Unclassified **ENV/JM/MONO(2015)30**

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development **07-Jul-2015**

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ENV/JM/MONO(2015)30
Unclassified

GUIDANCE MANUAL TOWARDS THE INTEGRATION OF RISK ASSESSMENT INTO LIFE CYCLE ASSESSMENT OF NANO-ENABLED APPLICATIONS

Series on the Safety of Manufactured Nanomaterials
No. 57

JT03379905

Complete document available on OLIS in its original format

English - Or. English

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OECD Environment, Health and Safety Publications

Series on the Safety of Manufactured Nanomaterials

No. 57

GUIDANCE MANUAL TOWARDS THE INTEGRATION OF RISK ASSESSMENT INTO LIFE CYCLE ASSESSMENT OF NANO-ENABLED APPLICATIONS

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris, 2015

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No. 34, *Current Development/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 9th Meeting of the Working Party on Manufactured Nanomaterials (2012)*

No. 35, *Inhalation Toxicity Testing: Expert Meeting on Potential Revisions to OECD Test Guidelines and Guidance Document (2012)*

No. 36, *Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (2012)*

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or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

The OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting) held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety (June 2005). This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety related aspects of manufactured nanomaterials. The scope of this session was intended to address the chemicals sector.

As a follow-up, the Joint Meeting decided to hold a Workshop on the Safety of Manufactured Nanomaterials in December 2005, in Washington, D.C. The main objective was to determine the "state of the art" for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee in September 2006. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, pesticides and Biotechnology of the OECD.

List of Abbreviations

ADI	Acceptable daily intake
AP	Acidification potential
BIAC	Business and Industry Advisory Committee
BW	Body weight
C	Carbon
CED	Cumulated energy demand
CEN	European Committee for Standardization
CF	Characterization factor
CML	Centrum voor Milieukunde (CML) of the University Leiden (NL)
CNT	Carbon Nano Tube
DOE	US Department of Energy
EC	European Commission
EC50	Half maximal effective concentration
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
ED50	Effective dose for 50% of people receiving the drug
ELCD	European Life Cycle Database
EMA	European Medicines Agency
EFSA	European Food Safety Authority
ENM	emitted nano-material
EP	Eutrophication potential
EPA	US Environmental Protection Agency
Eq	Equivalent
EU	European Union
FU	Functional Unit
GM	Guidance Manual
GWP	Global warming potential
ILCD	International Reference Life Cycle Data System
ISO	International Organization for Standardization
ITO	Indium tin oxide
JEMAI	Japanese Environmental Management Association for Industry
Kg	kilogram
LCA	Life cycle assessment
LCI	Life cycle inventory analysis
LCIA	Life cycle impact assessment
LOAEL	Lowest observed adverse effect level
MWCNT	Multi-walled CNT
NGO	Non-governmental organisation
Nm	Nano meter
OECD	Organisation of Economic Cooperation and Development
PDI	Predicted daily intake
PEC	Predicted environmental concentration
PM	Particulate matter
PNEC	Predicted no effect concentration
POCP	Photochemical ozone creation potential
RA	Risk assessment
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SETAC	Society of Environmental Toxicology and Chemistry
SG	Steering Group
SWCNT	Single-walled CNT
TCF	Transparent conductive film
TEM	Transmission electron microscopy
TiO_2	Titanium dioxide
UNEP	United Nations Environment Programme
WHO	World Health Organization
WPMN	Working Party on Manufactured Nanomaterials
WPN	Working Party on Nanotechnology

EXECUTIVE SUMMARY

1. As a background for this Guidance Manual (GM), the 5th OECD WPMN plenary meeting agreed to establish a Steering Group (SG9) to look into the potential of applications based on the use of manufactured nanomaterials to address major environmental challenges such as climate change, pollution of water, soil, and air, and natural resource depletion, as well as the potential negative impacts that such new technologies may have on environment and health. SG9's main focus is enhancing the knowledge base about life cycle aspects of manufactured nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development. As part of its programme a workshop was held on the Environmentally Sustainable Use of Manufactured Nanomaterials. This event took place on 14 September 2011 in Rome, Italy. Its basic objectives were to further improve the international scientific dialogue in the field of life-cycle aspects of manufactured nanomaterials. Its main overall conclusions were as follows:

- Life cycle analysis (LCA) per se is an important tool for providing a framework to evaluate the negative and positive environmental implications of a product, process, or technology that can also be employed for nanomaterials. However, it must be applied thoughtfully, keeping in mind the applications of nanomaterials, in order to provide answers that will be useful to decision-makers.
- It is key establishing linkages between LCA and risk assessment (Flemström et al. 2004), since any LCA working group will need risk assessment information to complete an LCA. Given the fact that there is no concept of functional unit in risk assessment, such linkages can only be established if both LCA practitioners and risk assessors share the LCA objectives or problem formulation and iterative results with each other.
- In line with other nano-LCA workgroups, the ISO 14040/44 framework is a suitable harmonized, user-friendly and validated framework applicable to nanomaterials and nanotechnology.

2. Based on the workshop's major conclusions, the OECD WPMN SG9 Project on the Environmentally Sustainable Use of Manufactured Nanomaterials developed this Guidance Manual (GM) aiming at supporting decision making in various situations; from research, innovation, product development, scaling-up of production, marketing, and end-of-life as well as regulatory decisions.

3. This document aims to incorporate knowledge of risk analyses of the environmental impact in life cycle assessment studies as decision-making tools during both upstream (research & development) and downstream (industrialisation, usage, re-use, end-of-life management: recycling, recovery, destruction) phases of a nanostructured product. In order to address these issues, especially the need to link better risk assessment and life cycle assessment information, this GM focuses in-depth on a "data-rich" case study, i.e. Carbon Nanotubes (CNTs) in semiconductors. This "data-rich" study was the only one where the majority of the necessary data elements for both a life cycle assessment and a risk assessment were completed and generally available to the SG9 group. It was recognized that it is important developing guidance based on an as complete a dataset as possible. Moreover, existing life cycle and risk data and assessments from the WPMN steering groups such as SG-TA on the Testing and Assessment and SG8 on Exposure Measurement and Exposure Mitigation and relevant outputs from member countries were used to avoid conducting new ones. This GM also makes use of the US document "Guidance to Facilitate Decisions for Sustainable Nanotechnology.", ILCD-Handbook (EU-LCA-Platform) and ISO 14040/44. The case study also considers the full lifecycles of products (raw materials extraction, materials processing, product manufacture, product use, recycling and disposal). This GM evolved after it commenced and includes nano-specific thinking with respect to characterization factors and cut-off rules.

4. In addition, this GM contributes, facilitates and could serve as a tool to further support technology or product development including, e.g., green nanotechnology which can have multiple roles

and impacts across the whole value chain of a product and can be of an enabling nature in connection with other concepts such as sustainable and green chemistry, as well as sustainable and green engineering including manufacturing, as outlined in the OECD (2013) “Nanotechnology for Green Innovation”, OECD Science, Technology and Industry Policy Papers, No. 5, OECD Publishing. http://dx.doi.org/10.1787/5k450q9j8p8q-en.

5. In view of these objectives and aims and to provide a stepping stone towards the integration of risk assessment of the environmental impact in life cycle assessment studies as decision-making tools during both upstream and downstream phases of a nanostructured product this Guidance Manual focuses in-depth on a “data-rich” case study. Here, as an example of a nano-enabled application, a conductive plastic sheet containing Carbon Nanotubes (CNTs) was compared with a reference product, a polycarbonate sheet including carbon black. By incorporating CNT instead of the currently used carbon black, it is possible to reduce the foil thickness by 20%, resulting in corresponding savings regarding the polycarbonate consumption.

6. On the level of the core datasets of this LCA especially for the production of CNTs, a high data quality could be achieved. This was not the case for the subsequent step of the foil production, However, as the same technology is applied for the foil production for both cases (i.e. carbon black and CNTs), it was concluded that the use of literature data for this process step has no relevant effect on the comparison but influences the overall uncertainty of the results in all cases by a similar amount. On the level of the assessment step, nowadays more comprehensive and more up-to-date Life Cycle Impact Assessment (LCIA) methods than the method used in this selected case study are available. Hence for example, the ILCD handbook provides a first summary of recommendations concerning the modelling approaches for the assessment of the various environmental aspects taken into account in common LCIA methods.

7. One of the main issues in the selected case study for this Guidance Manual is the missing quantification of releases of CNTs during the examined life cycle stages. Although the specific production process of CNTs takes place in a closed environment, there are subsequent process steps in the production of the foil that may lead to a risk for releases of nanomaterials into the environment.

8. Currently there are hardly any datasets available for the manufactured nanomaterials with a high potential for future industrial applications and only very few of these are published LCA studies in the area of nano-enabled applications involving the actual inventory data for the respective manufactured nanomaterial employed. This GM provides an overview of the present situation in the annexes, showing that more work is necessary in this area including, for example, the availability of complete sets of input and output data. On the level of Life-Cycle-Impact Assessment (LCIA) databases there is even more work to be performed. Hence, considerable efforts are required in the future to establish a basic set of LCIA datasets covering the most important share of nanomaterials, in order to offer a starting point for more adequate LCA studies for nano-enabled applications.

9. This GM also provides an overview on available risk assessment and life cycle assessment approaches useful for performing LCA of nanomaterials during their life cycle. It further updates aspects of reporting in relation to transparency, assumption selection, sensitivity and scenario designs. The latter also includes specific scenarios on so called "hot spots" of exposure to nanomaterials by humans, including especially consumer and indoor exposure as well as environmental compartments. It highlights uncertainties in the use of modelling scenarios in the absence of data. Uncertainties and date gaps regarding risks, inventory and impact assessment are a key issue for many nanomaterials and their application at both in the early and later stages of development.

10. Furthermore, the need for one suitable exposure metric including grouping approaches for nanomaterials especially for human and eco-toxicity testing, compatibility aspects of units and the

availability of harmonised protocols are emphasized, leading to different future possible activities for the OECD WPMN SG9 (Environmentally Sustainable Use of Manufactured Nanomaterials) and the need of being incorporated into on-going and future research and innovation programmes.

11. Primary recommendations to improve the LCA framework for assessing the relative impacts of baseline and nano-enabled applications include the material flowing aspects that were also described in the above mentioned OECD report entitled "*Nanotechnology and Tyres: Greening Industry and Transport*":

- Refining Life-Cycle-Inventory (LCI) data for the nanomaterial manufacturing step with primary data from producers (e.g. using data from quantitative evaluations based on testing or modelling).

- Refining LCI data for all life cycle steps of nanomaterials to assess better the potential nanoscale releases (e.g. using data from quantitative evaluations based on testing or modelling).

- Refining of nanomaterial release rates and environmental compartmentalisation in use and life cycle stages (e.g. using data from quantitative evaluations based on testing or modelling).

- Application of impact assessment factors for nanoscale versus macroscale substance releases for each environmental compartment to determine potential environmental impacts of estimated nanomaterial releases.

12. Keeping these overall requirements in mind, it is essential that all employed assumptions, data sources including their uncertainties, LCA-approach related uncertainties including the sensitivities of eventually performed models and limitations are documented and reported in a clear and transparent manner allowing the decision maker to easily understand the background and basic fundaments of the LCA performed. Additionally, data and methods used need to be explained at the very beginning of the report, allowing the reader to comprehend and interpret the results reported.

13. This GM is a stepping stone within a continuous process aiming towards the integration of risk assessment and LCA underlining the need for a regular update. Hence, and to allow for such updating, it is recommended to incorporate upcoming results and data reported by the other OECD WPMN Steering Groups including especially SGTA, SGAP and SG8.

Table of Contents

1 INTRODUCTION

Background

1. The 5th OECD WPMN plenary meeting (March 2009) agreed to establish a Steering Group (SG9) to look into the potential of applications based on the use of manufactured nanomaterials to address major environmental challenges such as climate change, pollution of water, soil, and air, and natural resource depletion, as well as the potential negative impacts that such new technologies may have on environment and health. SG9's main focus is enhancing the knowledge base about life cycle aspects of manufactured nanomaterials, as well as positive and negative impacts on environment and health of certain nano-enabled applications at their different stages of development. As part of its programme a workshop was held on the Environmentally Sustainable Use of Manufactured Nanomaterials. This event took place on 14 September 2011 in Rome, Italy (OECD 2013). Its basic objectives were to further improve the international scientific dialogue in the field of life-cycle aspects of manufactured nanomaterials. Its main overall conclusions were as follows:

- Life cycle assessment (LCA) per se is an important tool and framework in evaluating the negative and positive environmental implications of a product, process, or technology that can also be employed to nanomaterials. However, it must be applied thoughtfully keeping in mind the applications of nanomaterials in order to provide answers that will be useful to decision-makers.

- It is key establishing linkages between LCA and risk assessment (Flemström et al. 2004), since any LCA working group will need risk assessment information to complete an LCA. Given the fact that there is no concept of functional unit in risk assessment, such linkages can only be established if both LCA practitioners and risk assessors share the LCA objectives or problem formulation and iterative results with each other.

- In line with other nano-LCA workgroups, the ISO 14040/44 framework is a suitable harmonized, user-friendly and validated framework applicable to nanomaterials and nanotechnology.

2. The following figure 1 shows in an illustrative manner the possible links between risk assessment and LCA building upon the information available in the literature and as discussed in the Rome Workshop:

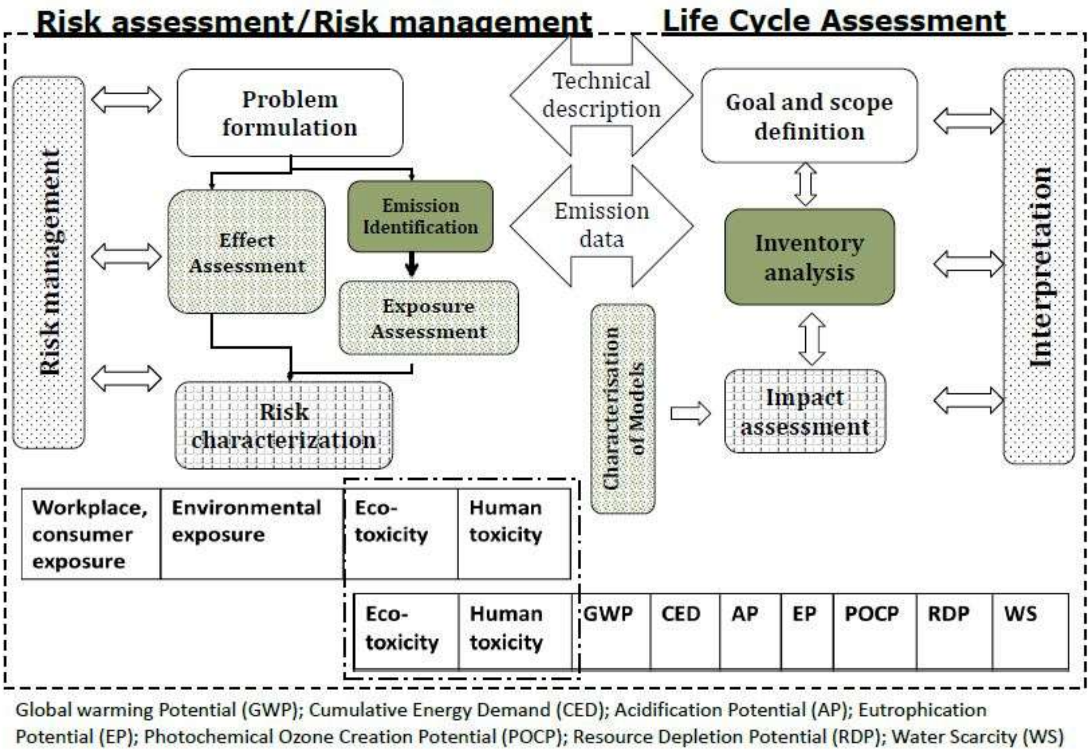

Figure 1: Methodological Framework Linking Risk Assessment with LCA Activities. These links between Risk Assessment and LCA are highlighted by means of the pattern of the text boxes, the arrows and the two bars at the bottom of this figure (modified after Barberio et al. 2014).

3. A literature review and a separate analysis of research focused on applying LCA and RA together for NM, illustrated that current research efforts have taken into account some key “lessons learned” from previous experience with chemicals while many key challenges remain for practically applying these methods to NM. However, scientific research and specific guidance on how to practically apply the two methods are still very much under development. Two main approaches for using these methods together for NM were identified: “LC-based RA” (traditional RA applied in a life cycle perspective) and “RA-complemented LCA” (conventional LCA supplemented by RA in specific life cycle steps), where only the latter genuinely combines LC- and RA-based methods for NM-risk research. One particular issue specific for NM was identified: the need to establish proper dose metrics within both methods. (Grieger et al., 2012).

4. Based on these workshop major conclusions, the OECD WPMN SG9 Project on the Environmentally Sustainable Use of Manufactured Nanomaterials developed this Guidance Manual (GM) aiming at supporting decision making in various situations; from research, innovation, product development, scaling-up of production, marketing, and end-of-life as well as regulatory decisions.

5. Finally, the conclusions of this GM were thoroughly discussed with relevant stakeholders and, additionally, with participants involved in the activity regarding sustainable growth and the responsible development of nanotechnology in the tyre industry. This project is being overseen by the OECD Working Party on Nanotechnology (WPN) and the OECD Working Party on Manufactured Nanomaterials

(WPMN). It was developed from a proposal made to the OECD by the BIAC (the Business and Industry Advisory Committee to the OECD) through the Tyre Industry Project of the World Business Council on Sustainable Development.

2 OBJECTIVES

6. Since the applicability of ISO 14040/44 (ISO 2006) LCA on nanomaterials and nano-enabled products ("nano-LCA") was reaffirmed, there are few nano-LCAs. A number of general and specific operational issues with LCA have been identified allowing its utilization for nanomaterials and nano-enabled applications

7. These key challenges for nano-LCAs include:

1. Identification of reference products; nano-enabled applications often fulfil functions that are quite new and for which it may be difficult to specify functional alternatives;

2. Cut-off rules need to be based on other relevant metrics for nanomaterials including, e.g., size;

3. Uncertainty and rapid production of scientific data means a quickly evolving field for a process that can take 1-2 years to complete and LCA can be a very useful tool optimizing products already in its development stage; and

4. Assessment and understanding of potential human health and eco- toxicity impacts, different exposure scenarios of nanomaterials and nano-enabled applications in an efficient manner is a major area of concern.

