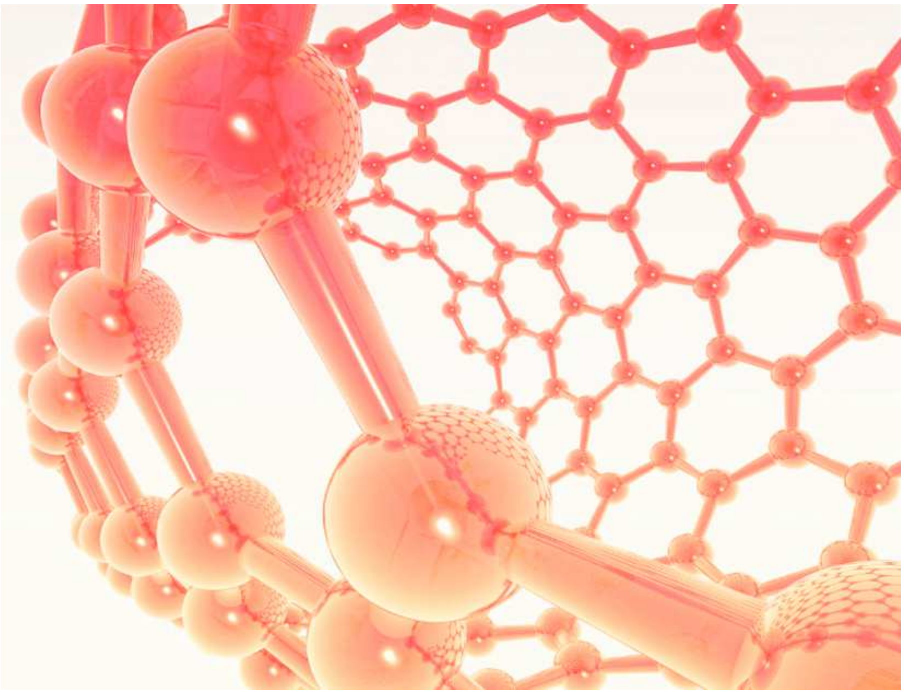
LIFE REACHnano

Development of a web based REACH Toolkit to support the chemical safety assessment of nanomaterials

Guidance for applying Life Cycle Assessment methodology to nanomaterials



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Guidance for applying Life Cycle Assessment methodology to nanomaterials

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1. Introduction and vision

The potential environmental impacts derived from engineered nanomaterials (ENMs) have bring many concern, since despite of the fact that ENMs and nanotechnology-based products are widely used nowadays in several products and different applications, the current knowledge of the possible impact of nanotechnology-based products on the environment and human health is limited.

Life Cycle Assessment (LCA) is the most extensively developed and standardized methodology for assessing the environmental potential impacts throughout a product full life, i.e. from raw materials, manufacturing, assembly, distribution, use and final disposition (scope from-cradle-to-grave). LCA is a structured, comprehensive and internationally standardised method. It quantifies all relevant emissions and resources consumed and the related environmental and health impacts and resource depletion issues that are associated with any good or service, i.e. products.

In order to gain a holistic and comprehensive view on emerging technologies such as nanotechnology the use of tools like LCA is needed. This tool allows analyzing, evaluating, understanding and managing the potential environmental and health effects of a product or a material. The performance of LCA can also provide information regarding the environmental behaviour of these new technologies and products when those are compared to conventional technologies.

The European Commission already stressed the importance of Life Cycle Thinking in nanotechnology in their Communications "Towards a European Strategy for Nanotechnology" (COM/2004/338) and "Nanosciences and nanotechnologies: An action plan for Europe 2005 – 2009" COM/2005/243, where it was stated that *"risk assessment related to human health, the environment, consumer and workers should be responsibly integrated at all stages of the life cycle of the technology, starting at the point of conception and including Research and Development (R&D), manufacturing, distribution, use and disposal or recycling"* and that *"R&D needs to take into account the impacts of nanotechnologies throughout the whole of their life-cycle, for example by using LCA tools."*

Although LCA is considered as the best approach to assess the environmental behaviour of nanomaterials, currently the potential impacts of the released ENM to human and environmental health are not introduced in LCA methods yet and several uncertainties and data gaps exist *(Hischier, 2012; Miseljic, 2014).*

The major challenge is the development of appropriate assessment tools in order to evaluate ENMs following the rapid progress of the nanotechnology. Current approaches for LCA, originally developed for application in mature manufacturing industries and commercial products, suffer from several shortcomings for nanotechnologies application such as uncertainties related to the variability of material properties, toxicity and risk, technology performance in the use phase, nanomaterial degradation and changes during the product life cycle and the impact assessment stage *(Seager, 2009).*

LCA is a relatively young method that became popular in the early nineties that has become a key focus in environmental policy making. The first definition for LCA was done by the Society of Environmental Toxicology and Chemistry (SETAC):

"A process to evaluate the environmental burdens associated with a product, process, or activity by identifying and quantifying energy and materials used and wastes released to the environment; to assess the impact of those energy and materials used and releases to the environment; and to identify and evaluate opportunities to affect environmental improvements. The assessment includes the entire life cycle of the product, process or activity, encompassing, extracting and processing raw materials; manufacturing, transportation and distribution; use, re-use, maintenance; recycling, and final disposal".

LCA is a standardized methodology (see Figure 1). The ISO framework is defined by ISO 14040 and ISO 14044, which fix the methodology of Life Cycle Assessment (LCA) including four interrelated stages:

- Definition of the goal and scope of the study – description of the product system in terms of the system boundaries and a functional unit.
- Life cycle inventory analysis – collection, compilation and calculation of flows data within the defined system.
- Life cycle impact assessment – data of life cycle inventory analysis is organized according to its environmental relevance, and the associated potential impacts are calculated using different impact categories.
- Life cycle interpretation – critical interpretation of results and derivation of conclusions as well as concrete recommendations.

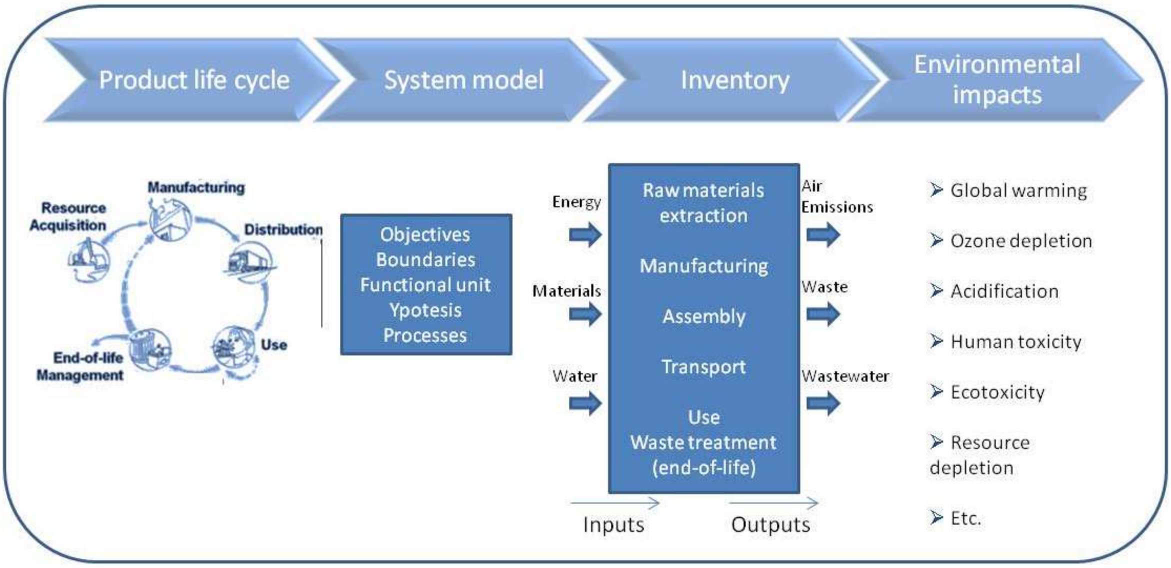


Figure 1. General flowchart for Life Cycle Assessment methodology.

