/+	-/+	n.a.	-/+*	-/+*	n.a.
– via ingestion	–	–	–	–	–	–	n.a.	–	–
– via skin contact	–	–	–	–	n.a.	n.a.	n.a.	–	n.a.
Mutagenicity									
	–	–	–	-/+	-/+	n.a	–	–	+
Chronic toxicity (long term effects to be expected)									
– via inhalation	+	+	+	+	-/+	n.a.	++	+	++
– via ingestion	-/+	-/+	–	–	-/+	–	n.a.	n.a.	–
– via skin contact	–	n.a.	–	–	n.a.	n.a.	n.a.	n.a.	–

*a) generally safe; b) uncertainty due to weak evidence; c) clear evidence of toxic effects; # AlOOH was investigated in the lungs; * often depends on contaminants in the samples (especially transition metals such as iron, nickel, cobalt, etc.); ++ high toxicity; + medium toxicity or crosses barriers ; -/+ weak evidence of toxicity; - low toxicity or does not cross barriers; n.a. no data available (high uncertainty).*

The total amount of nanomaterials that might enter a human body (an individual's total exposure level) is determined by adding together occupational exposure (at the workplace), consumer exposure (through product use) and environmental exposure (e.g. via outdoor air, drinking water or food) (see Figure 11).

As the markets for nanotechnology expand, so does the potential for human exposure. Research on occupational exposure focuses on nanomaterial inhalation as a major potential route of impacts on health. The potential for release is related to the type of activities performed with nanomaterials (Table 4, next page).

Activities involving handling large quantities of powdered nanomaterials or spraying products containing nanomaterials are considered to have a high potential for human exposure. Activities involving small amounts of nanomaterials in well controlled, enclosed environments or using nanomaterials incorporated in solid matrices are considered to have a low potential for human exposure.

Figure 11. Exposure routes:
1, 2. Occupational exposure;
3, 4. Consumer exposure;
5, 6. Environmental exposure.

Human exposure to nanomaterials can be reduced by using risk management measures and personal protective equipment. Several technical control measures are effective for exposure to nanomaterials, including fume hoods, local ventilation systems, glove boxes and enclosed systems.

Although occupational and consumer exposure scenarios may be similar, they usually differ in the duration, frequency and knowledge about what is occuring. On one hand, hardly any applications involving powdered nanomaterials are known in consumer products; on the other, nanocosmetics (sunscreens, deodorants, etc.) affect consumers rather than workers. The use of personal protective equipment by consumers may often be recommended but in reality they rarely pay attention to such advice.

Human exposure to nanomaterials via the environment is assumed to be low in comparison with occupational and consumer exposure.

Table 4. Potential for release of nanomaterials from nano-related activities.

Nano-related activity	Potential human exposure	Risk management measures for reducing exposure
Spraying nano-enabled coatings	High	Ventilated spray cabin, face mask
Handling large amounts of powdered nanomaterial	High	Enclosed systems, ventilation, face mask
Batch mixing of powdered nanomaterial with liquid	Medium	Enclosed systems, reduce mixing speed, ventilation, face mask
Handling small amounts of powdered nanomaterial	Low	Enclosed systems, ventilation, face mask
Brushing of nano-enabled coatings	Low	n.a.
Careful use of solid nano-enabled products	Low	n.a.

n.a. no data available

To fully estimate and understand the possible risks of nanomaterials and nanoproducts, an in-depth human health risk assessment is recommended. This involves measuring worker or consumer exposure and assessing the nanomaterial hazard using a combination of existing toxicity data and performing toxicity tests.

Because these measurements, studies and tests are expensive and time-consuming, screening tools (or risk-banding tools) have been developed which can qualitatively estimate the human health risks of exposure to nanomaterials. Although these tools are less accurate than an in-depth risk assessment, they can be used to rank or prioritize risks using a risk matrix (see Figure 12).

The European Agency for Safety and Health at Work (OSHA) published 'Good Practice examples on the risk management of nanomaterials'.

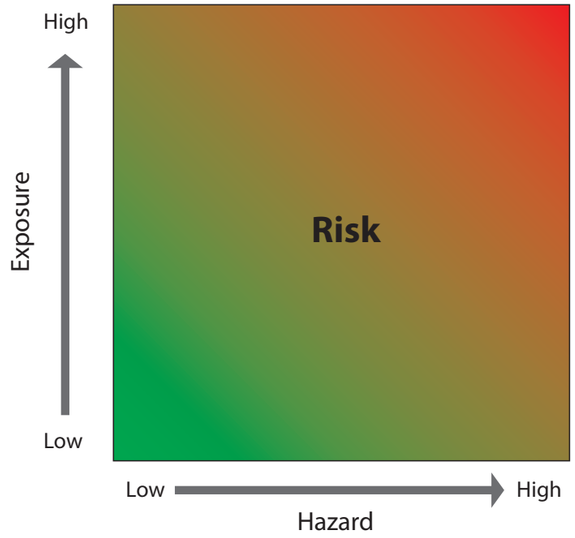


Figure 12. An example of a risk matrix: The magnitude of hazard and exposure defines areas with low risk (green) and high risk (red).