8. This document aims to incorporate knowledge of risk analyses of the environmental impact in life cycle assessment studies as decision-making tools during both upstream (research & development) and downstream (industrialisation, usage, re-use, end-of-life management: recycling, recovery, destruction) phases of a nanostructured product. In order to address these issues, especially the need to better link risk assessment and life cycle assessment information, this GM focuses in-depth on a "data-rich" case study, i.e. CNTs in semiconductors. This "data-rich" study was the only one where the majority of the necessary data elements for both a life cycle assessment and a risk assessment were completed and generally available to the SG9 group. It was recognized that it is important developing guidance based on an as complete a dataset as possible. Moreover, existing life cycle and risk data and assessments from the WPMN steering groups such as SG-TA on the Testing and Assessment and SG8 on Exposure Measurement and Exposure Mitigation and relevant outputs from member countries were used to avoid conducting new ones. This GM makes also use of the US document "Guidance to Facilitate Decisions for Sustainable Nanotechnology.", ILCD-Handbook (EU-LCA-Platform) (EC, JRC 2011) and ISO 14040/44 (ISO 2006). The case study is also considering the full lifecycles of products (raw materials extraction, materials processing, product manufacture, product use, recycling and disposal). This GM evolved as it commenced and includes nano-specific thinking with respect to characterization factors and cut-off rules.

9. The case study in this GM brought together risk assessors and life cycle practitioners and/or RA and LCA allowing to further enhance mutual understanding and facilitate early decision-making on the

positive and negative contributions of manufactured nanomaterials with LCA being the methodological focus. It also allowed for:

- An interpretation of human health and eco-toxicology and exposure information on nanomaterials for incorporation into LCA work;

- Develop a relevant holistic presentation approach of LCA and RA information to facilitate consideration by decision-makers, mindful that the goal is not to create single "super-tool";

- Identify areas for priority research and development to ensure further development of efficient assessment tools and systems for evolving applications.

10. This GM especially addresses initial product characterization and identification of potential risks using the case study. This work includes selection of reference cases and questions posed in the various LCA Guidance Documents such as:

1. What is the function of this product?

2. What is the anticipated target market?

3. What are the necessary materials?

4. Is there more than one approach?

5. Are there easily identifiable risks?

6. Where will my product end?

7. What are the potential risks? and

8. Which are (initial) nano-specific considerations potentially relevant to this specific LCA/RA (e.g. metrics, unknown eco-fate, lack of chemical or nanomaterial specific data)?

11. These questions helped articulating a working hypothesis of the case study.

12. Also, this GM contributes, facilitates and could serve as a tool to further support technology or product development including, e.g., green nanotechnology which can have multiple roles and impacts across the whole value chain of a product and can be of an enabling nature in connection with other concepts such as sustainable and green chemistry was well as sustainable and green engineering including manufacturing as outlined in the OECD (2013), "Nanotechnology for Green Innovation", *OECD Science, Technology and Industry Policy Papers,* No. 5, OECD Publishing. http://dx.doi.org/10.1787/5k450q9j8p8q-en.

13. To interpret nano-LCAs and their relevance to decision-making, this GM actively involved various stakeholders including:

- Chemical/nanomaterial manufacturers and processors who develop, adapt, and engineer nanomaterials and formulations containing nanomaterials;

- Product manufacturers who create and design nano-enabled applications;

- Policy makers who make decisions on: Research funding; chemical and product regulation, labelling, and end-of-life issues.

3 KEY ELEMENTS AND METHODS OF RISK ASSESSMENT

Introduction

14. The *hazard* of a substance is its potential to cause harm whereas *risk* is the likelihood of that harm occurring, taking into account wider considerations of *exposure* and *uncertainty*. Thus, risk assessment requires information on both the potential hazard, the release of the substance into the environments and the likelihood and/or degree of resulting short- and long-term exposure (OECD 2012a).

15. While various authorities may adopt slightly different terminology, risk assessment typically includes the following main stages (Royal Society of Chemistry 2013):

a) Identification of the property or situation that could lead to harm (problem formulation);

b) Identification of consequences if the hazard would occur (hazard identification);

c) Estimation of the magnitude of the consequences, which can include consideration of the spatial and temporal scale and the time to onset of the consequences (release assessment);

d) Estimation of the probability of the consequences, which considers the presence of the hazard, the probability of receptors being exposed to the hazard and the probability of harm resulting from exposure to the hazard (exposure assessment);

e) Evaluating the significance of a risk which is the product of the likelihood of the hazard being realized and the severity of the consequences (risk characterization).

16. More specifically in environmental risk assessment integration of hazard, release and exposure data can be carried out in three steps (Fairman et al. 1998):

a) Effects Assessment by identification of the hazard based on the physico-chemical properties, ecotoxicity and intended use, and estimation of a Predicted No Effect Concentration (PNEC), from ecotoxicity data and the application of assessment factors;

b) Exposure Assessment by calculation of a Predicted Environmental Concentration (PEC) derived using monitoring data, realistic worst cases scenarios and predictive modelling techniques taking into consideration control and mitigation measures, release, degradation, and transport and fate mechanisms;

c) Risk Characterization by calculation of the PEC/PNEC ratio, which if larger than 1 indicates that the substance presents a risk to the environment.

17. Similarly, the risk for human health can be characterized through the integration of an exposure level with a no-effect level. For example, under the European REACH Regulation (EC 2007) the exposure level is compared with the appropriate Derived No Effect Level (DNEL) obtained from toxicity data and the application of assessment factors. In this case the risk associated to a certain exposure scenario can be considered to be adequately controlled if exposure level does not exceed the appropriate DNEL (ECHA 2011). If the DNEL cannot be calculated, a semi-quantitative or qualitative risk assessment can be performed: e.g. for non-threshold endpoints the Derived Minimal Effect Level (DMEL) may be useful (ECHA 2011). In the US the exposure level is compared with the appropriate Reference Dose or Concentration (RfD, RfC) obtained from toxicity data and the application of assessment factors. In case the substance shows a non-threshold mode of action, the exposure level is integrated with the Slope Factor (SF), which indicates the increased risk from a lifetime exposure to a certain substance (US EPA 2005).

18. Natural and incidental man-made nanoparticles are ubiquitous in the human environment and their presence and behavior is generally known. However, limited data exist on manufactured nanoparticles in the workplace and the environment. There are major technical challenges to monitor their presence, including those pertaining to their small size and low concentration levels and to distinguishing particles of manufactured nanomaterials from natural or incidental nanoparticles. Detecting nanomaterials in complex matrices such as cosmetics, food, waste, soil, water or sludge is even more challenging. While some monitoring methods exist, these often remain to be validated, which hampers comparability of data (European Commission 2012).

19. A number of organizations are presently actively involved in developing methodologies and techniques to improve tools for risk assessment, including the OECD, WHO, ECHA, EPA, and ECETOC.

20. Since 2004, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Scientific Committee on Consumer Safety (SCCS), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) have been working on the risk assessment of nanomaterials (European Commission 2009, 2012).

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

22. It further asserted that "*health and environmental hazards have been demonstrated for a variety of manufactured nanomaterials. The identified hazards indicate potential toxic effects of nanomaterials for man and the environment. However, it should be noted that not all nanomaterials induce toxic effects. Some manufactured nanomaterials have already been in use for a long time (e.g., carbon black,* TiO_2*) showing low toxicity. Therefore, the hypothesis that smaller means more reactive, and thus more toxic, cannot be substantiated by the published data. In this respect nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case-by-case approach for the risk assessment of nanomaterials is still warranted.*" (European Commission 2012)

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

24. Despite certain limitations as mentioned by the Scientific Committees and Agencies, in particular the need for a case-by-case scientific approach when assessing differences between bulk and various nanoforms of the same chemical substance, it is possible to perform risk assessments of nanomaterials today (OECD 2012, European Commission 2012).

Conventional Risk Assessment Methodologies

25. Table 1 in Annex 1 provides a summary of different conventional risk assessment methodologies. These methodologies are outlined in different guides, toolkit documents, code of practices and chemicals regulation that provide a framework for dealing with health, safety and environmental risks such as REACH (Regulation (EC) No 1907/2006). The guides, toolkits and codes of practices are developed to allow their effective use by different end-users. In the various schemes there is an interaction among risk assessors, risk managers, and other stakeholders through the whole risk assessment process, especially in the project planning and problem formulation stage and the final risk characterization stage. The REACH approach to risk assessment, makes it overall suitable for nanomaterials. The key remaining question is to what extent data for one form of a substance can be used to demonstrate the safety of another form, due to the still developing understanding of, e.g. drivers of toxicity. In a case-by-case scientific approach (European Commission 2012):

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

- Information should be provided on which forms of a substance have been tested, with the test conditions adequately documented;

- Conclusions of a chemical safety assessment should cover all forms in a registration.

26. Where data from one form of a substance are used in demonstration of the safe use of other forms, a scientific justification should be given on how, applying the rules for grouping and read-across[1], the data from a specific test or other information can be used for the other forms of the substance. Similar considerations apply to exposure scenarios and the risk management measures.

Nano-Specific Risk Assessment Methods

27. Table 2 in Annex 1 provides a short summary of different nano-specific risk assessment methods. These are characterized by different frameworks, methodologies, strategies and regulations. They are established with the aim of providing assistance on the essential issues, which should be taken into account when dealing with nanomaterials, as well as offering support on the information required for performing risk assessment and risk management decisions. Some of these risk assessment methodologies were developed for specific manufactured nanomaterials, after noting that a general chemical risk assessment was difficult to apply for nanomaterials for the reason that nanomaterial's risk is influenced by the relationship between toxicity and physical properties rather than chemical properties alone. Different existing approaches offer various solutions in areas including product safety and toxicology, nanoparticle detection and analysis, and duty of care and risk assessment as well as aiming to assist compliance with

[1] REACH, Annex XI, section 1.5

different regulatory requirements and provide support by means of safety procedures and toxicity testing. Some strategies describe different actions proposed to improve the application of the precautionary principle to nanomaterials, including aspects such as increasing nanomaterial's risk research, specific legal frameworks for nanomaterials, labelling and product registration, review of chemical legislation, review of product legislation, review of environmental legislation and social dialogue.

28. The OECD has published recommendations on adaptation of current inhalation toxicity test guidelines for nanomaterials hazard assessment (OECD 2012b). Details of major EU projects dealing with nanosafety can be found in the NanoSafety Cluster Compendium (Riediker 2013)[2] and further guidance e.g. in testing and exposure assessment in the ECHA web page.

Databases

29. There are different databases available which can be used for information in order to feed the respective working steps of the Risk-Assessment process. Table 3 in Annex 1 provides an overview summarizing briefly each of these different databases.

4 KEY ELEMENTS AND METHODS OF LIFE CYCLE ASSESSMENT

General description

30. The methodology of a Life Cycle Assessment (LCA) is a compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product throughout its entire life cycle ("from cradle to grave").

31. According to ISO 14040:2006 and ISO 14044:2006 the following four stages of an LCA can be distinguished (figure 2):

- Goal and scope definition;
- Life Cycle Inventory (LCI) analysis;
- Life Cycle Impact Assessment (LCIA) of the inventory data and
- Interpretation of results.

[2] http://www.nanosafetycluster.eu/home/european-nanosafety-cluster-compendium.html

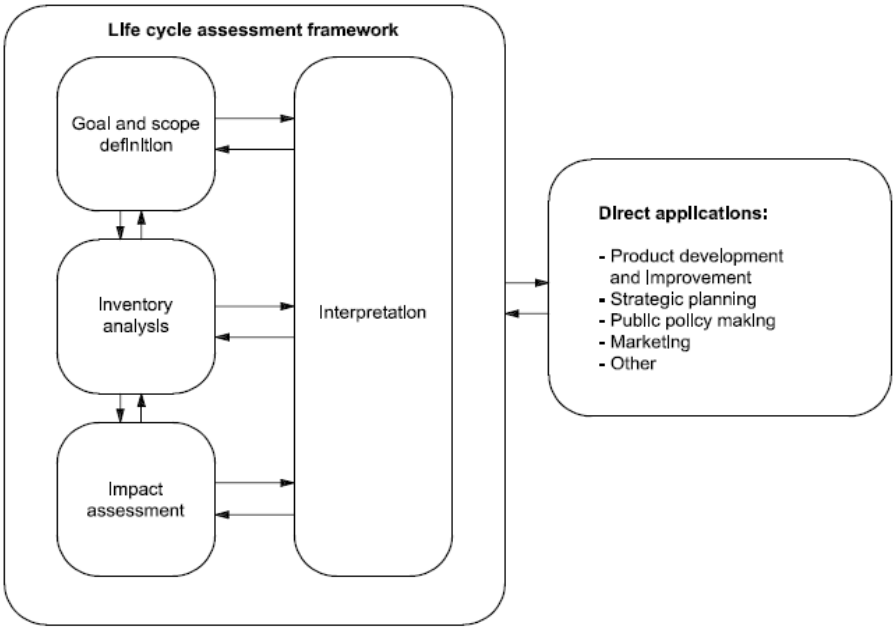

Figure 2: Stages of an LCA [ISO 14040:2006, Environmental management — Life cycle assessment — Principles and framework] [3]

32. The crucial stage of an LCA is the definition of its goal and scope. Within this step, all fundamental assumptions regarding the functionality of the investigated product system as well as functional unit, the system boundaries, allocation and the target audience of the study are defined. These assumptions determine the various unit processes within the study's scope, the corresponding data requirements as well as the relevant environmental impacts that need to be considered.

33. The functional unit is a quantitative measure of the functions that the products (or service) provide. In accordance with the functional unit, the reference flow shall be defined. Comparisons between systems shall be made on the basis of the same function(s), quantified by the same functional unit(s) in the form of their reference flows.

34. The other important step is the choice of the system boundaries, which shall be consistent with the goal of the study. In principle, an LCA always requires to analyze the entire life cycle of the investigated applications from the extraction of raw materials to waste treatment ("from cradle to grave"). However, simplifications can be made in order to reduce the complexity of the product system to a manageable size. When adopting such approach, it is necessary, however, to ensure that all aspects relevant for the environmental impacts will nevertheless be taken into account and that any shifting of a problem from one life-cycle stage to another can be excluded. In this context, it is recommended to prepare a schematic diagram of the product system showing all relevant processes, material and energy flows, as well as the interactions between the processes (see figure 3).

3 The Figures taken from ISO 14040:2006, Environmental management — Life cycle assessment — Principles and framework are reproduced with the permission of the International Organization for Standardization, ISO. This standard can be obtained from any ISO member and from the Web site of the ISO Central Secretariat at the following address: http://www.iso.org/. Copyright remains with ISO.

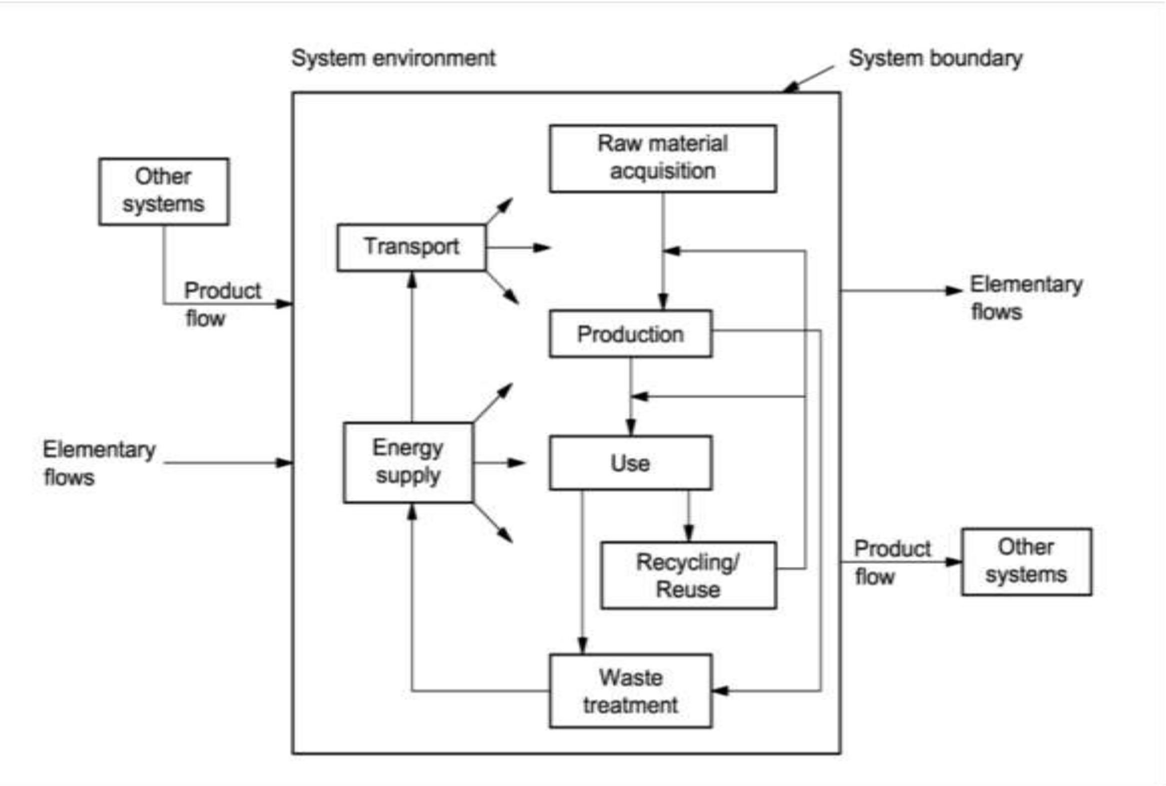

Figure 3: Example for System Boundaries of a Product System (ISO 14040:2006, Environmental management — Life cycle assessment — Principles and framework)[4]

35. The aim of the LCI is to acquire all necessary input (i.e. materials, energy and resources) and output data (i.e. emissions to air, water and soil) for the unit processes within the scope of the LCA. Further information is given in the section "data bases".