Life Cycle Thinking plays a key role at environmental European policy as it is considered that it provides the appropriate frame to meaningful decision oriented information for policy makers for an effective improvement of products and production processes. The Life Cycle Thinking approach is promoted in policy making by e.g. the Integrated Product Policy (COM/2003/0302) strategy, the new Sustainable Consumption and Production Action Plan of the European Commission (COM/2008/0397) and the Environmental Technology Action Plan (ETAP, 2004).

In the Communication on IPP (COM/2003/302), the European Commission concluded that LCA provides the best framework available for assessing the potential environmental impacts of products. However, the need for more consistent data and consensus LCA methodologies was highlighted. To support life cycle based EU policies, the European Commission created the "European Platform on Life Cycle Assessment (EPCLA)". The platform aims at providing coherent and quality-assured life cycle data, methods and studies. The European Commission developed the ILCD Handbook *(European Commission-JRC 2011);* a series of technical guidance documents to implement the ISO 14040 and 14044.

European Commission's Joint Research Centre has developed recently the Product Environmental Footprint (PEF). The aim of the PEF is the development of a harmonised LCA-based methodology for the calculation of the environmental footprint of products based on existing, extensively tested and used methods. This methodology has been developed building on the International Reference Life Cycle Data System (ILCD) Handbook as well as other existing methodological standards and guidance documents (ISO 14040-44, PAS 2050, BP X30, WRI/WBCSD GHG protocol, Sustainability Consortium, ISO 14025, Ecological Footprint, etc.).

2. Scope and objectives of the guidance

This guidance document is part of a series of guidance documents that are aimed at helping manufacturers and downstream users of ENMs to perform a complete risk and environmental assessment taking into account all life cycles and considerations of nanomaterials.

The development of the guidance was informed by research and technical activities undertaken as part of the REACHnano project, whose main purpose is to develop a web-based platform to support the chemical safety assessment (CSA) of nanomaterials according with the risk assessment procedures and information requirements laid down on REACH.

Overall, the guidance provides recommendations for the application of Life Cycle Assessment (LCA) in the field of nanotechnology and more specifically to nanomaterials and nano-enable products. The current harmonized LCA approaches and methodologies and available environmental impact assessment methods are evaluated in order to adapt them to nanomaterials, considering current gaps and specific characteristics of these nanomaterials. The guideline provides useful recommendations for LCA practitioners and ENMs manufacturers in order to be able to perform a complete environmental assessment of ENMs, identifying the hot spots of the processes during the whole life of nanomaterials in order to design measures to minimize the environmental impacts of these ENMs and the nano-enable products. The guidance particularly assists companies in the selection of adequate methodologies and approaches for environmental assessment following a life cycle approach. It is aimed at:

- Personal responsible for environment and sustainability within companies producing and/or using ENMs;
- Experts from industry associations and other stakeholder organizations informing companies about the sustainability issues for nanomaterials;
- Experts from standardization (i.e. ISO committees) and/or LCA platforms;
- Policy makers and corporate bodies;
- LCA practitioners, researchers from academia, non-profit research organizations and private research institutions.

This guidance can be obtained via the website of the REACHnano project (*http://www.lifereachnano.eu*). Further guidance documents will be published on this website when they are finalised or updated.

Users are reminded that the information in this document does not constitute legal advice.

3. Considerations on LCA Methodology for application on nanomaterials

As stated before, the ISO-framework for LCA (ISO 14040:2006) is considered to be suitable for nanomaterials and nanoproducts, even if data regarding the elementary flows and impacts might be uncertain and scarce. Nonetheless, there are several gaps which need to be taken into account and adaptations and special considerations are needed in order to apply LCA to nanotechnology field and nano-based products in a robust approach. Similarly, to other emerging technologies, the application of LCA to nanotechnology needs a prospective approach in order to assess in a comprehensive way the possible impacts and pathways of ENMs production and use.

Some issues defined by the ISO series 14040 that need further precision for nanotechnology are: a proper and adequate definition of a functional unit in the Goal and Scope phase, a comprehensive and adequate life cycle inventory data, and the development and inclusion of characterisation factors for nano-specific impacts in the Impact Assessment phase *(Kuiken, 2009).* These issues are treated in detail in the following sections of the guide document *(sections 3.1 - 3.5).*

3.1. General methodology of Life Cycle Assessment

Figure 2 shows the four interrelated steps and the iterative approach of the process that should be performed in any LCA study, according to the standardised framework from ISO 14040 and ISO 14044.

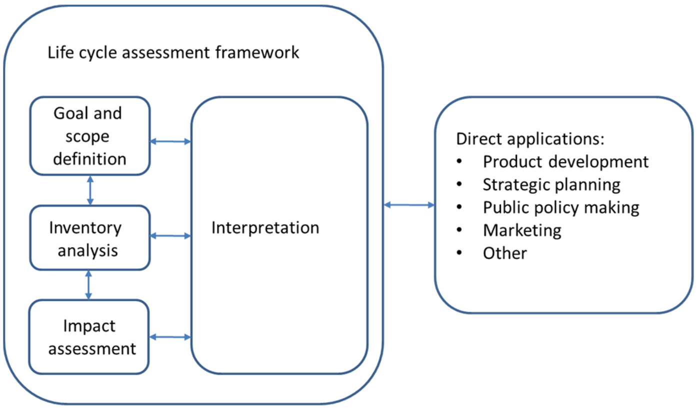


Figure 2. Steps in the preparation of Life Cycle Assessment [adapted from ISO 14040].

3.2. Goal and scope definition

The goal definition is the first phase of any LCA study, and it is decisive for all the other phases of the LCA. In the goal definition, parameters such as the intended application, the reasons for carrying out the study, the target audience or the limitations and assumptions of the analysis are identified and described.

Defining the scope of the LCA study consists in describing in detail the system to be evaluated along with the associated analytical specifications. Scope definition must be in alignment with the goals and the requirements defined previously. The unit of analysis (functional unit), reference flow, system boundaries, cut-off and allocation rules and environmental impact categories for product environmental footprint shall be clearly described in this step.

The unit of analysis, also called the "functional unit", describes qualitatively and quantitatively the function(s) or the service(s) provided by the product, as well as its duration or lifespan. The reference flow is the amount of product necessary to provide the defined function. It constitutes the flow(s) to which all other input and output flows in the analysis are quantitatively related. The reference flow can be expressed in direct relation to the functional unit or in a more product-oriented way.

The scope of the system defines which life stages of the product are included into the system (see Figure 3). Ideally all life stages from raw materials extraction/preparation and production to the end-of-life should by analysed, i.e. scope "from cradle to grave" or "from cradle to cradle". Nevertheless, depending on the objective of the study a more restrictive scope can be taken, assessing only the production stages "from cradle to gate".

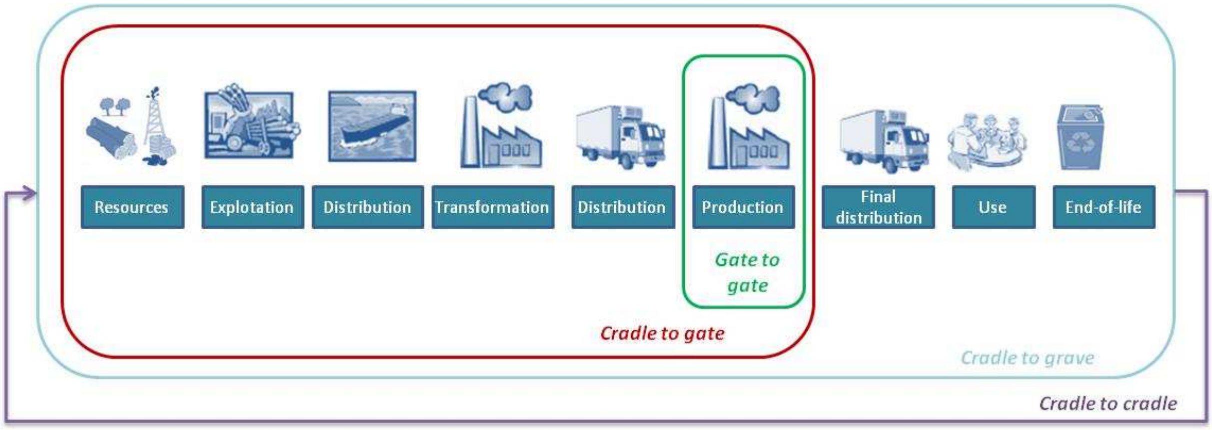


Figure 3. Possible scopes of LCA studies and life stages included.