Apply Boxes 4–6 in the LICARA nanoSCAN to assess the human health risks posed by the nanoproduct.

The environmental effects of nanomaterials are determined by their composition. Easily biodegradable nanomaterials (organic nanomaterials) will disappear quickly and have no effects on the environment. For dissolvable nanomaterials, the effects on the environment will depend on the underlying material: if the ions are benign (e.g. Ca) no further effects are expected, however, if the nanomaterials are made of toxic metals (e.g. Cu, Zn) then the effects of the dissolved metals must to be evaluated. Nanomaterials that are neither degradable nor dissolvable can have nano-specific effects and need to be evaluated for these properties. Depending on the kinetics of the degradation or dissolution reactions, nanomaterials may exhibit simultaneous nano-specific and dissolved-ion effects.

Nanomaterials can have a variety of different effects on organisms in the environment and many ecotoxicological tests have been performed. Different effects have been observed depending on the concentrations used in these tests.

Table 5 lists the most important effects observed in ecotoxicological tests on various important nanoparticles.

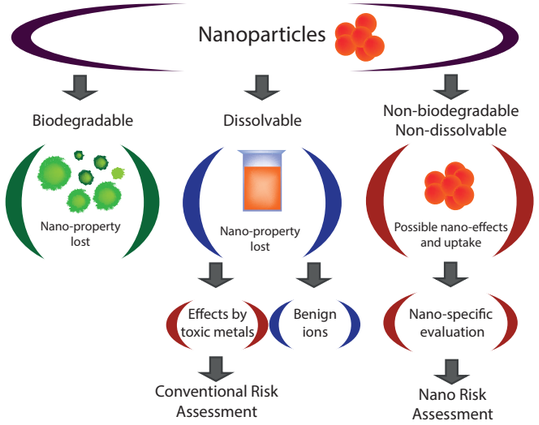


Figure 13. Effects of nanoparticles on organisms are determined by the composition of the particles themselves.

Particle-specific effects, such as the catalytic activity or phototoxicity, can be observed for nanomaterials with specific compositions whereas unspecific particle effects (e.g. shading, coating of organism) are observed for almost all materials at high concentrations.

Table 5. Effects of nanoparticles on environmental organisms.

	Ag	ZnO	CuO	TiO_2	SiO_2 amorphous	Al_2O_3	CNT
Dissolution and toxicity of dissolved ion	++	++	+	–	–	+	–
Catalytic activity / ROS formation	–	+	–	++	–	–	+
Phototoxicity	–	+	–	++	–	–	–
Indirect physical effects at high concentration	+	+	+	++	+	+	++

++ strong effects; + some effects; – not observed/not possible.

Nanomaterials can reach the environment from many direct or indirect sources. Some nanoproducts are designed in such a way that a release of nanomaterials during application or further use is inevitable, e.g. applying sunscreens presupposes almost complete release of the nanomaterials contained in them. For other products, unintended release occurs during use, e.g. from textiles during washing or paints during weathering. Indirect inputs of nanomaterials into the environment can originate from the application of wastewater sewage sludge onto soils. Modelling the flows of nanomaterials using a life cycle approach allows relevant flows to be identified. These models show that the major nanomaterial flows go via wastewater treatment plants, waste incineration plants or landfills. Concentrations of nanomaterials in the environment have been modelled at around 1 µg/l for nano-TiO_2 (titanium dioxide) in water, and at only the ng/l range or lower for most other nanomaterials. Most nanomaterials will end up in soils and sediments.

The technical systems used to treat wastewater and solid waste represent the most important life cycle stage affecting nanomaterial release into the environment. Current knowledge of nanomaterials' fates in these technical systems is summarized in Table 6.

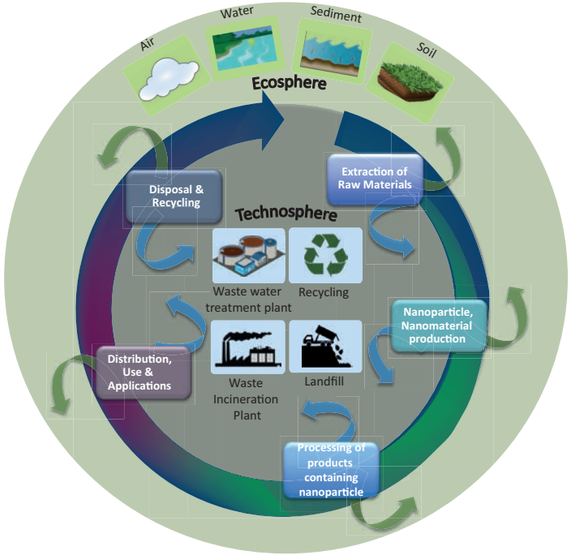


Figure 14. Nanomaterials can be released into the environment during the whole nanoparticle life cycle, from production and use of nanoproducts, through to disposal.