36. The LCIA aims to quantify the potential environmental impacts of a product by using the LCI results. This involves associating inventory data with specific environmental impact categories. According to the above mentioned ISO standards the following mandatory elements will be conducted:

- Selection of impact categories, category indicators and characterization models;
- Assignment of LCI results to the selected impact categories (classification);
- Calculation of category indicator results (characterization);
- Calculation of the magnitude of the category indicator results relative to some reference information (normalization)[5].

4 The Figures taken from ISO 14040:2006, Environmental management — Life cycle assessment — Principles and framework are reproduced with the permission of the International Organization for Standardization, ISO. This standard can be obtained from any ISO member and from the Web site of the ISO Central Secretariat at the following address: http://www.iso.org/. Copyright remains with ISO.

37. Within this context, the following environmental impact indicators and categories are considered to be relevant for most LCA studies:

- Cumulated Energy Demand (CED);
- Global Warming Potential (GWP);
- Acidification Potential (AP);
- Eutrophication Potential (EP);
- Photochemical Ozone Creation Potential (POCP);
- Resource Depletion Potential;
- Water scarcity;
- Ecotoxicity;
- Human toxicity.

38. Eco and human toxicity can be important impact categories of an LCA. However, the quality of existing LCI data sets concerning these aspects is currently often rather poor concerning their completeness and consistency.

39. Within the interpretation stage the results from the inventory analysis and the impact assessment are considered using an integrated approach. The interpretation provides a readily understandable, complete and consistent presentation of the results in accordance with the goal and scope definition. Important aspects to be addressed during this stage are:

- Determination of the contributions to the overall indicator results based on the outcomes of the LCI and LCIA,
- Evaluation of the results considering completeness, sensitivity and consistency checks,
- Identification of hot spots and significant issues for further improvements of the environmental performance of the product system,
- Life Cycle Inventory (LCI) modelling framework.

40. In the LCA it is important to define the principles to perform the LCI modelling and the method to approaches. Currently, two major LCI modelling principles are in use in LCA practice: attributional and consequential modelling modified by some variants (EC, JRC 2011). The attributional modelling is often referred to system product or average supply chain, including their use and end-of-life. This is a static approach and is referred to averaging effect. The consequential approach, however, is often referred to system product or scenario, which represents prospective marginal consequences concerning the analyzed

[5] This point is not mandatory. It is an optional element in the ISO and it is helpful in some situations as checking for inconsistencies, providing and communicating information on the relative significance of the indicator results, and preparing for additional procedures, such as grouping, weighting or life cycle interpretation.

system[6]. This is a dynamic approach, where the system interacts with the markets and produces some changes as an additional demand for the analyzed system (EC, JRC 2011).

Nano-Specific LCA

41. Table 3 in Annex 2 provides a short but not exhaustive summary of different nanospecific items to be included in LCA. The current nanospecific deficiencies in LCA can be reduced by method advancements in the inventory and impact assessment. These are characterized by different frameworks, methodologies and strategies. They are established with the aim of providing assistance on the essential issues, which should be taken into account when dealing with nanomaterials and nanoproducts.

Data Bases

42. The collection of the inventory of an LCA study can be very time-consuming, since a large quantity of data needs to be collected for each unit process within the system boundaries. So called "primary data" is collected directly on site, while "secondary data" is derived from literature and databases. In order to facilitate this exercise, many databases have been developed and are still under development worldwide in order to support LCA practitioners with predefined LCI datasets.

43. Several governments developed and/or promoted a national LCI database. For example, the U.S. Department of Energy (DOE) has promoted the US Life Cycle Inventory Database; in Japan, the Japanese Environmental Management Association for Industry (JEMAI) has developed a carbon footprint database; in Australia the Australian National Life Cycle Inventory Database (AusLCI) is a major initiative currently being delivered by the Australian Life Cycle Assessment Society (ALCAS). Furthermore the European Commission by mean of JRS has promoted the European Platform on Life Cycle Assessment (EPLCA), which has developed the European Reference Life Cycle Database (ELCD) of Life Cycle Inventory, the International reference Life Cycle Data System (ILCD) Handbook (EC, JRC 2011), and the Life Cycle Data Network (LCDN). Another important activity concerning databases is the Life Cycle Inventory Program launched by the UNEP/SETAC Life Cycle Initiative with the aim to spread Life Cycle Thinking. This initiative has developed a registry with the aim to exchange LCA data among providers and users of LCA data. The registry has been filled with information about international, sectorial, national, commercial and non-commercial databases for life cycle approaches worldwide. Moreover there are many commercial LCA databases available, as GaBi and Ecoinvent, as well as sector LCA database promoted by industrial association as European Federation of Corrugated Board Manufacturers (FEFCO); International Aluminum Association; International Copper Institute (ICI); Plastics Europe; world steel; Cotton Inc; European Aluminum Association; EuroFer; Agri-Footprint network.

44. The LCI database initiatives in US and Europe have built up networks of stakeholders to collect data, to share information and to provide useful information on data quality to users. In general, these databases pay attention to assure a high data quality especially by using clearly defined metadata for each data set (see Table 1 in Annex 2).

[6] http://globe.setac.org/2011/july/milan-lca.html

45. The mentioned databases and activities improve completeness, robustness and reliability of the LCI and thus the validity of LCA studies.

Reporting Formats

46. LCA studies shall be reported in transparent and accurate manner in order to avoid misunderstanding through the "LCA report" template. The aim of the LCA report is to present the results of the LCA study to the intended target audience by providing all the relevant information for reproducing the study. Clear and robust report documentation enables the experts and decision makers to fully comprehend all major findings and helps to identify the best environmental choice or possible improvement potentials.

47. Therefore, the LCA report shall clearly describe the goal and scope of the study including its assumptions and limitations. Furthermore, all information regarding the used data sets has to be reported, describing primary data with the methodologies used for data collection and all secondary data from literature or database. For each data set, the corresponding metadata (especially concerning geographical, time-related and technological coverage) shall also be reported.

5 STEP-BY-STEP APPROACH

48. RA and LCA have fundamentally different approaches to assess human health or environmental consequences posed by released nanoparticles. RA compares a nanoparticle exposure level to a threshold value (acceptable exposure level) and comes up with a clear answer "no risk" or a "risk" level. Depending on the outcome, risk management measures are recommended/ enforced. The goal is to prevent impacts. In contrast to this rather "black-white" concept of RA, LCA takes a relative approach with marginal impacts, i.e. any nanoparticle release will result in an impact, linearly increasing with increasing emission. This impact is related to an entire range of other impacts caused by other substances in order to put the (often marginal) impacts of (in this case) nanoparticles into a larger context (as explained earlier in the document). The goal of LCA is to provide an answer on the comparative advantages or disadvantages between two services or products. This answer is provided with quantified impacts from different categories, as e.g. human health, eco-toxicity, global warming potential, etc. These categories are also called "endpoints", which has a different meaning than in RA, where endpoint describes the consequence of a mode of toxic action, e.g. inflammation or genotoxicity.

49. Another difference between RA and LCA is that the life-cycle is understood differently: In LCA, the required resources and generated emissions from the entire life cycle of a product or service (defined by the functional unit) is considered. This stays on contrast to RA, where the risks of a single substance at particular points in its life cycle are assessed. Therefore, a life-cycle based RA is not the same as an LCA. The former reveals hotspots of potential nano-specific concern along the life-cycle of a nanomaterial while the latter provides a holistic, but less precise assessment along the entire life-cycle of an applied nanomaterial. This contrariety also leads to differences in the uncertainty assessment: the fate and exposure assessment is often less complex for RA with its clearer temporal and spatial boundaries while LCA often has much broader geographical and temporal boundaries because background data (i.e. generic production

processes and emissions from databases) are usually not case specific. Ideally, data from exposure assessment in RA can then be used for LCA which might decrease the uncertainties accordingly.

50. An important side note is that the starting point of the exposure assessment sometimes differs between RA and LCA. An example is the indoor exposure assessment: While release factors, i.e. emitted number of nanoparticles per time, are pivotal for the connection of the functional unit (LCA) with the exposure, the exposure assessment in RA starts with the concentration of nanoparticles (e.g. number of nanoparticles per volume). This fact makes the transfer of exposure data from RA to LCA difficult.

51. On the other hand, toxicity data from the hazard assessment in RA can be used for the calculation of effect factors in LCA. In any case it is important to consider new nanospecific modes of actions or physic-chemical phenomena which are not routinely assessed with the traditional methods (applied to conventional chemicals). Examples are different dissolution behaviour, nanoparticle surface and structure effects, but also particular cellular impacts because of the Trojan horse effect (Lynch et al. 2014). In parallel it is crucial to develop standardized procedures to determine the toxicity of nanomaterials in order to facilitate a consistent and robust interpretation of the studies for further use in LCA or RA.

52. The following chapter describes step by step the nano-specific challenges in LCA which sometimes can be supported or solved with data and approaches from RA. The case study is integrated – but separated in a grey box – into this step by step structure in order to underline the relevance and the content of each single of these steps. More information on challenges in the simultaneous use of LCA and RA are found in Christensen et al. (2004), and Seager et al. (2008) and Walser et al. (2013).

5.1 Step 1: Goal and Scope Definition

53. Nanomaterials do not represent a homogeneous substance group. These materials differ strongly from one another in their physical and structural properties. Therefore, a single elementary identity is not enough to describe nanomaterials, because depending on the structural composition of the elements (e.g. differences in core and surface) their potential for chemical and bio-chemical reactions is widely differing. Therefore, LCA studies of nano-enabled applications should be conducted as specific for the investigated nanomaterial as possible[7], as long as no grouping or read-across for the nanomaterial in question has been established.

54. In order to ensure a common standard when performing such case-specific studies, a clear definition of the goal(s) and scope of the analysis is indispensable. Within this context, it is proposed to take into account the following aspects by default:

- Definition of the application's functionality and its downstream use;
- Specification and quantification of the nanomaterial;
- Definition of the functional unit;
- Definition of the system boundaries;
- Definition of a reference application;

[7] LCA practitioner might need to chose existing nanospecific data from an inventory, because of a lack of resources to generate own data. Hence, some flexibility regarding the similarity of nanomaterials is needed.

55. These aspects will be further explained in the following paragraphs.

56. One of the basic principles of LCA in general is the finding that there is no absolute standard by which an ecological or sustainable product could be appropriately defined. This is due to the fact that any environmental performance of a product or service always needs to be assessed in the context of its functionality. For example, there is no “sustainable material”, but only most sustainable material for a certain purpose. Hence, reliable conclusions about the sustainability of a product or application can only be drawn in the context of an examination of (a) certain function(s). This requires a detailed consideration of the **functionality** of the investigated application and its benefit aspects. For this reason, the benefit aspects of the nano-enabled application being assessed should be carefully analyzed and identified at the very beginning of the process. The precise specification of benefit aspects is especially important for the scoping process, because otherwise the functional unit (see below) cannot be properly defined. Using this as a basis, benefit aspects that constitute basic technical functionalities should then be established and distinguished from those representing additional benefits. Furthermore, the **target market**(s) and the (possible) user(s) of the nano-enabled application need to be clearly specified.

57. Based on the functionality of the nano-enabled application, the characteristics of the used **nanomaterial** are required. A list of prioritized key properties is shown below (BMU 2010). It is necessary to keep the characterizers consistent along the life-cycle of the nanomaterial. Only the same measurement units (e.g. number distribution) in fate, exposure and impact assessment allows to connect the outcome of the individual assessments

- The following characteristics are of high importance:
  - Elemental composition
  - Aspect ratios (length-to-width ratio)
  - Particle size
  - Particle size distribution
  - Surface functionalization
  - Coating
- These further characteristics provide very valuable information:
  - Manufacturer
  - Brand name
- Information from safety data sheets;
- Further special features or characteristics.

58. Since LCA studies are considered to be especially meaningful when performing a comparison of two or more objects, a *comparative* view of the nano-enabled application relative to an already available application is recommended. Regarding the definition of such a **reference application**, it is proposed to select a product in which the functionality under examination is achieved without the use of nanomaterials. The reason for this is to enable a comparison of the nano-enabled application with a reference application

in order to establish which benefit and risk aspects result specifically from the use of nanomaterials or nanotechnology. When selecting a reference application, it is important to ensure that both nano and reference application have the same basic technical functionality (see above). This principle of functional equivalence is very important, since otherwise alternatives will be examined and evaluated that are not comparable. If the nano-enabled application is an entirely new product or has novel properties that could not have been produced hitherto, specification of a reference application with the same basic technical functionality will not be possible in the individual case. In such cases the "next best" reference application must be chosen instead, i.e. a product with a functionality most closely resembling that of the nano-enabled application. The choice should be guided by the question of which conventional product the nano-enabled application might substitute when it is placed on the market or if demand increases. Whatever the case may be, it is important to document transparently the assumptions on which the choice of the reference application is based and include this as supplementary information in the results of the assessment (BMU 2010).

59. The identification of the basic common functionality of the objects that are to be compared forms the basis for identifying the **functional unit**. The functional unit represents the quantified functionality, which has the same validity for both the nano-enabled application and the reference application. This parameter serves as comparison unit of the investigation and as a reference for all results of the impact indicators. An example might be the "use of a flatscreen monitor for one year", for which a nano-enabled and a conventional product exists which can both be used for the same "service", i.e. for working or enjoying a movie. The functional unit is then translated into different **reference flows** for each of the compared products or services which are providing same functional unit. The reference flow is expressed in physical variables and consists of all material and energy inputs which are required to fulfill the functional unit. Life Cycle Inventories support the investigation of all up-stream data for the completion of the reference flows. For the example above, this would mean the material and energy requirements for the production of the flat screen, as well as energy requirements during the use phase and disposal phase.

60. Another important assumption of any LCA study is the definition of the **system boundaries**, i.e. the modules which have to be taken into account. Modules represent processes, activities or aspects of the product system under investigation, for which data has to be collected. In this context, it is important for the nano-enabled application to ensure that all relevant environmental impacts are taken into account and that any shifting of a problem from one life-cycle stage to another can be excluded. Moreover, as presented in chapter 4 (Figure 2), it is helpful to prepare a schematic diagram of the product system.

61. System boundaries for the nano-enabled application and the reference application must be selected, in such a way that all processes, material and energy flows and aspects, which are relevant for providing the functionality of the product system and for a fair comparison between the two options, are within the system boundaries of the investigation. The examination should, among other things, cover energy savings made throughout the use phase resulting from certain product components, as well as any additional expenses or emissions produced throughout the waste treatment process. When limiting the comparison on the examination of different processes for the same material (e.g. various production pathways for a nanomaterial xy), then the system boundaries and the functional unit are related to a certain amount or volume of this material; the functionality of the material showing no differences.

Case Study "CNT in Semiconductors"

1. Application Profile and Scoping of the Case Study

1. Carbon nanotubes (CNT) demonstrate great promises in a variety of electrical and electronic applications due to their unique mechanical, thermal, and electrical properties. Especially, CNT and their

compounds exhibit extraordinary electrical properties for organic materials, and have a huge potential in electrical and electronic applications such as photovoltaics, sensors, semiconductor devices, displays, conductors, smart textiles and energy conversion devices (e.g., fuel cells, harvesters and batteries) (Thiele and Das 2013).

2. CNTs are composed of carbon fiber with nanometer-size diameter and micrometer-size length. Basically, they are sheets of graphite rolled up into a tube. They can be classified into two major types: single-walled CNT (SWCNT) and multi-walled CNT (MWCNT). MWCNT is comprised of 2 to 30 concentric graphite layers, whose diameter ranges from 10 to 50 nm and more than 10 µm in length. SWCNT has diameter from 1.0 to 1.4 nm. The unique characteristics of CNTs are due to the different electrical and thermal conductivities they exhibit when their hexagonal structures are oriented differently. These different structures allow the CNT to act like metal, semiconductor and insulator, respectively. (Lo 2006).

3. Generally, CNTs can be used for making transistors and applied as conductive layers for the rapidly growing touch screen market. For example, CNTs are considered as a viable replacement for ITO transparent conductors in some applications. Fabricated as transparent conductive films (TCF), carbon nanotubes can potentially be used as a highly conductive, transparent and cost efficient alternative in flexible displays and touch screens. Apart from TCF applications carbon nanotubes for thin-film batteries, super capacitors and ultra-conductive copper will reach a significant share of the overall market driving the further ramp-up of production capacity and with that cost reduction. (Thiele and Das 2013)

4. Within this case study, CNT used for electrically conductive plastic sheets as packaging material for electronic components are reviewed as an illustrative example on how to bring closer together risk assessors and LCA practitioners. SG9 evaluated various existing LCA reports and data inventories and came to the conclusion that this case study currently further elaborated within the NanoSustain Project (EU 7th Framework Programme[8]) covers (EU-NanoSustain Project 2013):

- a “data-rich” nano-enabled application,
- is well-documented and thus
- suitable as an appropriate case study for the Guidance Manual.

5. According to the aspects to be considered during the scoping of a study (section 5.1) the **functionality** of the application is defined to provide conductive plastic sheets made out of polycarbonate as antistatic packaging material for electronic components. By incorporating CNT instead of the currently used carbon black it is possible to reduce the foil thickness by 20%, resulting in 20% savings regarding the polycarbonate consumption. Relevant target market is the electronic industry, especially semiconductor industry.

6. The used CNT is specified as a MWCNT manufactured by Bayer with the brand name “Baytubes® C 150 HP”. The detailed material **specifications** are given in table 1.

Table 1: Product specifications of Baytubes® C 150 HP [Source: Baytubes C 150 HP datasheet]

[8] Details and reports can either downloaded from http://cordis.europa.eu/project/rcn/94362_en.html or obtain report free of charge via http://www.nanosustain.eu/component/content/article/1-latest-news/128-nanosu and http://www.nanosafetycluster.eu/eu-nanosafety-cluster-projects/seventh-framework-programme-projects/nanosustain.html.