The system boundaries define which parts of the product life cycle and which associated processes belong to the analysed system (i.e. are required for providing its function as defined by the functional unit). Therefore, the system boundary must be clearly defined for the product system to be evaluated.

In principle, all processes and flows that are attributable to the analysed system have to be included in the system boundaries. However, not all these processes and elementary flows may be quantitatively relevant. The cut-off criteria to be applied indicates which modelled flows must be account according to the relative contribution of each of the environmental impact categories considered. The allocation rules define the assigment of flows between different co-products of the same system. This allocation should be consistent with the characteristics of the different co-producs (physical characteristics like mass, quality or economic value).

Considerations for nanomaterials

Considering the fact that life cycle stages of ENMs such as use or end-of-life are determined by their application within nanoproducts, it becomes clear that release and potential impacts of ENMs are totally dependent on the life cycle of nanoproducts that contain these ENMs *(Som, 2010).* For this reason, LCA shall be focused on nano-enabled products and their application, and not only to the ENM particles.

Nanomaterials can experiment different changes during their life (functionalisation, changes on their properties due to aging, degradation, etc.). Nanomaterials degradation and potential changes during the nano-based product life cycle shall be analysed and considered since they can condition their environmental behaviour and their hazards.

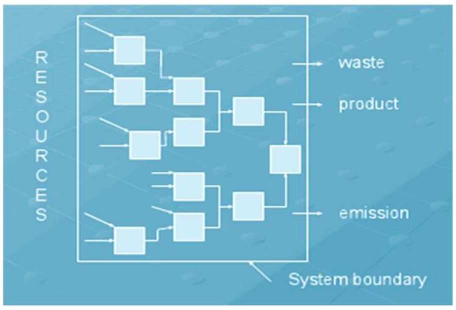
Nanotechnology can offer improved performance and novel functionalities to materials and products, such as the reduction in the use of hazardous chemical substances, the consumption of energy and materials, or the generation of waste, thus increasing efficiency and sustainability. There is a wide and increasing range of novel applications that shall be considered in LCA studies, associated to the functionality of these ENMs (improvement of durability, strength, technical performance, etc.). For this reason, it is especially important to take into account new nano-related functionalities and to cover them adequately in order to define an appropriate functional unit as well as the system boundaries. Normally, ENMs substitute the presence of a "conventional" additive, and this fact should be considered since it can be environmental advantagous comparing to the conventional product.

Regarding the scope, most LCA studies of nanomaterials are only focused on production stages, but it is proved that environmental impacts can occur during all life stages of nanoproducts. For this reason it is recommended to take "cradle to grave" scope, even though some limitations can be found for life stages beyond production since less data and knowledge is available, an estimations and prospective approaches can be needed.

Best practices and recommendations for ENMs

- To perform a cradle to gate LCA, i.e., including all life cycle of a nanoproduct from the extraction of raw materials, production of ENMs, functionalisation, transport processes (and any subsequent transportation), manufacture of ENMs-containing product(s), use of the product(s), recycling and final disposal of the product(s).
- For those stages with little information, consider different scenarios (e.g., end-of-life scenarios).
- To relate the functional unit with the function/use of the nanoproduct, considering the functionalities improved by the ENMs.
- For comparative assessment of an nano-enable product with other equivalent product, reflect the functionality of nanoparticles (durability, performance,…) in relation with the "conventional" product.
- To cover all inventory flows relevant within the system boundaries, including potential release of ENMs in the different life stages.

3.3. Life Cycle Inventory (LCI)



The inventory analysis comprises the data collection and the calculation procedures to quantify the inputs (energy, raw and ancillary materials, water, etc.) and outputs (emissions to soil, emissions to air, water emissions, waste, wastewater and products/subproducts) through the system boundaries. Each life stage is analysed to determine the relevant inputs and outputs of the system, performing a flow balance. To make the process easier, the system is usually divided in several interconnected subsystems.

Quality data requirements are necessary in order to guarantee their appropriateness and representativeness in terms of geography, temporality and technology, information source and accurateness.

Primary data comes from modelling/monitoring processes through real measurements. It is recommended to use primary data for core processes. Secondary data can be used for auxiliary processes; main sources for secondary data are literature and databases (such as the ELCD, European reference Life Cycle Database, or commercial databases like Ecoinvent or GABI).

Considerations for nanomaterials

Several shortcomings and uncertainties are found when applying Life Cycle Inventory (LCI) to nanotechnology-based products. LCI data associated to ENMs are lacking in existing LCA Databases. Representative and rigorous inventory data are needed in order to include this information on current LCA Databases and datasets (see Table 1).

There is a wide variety in the production processes of nanomaterials and these are evolving fast since new synthesis methods, materials, and applications are being developed continuously. Generally, **data on production of ENMs** is limited. The information is often confidential and estimations are needed, which generates uncertainty in data input. This is especially problematic with the amounts produced, consumed and the emissions of particles and gases during processing. Also the uncertainty related to the variability in material characteristics and performance is a challenge. Each synthesis method produces materials with different properties and therefore we need to consider a case-by-case study in each *LCA (Klöpffer, 2007; Seager, 2009).*

In some cases, as it is the case of research projects, synthesis processes are at lab-scale and very often consumptions and inventory data are not representative for industrial scale processes. In order to generate these data on production processes and amounts, close cooperation between scientists and industry is necessary.

For the **rest of the life stages beyond their production, especially for the use and end-of-life** (recycling / disposal) inventory data are scarce. For this reason, these stages are usually not covered in LCA studies of ENMs despite their importance.

Regarding the emission of nanoparticles in different life stages, these flows are usually missing in inventories and only traditional items like energy and material inputs and waste outputs are found in most studies. In order to have a comprehensive analysis of flows and potential impacts, releases of nanoparticles to the environment (to air, water, and soil) should be included. However, currently there is no consensus on how these releases shall be identified and measured. For that reason, it is necessary to collect as many inventory data as possible together to qualitative information in order to assess potential ENMs releases.

The quantity of nanoparticles that are released in the different processes depends on several factors: the concentration of ENMs in the final product, the product lifespan, the technique to incorporate ENMs in the material, the use of the product and disposal routes. Release of ENMs can occur within the different life stages, some potential critical points are the following:

- The synthesis of ENMs and their incorporation into final products are, in many cases, the stages with the greatest potential of ENMs release *(Som, 2010),* particularly during the handling of powders prior to the fabrication of the final nano-enabled products. Exposure to workers during production and handling of ENMs has been studied, but less data exists regarding the potential release to the environment during these stages.

- Release of ENMs during the use stage can be from intended applications (e.g., sunscreens) but also from unintended sources (e.g., nano-textiles). The release during use could be estimated using behaviour and anthropometric data, using statistics, and from the way of integration of ENMs in different product categories *(Som, 2010).* During use, release to wastewater effluent and sewage sludge is predicted to be important for nanomaterials used in many consumer products. The uncertainty and variability of potential nanomaterial inputs, nanomaterial properties, and the operation of the wastewater treatment plant contribute to the difficulty of predicting sludge and effluent nanomaterial concentration *(Hendren, 2013).*

- Release of ENMs into the environment can also occur at the end-of-life of nanoproducts when they are disposed in landfills or in incineration plants. Although the particle filters of incineration plants are very effective, low concentrations of ENMs may be released and transported by air. The degradation of nanoproducts containing ENMs in landfill is not well known. Another relevant question is the recyclability of the nanostructured materials containing ENMs as well as the potential release during recycling processes and the use stage of recycled materials incorporated in new products.

Best practices and recommendations for nanoparticles

- To prioritise primary data taken from real measures of processes analysed, especially for core processes.
- To model the own production/synthesis method since there is a huge variability on these methods, as well as characterize the properties of each ENM.
- To gather inventory data for processes covering all life stages.
- To quantify and include the release of nanoparticles to the environment (to air, soil and water) as an inventory flow.
- In cases where estimations shall be done, for instance for the release in some stages, take the principle of worst case scenario or different scenarios for comparison.
- In order to make the collection of inventory data easier, send a datasheet to the data responsible specifying all the data needed (including ENMs flows to the environment). See an example of datasheet below.