Table 6. Nanomaterial behaviour in technical systems.

Wastewater treatment plants	In general, the vast majority (around 95%) of nanomaterials are removed from water and end up in sludge. Applying sewage sludge to soils represents one of the major flows of nanomaterials into the environment
Waste incineration plants	European waste incineration plants are equipped with flue gas cleaning systems that remove the vast majority (>99.9%) of the nanoparticulate fraction. Nanomaterials therefore end up in filter ash or bottom ash and subsequently go to landfill
Landfills	The behaviour of nanomaterials in landfills is so far unknown
Recycling	No data are as yet available about the fate of nanomaterials during recycling, but it is expected that release may occur to some extent during recycling operations as product matrices may be destroyed

The adverse effects of nanomaterials can be assessed either by a comparison of their toxicity with that of a known reference substance or by modelling the environmental risks.

1. A vast amount of data is available on the effects of nanomaterials on environmental organisms. Different groups of nanoparticles exert different effects based on their reactivity. For soluble nanoparticles, comparing nano and dissolved metal toxicity is possible. LICARA project research has shown that, in most cases, nanoparticles toxicity is less than that of an equivalent amount of dissolved metal. As a precautionary approach, it is therefore reasonable to assess nanomaterial risks based on the risks of the metals they are made of.

2. In order to assess environmental risks, concentrations of nanomaterials in the environment should be compared to data on ecotoxicological effects. The REACH framework for chemicals suggests expressing the risk as the ratio between the predicted environmental concentration (PEC) and the predicted no effect concentration (PNEC).

$$Risk = \frac{Exposure}{Effect} = \frac{PEC}{PNEC}$$

A risk quotient <1 indicates that the risk – within the particular environmental compartment and under specific conditions – is controlled. Such risk quotients have been published previously and were mostly found to be well below 1, indicating no current risks. However, for nano-TiO2 and nano-Ag in water, values close to or slightly above 1 were predicted, necessitating further evaluations.

3. The LICARA project updated the calculation of risk probabilities for five important nanoparticles in three environmental compartments (water, soil, sediments). In general, the environmental risk posed by carbon-containing nanomaterials (carbon nanotubes and fullerenes) is zero in all compartments. The risks posed by all metal particles in freshwater are very small. There might be potential risks in the sediment compartment due to nano-TiO_2 and nano-ZnO.

The relative ranking of the environmental risks posed by these five nanoparticles is shown below. These relative ratios are valid for the current uses of these nanoparticles (resulting in specific releases) and the known data on their ecotoxicity in the different systems.

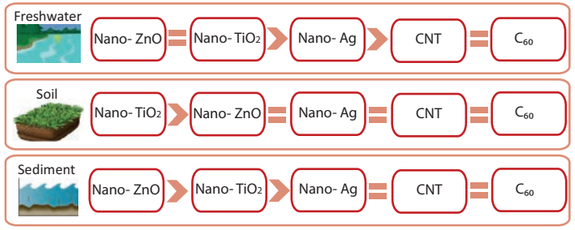


Figure 15. Relative ranking of environmental risks posed by nanoparticles in water, soil and sediments.

Apply Box 4 in the LICARA nanoSCAN to assess the environmental risks posed by the nanoproducts.

How can decision making on nanoproducts be supported?

The LICARA guidelines and their accompanying LICARA nanoSCAN tool provide background information and structured approaches to support decision making about continuing the development of a nanoproduct. They are based upon the well-defined methodologies of Risk Assessment (RA) and Life Cycle Assessment (LCA), which can at the very least give an insight intowhat information is known and what is missing.

Determining whether to continue nanoproduct development is based on the following factors:

- Benefits;
- Risks;
- Data uncertainty and paucity.

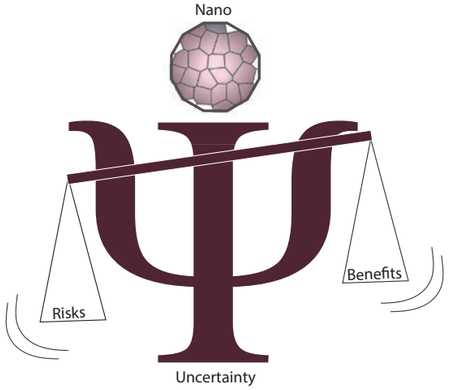


Figure 16. The uncertainty in decision making.