Product specifications	Value	Unit	Method
C-Purity	> 99	%	Elementary analysis
Free amorphous carbon	not detectable	%	TEM
Number of walls	3-15	-	TEM
Outer mean diameter	13-16	nm	TEM
Outer diameter distribution	5-20	nm	TEM
Inner mean diameter	4	nm	TEM
Inner diameter distribution	2-6	nm	TEM
Length	1 - >10	µm	SEM
Bulk density	140-160	kg/m³	EN ISO 60
Lose agglomerate size	0,3-1	mm	PSO

7. The **system boundaries** of the baseline case study (figure 4) encompass all life cycle stages from resource extraction and production of intermediates up to the production of the plastic sheets. The use phase was not covered within the existing case study, as it was assumed that there was no significant difference between the CNT and the reference product. The same assumption was made for the end-of-life stage (recycling and disposal). Possible risks caused by the usage of CNT will be addressed in this case study report only in a qualitative way.

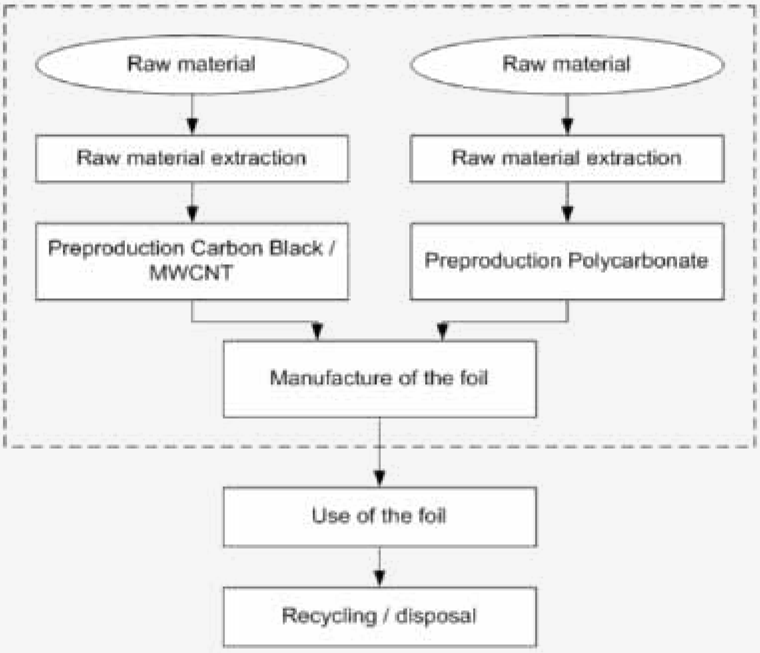

Figure 4: System boundaries of the case study

8. In the case study "new" foil (containing MWCNT) was compared with a prevailing product on the market. This "**reference product**" was defined as a polycarbonate sheet made conductive by using carbon black. In order to provide the same functionality, a significant higher additive content (15% carbon black vs. 3% MWCNT) was necessary. Hence, the reference product requires more polymer granulate for the same mechanical properties. As a result, functional equivalence was given when comparing 1'000kg of "old" foil (containing carbon black) with 800kg of "new" foil (containing MWCNT).

9. As additional information another case study was published in July 2014 by OECD: "*Nanotechnology and Tyres: Greening Industry and Transport*". This report provided insights into the policy issues related to nanotechnology use in the tyre industry, i.e. the status of nanotechnology innovation, the economic and social costs and benefits, their safe use, decision making[9].

10. The OECD report on tyres included a risk management framework to enable site-specific or company-specific risk assessments or risk management strategies for using nanomaterials as additives in tyres. It also gives insights into: the status of nanotechnology innovation in the sector and the drivers of innovation in the tyre industry; the economic and social costs and benefits of using nanotechnology in tyres; the preconditions of safe use of new nanomaterials at all stages of their life cycles; the identification of the tools and frameworks supporting decision making at various stages of product development; and the facilitation of outreach and knowledge transfer on the safe use of new nanomaterials. The report emphasises the importance of:

- The policies to support research in the environmental, health and safety risks, as well as those to support the commercialisation of nanotechnology research results, for fostering responsible innovation in the tyre sector;
- Using available tools (e.g. cost/benefit analysis, LCA) to gain better insight into the socio-economic and environmental impacts of nanotechnology applications;
- Collaboration between governments and industry to address the specific challenges raised by the introduction of new nanomaterials in different industry sectors.

Finally, this report summarises the conclusions of a two years project, which was originally proposed and supported by the Business and Industry Advisor Committee to the OECD (BIAC) through the Tyre Industry Project (TIP) of the World Business Council for Sustainable Development (WBCSD).

5.2 Step 2: Make use of Databases and Sources of Risk Assessment

62. Which of the various databases and sources for risk assessment summarized in chapter 3 contain actually suitable data for LCA studies? To answer this question, among the four stages of an LCA – shown in Figure 1, chapter 4 – only two of these stages have to be considered as relevant– Life Cycle Inventory Analysis and Life Cycle Impact Assessment –, then the two other steps (i.e. goal & scope definition, interpretation) do not deal directly with the actual numbers of the material and energy flows examined within an LCA study.

63. **Life Cycle Inventory Analysis**: The first of these two steps is focusing on the collection of the actual energy and material flow data (i.e. the process inputs and outputs) for each single process step of the investigated system. Thus, first of all, data sources containing quantitative information about material and energy inputs, waste amounts and emissions (to air, water, or soil) for the production of a defined amount of the used nanomaterial are required. But also respective data for one unit of the specific service that this nanomaterial is offering in the examined context are required. Hence, in this step, no input can be expected from the various RA databases, as they simply do not report such input and/or output data (like e.g. emissions of nanoparticles to the air) in relation to a functional unit. An example of life cycle inventory analysis is given in Chapter 4 of "*Nanotechnology and Tyres: Greening Industry and Transport*" (available on http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/nanotechnology-and-tyres_9789264209152-en#page1).

9 This report is available on http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/nanotechnology-and-tyres_9789264209152-en#page1

64. Currently there are indeed hardly any datasets available for the manufactured nanomaterials with a high potential for future industrial applications (see e.g. Hischier and Walser, 2012); then only very few of these published LCA activities in the area of nanotechnology applications contain in the paper and/or its supporting materials the actual inventory data for the manufactured nanomaterial. An overview of this situation can be found in Table 1 of Annex 3; table that shows clearly also that a majority of these data sources does not contain a complete set of these input and output data, but only part of such information. On the level of LCI databases the situation is even scarcer in this issue. The database ecoinvent (ecoinvent Centre, 2013) – one of the biggest databases for such life cycle inventory datasets, reporting its data in a transparent gate-to-gate approach – contains datasets for several metals or for carbon black – but specific datasets for any kind of manufactured nanomaterials are not available yet within this database neither. The situation is similar in the other relevant LCI databases, e.g. the GaBi database (Thinkstep GaBi LCA Databases). Hence, considerable efforts are required in the future to establish (at least) a basic set of LCI datasets covering the most important share of nanomaterials, in order to offer a starting point for more adequate LCA studies for application cases of manufactured nanomaterials.

65. **Life Cycle Impact Assessment**: The situation is quite different for the second step, as here substance specific data – similar as in RA – are required in order to calculate the so-called characterization factors (CFs), i.e. a substance-specific factor that is calculated with a characterization model in order to express the impact from a particular emission in terms of the common unit of the category indicator representing a specific ecological impact, like e.g. Global Warming (EC-JRC, 2010). As stipulated in Smita et al., 2012, 'various environmental processes that depend on the presence of physical entities are likely to be altered by the accumulation of nanomaterials in the environment'. Part of these processes is e.g. the formation of dust clouds, the influence on atmospheric composition, the influence on stratospheric temperature, or the accumulation in biological matrices (i.e. toxicity issues).

66. For this guidance manual, the focus is applied on the toxicological impacts (eco-toxicity, human toxicity) of emissions of (engineered) nanoparticles into the environment, as "toxicity" is the by far most often cited concern in publications dealing with emissions of (engineered) nano-particles into the environment (see e.g. Colvin, 2003 or The Royal Society and The Royal Academy of Engineering, 2004). Within the LCA community, a consensus model for the assessment of these toxicological categories has been developed in the last years under the umbrella of the UNEP-SETAC Life Cycle Initiative (see Fava, 2002; Töpfer, 2002), called the USEtox LCIA model (Rosenbaum et al., 2008). However so far, the model developers of this consensus model did not include any emissions of (engineered) nanoparticles; actually the current approach has been developed specifically for releases of (organic) chemicals. With Eckelman et al., 2012, and Salieri et al. 2015, two recent publications reporting eco-toxicity CFs (for carbon nanotubes (CNT) resp. nano-TiO_2) for the USEtox model can be found in the literature. Due to high uncertainties especially concerning the actual mechanisms of toxicity of these nanomaterials, Eckelman and Salieri report in the end quite large uncertainties for the actual values of the CFs of CNT resp. nano-TiO_2.

67. The USEtox LCIA model for toxicological impacts consists in both cases (i.e. for eco-toxicity and for human toxicity) of three distinguished parts – a fate model, followed by an exposure model and in the last part an effect model. Each of these three parts has different requirements concerning sub-stance-specific information and data that are necessary in order to model the respective step. In parallel to the evaluation of the availability of such data, the model structure itself must be evaluated regarding the suitability for nanomaterials. Once the modelling is declared "suitable", tailored data collection and integration can start. The particularities of fate, exposure and impact assessment are examined in more details in the following paragraphs (focused on emissions of nanomaterials).

68. One particular shortcoming related to nanoparticle exposure is that workplace exposure and direct exposure of consumers by products are seldom assessed with LCA even though they have been shown to be relevant during production and handling of nanomaterials. USEtox was recently extended by

an indoor compartment, applicable to worker and consumer exposure to conventional chemicals. It might also be applicable for nanomaterials after further evaluation.

69. Concerning the fate model in LCIA, the main challenge today lays in the fact that neither of the two main fate models (i.e. the USEtox model, described in Birkved and Heijungs, 2011, and the particulate matter (PM) assessment model described in Humbert et al., 2011) used, has been adapted for emissions of nanoparticles; deducted from the fact that neither of these models is mentioning this type of emissions in its publication. The PM assessment model actually explicitly excludes what is called ultrafine particles (UFP), i.e. particles with a diameter below 100 nm (Fantke et al., submitted). When looking into the area of risk assessment, several recent publication in this issue – i.e. how to model (in a first step at least) the fate of manufactured nanomaterials – can be identified, applying either a so-called 'flow model' approach (e.g. Boxall et al., 2007; or Gottschalk et al., 2009) or a so-called 'mechanistic model' (e.g. Arvidsson et al., 2011; Quik et al., 2011; or Praetorius et al., 2012). While the first approach ('flow model') – taking into account the total emission of a substance and the volume of the receiving compartment only – is not specific to nanomaterials, the latter approach is using physiochemical parameters related to the emitted material (e.g. the manufactured nanomaterial). According to Arvidsson et al., 2011, there is so far however only a limited under-standing of this issue, due to the fact that the well-established knowledge of chemical substances for fate processes cannot be transferred 1:1 to the emissions of manufactured nanomaterials. Between the various authors stipulated here, there is an agreement on the fact that emissions of manufactured nanomaterials behave differently than ordinary chemicals in this issue. Klaine and co-workers highlight in their 2012 publication another crucial point in this context: the emitted nanomaterials are different from the pristine material (i.e. from the material used in the production) – they are aged, altered (e.g. from surface processing, etc.) and thus most probably behave – on the level of fate (but eventually also on the level of exposure and/or the level of the effect) – differently than the original pristine materials (Klaine et al., 2012). In the same time, Klaine and co-workers end up with the same conclusion like the above listed further authors – i.e. that information in the issue of the fate prediction of such materials is lacking so far.

70. A multimedia model specifically for the behavior of releases of engineered nanomaterials has been published by Meesters and co-workers (Meesters et al., 2014). Building upon the SimpleBox model that is used for the exposure assessment in REACH, this modified version takes into account especially nanospecific transformation processes like aggregation, attachment or dissolution. The whole model is based on first-order kinetics in order to estimate the steady-state concentrations in the various compartments distinguished within the model by making use of physical and chemical properties of the emitted engineered nano-material (ENM).

71. The picture for the next step, i.e. the exposure modelling, looks for the moment much more challenging. Then a recent publication from Klaine and co-workers stipulates that "quantifying nanomaterial exposure and effects are challenges facing environmental scientists" (Klaine et al., 2012). According to Klaine and co-workers the knowledge gap in the issue of quantifying the exposure is one of the main points that need to be solved. And similar to the fate modelling, manufactured nanomaterials add one level of complexity by the fact that these materials alter and can be transformed in the product's use, resulting in emissions with different properties than the original (pristine) nanomaterials.

72. The third element in the LCIA model is the effect modelling. The USEtox model is requiring – similar to other assessment models for toxicological issues – EC_{50} (in case of freshwater ecotoxicology) resp. ED_{50} (in case of human toxicity) values in order to calculate the effect factor. However, the USEtox model contains approximation procedures, allowing deducting these values from animal data – which seems rather problematic. Instead, a procedure for the use of in vitro data for the extrapolation would make more sense. Furthermore, a recent examination of literature dealing with toxicological effects of manufactured nanomaterials identified composition, size resp. particle size distribution, surface chemistry

and zeta potential as the most relevant properties in this context (Hischier, 2014); meaning that the actual values of these properties have a major influence on the actual toxicological effect of the respective manufactured nanomaterial. Thus, in order to fill the LCIA model, EC resp. ED_{50} values in function of the listed properties are required. A study published by Kahru and Dubourguier reviewed EC_{50} values for some of the most often used manufactured nanomaterials (Kahru and Dubourguier, 2010); but, there is just one value shown there per type of nanomaterial; but no influence on the toxicity values due to other material properties are highlighted in this review article. The various RA databases listed in Annex 1, Table 3 do not contain a systematic overview of these kinds of data; a majority of the listed RA databases contain qualitative information (especially links to publications and/or projects) about the various manufactured nanomaterials covered by the respective tool. Hence, currently there is no other way for getting human ED_{50} values than doing an individual literature survey for the ENM used.

Case Study "CNT in Semiconductors"
2. Make use of Databases and Sources of Risk Assessment

1. For the **Life Cycle Inventory Analysis** the authors of the case study were using umberto as the modelling software and the version v2.01 of ecoinvent (ecoinvent Centre 2007) as background database for all their calculations.
2. The production data for carbon black, polycarbonate as well as the data for the manufacture of the foil are taken from the mentioned background database. No own data collection for these materials and processes has taken place in the framework of this case study.
3. For the production process of MWCNT, the authors of the case study cooperated very closely with Bayer MaterialScience Ltd, the producing company of the used CNTs "Baytubes® C 150 HP". Bayer MaterialScience Ltd uses for the production a specific form of CVD (chemical vapor deposition) in a fluidized bed, i.e. a catalytic chemical vapor deposition (CCVD) process. A big advantage of this specific production process is the fact, that an up-scaling of this technology is quite easily possible (although, in 2013 Bayer MaterialScience Ltd announced the shutting down of its pilot plant[10]). A schematic overview of this process is shown in Figure 5.

[10] See e.g. http://www.rsc.org/chemistryworld/2013/05/carbon-nanotubes-not-commercially-viable-bayer

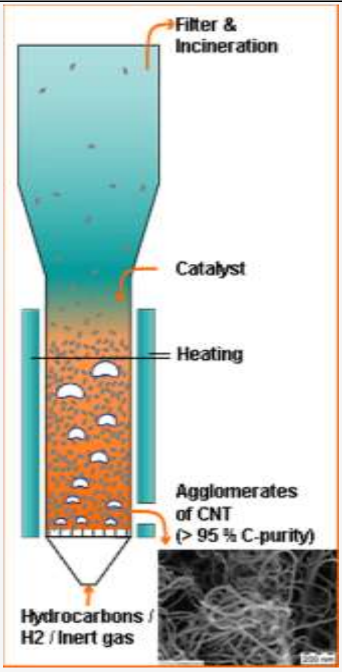

Figure 5: Schematic overview of the CCVD process for the production of Baytubes® C 150 HP [Source: Steinfeldt et al, 2010]

Based on literature data and information from Bayer Material Science Ltd., the production process for MWCNT has been modelled by the authors of the study in the following way:

- Various hydrocarbons can be used as starting material. For this study a gas mix of 40Vol.-% ethylene, 40 Vol.-% hydrogen and 20 Vol.-% nitrogen has been used.

- As default, an efficiency of 65% concerning the transformation of the carbon (from the ethylene input) to CNT is used here – based on the range of 40-90%, indicated by Bayer Material Science Ltd.

- The process requires a catalyst, on which the growing of the CNTs takes place. This catalyst is assumed to be a composed of 37% manganese and 43% cobalt on a carrier material, consisting of 10% magnesium oxide and 10% aluminum oxide.

- As default, a consumption rate for the catalyst of 1:15 (i.e. 15g of MWCNT are produced per gram of consumed catalyst, as the catalyst is discharged together with the product) is used here – based on the range of 5-25 g of MWCNT production per gram of catalyst, indicated by Bayer Material Science Ltd.

- The electricity consumption of the pilot installation that Bayer Material Science Ltd was running in 2007 was in the order of 2 kWh/kg of produced MWCNT, value that has been taken by the authors of the study as default value.

- Concerning the heating energy, it is assumed as default situation that the educts (i.e. ethylene and hydrogen) cover the required energy amount – i.e. there is no additional fuel input assumed for this study here.

- It results a total primary energy consumption of 165.46 MJ-Eq/kg (including the above reported electricity consumption) for the overall production process of MWCNTs.

Table 2 summarizes the life cycle inventory data for the production of 1 kg MWCNTs (type Baytubes® C 150 HP) in the pilot installation of Bayer Material Science Ltd in 2007.