Table 1. Check-list template for LCI data gathering

	Type of information	Data requested
	Process description	*General description of the process (Ex. Synthesis of LFP nanoparticles)*
	Productive process	Typology of process /route of production
	Partner/company responsible	
Resulting material/product description. Flow reference:	Material produced	Type of material synthesized. *For ENMS, specify the format of the final product (powder, dilution,...)*
		Quantity (g)
	Co-products (if any)	Quantity (g), use of co-products
Process description	Phases of the process	
	Duration (hours)	
	Equipment used	
	Process scale	Scale (lab, pilot, industrial,...)
		Production capacity (kg/year)
Inventory of INPUTS	Energy consumption (Electricity)	Source /origin
		Quantity (kWh)
		Function/use (phase, equipment used,...)
	Energy consumption (heat)	Source /origin
		Quantity (MJ)
		Function/use (phase, equipment used,...)
	Water consumption	Source /origin
		Quantity (l)
		Function/use (process water or cleaning water,...)
	Raw Materials (precursors, gases, solvents, others...)	Name /source
		Quantity (g)
	Other materials/substances used within the process, including ancillary materials (cleaning,..)	Function/use (precursor, solvent,...)
		Origin: geographical (km), synthesis process,...
		Other information (supplier, % recycled content....)
	Packaging	Packaging material (type), weight (g),...
		Size and capacity of packaging
	Transport processes inputs	Distance (km), type of vehicle
Inventory OUTPUTS	Direct emissions to air (including ENMs emissions)	Name/type of emission
		Quantity (g)
		Process origin
		Treatment/filtration (% of elimination of ENMs in filtration)
	Emissions to water (including ENMs emissions)	Pollutants, % of ENMs, type of effluent
	Wastewater produced	Type of wastewater (characterisation, pollutants)
		Origin process (cleaning,...)
		Potential content of ENMs (% of ENMs)
		Treatment/Final Destination (% of degradation of ENMs, elimination and release of ENMs)
	Solid waste	Name/ Type
		Classification /code
		Content of ENMs
		Origin process
		Quantity (g)
		Treatment / Destination (ENMs degradation and liberation)
	Liquid waste	Name
		Classification /code
		Content of ENMs
		Origin process
		Quantity (g)
		Treatment / Destination (ENMs degradation and liberation)
	Other outputs (scraps, subproducts, co-products..)	

Key aspects that should be gathered for the use phase

- Lifespan and application of the product.
- Inputs consumed and outputs consumed during use, necessity of maintenance, cleaning, etc.
- Possible liberation of ENM during use:
  - *In which state? Do they suffer any type of degradation/change? Which environmental compartments are foreseen these ENMs will be released to? Amounts?*

Aspects that should be gathered for the end-of-life phase

- Which are the typologies of the wastes generated at the end of life of the nano-enable product?
- Which are the treatment and final disposal of each fraction of waste?
- Do the waste contain ENMs? In which concentration? Would they be:
  - *Recycled: type of recycling process? release of ENMs during recycling? content of ENMs in recycled material? foreseen application of recycled material?*
  - *Disposed to landfill: In which state? Do they suffer any type of degradation/change? to which environmental compartments are foreseen these ENMs will be released? In which quantities?*
  - *Incinerated: % of elimination of ENMS? Release of ENMs (air emissions)? ENMS contained in ashes? Final destination of ashes?*

3.4. Life Cycle Impact Assessment (LCIA)

LCIA is the estimation of indicators of the environmental pressures associated with the environmental interventions attributable to the life-cycle of a product. In this step, the LCA the inventory flows are converted into the associated potential environmental impacts (see Figure 4).

LCIA stage has four steps:

1. Classification (Mandatory): Assignation of the different material/energy inputs and outputs inventoried to the relevant impact categories.
2. Characterisation (Mandatory): Calculation of the magnitude of the contribution of each classified input/output to their respective impact categories and aggregation of the contributions within each category.
3. Normalisation (Optional): impact assessment results are multiplied by normalisation factors (e.g., European reference values) in order to calculate and compare the magnitude of their contributions to the impact categories in an adimensional way.
4. Weighting (Optional): in order to support the interpretation of results, normalised results are multiplied by a set of weighting factors which reflect the perceived relative importance of the impact categories considered. The different impact values are pondered and they can be aggregated in one single punctuation.

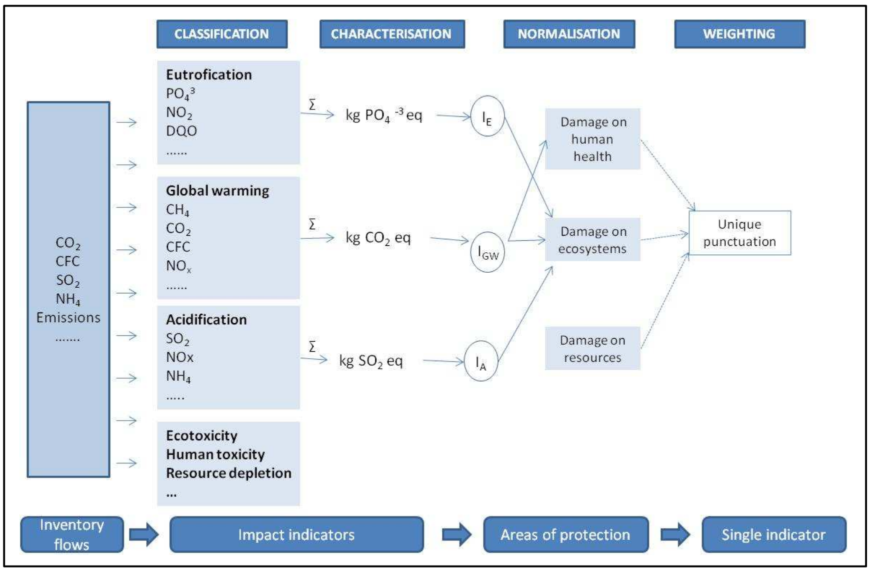


Figure 4. Life Cycle Impact Assessment mechanisms and steps.

Environmental impact categories refer to specific categories of environmental impacts considered in a product environmental study. These are generally related to resource use or emissions of environmentally problematic substances, such as greenhouse gases or toxic chemicals. Environmental impact assessment methods use models for quantifying the causal relationships between the material/energy inputs and emissions associated with the product life cycle and each environmental impact category considered. Each impact category hence has an associated, stand-alone environmental impact assessment method.

A wide number of methods used for LCIA convert the emissions of hazardous substances and extractions of natural resources into impact category indicators at the midpoint or impact level (such as acidification, climate change and ecotoxicity), while others employ impact category indicators at the endpoint level related to damage to areas of protection (such as damage to human health and damage to ecosystem quality). Midpoint modelling provides results which are meaningful and robust from a scientific perspective whereas endpoint indicators show results easier to understand and communicate but they have a higher uncertainty.

Considerations for nanomaterials

Despite of the fact that several consensus impact methods exist at European level such as CML or ReCiPe, and that established characterisation methods and factors are available for a wide number of substances and materials, there are some LCA impact categories for which generally accepted impact models do not exist yet because they do not have enough scientific consensus. This fact is particularly relevant for those categories that might be significant for the effect of released nanomaterials such as human toxicity and ecotoxicity.

In the current impact assessment methods, there is a complete lack of characterization factors for release of nanoparticles indoors and outdoors. For this reason, released nanomaterials quantified in the inventory stage, do not have associated impacts if current methods are used in a conventional way and therefore these flows will be not reflected into impact results. Consequently, prospective approaches are needed in order to include the effect of nanomaterials in all relevant impact categories. At the moment, only few LCA studies have derived characterisation factors for released ENMs, but a consensed method to do that is not available yet.