For a nanoproduct to receive a positive assessment, sufficient data must show high potential benefits and low potential risks with a high confidence level. A recommendation can then be given to continue product development and prepare for manufacturing. Less positive assessments require further steps:

- Low assessed benefits suggest a need to modify the nanoproduct or choose another field of application for the nanomaterials in order to increase potential benefits;
- High assessed risks suggest a need to identify ways to lessen nano-related risks;
- Uncertainty suggests the need to collect more data and knowledge in order to reduce the uncertainty, possibly involving a full RA and LCA.

Of course, different benefits and risks are not directly comparable. Different scores with respect to benefits and risks, therefore, have to be weighted against each other in order to be able to interpret the overall score. The LICARA nanoSCAN does this by using the principles of Multi Criteria Decision Analysis (MCDA). A final weighing up of the product-specific factors must be done by the guidelines' user.

The notion that high risks may not be mitigated by high benefits is important. When a product is considered too 'risky' in one aspect or another, it may not be acceptable to the public, the market or policy regulators.

Which data are uncertain for nanoparticles?
In LCA, the actual emission of many nanoparticles and their environmental impacts may be unknown for the production, use and end-of-life stages. For RA, there is great uncertainty in developmental and reproductive toxicity data (used in the hazard assessment), as well as in data on exposure and exposed populations. This means that further in-depth literature research and carrying out an LCA or RA is not always a valid option: in many cases data are simply not available.

How can such data gaps be filled?
In such cases, only a limited number of techniques are able to generate new data. In addition to extensive laboratory testing, consulting experts, stakeholder participation and extended peer review perform best. However, in most cases, these techniques are relatively time consuming and costly.

It is always worth judging, particularly in the case of SMEs, whether the costs of improving knowledge about a nanoproduct are outweighed by the true value of that additional information. It may be more cost-effective to accept the uncertainty in the assessment and deal with it.

How can uncertainty be dealt with?
Uncertain information is inherent to new innovative technologies and products such as nanomaterials. Hence, decision making has to deal with that uncertainty.

One way is to assess relative differences in comparison to a conventional reference product, for instance, indicating the improvements or deteriorations brought by the new innovative product.

MCDA and scenario analysis are especially helpful techniques for dealing with uncertainty without collecting new data. At relatively low cost, they enable users to explore the impacts of possible variations in data or perceptions about the results. LICARA nanoSCAN uses these techniques to evaluate data sensitivity.

Nevertheless, potential nanoproduct manufacturers should be aware that despite all these techniques, in the end, the most important thing is a solid argument to back up the final decision. This is why a transparent, structural approach helps the manufacturer to give stakeholders a convincing explanation of the next steps in the development of a nanoproduct. This is the conceptual approach taken by the LICARA nanoSCAN.

Apply Box 7 in the LICARA nanoSCAN facilitates decision making on the nano-products.

LICARA nanoSCAN
Introduction

What is the LICARA nanoSCAN?
The LICARA nanoSCAN is a first version of a tool that guides SMEs through their decision-making processes about new nanoproducts. It does this by:

- Scanning both the benefits and risks over the nanoproduct's life cycle in comparison to a conventional product with a similar functionality;
- Estimating economic, environmental and social opportunities;
- Identifying the nano-specific risks facing consumers, workers and the public and the environment;
- Supporting interpretation of the results, reflected in a consistent argument about the weaknesses and strengths of the nanoproduct;
- Giving guidance on next steps;
- Using little quantitative data;
- Combining state-of-the-art know-how in Life Cycle Assessment and Risk Assessment;
- Integrating existing tools that are backed by renowned agencies or private institutions;
- Using a modular approach.

The LICARA nanoSCAN supports SMEs in checking supplier risks, competing products, market opportunities or in making a complete internal risk and benefit analysis (Figure 17). The final result should not be regarded as the scientific truth (since scientific evidence on nanoproducts is still limited), but rather as a convincing argument about a nanoproduct's strengths and weaknesses, including uncertainties and knowledge gaps and their relevance.

This supports manufacturers and their stakeholders in their decision making on further assessment, research, development and production of a particular nanoproduct.

What is the status of LICARA nanoSCAN?
The LICARA nanoSCAN was tested using four selected case studies. In order to simplify LICARA nanoSCAN's use by SMEs, its questions and potential responses have been developed into a first-version Excel tool.

This facilitates the execution of all the different assessment steps, translates current state-of-the-art know-how into understandable information and advice and gives an evaluation of the results. Thus, the first version of the Excel tool itself, is not completely validated.

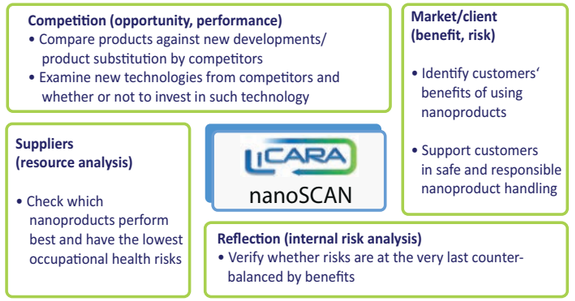


Figure 17. How the LICARA nanoSCAN supports decision making.