Table 2: Life Cycle Inventory of the production of 1 kg of Baytubes® C 150 HP MWCNT (data sources, see text above)

Input	Amount	unit
Ethylene	1.795	kg
Hydrogen	0.137	kg
Nitrogen	0.953	kg
Aluminium oxide	6.667	g
Magnesium oxide	6.667	g
Manganese	24.667	g
Cobalt	28.667	g
Electricity	2.0	kWh
Output		
MWCNT (Baytubes® C 150 HP)	1	kg

For all inputs, respective datasets from the database ecoinvent (v2.01) have been used by the authors in their model calculation.

4. For the **Life Cycle Impact Assessment** step, the authors applied the CML 2001 method; i.e. a LCIA method on the midpoint level that takes into account the classic categories (like e.g. global warming potential, acidification potential, eutrophication potential or the consumption of non-renewable resources) in a quantitative way; eventual releases of nanoparticles are not taken into account in neither of the various midpoint categories of this LCIA method. Therefore the study contains in addition a qualitative discussion for the topic of these eventual releases of nanoparticles along the examined life cycle.

5.3 Step 3: Use of Scenarios for Modelling-based Assumptions

73. Scenario Modelling is a well-known issue in LCA and various publications about this topic can be found in literature over the past about 15 years. The paper from Pesonen and co-workers, summarizing the work of a SETAC-Europe working group about this topic, can be considered as a first cornerstone in this topic (Pesonen et al., 2000). One of the key elements of that paper is the definition of the term 'scenario' for the area of LCA – i.e. a scenario is "a description of a possible future situation relevant for specific LCA applications, based on specific assumption about the future, and (when relevant) also including the presentation of the development from the present to the future".

74. According to Börjeson et al., 2006, three categories can be distinguished among the scenarios – predictive, explorative, and normative ones – and each of these categories can further be divided into two sub-categories (i.e. predictive into forecast and what-if; explorative into external and strategic; normative into preserving and transforming).

75. In the context of LCA studies dealing with ENM and their applications, lacking currently a lot of quantitative information in the inventory modelling of the production of ENMs (and products containing ENMs), but especially also in the modelling of eventual releases of ENMs along the complete life cycle as well as their potential impacts, explorative scenario modelling appears to be the most relevant category. Concerning the application phase for ENM-containing products, what-if scenarios could be seen as another

relevant (sub-)category of scenarios; while the remaining in Börjeson et al., 2006, listed types of scenarios play only a minor role in the context of ENM studies.

76. In the center of this explorative scenario modelling is the modelling of eventual ENM releases; the modelling of all (other) input and output flows during the production process of a specific ENM is done, based on traditional modelling principles and approaches for chemical substances – like described e.g. in Hischier et al., 2005.

77. For the modelling of eventual ENM releases along the life cycle a common modelling approach should to be applied. In order to overcome the lack of experimental data in this area, release scenarios based on a stochastic (probabilistic) material flow model and oriented towards a complete life cycle assessment of the ENM produced and used could to be applied. Information for these scenarios needs to be gathered from all available data (sources) possible – covering from experimental evidence due to own experiments, via literature data, the Environmental Release Categories (ERC) of the European technical guidelines from the European Chemicals Agency (ECHA, 2010), to inputs from respective producing industry, and – as the last solution – to expert judgment and assumptions. In order to overcome the high uncertainty that lays on such a scenario and in order to cover as much of the spectrum of likely releases as possible, usually more than one scenario need to be developed and modelled – representing e.g. low, mean (i.e. realistic), and high release factors. Taken together, these various scenarios can cover then the entire spectrum of possible releases (and environmental concentrations) – and the related environmental impacts. Obviously, all such scenarios are determined by inherent release volume uncertainties and in addition, are influenced by the distinct uncertainty related to the application and manufacturing quantities of the ENM. Based on such data, a computer based modelling can be performed in order to derive predicted environmental concentrations (PEC) of the ENM along its entire life cycle; knowing that such PECs are crucial when estimating the environmental risks of an ENM (see e.g. Müller & Nowack, 2008).

78. Another possibility – especially when dealing with future impacts due to the use of a ENM-containing product – is the use of so-called formative scenario analysis, as applied e.g. in the study of a nano-Ag containing T-Shirt, reported by Walser and co-workers (Walser et al., 2011a). Formative Scenario Analysis is a useful tool for integrating qualitative and quantitative data to determine hazard and risk scenarios (Scholz & Tietje, 2002). According to Scholz & Tietje, 2002, this type of scenario analysis provides a script describing steps that a study team must take in response to the current state and possible future states of a case. Because the term scenario analysis is often overused and applied inaccurately in science and everyday language, the adjective formative is added to indicate that a technique that is organized in a strictly systematic way is presented.

Case Study "CNT in Semiconductors"
3. Use of Scenarios for Modelling-based Assumptions

1. A total of five different scenarios have been modelled by the authors of this LCA comparison for the MWCNT-based type of a conductive polycarbonate plastic foil, used as antistatic packaging material for electronic components. In addition to the, above in details described, default scenario – assuming a 20% reduction in the foil thickness (and with this a 20% reduction in the material amount necessary) – the in table 3 summarized further four scenarios have been examined in this study here.

Table 3: Summary of the key figures of the additional scenarios examined in this study

<table>
<tr><th>Name of Scenario</th><th>Amount</th><th>yield</th><th>electricity input in kWh/kg</th><th>catalyst consumption rate</th><th>catalyst composition</th></tr>
<tr><td>New Catalyst</td><td rowspan="3">800 kg</td><td>65%</td><td rowspan="2">2</td><td>01:15</td><td>Mangan (32 weight-%),
Kobalt (38 weight-%),
Molybdän (10 weight-%),
MgO (10 weight-%),
Al_2O_3 (10 weight-%)</td></tr>
<tr><td>Optimum</td><td rowspan="2">90%</td><td rowspan="2">01:25</td><td rowspan="3">Mangan (37 weight-%),
Kobalt (43 weight-%),
MgO (10 weight-%),
Al_2O_3 (10 weight-%)</td></tr>
<tr><td>Mass production, future</td><td>0,66</td></tr>
<tr><td>Same amount</td><td>1000 kg</td><td>65%</td><td>2</td><td>01:15</td></tr>
</table>

2. Within three out of these four additional scenarios, the study takes into account the various topics and issues of uncertainty that have been identified within the life cycle inventory analysis step – i.e. the data collection step. The examined scenarios represent thereby the following changes, compared to the above described default situation:

- Scenario “New Catalyst”: in this scenario, 10% of Molybdenum (replacing equal amounts of Manganese and Cobalt) have been added to the catalyst – all other parameters have been kept equal to the default scenario;

- Scenario “Optimum”: in this scenario, an increase in the yield from 65 to 90% is assumed, resulting also in a higher output per g of consumed catalyst (25 instead of 15 g); while all further parameters are kept equal to the default scenario;

- Scenario “Mass production, future”: last but not least, in this scenario, in addition to the increase of the yield to 90% and the increase in the consumption rate of the catalyst to 1:25, a reduction in the electricity consumption (due to scaling effects of the installation) is assumed – resulting in a consumption of 0.667 kWh per kg of produced MWCNTs.

3. The fourth scenario (called “same amount”) – assuming no reduction in the amount of foil that is used – has been calculated in order to identify/show more clearly the effects resulting from the 20% gain in material (applied in the default, as well as all the other, above described scenarios).

4. When comparing these scenarios with the nomenclature for scenarios according to Börjeson et al., 2006, (section 5.3), the first three scenarios could clearly be stipulated as “predictive, forecast” scenarios, describing possible changes in the development of the pilot production installation, analyzed for the default data. The fourth scenario (assuming no reduction in the amount of foil that is used) can be rather seen as a “predictive what-if” scenario, as the objective here is clearly to facilitate the analysis of the results for the default situation.

5. All in all, the chosen bunch of scenarios allows this study to get a very clear picture of the advantages (and constraints) due to an eventual change from carbon black to MWCNTs in the framework of the production of conductive plastic foil, used as antistatic packaging material for electronic components.

6. On the output side, no scenario modelling of eventual releases of nanoparticles along the examined product life cycle has been established in the framework of this study, as described in point 4 of section 5.3. Instead, a qualitative evaluation of this topic has been established and reported (details, see next section).

7. However, in the framework of a further case study within the EU-NanoSUSTAIN project, the use of CNTs in epoxy resins for plastics. In this case, a scenario modelling approach for the estimation of

eventual releases of nanomaterials has been done. Due to its application example (i.e. the integration into the rotor blade for a wind power plant), its results can be used very well for the above described CNT in Semiconductor case study. The following steps have been distinguished for this epoxy case: (i) the production of the CNTs (MWCNT), (ii) the production of the master batch, (iii) the production of the application example, i.e. a rotor blade for a wind power plant, (iv) the use phase, and (v) various forms of the end-of-life treatment.

The mean ENM release parameters (see Table 4) were estimated based on the following sources and specific analogy estimation: (i) Environmental Release Categories (ERC) and release factors in the European technical guidelines (ECHA 2012a, ECHA 2012b), (ii) OECD Emission scenario documents (ESD) (OECD 2004), (iii) industrial (personal) information, and (iv) a few available peer reviewed articles.

Table 4: MWCNT in epoxy application: overview of the release factors for each scenario through the life cycle in technical environments – based on technical information or data derived from REACH and OECD Emission scenario documents (ESD)

Life cycle stage / ERC No	**Release factor**			
	To air	**To water**	**To waste**	**To soil**
Production MWCNT[11]	0.0003 %	0.0003 %	0.023%	n.a.
Manufacture of Masterbatch[12]	0.0003 %	0.6%	1%	0%
Manufacture application (epoxy) rotor blade[13]	0.0003 %	0.05%	0%	n.a.
Use phase (Weathering)[14]	2.5%	0%	0%	0%
End-of-Life				
Shredding[15]: 100%	1%	0		0
Municipal waste incineration[16]: 20%[17]	~0%	1%	1.5%	0

Due to the rather analog use, these same scenario could be applied to the here shown case study of CNT in Semiconductor industry.

[11] Analogy to metal power production, factor of 100 lower, as OEL and thus workplace concentrations compared to fine particulate matter (limit 5 mg/m³) or for carbon black (3.5 mg/m³) is reduced by this factor

[12] Analogy to emissions estimates of plastic additives (raw materials' handling), Source: OECD 2004, p 62

[13] Analogy to emissions estimates of plastic additives (compounding), Source: OECD 2004, p 62

[14] Analogy to industrial processing of articles with abrasive techniques, low release (ERC No 12A) for air release, Source: ECHA 2012a, Table 16-23: Default parameters to derive the environmental release rate, p 115

[15] Source: ECHA 2012b, Table R.18-6: Defaults for shredding, p 53

[16] Maximum case: Default parameters as used in Gottschalk et al. 2009 Realistic case: Source: ECHA 2012b, Table R.18-5: Defaults for the municipal waste incineration scenario, p 50

[17] Source: ECHA 2012b, p 49: "Around 20 % of the municipal solid waste (MSW) produced in the EU-27 is treated by incineration …"

5.4 Step 4: Communication of Results for Decision-Making

5.4.1 Methodology-related issues

79. As explained in the introductory chapter of this Guidance Manual and based on the major workshop conclusions its aim is to support decision making in various situations; from research, innovation, product development, scaling-up of production, marketing, and end-of-life as well as regulatory decisions. Hence, the communication needs to take into account both the purpose and the target audience of decision makers at different decision making levels including their respective needs (e.g. from execution of research activities on nanomaterials up to use of the LCA results for standards setting or regulatory purposes).

80. The reporting should also include the stated reasons for a LCA work being performed indicating the quality ambitions and the basis allowing for an objective judgement of this reported work in comparison to others.

81. Keeping these overall requirements in mind, it is essential that all employed assumptions, data sources including their uncertainties, LCA-approach related uncertainties including the sensitivities of eventually performed models and limitations are reported up-front in a clear and transparent manner allowing the decision maker to easily understand the background and basic fundaments of the LCA performed. Additionally, data and methods used need to be informed about at the very beginning of the report allowing for the reader to comprehend and interpret the results. The transparency of the reporting is crucial including the need that also all (co-)financing or other organisations having any relevant influence on the work are to be specified.

82. Moreover, any of such report will need to be available to any third party according to ISO 14040. This report, in accordance with ISO 14040 needs also to include general aspects such as date, name of the LCA practitioner, etc., definition of the aim and scope, data collection and calculation procedures, any methodology employed and results of the impact assessment performed, its results, uncertainties, sensitivity in case a model was used, any other limitations and assumptions of the interpretations included (Environmental Management). In case an optional review was performed, including further comparative analyses that will also be presented to the public, information about the review preformed in terms of name of the reviewer, the other comparative analyses and data, review report and responses to eventual recommendations need to be included as well (Environmental Management). Referring to other comparative analyses it is also important to note that the term "comparison" in this case refers to a comparison between systems (e.g. products).

83. In accordance with the different risk assessment guidelines and also according to existing regulations, a written report compliant with these guidelines and regulation needs to be prepared. The use of such a report as input for the performed LCA should also be reported. In addition, any updated information becoming available during the LCA work being carried out needs also to be included making any revision of the LCA work in the light of additional information possible.

84. The ILCD Handbook (see reference) provides further useful guidance in chapter 5.3 on reporting, if the LCA work is either of decision or descriptive character It also takes into account different situations such as “Micro-level decision support"; “Meso/macro-level decision support”; and “Accounting” including “Accounting with or without interactions”.

5.4.2 Study object-related issues

85. Organizations involved in nanotechnology activities should consider stakeholders' concerns including regulators and non-governmental organizations (NGOs) through transparent communication and public engagement policy. Continuous improvement of its processes and transparent disclosure of the organization's involvement should be undertaken.

86. The engagement should be more than just information dissemination and should provide a platform for a multilateral dialogue.

87. The stakeholders may (not exclusively) involve employees, customers (business-to-business and end-consumers), shareholders, suppliers, NGOs, civil society organisations, academics, consumer bodies, trade unions, national governments, international governing bodies and the general public. As the agreement with all stakeholders is not always possible the organisation should be able to explain the reasons for the lack of agreement.

88. Decision-making regarding nanomaterials and nanotechnology will generally involve not only the consideration of risk, but also the impacts and their proportionality to the risks. Therefore, communication of results for decision-making will not be limited to the risks assessed under this GM, but will also rely on information regarding the impacts and their comparison to the risks[18].

89. Stakeholders might be involved under different perspectives, like but not limited to: understanding the function of the product, identifying alternatives (including solutions that do not contain nanomaterials), defining metrics to assess the risks and the impacts, understanding uncertainties and ambiguities.

90. More emphasis on the involvement of stakeholders, and a diversity of stakeholders is relevant in situations where risks or impacts are particularly complex, highly uncertain, and especially if they are ambiguous.

91. Basically, an LCA report can have three major uses:

- Report for internal use,
- Report for third party and
- Report on comparative studies to be disclosed to the public.

92. The report for internal use often has the goal to identify internal improvement potential and hot spots concerning product development (ILCD Handbook, 2010); it can be confidential. A third-party report that includes confidential information has to be available for reviewers of the study with the confidential information to be documented separately (ISO 14044:2006; ILCD Handbook, 2010). The third party report is addressed to an external party with a well-defined list of recipients. The ILCD Handbook suggests that this report should have an executive summary for non-technical audience. The report on comparative studies to be disclosed to the public is used as a declaration for non-experts. This report requires a critical review from a panel of LCA experts not directly involved in the study. Table 2 of annex 2 shows a

[18] More information regarding frameworks to assess the impacts of nanotechnology and their relation to risks, and communication to stakeholders can be found in particular in preparatory work for a CEN Technical Specification being developed by Technical Committee CEN/TC 352 "Nanotechnologies".

description of all aspects, which have to be covered in the LCA studies reporting format for third party report and report on comparative studies to be disclosed to the public.

Case Study "CNT in Semiconductors"
4. Communication of Results for Decision-Making

1. This case study has been published as example in a report of the German Environmental Agency UBA (Umweltbundesamt), dealing with "Environmental Relief Effects through Nanotechnological Processes and Products" (Steinfeldt et al, 2010). The objective of the research project behind this UBA report was to identify and (as far as possible) quantify with the support of selected examples, the environmental and sustainability opportunities and risks associated with this rapidly developing line of technology.
2. In Steinfeldt et al., 2010, the authors present – besides other case studies and examples – this case of a (with the aid of carbon black resp. of MWCNTs) conductive plastic foil, used as antistatic packaging material for electronic components. In a first part, the modelling of CNT production is explained in all details – information that is summarized here in the case study parts of the two preceding sections (section 5.2 and 5.3).
3. In a second part of the description of this case study, exemplary results are shown of the comparison of the various scenarios for such a MWCNT containing plastic foil with a foil using carbon black instead of the MWCNTs. Listed are the following (classic) LCIA indicators: Cumulative Energy Demand (in MJ-Eq per functional unit (FU), i.e. for the equivalent to 1'000 kg of conventional, carbon black-containing foil), Global Warming Potential (in kg CO_2-Eq/FU), Eutrophication Potential (in kg PO_4-Eq/FU), and Stratospheric Ozone Depletion Potential (in kg CFC-11-Eq/FU) – shown below as Figures 6 to 9.

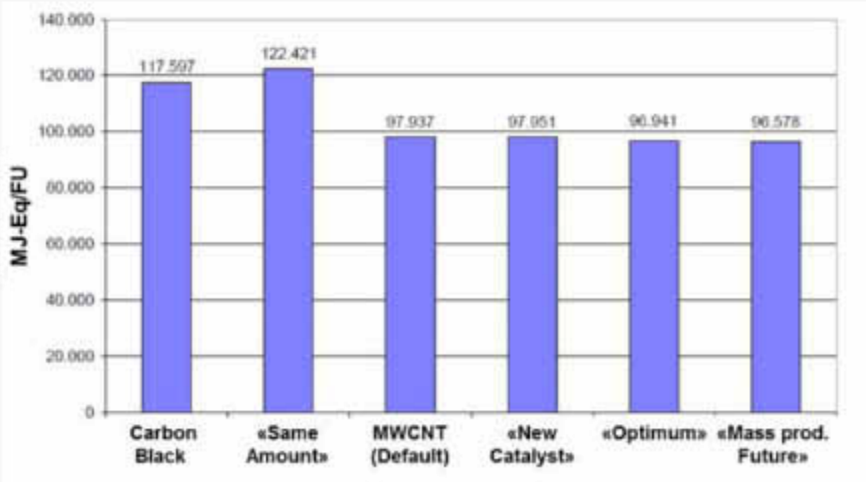

Figure 6: Cumulative Energy Demand (in MJ-Eq/FU) of the examined scenarios of the production of a conductive plastic foil, used as antistatic packaging material.