As it was pointed before, in the inventory stage it shall be defined if ENMs are likely to be released into the environment during the different life stages. Once the liberation of these ENMs is defined, more knowledge on the **fate** of the released nanoparticles indoors and outdoors is needed. Until measurements of ENMs in natural environments become available, it will be necessary to design robust predictive modelling approaches. Multi-media modelling approaches have been attempted to assess the annual mass of ENMs that would reach the different compartments within aquatic and terrestrial environments *(Gottschalk, 2009).*

Besides fate, more knowledge on the **transformations of nanomaterials in the environment** is needed**.** In this context, it is important to know whether nanoparticles change their form (shape, coating, etc.) and physico-chemical properties during their life cycle, for instance due to aging and other influences such as weather, mechanical stress/pressure, electromechanical fields, catalysis or interactions with other chemicals in the environment. The relationship between these characteristics and the fate and the hazard presented by nanoparticles is crucial to define toxicity models and to ensure accurate risk assessments and LCA studies.

The **uncertainty in toxicity** is another challenge as the mechanisms of toxicity for ENMs is still unknown in many cases. Several factors such as the surface properties, functionalization or the interaction with environmental media may affect the nanomaterial toxicity. Data on the toxicity of nanomaterials is being generated at an increasing pace. However, consensus protocols and practical methodologies for the toxicological and ecotoxicity studies are still needed.

Besides toxicity through environment, it is known that risks from worker's exposure to engineering nanoparticles, especially for potential inhalation, may be relevant. Therefore, an integration of indoor and outdoor emissions of nanoparticles and potential impacts to workers assessed with risk assessment should be used together to LCA in order to perform adequate nanomaterials impact and risk assessments in a holistic approach.

Best practices and recommendations for nanoparticles

- To use the impact methods recommended at European level (according to ILCD Handbook recommendations).
- When selecting the set of criteria for the study, use all recommended impact methods which can be especially relevant for nanoproducts, including toxicity categories.
- To derive characterisation factors for released nanoparticles when possible, using prospective approaches based on consensus and stablished models and considering the characteristics of these ENMs, the fate, intake and effect factors considerations.
- To work with a multidisplinary team with experts of risk assessment, modelling and toxicology, in order to derivate characterisation factors for ENMs in a scientifically robust way.
- If the derivation of characterisation factors is not possible, to take a worst-case approach, using characterisation factors of equivalent substances (i.e. bulk substances of the same chemical nature than ENMs, checking the similar or worst effect potential).

3.5. Interpretation of results

The final step of the LCA consists on the interpretation of results, where a critical revision of the inventory data and impact results are analysed in order to draw conclusions and improvement measures and to identify the limitations of the study. In this step the completeness, sensitivity and consistency of data gathered and results obtained are checked in order to guarantee their representativeness and robustness when the conclusions or assertions are extracted from the LCA studies.

Sensitive analysis will be also carried out, by varying key parameters in order to see the variation that these parameters (for instance the waste scenario or the lifespan of the product) could cause in the final results and the relative influence they can have over the results.

The execution of iterative analysis is foreseen on the course of the Life Cycle Assessment process to internally control the quality of data, while informing on its relative importance to the full LCA analysis. So that the methodology proposed should be redefined and adapted during the LCA study development.

ISO standards recommend to perform a critical review of the LCA studies (it is mandatory for public comparative assertions) as well as an uncertainty analysis in order to validate the reliability and representativeness of the results. The critical review consists on an external review in order to check if the requirements for the methodology, data and results are fulfilled properly. It is recommended that the critical review is done by an expert or a panel of experts of the field.

The uncertainty analysis allows knowing to what extent the outcome of the LCA study is affected by various types of uncertainty, such as variations in the data and parameters, scenario and model uncertainty. The uncertainty can be associated to the goal and scope definition, the inventory analysis and the impact assessment of an LCA. Information on the uncertainty of the model outcomes provides useful information to assess the reliability of LCA-based decisions and to guide future research towards reducing uncertainty. Variation in the data can be described by a distribution, expressed as a range or standard deviation. Statistical methods, such as Monte Carlo techniques can be used to handle these types of uncertainties, and calculate the data uncertainty in the LCA results. This statistical analysis can be done with the commercial software available.

Considerations for nanomaterials

LCA on ENMs and nanoproducts should deal with a high level of uncertainty related to different issues: inventory data, impact methods and hypothesis of the model. For this reason, it is of high importance knowing the sources of uncertainties when the results are analysed and interpreted. This knowledge is crucial in order to know how we can use the results obtained from our study.

As it has been seen in the previous steps of the methodology, when applying LCA to nanotechnologies, novel approaches and prospective adaptations are needed. Nevertheless, the consistence of the whole study and the respect for the hypothesis and the model built should be maintained during the study. In order to guarantee this consistence and transparency of the study, it is highly recommended to perform several iterative quality reviews. Furthermore, it is recommended to do an external critical review to improve the quality of the study.

Obtaining reliable and robust results from the LCA studies on nanoproducts is important not only for the individual studies and areas of research, but also to create new knowledge and data for the LCA and nanotechnology community and to strength the potential application of LCA studies to nanomaterials and nanoproducts. For this reason, the outputs of LCA studies are of high value to feed current LCA databases and to improve existing impact methods. The development of these tools will allow performing future LCA studies of ENMs in a comprehensive way.

Best practices and recommendations for nanoparticles

- To perform an iterative quality control during all the execution of the LCA study, revising the hypothesis and the considerations taken at each step.
- To perform an external critical review by a panel of experts with knowledge on LCA and nanotechnology.
- To perform an uncertainty analysis in order to check the level of uncertainty of the data and the results and check their consistence.
- To analyse the results of the LCA study in order to draw conclusions in coherence with the goal of the study.
- To propose measures of improvement and ecodesign to advance for a more sustainable nanotechnology.
- To use the results obtained in LCA studies to generate new inventory data for existing databases and to improve current impact methods.
- To share the results with the scientific community following the different initiatives and advances at European and Interantional level.

4. Recommended impact methods and current limitations for ENMs

Recent European Product Environmental Footprint (PEF) Guide *(European Commission Joint Research Centre, 2012)* proposes a set of 14 environmental impact categories to be included in order to perform a coherent Life Cycle Assessment of a product. For each category, recommended impact categories and related assessment methods are provided in accordance with ILCD Handbook *(European Commission-JRC, 2011).*

Among all methods analysed in each category, a default method is proposed by ILCD Handbook *(European Commission-JRC, 2011)* according to two criteria: overall evaluation of science based and overall evaluation of stakeholders' acceptance. These recommended default methods are classified as: I, recommended and satisfactory; II, recommended but in need of some improvements; and III, recommended but to be applied with caution.

In the table below, the ILCD Handbook recommended default method and its classification are detailed for each impact category. Moreover, it is indicated which categories can be significant for LCA on nano-enable products according to results from existing LCA studies analysed. In the last column, those methods that may be relevant for specific impacts caused by released nanoparticles are identified.

These recommendations on methods for each impact category are fully applicable to nanomaterials LCA studies, for the part where impacts associated to processing inputs and outputs are calculated. Nevertheless, some methodological considerations have to be taken since prospective approaches are needed, as it is the case of other emerging technologies.

The two categories where default methods are considered as *level III* (to be applied with caution), i.e. water depletion and land transformation are considered not significant for LCA applied to nanomaterials according to LCA studies analysed. Thus, it is not recommended to include them into LCA studies of nanomaterials. For the rest of impact categories, recommended impact methods by CE are all classified with I or II classifications, and consequently they are considered the best methods to be used in LCA studies for nanomaterials.

However, when applying impact assessment methods to nano-products it would be necessary to include specific hazards caused by nanoparticles and their specifications. In that sense, any of the existing methods include characterisation factors for nanomaterials and therefore nanomaterials flows are not covered by these methods. They referred to bulk materials and they do not distinguish the specific effects of nano-forms for the different substances. This point is crucial since potential impacts that released nanomaterials can pose when they are released to environment (to soil, air, water) in different forms and in different life stages shall be included for comprehensive environmental assessments.

The impact categories (see Table 2) considered as potentially relevant for released nanomaterials are:

- Ecotoxicity for aquatic fresh water. Models for ecotoxicity for marine water and soil are not considered mature enough for generic LCA, for that reason they are not considered in this document.
- Human Toxicity – cancer and non-cancer effects.
- Particulate Matter.