How does the LICARA nanoSCAN work?

LICARA nanoSCAN is designed in a modular way and contains eight sections or boxes (Figure 18). Each box is relevant to a specific aim. Whatever the aim, the process should start with the blue Box 0. This box will help to: (1) characterize the nanoproduct in order to assess whether performing the LICARA nanoSCAN is actually relevant; and (2) check whether the product is compliant with current regulation.

Subsequently, three types of benefits (the second-row green Boxes 1–3) and three types of risks (the third-row red Boxes 4–6) are assessed. Each box can be used independently to assess its particular benefits or risks. Results are presented at the end of each box on a scale from 0 to 1.

Purple Box 7 evaluates the overall synthesized result and thus can only validly support decision making about a product if all the benefit and risk boxes have been completed.

The questions involved are qualitative and semi-quantitative and can thus be answered without detailed nanomaterials and technology data.

What is the LICARA nanoSCAN based upon?

LICARA nanoSCAN is based upon principles of LCA, RA and MCDA. LCA is suited to assessing the environmental benefits of a new product over its full life cycle, in comparison to a reference product (mainly Box 1). RA is used to assess the risks (based upon hazard and exposure) of certain activities or processes (Boxes 4–6). MCDA is used as it is a method particularly applicable when decisions need to be made, yet there is uncertainty and a paucity of data. This is especially the case when developing new innovative products such as nanoproducts.

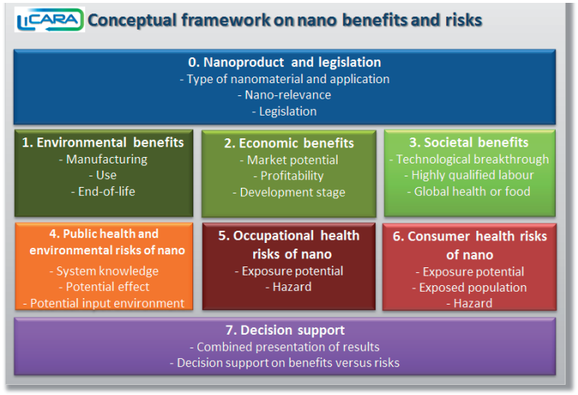


Figure 18. Conceptual framework for LICARA nanoSCAN.

In order to best take full advantage of all the relevant existing know-how and experiences concerning the assessment of nanoproducts, LICARA nanoSCAN is based upon parts of a number of existing tools:

Precautionary Matrix:

- Scope: nano characterization (Box 0) and public health and environmental risk (Box 4).
- By: Swiss Federal Office for Public Health and Federal Office for the Environment.

Stoffenmanager Nano:

- Scope: occupational health risks (Box 5)
- By: TNO, ArboUnie, Beco.

NanoRiskCat:

- Scope: consumer health risks (Box 6).
- By: Danish Environmental Protection Agency, the Technical University of Denmark and National Research Centre for the Working Environment.

How are the benefits and risks presented?

The benefits and risks of the nanoproduct are presented using two graphs (Figure 19). The benefits and risks are presented for each of the three categories (dark-coloured bars) and their underlying subcategories (light-coloured bars). The dark-coloured bar is the average of the underlying scores of the light-coloured bars (if there are any), assuming that each underlying issue is equally important.

The error bars represent the incompleteness of the analysis, indicating the possible minimum and maximum scores resulting from the ambiguity caused by unanswered questions (left blank or 'unknown'). When questions are left unanswered, a worst case scenario approach is used, specifying the most negative answer (negative benefit or highest risk). Large error bars can thus be reduced and the assessment improved, by answering more questions.

What does the scale mean?

Both the benefits and risks of a nanoproduct are evaluated in comparison with a conventional non-nanoproduct.

For nanorisks, this is easy, since only nanoproducts have nanorisks; conventional products do not. This does not mean that the overall health risk (e.g. caused by conventional chemicals) of the conventional product is necessarily lower. These risks are addressed in a simplified manner in the environmental benefits section, and in a more detailed way in the in-depth assessment section (integration of LCA and RA).

Nanoproduct risks are presented on a scale from 0 to 1. Scores below 0.3 indicate low nanomaterial risks, scores from 0.3 to 0.7 indicate moderate risks, and