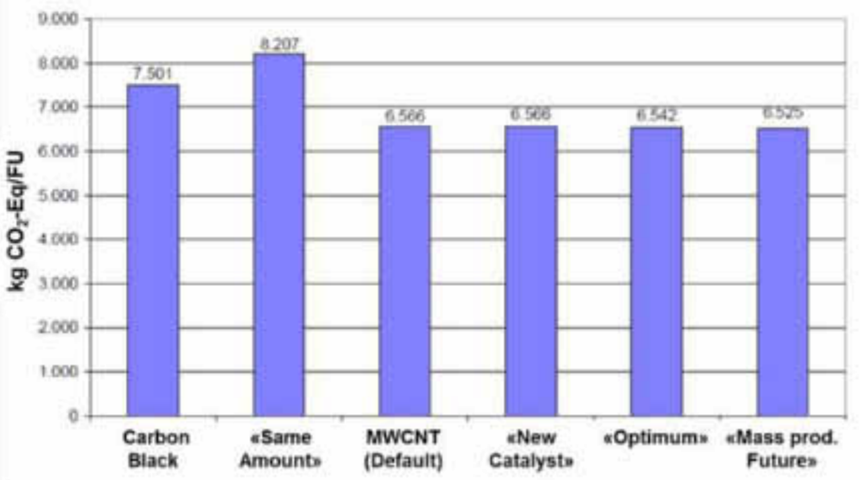

Figure 7: Global Warming Potential (in kg CO_2-Eq/FU) of the examined scenarios of the production of a conductive plastic foil, used as antistatic packaging material.

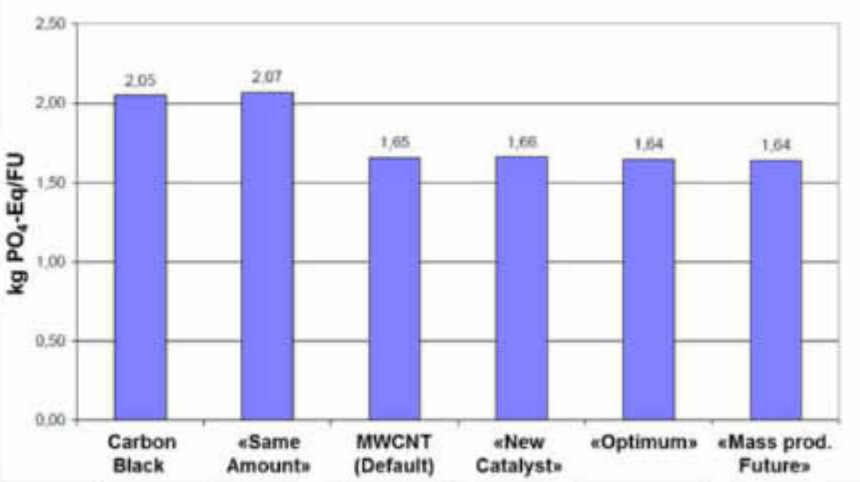

Figure 8: Eutrophication Potential (in kg PO_4-Eq/FU) of the examined scenarios of the production of a conductive plastic foil, used as antistatic packaging material.

In all these three situations (Figures 6 to 8), the overall impact is to a large extend dominated from the impact of the polycarbonate production – being responsible for 80 to 90% of the overall impact in the foil containing carbon black. Thus, the higher impact from the MWCNT production is more than compensated by the lower overall material consumption in the various scenarios (except scenario "same amount" – showing actually the increase resulting from the MWCNT production; in comparison to the carbon black production).

The situation is completely different in case of the Stratospheric Ozone Depletion Potential (Figure 9). In this case, the impact of the original product is dominated to about 80% from the carbon black production process (due to its high emissions of polycyclic aromatic hydrocarbons, PAH) – resulting for all examined MWCNT scenarios in a reduction of about 90% of the overall impact, as the modelled MWCNT process is not resulting in such kind of releases into air.

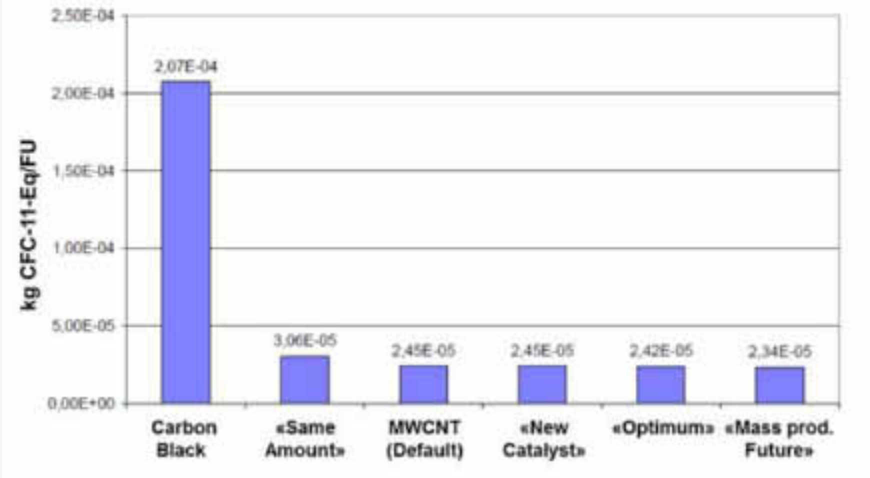

Figure 9: Stratospheric Ozone Depletion Potential (in kg CFC-11-Eq/FU) of the examined scenarios of the production of a conductive plastic foil, used as antistatic packaging material.

4. A qualitative assessment of risks due to the release of CNTs along the complete life cycle of such a packaging foil for the electronics industry has been established in the framework of activities of Working Group 2 of the NanoKommission of the German Federal Government for the report "Responsible use of Nanotechnologies" (NanoKommission, 2009). A summary of this evaluation has then been included as third part of the case study report in Steinfeldt et al., 2010.

Concerning toxicological and eco-toxicological aspects the specific properties of "free" MWCNT unaggregated or unagglomerated forms are presumed to be respirable, insoluble and because of their inert carbon composition have only limited biodegradability. Likewise, the morphology of some nanotubes – in analogy to asbestos or wood dust, both of which have in combination with persistence been determined to be carcinogenic – is also a cause of concern.

According to this, decisive is the question whether or precisely where in the product life cycle of conductive films, an exposition to free 'CNTs is possible at all. This seems most probably in the beginning (i.e. in the preparation of the MWCNTs, and the incorporation of MWCNTs into the polymer during the subsequent compounding), and may be possible at the end of the product life in the waste incineration. During the extrusion, forming and application of the foil airborne exposure to MWCNTs is not possible as the nanoparticles are incorporated into the polymer matrix. For the same reason any dermal absorption of MWCNTs by skin contact with the film seems very unlikely. Hence, this foil represents few risks for users and consumers.

5.5 Remaining Uncertainties and/or Data Gaps

5.5.1 Uncertainties

93. As suggested by Heijungs and Huijbregts, (2004), dealing with uncertainty it is a problem, indeed the terminology is scattered and non-standardized, moreover they highlight that there are different levels of uncertainty perception, for the scientist the uncertainty is related to rigorous probabilistic concepts while for the decision maker it is related to the choice to be taken. In the ISO 14044/2006 uncertainty analysis is defined as "systematic procedure to quantify the uncertainty introduced in the results of a life cycle inventory analysis due to the cumulative effects of model imprecision, input uncertainty and data variability", this is a definition to describe the uncertainty propagation. Furthermore, the ILCD Handbook (EC-JRC, 2010) presented an uncertainty classification, where are distinguished three main source of uncertainty:

1. stochastic uncertainty, related to the process and assessment data in terms of elementary flow and characterization factor, that can be describe in statistical terms;

2. choice uncertainty, related to the methodological choice, (system boundary setting, cut-off criteria, selection of impact assessment, assumption, etc.);

3. lack of knowledge of the studied system.

94. The first type of uncertainty can be dealt with statistical techniques (e.g. Monte Carlo). This can apply on nanomaterial in case of inventory data present information on stochastic variable as variance, mean, and probability distribution. Walser et al. (2011a) applied this approach in the LCA study to compare nanosilver T-shirts with conventional T-shirts with and without biocidal treatment. They used as background data, derived from Ecoinvent DB, 2.2, which includes for each unit process mean values and probability distribution, and they proposed a method to calculate this values for unit process developed in their study (Walser et al., 2011b). Finally, a Monte Carlo Simulation (1000 iterations) was conducted to calculate the uncertainty of the accumulated LCI data. Another application of Montecarlo analysis was performed by Piazza et al, (2014), but they analysed only the uncertainty of background data. While the application of these techniques on the assessment data for nano-products are impossible, because as motioned above no specific impact factors are available.

95. The second type of uncertainty can be dealt with sensitivity analysis by means a scenario analysis, where one or more methodological choices are modified. This approach is very useful in the LCA study that involved nano-products and nanotechnology, indeed these applications are quite new and many assumptions are often done. Nevertheless rarely this approach is performed on nano-products and nanotechnologies as shown in literature review reported in Annex 4 table 1.

96. Besides the uncertainties mentioned above, possible limitations of an integrated RA/LCA approach can go beyond data uncertainty, choice uncertainty and lack of knowledge of the studied system. Even in case of a complete data base (with all necessary RA and LCA data available) that may exist for a certain case study, it still might be very difficult to assess potential trade-offs between different analysed impacts, e.g. less energy / resource consumption vs. increased release of nanomaterials to the environment. Since from the methodological point of view, an combination of the various environmental impacts as well as risk-related endpoints is not feasible and thus cannot be recommended, divergent results and trade-offs between the different impact indicators shall be clearly documented as such and need to be discussed carefully on a qualitative level.

5.5.2 Remaining data gaps

97. On the level of Life Cycle Inventory Analysis, there is a lack of adequate and comprehensive LCI data for engineered nanomaterials, including eventual emissions of nanoparticles into the different environmental compartments, including the indoor environment. Available emission data is not reported in a harmonized way and hence the link to the exposure and effect assessment is not possible. Emission factors are virtually inexistent for any nanoparticle production technology or nano-enabled applications downstream. Measured concentrations can help to estimate the release factors. However, over the long term, release factors must become available to enable the fate and exposure modeling based on the chosen Functional Unit.

98. On the level of Life Cycle Impact Assessment, the currently used assessment methods assess only *outdoor* emissions of larger particulate matter (PM) of size <10 and <2.5 µm for their contribution to, amongst others, eco-toxicity and human toxicity. The CFs are solely based on mass concentration (without

size distributions, elemental differentiation, etc.). Factors for nano-specific impacts are almost completely lacking so far.

99. For the evaluation of nano-specific human health impacts upon nanoparticle exposure, the calculation of effect factors requires an inclusion of further information on their in- and uptake fractions. In the current framework, 100% of chemicals inhaled are considered as being taken up in the body. A size and nanomaterial specific deposition and retention factor is missing. Beside inhalation, also other routes of exposure require further investigation, i.e. oral and dermal.

100. A further complication of effect quantification for engineered nanomaterials in LCA is the need for (not yet existing) epidemiological data in order to derive robust effect factors for human toxicity. Ideally, conversion factors between in vitro and in vivo studies (which do not exist in LCIA methods) would reduce the efforts for in vivo studies. Often, only allometric scaling is used to derive health effect factors (if dose is expressed per kg body weight (BW) and not as a concentration) and there is no consensus on assessment factors for inter- and intra-species variability. The only other extrapolations used are Lowest Observed Adverse Effect Levels (LOAEL) to ED_{50} and sub-acute or sub-chronic to chronic exposure. Up to now, no in vitro studies (or acute in vivo studies) are used to evaluate human toxicity in the context of LCA.

101. These data gaps can be split into *structural* (missing nano-specific framework capabilities) and *numerical* (missing knowledge on values to fill into the framework) issues. Figure 10 summarizes the knowledge gap, splitting them into items that are relevant for both RA and LCA and also into items which are only valid for RA *or* LCA.

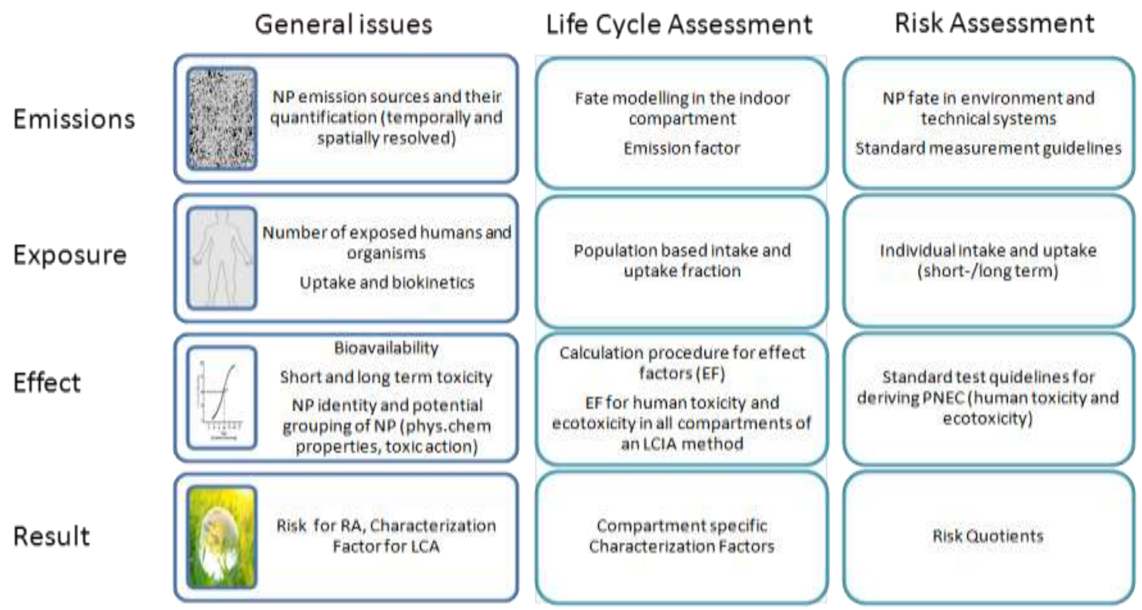

Figure 10: Open questions along the life cycle of a nanomaterial (rows). Distinguished between general issues (column, left) and Life Cycle Assessment and Risk Assessment (columns, middle and right). All statements are specifically for *nano-related* issues.

5.5.3 Solutions to close data gaps in LCA

102. Definition of clear rules for the identification and nomenclature of a nanomaterial (multi-element particles, coatings), in order to facilitate the inventory assessment in LCA. An LCA practitioner must know whether the assessed (or a similar) nanomaterial is already available in a database or whether the inventory data is to be collected from scratch.

103. Scientifically derived grouping rules can facilitate a risk assessment for NM in regulatory settings (Wohlleben W. et al. 2011, Hsu L et al. 2007, Göhler et al. 2010; Tervonen 2009, Hansen 2008, Oomen 2014, Sayes 2013).

104. Ensure the compatibility of units along the assessment route: Physico-chemical data and concentration units have to be the same for the emission and exposure assessment as well as for the effect assessment. Accordingly, measurement capabilities have to be critically evaluated and selected, in order to provide robust and validated results for the characterization of NP along their life cycle.

105. Further development of internationally harmonized measurement protocols for various stages in the life cycle of nanoparticles is needed to support and harmonize exposure analysis of nanoparticles indoors and outdoors. Standardized guidance documents and technical guidelines (e.g. OECD, CEN, ISO) can help to harmonize measurement campaigns and consequently to increase knowledge on ENM emissions and concentrations in environmental and technical compartments arising from nanoparticle production, from consumer products, and from waste treatment.

106. Evaluate in a systematic way the differences between the nano and bulk form of a material, regarding the mobility (environment and human body; biokinetics) and consequently a definition of a size (range) where nano-specific effects (biologically, physically) can occur. This would provide guidance on whether existing data in fate and impact assessment in LCA is sufficient for the assessment of nanomaterials or whether new nano-specific information is needed.

107. Establishing reliable nano-specific toxicity tests (preferably in-vitro) which allow the detection of long-term effects or which can be used in a tiered assessment approach. Furthermore a harmonization of NP fate, exposure, and toxicity testing in order to facilitate the interpretation of toxicity studies needs to be established. In a more long-term perspective, this should then allow a further grouping of NP according to their toxicity (based on physico-chemical data or modes of toxic action). Such classes of similar NP would reduce the efforts for (i) toxicity testing in RA and (ii) the number of effect factors in LCA. As a result, LCI developers could concentrate on a reduced number of still missing nanomaterials in the databases (representing an entire group of nanomaterials) and the LCA practitioner would have clear guidance on whether her/his nanomaterial under investigation is already available in a similar form in the databases (and hence does not need further efforts to collect new data).

6. CONCLUSIONS AND OUTLOOK

108. Nanotechnology is one of the avenues for future innovation. New nanomaterials are under research and entering the market, with the potential to significantly improve characteristics of products. The basic objective of this Guidance Manual is to further improve and facilitate the international scientific dialogue in the field of life-cycle aspects of manufactured nanomaterials. To this effect it aims to support

decision making in various situations of manufactured nanomaterials throughout their whole life-cycle from research to their final product phase. It is not a new guideline nor is it a “super tool” but it serves as supplementary guidance to conduct a LCA for manufactured nanomaterials. Since risk assessment information is necessary to complete a life cycle assessment analysis, it represents a step towards establish linkages between LCA and risk assessment. Precisely as emphasized in the OECD report “*Nanotechnology and Tyres: Greening Industry and Transport*” this Guidance Manual underlines the importance of collaboration between governments and industry to address the specific challenges raised by various nano-enabled products. It also helps to identify areas for future priority activities including research to ensure further development of efficient assessment tools and systems for evolving nano-enabled applications.