Table 2. Recommended impact categories and methods from PEF guide

PEF Impact Categories	**ILCD recommended Impact Assessment Model**	**Classification of recommended impact method (ILCD)**	**Significant for LCA of nanoproducts**	**Relevant for released Nanoparticles**
1. Climate Change	Bern model - Global Warming Potentials (GWP) over a 100 year time horizon.	I *(recommended and satisfactory)*	Potentially significant during all life cycle, especially manufacturing	NO*
2. Ozone Depletion	EDIP model based on ODPs of the World Meteorological Organization (WMO)	I *(recommended and satisfactory)*	Potentially significant during all life cycle	NO*

PEF Impact Categories	ILCD recommended Impact Assessment Model	Classification of recommended impact method (ILCD)	Significant for LCA of nanoproducts	Relevant for released Nanoparticles
3. Climate Change	Bern model - Global Warming Potentials (GWP) over a 100 year time horizon.	I *(recommended and satisfactory)*	Potentially significant during all life cycle, especially manufacturing	NO*
4. Ozone Depletion	EDIP model based on ODPs of the World Meteorological Organization (WMO)	I *(recommended and satisfactory)*	Potentially significant during all life cycle	NO*
5. Ecotoxicity for aquatic fresh water	USEtox model (Rosenbaum et al, 2008)	II *(recommended but in need of some improvements) / III (recommended, but to be applied with caution)*	Potentially significant during all life cycle, especially end-of-life	**YES**
6. Human Toxicity - cancer effects	USEtox model (Rosenbaum et al, 2008)	II *(recommended but in need of some improvements) / III (recommended, but to be applied with caution)*	Potentially significant during all life cycle, especially end-of-life	**YES**
7. Human Toxicity – non-cancer effects	USEtox model (Rosenbaum et al, 2008)	II *(recommended but in need of some improvements) / III (recommended, but to be applied with caution)*	Potentially significant during all life cycle, especially end-of-life	**YES**
8. Particulate Matter / Resp. Inorganics	RiskPoll model (Rabl and Spadaro, 2004) and Greco et al 2007	I *(recommended and satisfactory)*	Potentially significant during all life cycle	**YES**
9. Ionising Radiation – HH effects	Human health effect model as developed by Dreicer et al. 1995 (Frischknecht et al, 2000)	II *(recommended but in need of some improvements)*	Potentially significant during all life cycle	NO
10. Photochemical Ozone Formation	LOTOS-EUROS model (Van Zelm et al, 2008) as applied in ReCiPe	II *(recommended but in need of some improvements)*	Potentially significant during all life cycle	NO*
11. Acidification	Acumulated Exceedance model (Seppälä et al.2006, Posch et al, 2008)	II *(recommended but in need of some improvements)*	Potentially significant during all life cycle	NO*
12. Eutrophication – terrestrial	Acumulated Exceedance model (Seppälä et al. 2006, Posch et al, 2008)	II *(recommended but in need of some improvements)*	Potentially significant during all life cycle	NO*
13. Eutrophication – aquatic	EUTREND model (Struijs et al, 2009b) as implemented in ReCiPe	II *(recommended but in need of some improvements)*	Potentially significant during all life cycle	NO*
14. Resource Depletion – water	Swiss Scarcity mod. (Frischknecht et al, 2008)	III *(recommended, but to be applied with caution)*	Not significant	NO
15. Resource Depletion – mineral, fossil	CML2002 model (Guinée et al., 2002)	II *(recommended but in need of some improvements)*	Potentially significant for manufacturing processes	NO
16. Land Transformation	Soil Organic Matter (SOM) model (Milà i Canals et al, 2007b)	III *(recommended, but to be applied with caution)*	Not significant	NO

*Some nanoparticles could contribute to these impacts due to their physico-chemical characteristics, similar to bulk substances.

In the next sections methods and models for those impact categories considered as the most potentially relevant for released nanomaterials (i.e. human toxicity, ecotoxicity) are analysed in order to assess the feasibility of deriving characterisation factors for nanomaterials that can be released into the environment in the different life stages.

4.1. Ecotoxicity

Ecotoxicity covers the potential stressors that may impact ecosystems through direct toxicity to the species. Different impact methods have been developed for terrestrial ecotoxicity, freshwater ecotoxicity and marine ecotoxicity (see Figure 5). LCA characterisation models and factors for ecotoxicity effects must be based on models that account for a chemical fate in the environment, species exposure, and differences in toxicological response (likelihood of effects and severity). For that reason, according to ILCD recommendations *(European Commission-JRC, 2011),* some LCA midpoint methods are not seen appropriated since they do not have an ecotoxicity model behind the calculations.

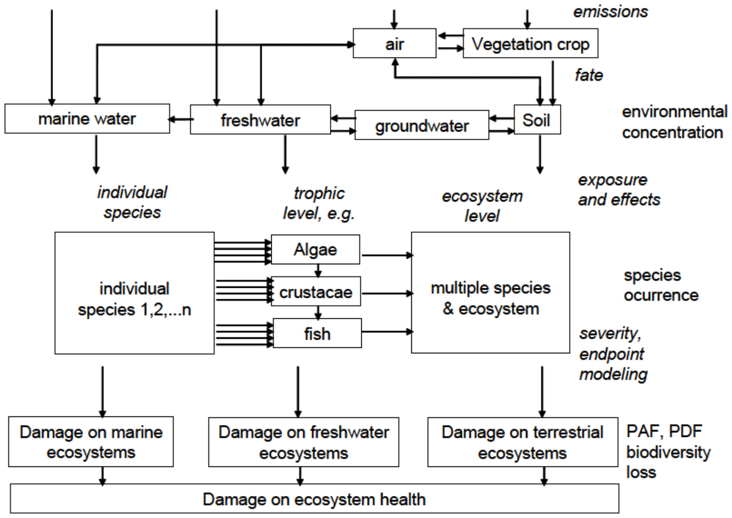


Figure 5. General flow diagram for ecotoxicity methods on LCA *(Source: ILCD Recommendations, European Commission-JRC 2011).*

Different ecotoxicity methods were evaluated by the European Commission in the ILCD recommendations document assessing the advantages and drawbacks of different methods for freshwater toxicity. As result, each model is classified according to the overall scientific evaluation (A=Best, E=worst).

As conclusion, the USEtox midpoint model *(Rosenbaum, 2008)* is the recommended method for the midpoint calculations for freshwater ecotoxicity. USETtox is recommended for non polar organics but needs minor improvements (Level II). And for metals, dissociating substances and amphiphilics (e.g. detergents) the method is classified as Level III.

No method is recommended for the endpoint assessment of ecotoxicity, as all endpoint characterisation ecotoxicity models for all chemicals are classified as immature to be recommended due to the preliminary nature of the results available and the assumptions made between the midpoint indicator and impacts on ecosystems. Substantial research still needs to be carried out on this issue before general conversion rules can be developed to address toxicity effects on biodiversity. For the same reasons, no method is recommended for marine and terrestrial ecotoxicity.

Nevertheless, no ecotoxicity impact method, included USEtox[1], does have characterisation factor for ENMs. USEtox is classified with B for the overall science based criteria (Compliance in all essential aspects). In the table below the main advantages and disadvantages of the recommended model USEtox are detailed:

[1] Model developed under auspices of UNEP/SETAC Life Cycle Initiative *(Rosenbaum, 2008)*

Table 3. Advantages and drawbacks of USEtox method for ecotoxicity

Advantages	• Full multimedia fate modelling • The model addresses the freshwater environment, includes all vital model elements in a scientifically sound way, and is sufficiently documented (except for metals where improvements are needed).
Disadvantages	• Only assess freshwater toxicity (no soil and marine toxicity). • Current method does not assess indoor emissions (under development). • Not directly applicable to ENMs. Derivation of characterisation factors is not possible applying the principles and formulas which are designed for organic substances (especially for deriving the fate factor where several adaptations will be needed).

USEtox provides a parsimonious and transparent tool for human health and ecosystem Characterization Factors (CF) estimates[2]. The general scheme for USEtox is represented in the Figure 6.