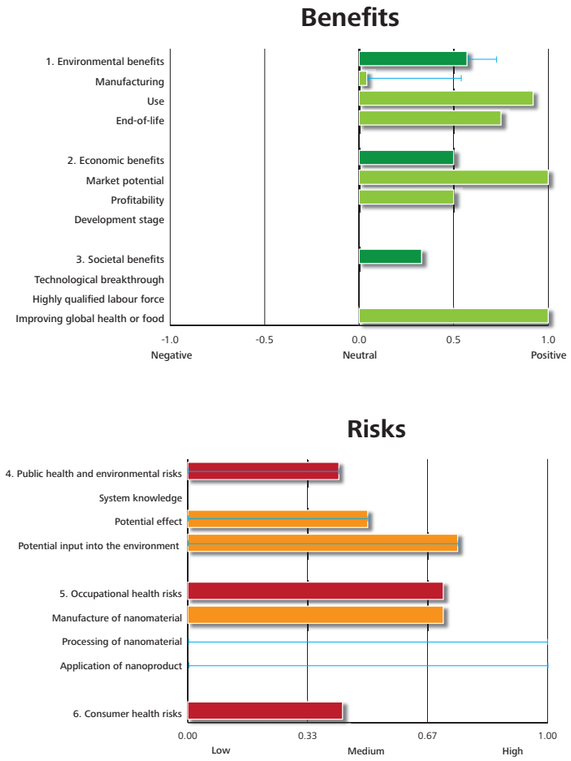


Figure 19. Presentation of benefits and risks in the LICARA nanoSCAN.

a score higher than 0.7 indicates a high risk from nanomaterials. Again, it should be noted that high risks may not be mitigated by high benefits; such a nanoproduct would be considered as too 'risky' and would not be acceptable to the public.

For benefits, the situation is different, since a nanoproduct can be better or worse than the conventional product. The benefits of nanoproducts are therefore presented on an axis ranging from −1 to +1. Minus 1 indicates the lowest, negative benefit (i.e. all aspects of the nanoproduct are worse than the conventional alternative) and plus 1 indicates the highest possible, positive benefit (i.e. all aspects of the nanoproduct are better than the conventional alternative). A score around 0 is 'neutral'; the nanoproduct is as good as the conventional alternative.

How can the example be interpreted?

The graphs in Figure 19 give an indication of the three main benefits and three main risks, including their underlying issues. The benefit profile shows that the nanoproduct has expected benefits over a conventional product in all three benefit categories. Environmental benefits are expected to be highest, and to be primarily found in its use and end-of-life phases. There might also be benefits in the manufacturing phase of the nanomaterial, as indicated by the error bar of 0.5 points. However, this can not be confirmed by the assessment, and questions remain. This unknown aspect in manufacturing translates into an uncertainty of 0.17 points on the total environmental benefits scale.

Medium-range economic benefits are expected due to high market potential and improved profitability; the product is not yet fully developed and hence not ready for marketing and sales.

The societal benefits come in the form of a contribution to global health, not in the provision of enhanced technology or labour skills.

From the risk pattern, it becomes clear that occupational risks in the nanomaterial manufacturing phase are expected to be high. Consumer risks and public health and environmental risks are estimated to be medium. The public health and environmental risk scores are the result of unknowns, as indicated by the large error bars. These risk scores come from applying a worst case scenario approach. In reality, the public health and environmental risks may be lower, but in order to prove this, more information is needed on the nanomaterial's potential effect and potential input into the environment.

How can these results be used?

The graphs are designed in such a way that an estimation of the underlying benefits and risks of a nanoproduct becomes clear, including on issues yet to be resolved, giving differentiated profiles of the nanoproduct's benefits and risks. It gives clues as to possible improvements in different aspects of the assessment and of the nanoproduct itself. Nevertheless, the question which only the integrated evaluation of a nanoproduct can answer remains: is further development of the nanoproduct wise and desirable, or should this be reconsidered?

How should results be interpreted?

Box 7 supports the user for the interpretation of results. The different benefits and risks of nanoproducts are not directly comparable, hence weighting is needed for decision making. The standard evaluation assumes that each benefit and risk category is equally important. Total risks and total benefits are presented in a graph.

It should be noted that the horizontal axis shows net benefits, indicating an improvement of the nanoproduct over the conventional product. If the nanoproduct has fewer benefits than a conventional product, the indicator falls outside the benefit-risk square, meaning that it does not seem worthwhile developing this product further, from a benefit point of view. Again, the error bars represent the incompleteness of the analysis, indicating the possible minimum and maximum scores resulting from the ambiguity caused by unanswered questions (left blank or 'unknown').

When benefits clearly outweigh risks (green area), the nanoproduct is better than the conventional product and nanoproduct development deserves to go ahead. Conversely, if the risks clearly outweigh the benefits (red area), the nanoproduct has disadvantages compared to the conventional product and it does not merit further development. This is almost certainly also the case if the risk in one or more underlying categories is high (as shown in the graph), indicating that the nanoproduct will probably not be acceptable to the public.

In between, an 'Undecided' area (yellow) exists, where benefits and risks are more or less equally important and it is very hard to distinguish the value of the nanoproduct from that of the conventional product. In this situation, an SME could decide to go ahead if it can control risks by minimising exposure or it could do further research.