109. In view of these objectives and aims and to provide a stepping stone towards the integration of risk assessment of the environmental impact in life cycle assessment studies as decision-making tools during both upstream and downstream phases of a nanostructured product this Guidance Manual focuses in-depth on a “data-rich” case study, because it is important to develop guidance based on an as complete a dataset as possible. Here, as an example of a nano-enabled application, a conductive plastic sheet containing Carbon Nannotubes (CNTs), was compared with a reference product, a polycarbonate sheet used as semiconductor packaging containing carbon black. By incorporating CNT instead of the currently used carbon black, it is possible to reduce the foil thickness by 20%, resulting in corresponding savings regarding the polycarbonate consumption. The selected case study considers the full lifecycle of products as already stated above. Moreover, existing information and activities related to life cycle, risk data and assessments published and available from other OECD-WP-MN steering groups and relevant outputs from its member countries were actively used in preparing this Guidance Manual.

110. On the level of the core datasets of this LCA, especially for the production of CNT, a high data quality could be achieved. This was not the case for the subsequent step of the foil production. However, as the same technology is applied for the foil production for both cases (i.e. carbon black and CNT), it was concluded that the use of literature data for this process step has no relevant effect on the comparison but influences the overall uncertainty of the results in all cases by a similar amount. On the level of the assessment step, nowadays more comprehensive and more up-to-date Life Cycle Impact Assessment (LCIA) methods than the method used in this selected case study are available. Hence for example, the ILCD handbook provides a first summary of recommendations concerning the modelling approaches for the assessment of the various environmental aspects taken into account in common LCIA methods.

111. One of the main issues in the selected case study for this Guidance Manual is the missing quantification of releases of CNTs during the examined life cycle stages. Although the specific production process of CNTs takes place in a closed environment, there are subsequent process steps in the production of the foil that may lead to a risk for releases of nanomaterials into the environment.

112. Currently there are hardly any datasets available for the manufactured nanomaterials with a high potential for future industrial applications and only very few of these are published LCA studies in the area of nano-enabled applications involving the actual inventory data for the respective manufactured nanomaterial employed. This Guidance Manual provides an overview of the situation in the annexes, showing that more work is necessary in this area including, for example, the availability of complete sets of input and output data. On the level of Life-Cycle-Impact Assessment (LCIA) databases there is even more work to be performed. Hence, considerable efforts are required in the future to establish a basic set of LCIA datasets covering the most important share of nanomaterials, in order to offer a starting point for more adequate LCA studies for nano-enabled applications.

113. This Guidance Manual provides also provides an overview on available risk assessment and life cycle assessment approaches useful for performing LCA of nanomaterials during their life cycle. It further updates aspects of reporting in relation to transparency, assumption selection, sensitivity and scenario

designs. The latter also includes specific scenarios on so called "hot spots" of exposure to nanomaterials by humans, including especially consumer and indoor exposure as well as environmental compartments. It highlights uncertainties in the use of modelling scenarios in the absence of data. Uncertainties and date gaps regarding risks, inventory and impact assessment are a key issue for many nanomaterials and their application at both in the early and later stages of development. Firms face a challenge in deciding whether and how to invest, given the difficulties associated in measuring the risks and the fact that any risks to human health and the environment would be considered unacceptable. Good practice policies should include elements allowing that high levels of safety are maintained.

114. Furthermore, the need for one suitable exposure metric including grouping approaches for nanomaterials especially for human and eco-toxicity testing, compatibility aspects of units and the availability of harmonised protocols are emphasized leading to different future possible activities for the OECD WPMN SG9 (Environmentally Sustainable Use of Manufactured Nanomaterials) and the need of being incorporated into on-going and future research and innovation programmes.

115. Primary recommendations to improve the LCA framework for assessing the relative impacts of baseline and nano-enabled applications include the material flowing aspects that were also described in the above mentioned OECD report entitled "*Nanotechnology and Tyres: Greening Industry and Transport*":

- Refining Life-Cycle Inventory (LCI) data for the nanomaterial manufacturing step with primary data from producers (e.g. using data from quantitative evaluations based on testing or modelling).
- Refining LCI data for all life cycle steps of nanomaterials to assess better potential nanoscale releases (e.g. using data from quantitative evaluations based on testing or modelling).
- Refining of nanomaterial release rates and environmental compartmentalisation in use and life cycle stages (e.g. using data from quantitative evaluations based on testing or modelling).
- Application of impact assessment factors for nanoscale versus macroscale substance releases for each environmental compartment to determine potential environmental impacts of estimated nanomaterial releases.

116. Keeping these overall requirements in mind, it is essential that all employed assumptions, data sources including their uncertainties, LCA-approach related uncertainties including the sensitivities of eventually performed models and limitations are documented and reported in a clear and transparent manner allowing the decision maker to easily understand the background and basic fundaments of the LCA performed. Additionally, data and methods used need to be explained at the very beginning of the report allowing the reader to comprehend and interpret the results reported.

117. This GM is a stepping stone of a continuous process aiming towards the integration of risk assessment and LCA underlining the need for a regular update. Hence and to allow for such updating, it is recommended to incorporate upcoming results and data reported by the other OECD WPMN Steering Groups including especially SGTA, SGAP and SG8.

7 REFERENCES

Arvidsson R, Molander S, Sanden BA, Hassellöv M (2011) Challenges in Exposure Modelling of Nanoparticles in Aquatic Environment, Human and Ecological Risk Assessment 17:245-262. doi:10.1080/10807039.2011.538639

Barberio G, Scalbi S, Buttol P, Masoni P, Righi S (2014) Combining life cycle assessment and qualitative risk assessment: The case study of alumina nanofluid production, Science of the Total Environment 496: 122–131

Baytubes C 150 HP datasheet

Birkved M, Heijungs R (2011) Simplified fate modelling in respect to ecotoxicological and human toxicological characterisation of emissions of chemical compounds, Int J LCA 16:739-747. doi:10.1007/s11367-011-0281-y

BMU (2010) German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Ed.): Final Report of NanoKommision Issue Group 2; Guidelines for Collecting Data and Comparing Benefit and Risk Aspects of Nanoproducts; 2. dialogue phase 2009-2010; available online at http://www.bmu.de/fileadmin/bmu-import/files/english/pdf/application/pdf/nano_finalreport2_bf.pdf .

Börjeson L, Höjer M, Dreborg K-H, Ekvall T, Finnveden G (2006) Scenario types and techniques: towards a user's guide, Futures 38:723-739

Boxall ABA, Chaudhry Q, Sinclair C, Jones A, Aitken R, Jefferson B, Watts C (2007) Current and Future Predicted Environmental Exposure to Engineered Nanoparticles, Central Science Laboratory, York University, York (United Kingdom)

Christensen F M, Stig I Olsen (2004) The potential role of life cycle assessment in regulation of chemicals in the European Union, The International Journal of Life Cycle Assessment 9.5: 327-332.

Colvin VL (2003) The potential Environmental Impact of Engineered Nanomaterials, Nature Biotechnology 21 (10):1166-1170

EC-JRC (2010) Analysis of existing Environmental Impact Assessment methodologies for use in Life Cycle Assessment.ILCD handbook - International Reference Life Cycle Data System. European Commission - Joint Research Centre (EC-JRC), Ispra (Italy)

EC-JRC (2011) Recommendations for Life Cycle Impact Assessment in the European context - based on existing environmental impact assessment models and factors, ILCD handbook - International Reference Life Cycle Data System. European Commission - Joint Research Centre (EC-JRC), Ispra (Italy)

Eckelman MJ, Mauter MS, Isaacs JA, Elimelech M (2012) New Perspectives on Nanomaterial Aquatic Ecotoxicity: Production Impacts Exceed Direct Exposure Impacts for Carbon Nanotubes, Environmental Science & Technology 46: 2902-2910

ECHA (2010) Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation. ECHA-10-G-06-EN. European Chemicals Agency

ECHA (2012a) Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation. ECHA-10-G-06-EN. European Chemicals Agency

ECHA (2012b) Guidance on information requirements and chemical safety assessment Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage. ECHA-2010-G-20-EN. European Chemicals Agency

ecoinvent Centre (2007) ecoinvent data v2.01. Swiss Centre for Life Cycle Inventories, Dübendorf, CH

ecoinvent Centre (2013) ecoinvent data v3.0 - Online Database - available at www.ecoinvent.org. Swiss Centre for Life Cycle Inventories, Dübendorf, CH

Environmental management – Life cycle assessment – Principles and framework (2007), ISO 14040:1997(E)

European Commission (2006) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 29.5.2007. Official Journal of the European Union.

European Commission (2009) Risk Assessment of Products of Nanotechnologies, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) DG Health and Consumers, Brussels: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf

European Commission (2012) Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - Second Regulatory Review on Nanomaterials, COM(2012) 572 final, Brussels, 3.10.2012.

EU-NanoSustain-Project (2013) NanoSustain Factsheet and Case Studies - 20 March 2013 – "Case Study #3: Carbon nanotubes epoxy resins for plastics"; for obtaining free copies click on http://www.nanosustain.eu/case-studies/ or via http://www.nanosustain.eu/component/content/article/1-latest-news/128-nanosu or via http://www.nanosafetycluster.eu/eu-nanosafety-cluster-projects/seventh-framework-programme-projects/nanosustain.html ; final project summary report is available from http://cordis.europa.eu/project/rcn/94362_en.html .

Fairman R, Mead C D, Williams WP (1998) Environmental Risk Assessment – Approaches, Experiences and Information Sources. Environmental Issues Report No. 4, European Environment Agency, Copenhagen.

Fantke P, Jolliet O, Evans JS, Apte JS, Cohen AJ, Hänninen OO, Hurley F, Jantunen MJ, Jerrett M, Levy JI, Loh MM, Marshall JD, Miller BG, Preiss P, Spadaro JV, Tainio M, Tuomisto JT, Weschler CJ, McKone TE (submitted) Confronting Health Effect of Fine Particulate Matter in Life Cycle Impact Assessment.

Fava JA (2002) Life cycle initiative: a joint UNEP/SETAC partnership to advance the life-cycle economy, Int J Life Cycle Assess 7 (4): 196-198, doi:10.1007/BF02978873

Flemström K, Carlson R, Erixon M. (2004) Relationships between Life Cycle Assessment and Risk Assessment – Potentials and Obstacles, ISBN 91-620-5379-5.pdf, ISSN 0282-7298, Naturvaerdsverket 2004, available from www.naturvardsverket.se .GöhlerD, Stintz M, Hillemann L, and Vorbau M, Characterization of Nanoparticle Release from Surface Coatings by the Simulation of a Sanding Process, Ann OccupHyg. 2010 August, 54(6): 615–624.

Gottschalk F, Sonderer T, Scholz RW, Nowack B (2009) Modeled environmental concentrations of engineered nanomaterials (TiO2, ZnO, Ag, CNT, fullerenes) for different regions, Environmental Science and Technololgy 43: 9216-9222

Gottschalk, F., Sonderer, T., Scholz, R.W. and Nowack, B. (2010) Possibilities and limitations of modeling environmental exposure to engineered nanomaterials by probabilistic material flow analysis, Environmental Toxicology and Chemistry, 29(5): 1036-1048.

Grieger K, et al. (2012) Analysis of current research addressing complementary use of life-cycle assessment and risk assessment for engineered nanomaterials: have lessons been learned from previous experience with chemicals? J Nanopart Res 14: 958

Grieger K, et al. (2012) Environmental risk analysis for nanomaterials: Review and evaluation of frameworks. Nanotox. 6 (2): 196-212

Heijungs R., Huijbregt M.A.J., (2004) A review of approaches to treat uncertainty in LCA, Source: CiteSeer

Hendren, C.O., Mesnard, X., Dröge, J. and Wiesner, M.R. (2011) Estimating production data for five engineered nanomaterials as a basis for exposure assessment, Environ. Sci. Technol. 45: 2562-2569.

Hischier R (2014), Framework for LCI modelling of releases of manufactured nanomaterials along their life cycle, Int J Life Cycle Assess,1-12, doi:10.1007/s11367-013-0688-8

Hischier R, Hellweg S, Capello C (2005) Different Approaches how to investigate Chemicals, Int J LCA 10 (1):59-67

Hischier R, Walser T (2012) Environmental Sustainability Assessment of Engineered Nanomaterials: State of Art & Strategies to Overcome Existing Gaps, Science of the Total Environment 425: 271-282

Hsu L, Chein H (2007), Evaluation of nanoparticle emission for TiO2 nanopowder coating materials. J Nanopart Res, 9(1):157-163.

Humbert S, Marshall JD, Shaked S, Spadaro JV, Nishioka Y, Preiss P, McKone TE, Horvath A, Jolliet O (2011) Intake Fraction for Particulate Matter: Recommendations for Life Cycle Impact Assessment, Environ SciTechnol 45: 4808-4816, doi:10.1021/es103563z

EC, JRC (2010), ILCD (International Reference Life Cycle Data System) Handbook: general guide for Life Cycle Assessment - detailed guidance

ISO 14040:2006 (2006) Environmental Management – Life Cycle Assessment – Principles and Framework, International Standard, October 2006.

ISO 14044:2006 (2006) Environmental Management – Life Cycle Assessment – Requirements and Guidelines. International Standard, October 2006.

Kahru A, Dubourguier H-C (2010) From ecotoxicology to nanoecotoxicology, Toxicology 269: 105-119, doi:10.1016/j.tox.2009.08.016

Khanna V, Bakshi B R, Lee L J (2008) Carbon Nanofiber Production process life cycle assessment (LCA) Life Cycle Energy Consumption and Environmental Impact Journal of Industrial Ecology, Volume 12, Number 3

Klaine SJ, Koelmans AA, Horne N, Carley S, Handy RD, Kapustka L, Nowack B, Von der Kammer F (2012) Paradigms to Assess the Environmental Impact of Manufactured Nanomaterials, Environmental Toxicology and Chemistry 31 (1): 3-14

Li B, Gao X, Li J, and Yuan C, (2014) Life Cycle Environmental Impact of High-Capacity Lithium Ion Battery with Silicon Nanowires Anode for Electric Vehicles, Environmental Science Technology 3047−3055, dx.doi.org/10.1021/es4037786 |

Lo, S-O (2006) Introduction to Carbon Nanotubes and Its Applications in Semiconductor Industry. ONLINE document, Course MatE 297, accessed on xyz at www.engr.sjsu.edu/MatE297/Lo_CNT.doc

Iseult L, Weiss C, Valsami-Jones E (2014) A strategy for grouping of nanomaterials based on key physico-chemical descriptors as a basis for safer-by-design NMs. Nano Today 9.3: 266-270.

Meesters JAJ, Koelmans AA, Quik JTK, Hendriks AJ, Van de Meent D. (2004) Multimedia Modeling of Engineered Nanoparticles with SimpleBox4nano: Model Definition and Evaluation, Environ Sci Technol, 48: 5726-5736

Müller NC, Nowack B (2008) Exposure Modeling of engineered Nanoparticles in the Environment. Environmental Science & Technology 42: 4447-4453

NanoKommission (2009) Responsible Use of Nanotechnologies: Report and recommendations of the German Federal Government's NanoKommission for 2008. Berlin, Germany: http://www.bmu.de/english/nanotechnology/general_information/doc/44143.php.

OECD (2004) Environmental Health and Safety Publications, Series on Emission Scenario Documents No. 3. Emission scenario document on plastic additives. Paris, 2004, revised in 2009

OECD (2012a) Important Issues on Risk Assessment of Manufactured Nanomaterials - Series on the Safety of Manufactured Nanomaterials No. 33, ENV/JM/MONO(2012)8, Paris.

OECD (2012b) Inhalation Toxicity Testing: Expert Meeting on Potential Revisions to OECD Test Guidelines and Guidance Document - Series on the Safety of Manufactured Nanomaterials No. 35, ENV/JM/MONO(2012)14, Paris.

OECD (2013) Workshop Report, Environmentally Sustainable Use of Manufactured Nanomaterials, Workshop held on 14 September 2011 in Rome, Italy, Series on the Safety of Manufactured Nanomaterials No. 39, ENV/JM/MONO(2013)17, available from http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)17&doclanguage=en .

OECD (2014) Nanotechnology and Tyres, Greening Industry and Transport, OECD Publishing, Paris, DOI : 10.1787/9789264209152-en, ISBN 978-92-64-20914-5 (print), ISBN 978-92-64-20915-2 (PDF), available from via http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/nanotechnology-and-tyres_9789264209152-en#page1.

Pesonen H-L, Ekvall T, Fleischer G, Huppes G, Jahn C, Klos ZS, Rebitzer G, Sonnemann GW, Tintinelli A, Weidema BP, Wenzel H (2000) Framework for Scenario Development in LCA. Int J LCA 5 (1): 21-30, doi:dx.doi.org/10.1065/lca199912.011

Pizza A, Metz R, M Hassanzadeh M, Bantignies J-L, (2014) Life cycle assessment of nanocomposites made of thermally conductive graphite nanoplatelets, International Journal of Life Cycle Assess 19: 1226–1237, DOI 10.1007/s11367-014-0733-2

Praetorius A, Scheringer M, Hungerbühler K (2012) Development of Environmental Fate Models for Engineered Nanoparticles - A Case Study of TiO2 Nanoparticles in the Rhine River, Environmental Science & Technology 46: 6705-6713

Quik JTK, ArieVonk J, Foss Hansen S, Baun A, Van de Meent D (2011) How to assess exposure of aquatic organisms to manufactured nanoparticles? Environmental International, 37: 1068-1077, doi:10.1016/j.envint.2011.01.015

Riediker M. (Ed.) (2013), Compendium of Projects in the European NanoSafety Cluster 2013 Edition, CSEM Centre Suisse d'Electroniqueet de Microtechnique SA, Neuchâtel.