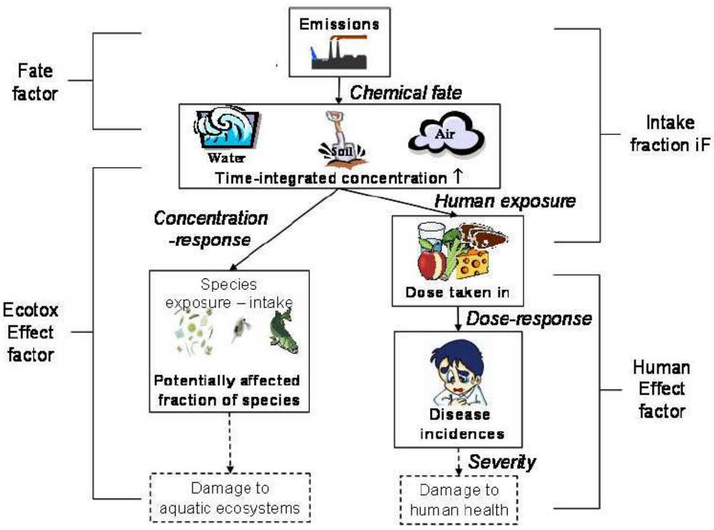


Figure 6. Principles and main steps of the USEtox assessment. (*Source: USEtox user manual)*

Characterisation factors for freshwater aquatic ecotoxicological effects include impacts for emissions to urban air, rural air, freshwater and/or agricultural soil. In USEtox, the ecotoxicological characterisation factor of chemicals includes a fate factor (FF), an exposure factor (XF) and an effect factor (EF): *CF = FF* x *XF* x *EF.*

Fate factor is further explained in *section* 4.3. For soluble compounds, the **environmental exposure** factor for freshwater ecotoxicity is the fraction of the chemical dissolved in freshwater. In the case of nanomaterials, the environmental exposure factor will be the fraction of nanomaterials that are stable in suspension in the water column.

Apart from the fate factors and exposure factors, **effect factors** are also required in the calculation of ecotoxicological characterisation factors. The ecotoxicological effect factor (EF) reflects the change in the Potentially Affected Fraction (PAF) of species due to change in concentration ($PAF \cdot m^3 \cdot kg^{-1}$). The ecotoxicological effect factor for freshwater environments is defined in USEtox as: 0.5 / HC_{50}. Where HC_{50} is the concentration at which 50% of the species are exposed above their EC_{50}. Ideally, data for several species and from different trophic levels should be available to estimate a HC_{50}, based on geometric means of single species EC50 tests data where Chronic values have priority as long as they represent measured EC50 values.

The same approach can be applied to nanomaterials. The main difficulty is to have available and robust data on HC50 values for nanomaterials for several species and from different trophic levels.

[2] USEtox – the UNEP-SETAC toxicity model: recommended characterisation factors for human toxicity and freshwater ecotoxicity in life cycle impact assessment. Rosenbaum, R.K. et al. Int J Life Cycle Asess (2008) 13:532-546

4.2. Human toxicity

Human toxicity in LCA is based on the relative risk and associated consequences of chemicals that are released into the environment, which could cause problems for human health. When modelling, the characterization factor depends on chemicals fate in the environment, human exposure, and differences in toxicological response. A generic flowchart can be seen in Figure 7.

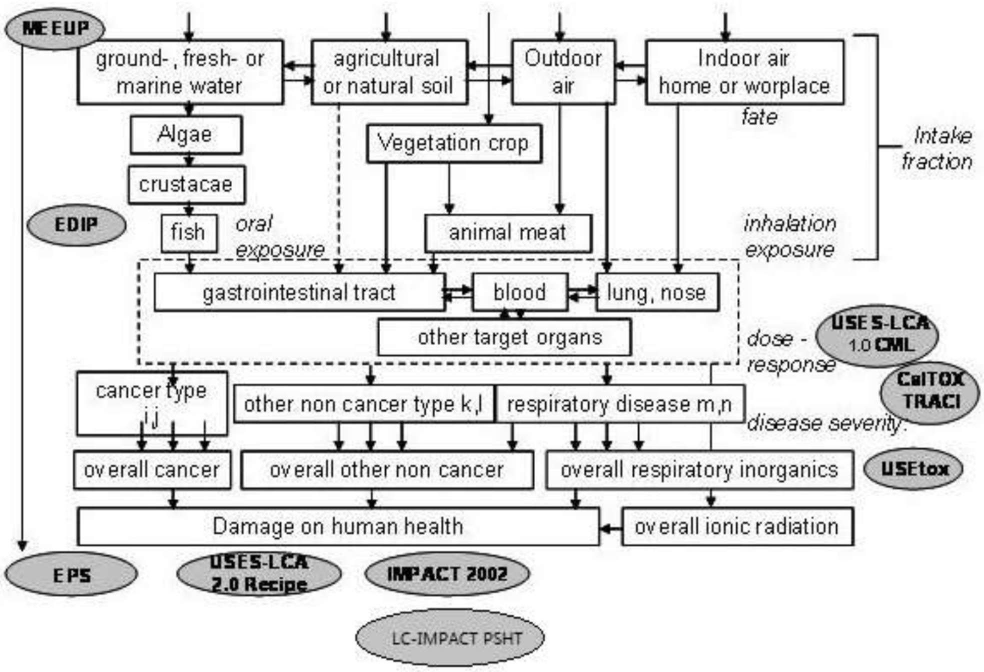


Figure 7. General flow diagram for Human Toxicity methods on LCA *(Source: ILCD Recommendations, European Commission-JRC 2011).*

This section is focused on human toxicity assessed in LCA studies, but other environmental tools such as risk assessment, substance flow analysis or environmental impact assessment provide complementary information and are more appropriate to assess e.g. localized health impacts associated with peak individual exposures.

USEtox is classified with B for the overall science based criteria (Compliance in all essential aspects). In the table below the main advantages and disadvantages of the recommended model USEtox are detailed in Table 4.

Table 4. Advantages and drawbacks of USEtox method for Human toxicity.

Advantages	• USEtox reflects the latest consensus amongst multimedia modellers and their associated models on fate and human exposure • USEtox includes all vital model elements in a scientifically sound way, except for metals and direct impact of pesticides. It is sufficiently documented and has the largest substance coverage.
Disadvantages	• Uncertainty may require further attention, since USEtox has similar uncertainties when compared to many of the other fundamentally similar models such as USES-LCA, Impact 2002, and CALTOX. • Model calculation for chemicals. It requires the availability of the needed substance Properties. • Not directly applicable to NMs, equations and data inputs shall be adapted. Derivation of characterisation factors is not possible applying the principles and formulas which are designed for organic substances (especially for deriving the fate factor where several adaptations will be needed).

The human-toxicological characterisation factor in USETox reflects the change in life time disease probability due to change in life time intake of a pollutant (cases/kg intake). Chemicals that have a potential to increase human disease have a characterization factor that includes a fate factor (FF), an exposure factor (XF) and an effect factor (EF): CF = FF x XF x EF.

The fate factor and exposure factor are combined to reflect the intake fraction (iF) of a chemical, representing the fraction of the emitted mass that enters the human population: *iF = FF* x *XF.*

Fate factor is further explained in *section Fate* **modelling for toxicity categories**. A human **exposure model** describes the transport from environmental compartments to the human via inhalation and ingestion. In order to define exposure factors for nanomaterials, we can consider that some exposure factors for chemicals are fully applicable to nanomaterials since they do not depend on the characteristics of the substance. For instance, the exposure via air inhalation, which only depends on the volume of air inhaled in relation to the volume of the air compartment considered. Nevertheless other exposure factors, such as exposure from food products, depend on both, constant estimates (such as intake rates) and on values that are compound-specific, namely the bioaccumulation factors for different food products. The USEtox model can estimate these values from physicochemical data of organic substances. Such estimations will, however, not be possible for nanomaterials. Instead, experimental data will be needed, as it is the case of USEtox for inorganic substances.

Apart from the fate factors and exposure factors, **effect factors** are also required in the calculation of human-toxicological characterisation factors. The effect factor (EF) reflects the change in life time disease probability due to change in life time intake of a pollutant (cases/kg_{intake}). In USEtox separate effect factors are derived for non-carcinogenic effects and carcinogenic effects. Furthermore, for each effect type (non-carcinogenic and carcinogenic) the two exposure routes, i.e. inhalation and ingestion are addressed separately. The human-toxicological effect factor of a chemical equals: $E = 0.5 / ED50$.