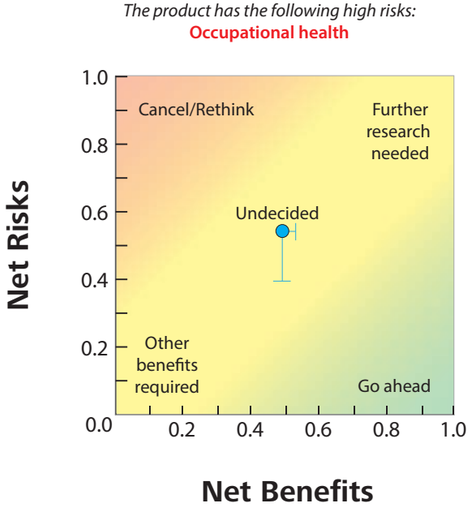


Figure 20. Net benefits and risks as displayed in the LICARA nanoSCAN. The blue spot represents a LICARA nanoSCAN result for even weighting of the benefits and risks. In this case, the error bars indicate space for improvement.

When both benefits and risks are high, further research may be worthwhile to see whether benefits can be claimed with fewer risks, for instance by taking risk mitigation measures. When both the assessed benefits and risks are low, the nanoproduct will probably not generate enough added value. If an SME wishes to continue its development then additional benefits, outside of the scope of the LICARA nanoSCAN tool, will have to be found or the nanoproduct may have to be modified or applied to another field to increase the benefits.

How should results be validated?

As expressed earlier, the LICARA nanoSCAN gives a first, inherently uncertain, indication of the pros and cons of a new nanoproduct. More elaborate, in-depth methods to assess the risks and benefits of a specific nanoproduct in detail are available. These are based upon quantitative data and state-of-the-art RA and LCA methods. This type of assessment generally takes place at a later stage of product development as it requires expert knowledge, voluminous data and a lot of time; it can usually only be conducted by LCA and RA professionals. Performing such an in-depth assessment may nevertheless be a prerequisite for decision making about large investments.

In-depth assessment
Integration of Life Cycle Assessment and Risk Assessment

Objective

In-depth assessments look at benefits and risks in more detail using quantitative data and state-of-the art assessment methods.

Life Cycle Assessment (LCA) is combined with Risk Assessment (RA) focussing on human risks in a situation of significant data paucity and uncertainty. This approach provides a more accurate and detailed picture than the rather qualitative result given by the LICARA nanoSCAN. However, due to its much higher resource requirements, in-depth assessment needs to be carried out by LCA/RA professionals.

Life Cycle Assessment

LCA is a technique to evaluate the environmental impacts associated with a product/service throughout its entire life cycle, usually every stage, from cradle to grave. Specific questions, stages or partial systems (e.g. gate-to-gate systems) can also be assessed using LCA. LCA prevents the shift of burden from one life cycle stage to another (e.g. from production to use) or from one impact to another (e.g. from climate change to human toxicity). The ISO 14040 and 14044 standards describe the techniques for establishing a complete LCA and all the necessary details. LCA is a 'relative' approach; all the system's inputs and outputs are collected in relation to the specific function examined. This represents a benchmark for the comparison of alternatives that cannot be compared *a priori*.

The so-called ReCiPe method is used for impact assessment. In order to evaluate the relevance of the various environmental issues covered by this method, results are shown in a common 'currency' (e.g. 'shadow prices' or ReCiPe points), which allows the overall impact to be calculated as a single indicator.

Risk Assessment

RA's focus on human health issues complements the results of LCA. RAs derive health effect factors and estimate the amount of exposure linked to specific activities and processes along the life cycle of nanoparticles. Nanomaterial impacts are not yet covered by the existing impact assessment methods of LCA.

Combining the results of human health RA with those of LCA produces a more accurate and thus more realistic picture. Results are expressed as disability-adjusted life years (DALY). This is a measure of the overall human health impacts from the releases analysed.

How should results be combined?

'Shadow prices' are used to combine the LCA results of a variety of different midpoint indicators with those of the RA approach described above. This approach uses the highest acceptable costs for mitigation measures as weighting factor, and allows an overall (impact) indicator to be calculated, as well as illustrating the relevance of various impact categories against each other.

For LCA results, 'shadow prices' equivalent to the ReCiPe midpoint indicators are used based on data from CE Delft's 'Shadow Price Handbook'. For the RA result, a conversion factor of EUR 40,000/DALY is used (as established in the framework of the NEEDS project). This combination allows an easy comparison of nanoparticle releases against the impacts of further releases during the life cycle.

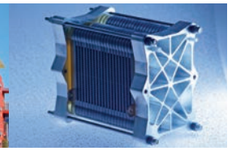
Case studies
As an integral part of the LICARA project, the four case studies below were made in order to verify whether the proposed nanoSCAN concept was applicable.

What do the case studies show?
Each of these four case studies will be documented in its own short report, summarizing the results from the different steps along the nanoSCAN. Each case study begins with a short introduction.

A second part summarizes the results obtained from the LICARA nanoSCAN tool itself.

The third part gives comparative results from the corresponding full assessments using LCA and RA, together with an overall evaluation of the particular case study. These reports will be available on the LICARA project website.

Table 7. Case studies

(1) Microfibre cloth	(2) Antibacterial coating	(3) Self-cleaning coating for outdoor facades	(4) Catalyst for fuel cell applications[6]
			
Two microfibre cloths were compared using different biocides: (i) nano-Ag and (ii) Triclosan	Hospital door handles were coated with a nano-Ag solution in order to reduce infections	A coating with nano-TiO_2 was compared with a normal facade paint	Two PEM fuel cells were compared using: (i) MWCNT, and (ii) carbon black
The environmental performance of the microfibre cloths was examined over their entire life cycle	A total surface area of 1 m^2 of coated door handles was examined over 1 year	The protection of a 1 m^2 coated surface was examined over 75 years	The environmental performance of PEM fuel cells was examined over their life cycle
Nano-Ag has an antimicrobial effect	Nano-Ag has an antimicrobial effect via the release of silver ions	Nano-TiO_2 has a photocatalytic effect (i.e. decomposes organic pollutants, solids or gases on the facade)	MWCNT increase effective surface area and allow a better distribution of platinum in the fuel cell

[6] Picture Nr 4: PEM fuel cell stack with integrated air cooling for 350 W power. Source: ©Fraunhofer ISE.

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
Aggregate	Particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of the calculated surface areas of the individual components
DALY	Disability-adjusted life years. The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability
Functionalization	Configuration of materials or products with new properties by targeted chemical modification of the material or surface properties. For example, by coating, introduction of fillers or structuring of the material
Life Cycle Assessment	A systematic analysis of the environmental effects of products during their entire life cycle. Includes all environmental impacts during production, use and disposal phases, and the associated upstream and downstream processes (e.g. production of raw materials and supplies)
Nanocomposite	Solid comprising a mixture of two or more phase-separated materials
Nanomaterial	Material with any external dimension in the nanoscale or having internal structure or surface structure at the nanoscale (1–100 nm)
Nano-object	Newest designation of ISO/TS 80004-4 (2011) for all materials with one, two or three external dimensions at the nanoscale (i.e. 100 nm). According to their shape, these are divided in nanoparticles, nanofibres and nanoplates
Nanoparticle	Particles with 1–100 nm size in all dimensions
Nanofibre	Fibres with 1–100 nm size in two dimensions
Nanocoating	Coating with 1–100 nm size in one dimension
Nanoproduct	Product that has nanomaterials integrated in its composition
Nanoscale	Size range from approximately 1 nm to 100 nm
Nanosubstance	A substance containing nanomaterials
Precautionary principle	A principle to be used by companies to prevent potential risks or hazards to the environment and human health. A uniform definition of this term does not exist
Risk Assessment	Evaluation of exposure and hazard for human health and the environment

Abbreviations

C_{60}	Fullerenes
CB	Carbon Black
CNT	Carbon Nanotube
ECHA	European Chemicals Agency
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
LCT	Life Cycle Thinking
MCDA	Multi Criteria Decision Analysis
MWCNT	Multi-Walled Carbon Nanotube
NEEDS	New Energy Externalities Development for Sustainability
PA, PET, PP	Polyamide, Polyethylene terephthalate, Polypropylene
PEC	Predicted Environmental Concentration
PEM	Polymer Electrolyte Membrane
PNEC	Predicted No Effect Concentration
RA	Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
ROS	Reactive Oxygen Species
SMEs	Small and Medium-sized Enterprises
SWCNT	Single-Walled Carbon Nanotube
UV	Ultraviolet

Legal and publishing details

Publishers
Empa, TNO, NCB

Acknowledgements
We are thankful to the whole LICARA consortium, EU FP7, Igor Linkov (US Army Engineer Research and Development Center), Tobias Walser (Bundesamt für Gesundheit), Jürgen Höck (Temas), Darren Hart (Publish or Perish), Tanja Grossmann (Communication section, Empa).

Citation
Som C., Zondervan-van den Beuken E., Van Harmelen T., Güttinger J., Bodmer M., Brouwer D., Buist H.E., Carroll R., Coll C., Fransman W., Hartmanis A., Hincapie I., Hischier R., Karachalios T., Kouravelou K., Kuijpers E., Ligthart T., Notter D., Nowack B., Seibold U., Schneider G.: LICARA Guidelines for the sustainable competitiveness of nanoproducts, Dübendorf, St. Gallen, Zeist, 2014.

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Should you require further support in applying the LICARA concept to your nanoproduct, please contact:

- Your industrial sector's association;
- An industrial association for nanotechnologies;
- National authorities;
- Consultants specialising in supporting innovation in SMEs;
- Consultants specialising in Life Cycle Assessment or Risk Assessment.

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