The calculation to fill data gaps requires the availability of the needed substance properties among which particularly the toxicity and degradability data can be uncertain and difficult to find. These are normally the input parameters contributing most to the overall uncertainty of the characterisation factor for chemicals, and it is foreseen to cause huge uncertainty for nanomaterials, since no fully standardized methods exist to evaluate toxicity caused by nanomaterials and to define physico-chemical data for ENMs.

4.3. Fate modelling for toxicity categories

Models and factors for toxicity effects (**human toxicity** and **ecotoxicity**) in LCA are based on the relative risk and associated consequences of nanomaterials and chemicals that are released into the environment.

The derivation of characterization factors requires taking into consideration the environmental and biological fate, intake fractions, and the (eco)toxicological responses. Consequently, an elementary step towards a quantitative assessment of the toxicity of new pollutants to the environment is to estimate their environmental concentrations *(Gottschalk, 2010).*

Environmental fate models have been established and used to assess the fate and transport of organic chemicals. A robust understanding of the relationship between the physicochemical properties of a chemical and its behaviour in the environment has enabled scientists to make accurate predictions of the fate of many different chemicals. But on the other hand, predictive environmental fate modelling for nanomaterials is still immature *(Praetorius, 2012).*

Detecting engineered nanomaterials in the environment is difficult by currently available methods. There are currently almost no specific trace analytical methods available to quantify ENM in environmental samples, e.g. water, wastewater or biosolids *(von der Kammer, 2012)*. In the absence of robust monitoring capabilities, it becomes necessary to rely on modelling approaches to support an evaluation of potential environmental exposure risk. All models of nanomaterials are based on a broad number of assumptions about the production, use, and release of these materials to the environment *(Hendren, 2013).* To date, only a few modelling studies have presented quantitative estimations of the environmental concentrations of ENM *(Salieri, 2015; Blaser, 2008; Boxall, 2007; Gottschalk, 2013, 2009; Hendren, 2013; Keller, 2013; Mueller, 2008).*

When modelling the fate of chemicals after discharge to the environment, mass balance multi-compartment models are the most commonly used approach. Multimedia fate models can predict environmental fate factors and exposure factors of a pollutant. In this type of model, the study area is represented by a number of homogeneous compartments, each representing a specific part of the environment (i.e. atmosphere, water, soil).

➢ **Multimedia fate modelling: USEtox**

In USEtox, two geographical scales are specified, as represented in Figure 8:

- the continental scale with the following compartments: urban air, rural air, freshwater, sea, natural soil and agricultural soil;
- the global scale with the following compartments, air, freshwater, ocean, natural soil and agricultural soil.

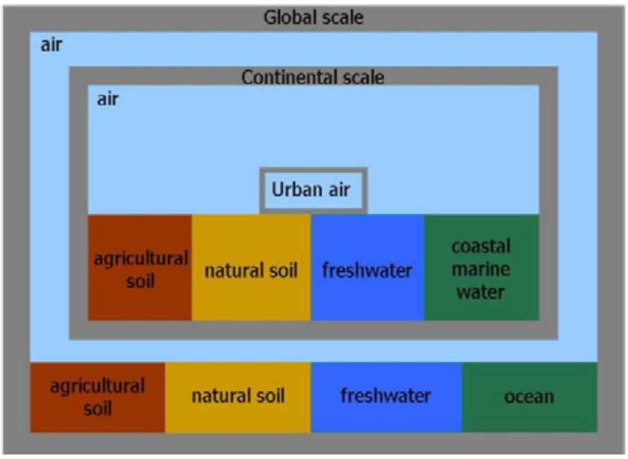


Figure 8. Environmental compartments structure in USEtox *(Rosenbaum, 2008)*

The fate factor and exposure factor of a chemical in a certain compartment are calculated by solving a set of mass balance equations that describe processes such as degradation and inter-compartment transfer.

The fate model part of USEtox calculates the residence time of a chemical, based on the quantification of all these environmental processes. This is done by solving the mass balance under steady state conditions with the help of linear algebra calculation rules. Steady state means that concentrations do not change over time in the compartments considered, when there is a constant emission rate.

To run the fate model for organic chemicals a set of substance-specific input parameters must be provided in USEtox, detailed in Table 5.

Table 5. Fate mechanisms and input parameters used in USEtox for organic chemicals.

Transport/Elimination mechanism	USEtox™
Dry Deposition in Air	K_H + water (aerosols) deposition
Wet Deposition in Air	Aerosol washout + gas washout (K_H)
Gas absorption / volatilization	K_H
Water / sediment partition	Kp_{SS}+Kp_{Sd}+K_{DOC} (K_{OW})
Run off / leaching from soils	Kp_{Sl} (K_{OW})
Degradation	Deg rate
Metal leaching	Not considered
Bioaccumulation Fish	K_{OW} (only for organics)
Bioaccumulation Leaf	K_{OW} +K_H (only for organics)
Biotransfer factor meat and milk	K_{OW} (only for organics)

Regarding the potential application to this fate model to nanomaterials, the general equations that are used to generate fate factors in the USEtox model and other similar models are designed for soluble compounds and are not directly applicable to nanomaterials. ENMs have so many characteristics governing their fate (size, shape, porosity, agglomeration state, surface area, surface charge, global charge, composition, density, reactivity,…) that almost a case by case study would be needed to predict their environmental distribution, since different nanomaterials have different characteristics that can drive diverse fate behaviours. Although some preliminary experiences has been done in order to adapt these multimedia models to nanomaterials characteristics, deep adaptation shall be done in order to adapt fate equations to characteristics of nanomaterials in order to develop robust models. Moreover, steady state is not feasible for nanomaterials. Some shortcomings of USEtox are that it does not include uncertainty analyses and spatial information.

Probabilistic flow modelling

Modelling fate of nanomaterials using multimedia models like USEtox is hard since it is dependant on several nanomaterial data. Other approaches like computational fate models on probabilistic flow modelling can be used instead when data is scarce. In this regard, some probabilistic flow modelling have been developed or adapted to nanomaterials.

One example is the model developed by Gottschalk *(2010).* It is a probabilistic method to compute distributions of PECs by means of a stochastic stationary substance/material flow modelling. The evolved model is basically applicable to any substance with a distinct lack of data concerning environmental fate, exposure, emission and transmission characteristics. The model input parameters and variables consider production, application quantities and fate of the compounds in natural and technical environments. To cope with uncertainties concerning the estimation of the model parameters (e.g. transfer and partitioning coefficients, emission factors) as well as uncertainties about the exposure causal mechanisms (e.g. level of compound production and application) themselves, it utilizes and combines sensitivity and uncertainty analysis; Monte Carlo simulation and Markov Chain Monte Carlo modelling.

The combination of these methods is appropriate to calculate realistic PECs when facing a lack of data, as it is the case of nanomaterials. In fact, Gottschalck model was tested for nano-TiO_2 as case study. Based on Gottschalk model a more advanced model was developed *(Sun, 2014),* with a more comprehensive description of the processes in technical systems. They modelled fate for several types of nanomaterials (nano-TiO_2, nano-ZnO, nano-Ag, CNT and fullerenes). The basis for the modelling is knowledge about the total use of certain ENM in a defined region and the distributions of their mass to different product categories. Product life-cycles then it determines any possible releases of ENM into the environment.

The material flows of ENM can be used to predict average concentrations of ENM in technical and environmental systems. This was achieved by calculating the total input flows into compartments using the material-flow calculation and then dividing the amounts remaining in each compartment by the volumes of the respective compartments. Amounts of application of each nanomaterial and characteristics of the NP translocation to and within the environment such as emission factors were required to run the model. In the first Gottschalk model it was concluded that calculations of flows among compartments were based on very crude assumptions because of lack of available data *(Gottschalk, 2010).* Nevertheless, latest version incorporated new information on fate and behaviour that allowed a better understanding of the behaviour of ENM in the environment. With this novel knowledge a much more robust and comprehensive understanding of the flows was achieved from the model *(Sun, 2014).*

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