Rosenbaum R, Bachmann TM, Swirsky Gold L, Huijbregts MAJ, Jolliet O, Juraske R, Koehler A, Larsen HF, MacLeod M, Margni M, McKone T, Payet J, Schuhmacher M, Van de Meent D, Hauschild M (2008) USEtox—the UNEP-SETAC toxicity model: recommended characterisation factors for human toxicity and freshwater ecotoxicity in life cycle impact assessment, Int J Life Cycle Assess 13: 532-546

Royal Society of Chemistry (2013) Environment, Health and Safety Committee: Note on Environmental Risk Assessment - Version 2. http://www.rsc.org/ScienceAndTechnology/Policy/EHSC/EnvironmentalRiskAssessment.asp

Salieri B, Righi S, Pasteris A, Olsen SI (2015) Freshwater eco-toxicity characterisation factor for metal oxide nanoparticles: A case study on titanium dioxide nanoparticle. Science of the Total Environment 505: 494-502.

Scholz RW, Tietje O (2002) Embedded Case Study Methods. Thousand Oaks, Sage, London. doi:dx.doi.org/10.4135/9781412984027

Seager T P, Linkov I (2008) Coupling multicriteria decision analysis and life cycle assessment for nanomaterials, Journal of Industrial Ecology, 12.3: 282-285.

Smita S, Gupta SK, Bartonova A, Dusinska M, Gutleb AC, Rahman Q (2012) Nanoparticles in the environment: assessment using the causal diagram approach. Environmental Health 11 (Suppl.1), S13

Steinfeldt M, von Gleich A, Petschow U, Pade C, Sprenger R-U (2010) Entlastungseffekte für die Umwelt durch nanotechnische Verfahren und Produkte. Texte 33/2010. Umweltbundesamt (UBA), Dessau-Roßlau (Germany), http://www.umweltbundesamt.de/publikationen/entlastungseffekte-fuer-umwelt-durch-nanotechnische

Stropp G (2010) Studienergebnisse mit Baytubes® - Übersicht (results of investigations with Baytubes® - overview). Presentation on Inno.CNT Jahreskongress, 20. Januar 2010. (in german).

The Royal Society, The Royal Academy of Engineering (2004) Nanoscience and Nanotechnologies: Opportunities and Uncertainties. London (Great Britain)

Thiele C, Das R (2013) Carbon Nanotubes (CNT) for Electronics & Electrics, 2013-2023: Forecasts, Applications, Technologies. IDTechEx, May 2013, http://www.idtechex.com/research/reports/carbon-nanotubes-cnt-for-electronics-and-electrics-2013-2023-forecasts-applications-technologies-000342.asp

Thinkstep GaBi LCA Databases: http://www.gabi-software.com/international/databases/gabi-databases/

Töpfer K (2002) Editorial for Int J LCA on the launch of the UNEP-SETAC life cycle initiative.Int J Life Cycle Assess 7 (4): 191-191, doi:10.1007/BF02978871

US EPA (2005) Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. March 2005. Risk Assessment Forum. U.S. Environmental Protection Agency, Washington, DC

Walser T, Demou E, Lang DJ, Hellweg S (2011a) Prospective Environmental Life Cycle Assessment of Nanosilver T-shirts. Environmental Science & Technology 45 (10):4570-4578 Supporting Information

Walser T, et al. (2013) Indoor Exposure to Toluene from Printed Matter Matters: Complementary Views from Life Cycle Assessment and Risk Assessment. Environ. Sci. Technol., 2014, 48 (1): 689–697

Wohlleben W, Brill S, Meier MW, Mertler M, Cox G, Hirth S, von Vacano B, Strauss V, Treumann S, Wiench K, Ma-Hock L, Landsiedel R (2011): On the Lifecycle of nanocomposites: Comparing Released Fragments and their In-Vivo Hazards from Three Release Mechanisms and Four Nanocomposites.

ANNEXES

Annex 1

Table 1: Overview on Current General Risk Assessment Methodologies

Risk Assessment Methodology	Organization	Country	Description
OECD Environmental Risk Assessment Toolkit[19]	Organization for Economic Co-operation and Development (OECD)	INTERNATIONAL	This approach offers access to practical tools on environmental risk assessment and management of chemicals. It describes the work flow of environmental risk assessment and management with links to relevant OECD products that can be used in each step of the work flow. The Toolkit has been revised to include resources other than OECD products, and to incorporate three examples (i.e. textile dye, pesticide and environmental quality standard setting) which show the risk assessment steps involved in each case. Generation of comprehensive data for a substance is not always necessary in the first step of environmental risk assessment. In some cases, for example, the exposure potential of the target chemical can determine the extent to which hazard information is required.
Human Health Risk Assessment Toolkit for Chemical Hazards[20]	World Health Organization (WHO)	INTERNATIONAL	The is toolkit described by the WHO provides guidance to identify, acquire and use the

[19] http://www.oecd.org/chemicalsafety/risk-assessment/theoecdenvironmentalriskassessmenttoolkittoolsforenvironmentalriskassessmentandmanagement.htm

[20] http://www.who.int/ipcs/methods/harmonization/areas/ra_toolkit/en

			information needed to assess chemical hazards, exposures and the corresponding health risks with respect to their health risk assessment contexts at local and national levels. It contains road maps for carrying out a human health risk assessment, identifies the information required and lists electronic links to international resources from which information can be obtained on methods for conducting human health risk assessment. It was developed for use by public health and environmental professionals, industrial managers, regulators and decision-makers who have responsibility for assessing and managing the human health risks posed by chemicals. A tiered approach to risk assessment is adopted, taking into account the severity of the problem and availability of resources.
Guidelines for Ecological Risk[21] Assessment and Environmental Models	US-Environmental Protection Agency	US	These EPA Guidelines described draw on a wide range of sources including peer-reviewed issue papers and case studies previously developed by the EPA Risk Assessment Forum. A major theme is the interaction among risk assessors, risk managers, and other stakeholders in the project planning and problem formulation stage and the final risk characterization and risk assessment process. Risk characterization involves estimating, interpreting, and reporting risks to achieve clear, transparent, reasonable, and consistent risk assessment. The Guidelines are not regulations but rather internal guidance that also informs the public and the regulated community about the EPA's approach to risk assessment.
REACH [22]	European Chemicals	EU	EU chemicals regulation provides a framework for

[21] http://www.epa.gov/raf/publications/guidelines-ecological-risk-assessment.htm
[22] http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation

	Agency		dealing with health, safety and environmental risks related to nanomaterials. REACH (Regulation (EC) No 1907/2006) will progressively replace various existing directives and regulations applicable to chemicals, dealing with classification/labelling, notification and risk assessment of new substances and preparations, information, risk assessment and management of existing substances, and market restrictions. It brings about significant changes to the current regulatory system by transferring the responsibility for the safe use of chemicals to manufacturers, importers and users of substances instead of authorities, by widening the scope for their registration, by introducing a centralized European system, to ensure consistency in implementation, and by replacing disparate rules by a single unified regulatory system. RIPoN on Information Requirements (RIPoN2) and the RIPoN on Chemical Safety Assessment (RIPoN3) address – inter alia - the question whether the existing REACH requirements and the relevant guidance are appropriate to assess nanomaterials. They contain a number of specific proposals. RIPoN 2 concluded that, with a few caveats, the guidance at the time of the project and the information requirements were considered applicable for the assessment of nanomaterials. RIPoN3 concluded that known exposure assessment methods were generally applicable but may still experience methodological challenges. The REACH approach to hazard assessment and risk characterization, with its built-in flexibility, makes it overall suitable for nanomaterials. The key remaining question is to what extent data for one form of a substance can be used to demonstrate the safety of another form, due to still developing understanding of e.g. drivers of

			toxicity.
Targeted Risk Assessment (TRA) tools[23]	European Centre for Ecotoxicology and Toxicology for Chemicals (ECETOC)	EU	The targeted risk assessment (TRA) informs about the concept that, by making adequately conservative assumptions, broad exposure/risk models can be applied to determine where further detailed risk assessment may be needed. The approach is founded on the premise that depending on the exposure and the hazard, different information requirements will be needed to demonstrate safe and responsible production, use, and disposal of a chemical. The use of the tiered approach to risk assessment ensures that the level of refinement and detail of the information required for a risk evaluation is proportional to the potential risks of a chemical taking into consideration both hazards and exposures.
Managing Risks of Hazardous Chemicals in the Workplace[24]	Safe Work Australia	AU	This Code of Practice relating to managing the risks associated with hazardous chemicals in the workplace is a practical guide to achieving the standards of health, safety and welfare required under the Work Health and Safety Regulations (the WHS Regulations). It applies to substances, mixtures and articles used, handled, generated or stored at the workplace which are defined as hazardous chemicals under the WHS Regulations and the generation of hazardous chemicals from work processes. Under the WHS Regulations, a hazardous chemical is any substance, mixture or article that satisfies the criteria of one or more Globally Harmonized System of Classification and Labelling of Chemicals (GHS) hazard classes.
Stoffen-manager[25]	Netherlands - Ministry	NL	This is a tool for prioritizing worker health risks to

[23] http://www.ecetoc.org/tra
[24] http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/633/How_to_Manage_Work_Health_and_Safety_Risks.pdf

	of Social Affairs and Employment		dangerous substances and is officially recognized as REACH instrument. It was developed for allowing SME's to prioritize their health risks to dangerous substances and to determine effective control measures. The tool combines hazard information of a substance or product with an inhalation and/or dermal worker exposure assessment to calculate a risk score. When risks are presumed, effects of control measures can be examined. An action plan shows an overview of the risk assessments with control measures. The worst case estimation can be compared to the DNEL of the substance concerned.

[25] https://stoffenmanager.nl/Default.aspx

Table 2: Overview on Current Nanomaterial Specific Risk Assessment Methodologies

Nanomaterial Specific Risk Assessment Methodology	Organization	Country	Description
Precautionary Matrix for Synthetic Nanomaterials[26]	Federal Offices of Public Health and Environment (FOPH &FOEN)	CH	This tool allows the identification of potential risks for existing or new nanotechnology products and processes in the development, production, use and disposal stages by means of a methodical procedure. The potential risk of the nanomaterial or its associated products can be classified according to whether the requirement for nanospecific measures is estimated as low, or whether measures should be taken such as the evaluation of the current procedures, additional specifications, and, if necessary, practice measures to decrease the risks.
Nano Risk Framework[27]	DuPont & Environmental Defense	US	This framework is established with the aim of providing assistance for the essential issues which should be taken into account when dealing with nanomaterials as well as offering support on the information required for performing risk evaluation and risk management decisions. The use of logical suppositions and suitable risk management procedures allow it to be adaptable enough to be applied in situations in which there is lack of knowledge or uncertainties. On the other hand, it offers the possibility of being used as a reference point when new developments take place or suppositions are made at the moment that new data is accessible. It is designed to be used iteratively as new data are generated and new information is gathered and includes a list of test methods for toxicity, ecotoxicity and environmental fate.
Risk Assessment of manufactured nanomaterials[28]	New Energy and Industrial Technology Development Organization (NEDO)	JP	This risk assessment methodology has been developed for three selected manufactured nanomaterials: TiO_2, fullerenes C60 and carbon nanotubes. The original concept had to be modified because a general chemical risk assessment was difficult to apply for nanomaterials. The reason for this is that the nanomaterials risk is influenced by the relationship between toxicity and physical properties rather than chemical properties alone. An additional difficulty encountered was the scarcity of toxicity and exposure data of the selected nanomaterials. The features taken into account are: the possibilities

[26] www.bag.admin.ch/nanotechnologie/12171/12174/12175/index.html?lang=en
[27] www.nanoriskframework.com
[28] www.aist-riss.jp/main/modules/product/nano_rad.html?ml_lang=en

			of functionalization of nanomaterials resulting in new biological reactions, small size or large specific surface area which allow nanoparticles to enter internal organs or may increase the activity of chemical reactions, persistence of nanoparticles and effect of shape on biopersistance.
NanoCommission Assessment Tool[29]	Federal Ministry for the Environment, Nature Conservation & Nuclear Safety	DE	This methodology is based on the knowledge gained with the Precautionary Matrix for Synthetic Nanomaterials. This assessment tool is in the format of a downloadable questionnaire (available only in German). The set of criteria applied to all life-cycle stages are possibility of exposure, physico-chemical properties, environmental fate and toxicology/ecotoxicology. Beneficial and risk aspects of nanomaterials are considered for consumers, society, environment and companies at different stages of the life-cycle of a nanomaterial. A classification into two groups is made depending on whether there is no cause or cause for concern. Cause for concern arises when there is a risk of exposure due to high production and use volumes, high mobility of the nanomaterial, bioaccumulation, hazardous effects such as high reactivity, difficulties in risk management, i.e. due to low detectability and uncertainties in the fate of the nanomaterial.
Precautionary Strategies for Managing Nanomaterials[30]	Advisory Council on the Environment	DE	This strategy describes the following actions which are proposed to improve the application of the precautionary principle to nanomaterials: increase on nanomaterial risk research; specific legal framework for nanomaterials; labelling and product register; review of chemical legislation; review of product legislation; review of environmental legislation and social dialogue. It is advised to consider nanomaterials as substances by themselves instead of as their conventional equivalents because nanomaterials can show additional risks than the bulk form. A basic data set for each nanomaterial, independently of the quantity produced, needs to be provided. Attention should be paid to waste incineration, landfilling, recovery and recycling, where waste containing nanomaterials should be sorted as hazardous.
SafeNano Scientific Services[31]	Institute of Occupational Medicine (IOM)	GB	This commercially available service provides independent consultancy on nanomaterials risk and safety. It offers solutions on the following areas:

[29] www.bmu.de/en/service/publications/downloads/details/artikel/responsible-use-of-nanotechnologies-1
[30] www.umweltrat.de/SharedDocs/Downloads/EN/02_Special_Reports/2011_09_Precautionary_Strategies_for_managing_Nanomaterials_KFE.pdf?__blob=publicationFile
[31] www.safenano.org

			product safety and toxicology, nanoparticle detection and analysis, and duty of care and risk assessment. It helps to comply with regulatory requirements and provides support by means of safety procedures and toxicity testing. It offers expertise in determining possible nanoparticle exposure due to particle release in the workplace. The approach consists of obtaining the data needed for risk management due to problems arising throughout the supply chain. The areas covered include toxicology, hazard identification, ecotoxicology, hazard assessment on ecological systems and bioaccumulation, safety issues and legislation, occupational hygiene and training for workers on nanomaterial safety and exposure risks.
NanoRiskCat – A Conceptual Decision Support Tool for Nanomaterials [32]	Danish Ministry of the Environment – Environmental Protection Agency	DK	Through this project, DTU Environment and the National Research Centre for the Working Environment have initiated the development of a screening tool, NanoRiskCat (NRC), that is able to identify, categorize and rank exposures and effects of nanomaterials used in consumer products based on data available in the peer-reviewed scientific literature and other regulatory relevant sources of information and data. The primary focus was on nanomaterials relevant for professional end-users and consumers as, as well as nanomaterials released into the environment. The wider goal of NanoRiskCat is to help manufacturers, down-stream end-users, regulators and other stakeholders to evaluate, rank and communicate the potential for exposure and effects through a tiered approach in which the specific applications of a given nanomaterial are evaluated. This is done by providing detailed guidance on mapping and reporting.
REACH Implementation Projects on Nanomaterials (RIPoN)[33]	European Chemicals Agency	EU	The European REACH legislation does not specifically mention nanomaterials although it comprises areas where nanomaterials are used and therefore it can be applied. Nanomaterials are deemed equivalent to their analogues in the bulk form for the purposes of registration In the case that the bulk and the nano form have different uses and properties, these must be specified and additional information, such as hazardous properties, operational conditions, safety assessment and risk management, needs to be provided. The particular hazards related to the specific nanomaterials need to be tackled and therefore the test guidelines may need to be adjusted accordingly and further testing may be necessary.

[32] http://www2.mst.dk/udgiv/publications/2011/12/978-87-92779-11-3.pdf
[33] http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/ripon_en.htm

Work Health & Safety Assessment Tool for Handling Engineered Nanomaterials[34]	Safe Work	AU	This tool was developed to assist regulators, research laboratories and organizations in managing engineered nanomaterials. It consists of a questionnaire which helps to register the chemical composition and the physical form of the nanomaterials manufactured, used, and the safety measures applied to nanoparticle exposure prevention at the work place. Consumer protection or environmental considerations are not taken into account.
StoffenmanagerNano Module[35]	Ministry of Social Affairs and Employment	NL	This web-based application focuses on the safety at the work place when dealing with not biodegradable engineered nanomaterials. The classification of the risk is made according to the physico-chemical characteristics and hazard properties of the nanomaterial. At the moment only a qualitative output can be obtained, which classifies the risk priority in low, medium or high. It evaluates the exposure to nanomaterials only via inhalation.
NanoSafer[36]	The Industries Council of Occupational Health and Safety	DK	A risk evaluation methodology for the work place is described which takes as a reference the known hazards of the analogue bulk material and it only considers nanopowders. It employs a control banding method to estimate the hazard and exposure to airborne nanoparticles in the work place. Only a Danish version is available.
ANSES[37]	National Agency for Food Safety, Environment and Labor	FR	A control banding approach is applied for the work place, combining risk assessment and management. It allows the use of data on toxicity of the similar conventional chemicals. Solubility and reactivity are considered as factors increasing the hazard. Biopersistent fiber-like shape substances are considered to be of maximum hazard. It is requested to report the amount produced, the uses of the nanomaterial, the frequency of exposure and the final users.

[34] http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/at201008workhealthandsafetyassessmenttool
[35] http://nano.stoffenmanager.nl
[36] http://www.ibar.dk
[37] http://nanoparticlelibrary.net/

Table 3: Overview on Current Databases

Database	Organization	Country	Description
OECD Database on Manufactured Nanomaterials to Inform and Analyse EHS Research Activities[38]	OECD	INTERNATIONAL	As part of the OECD activities to promote international co-operation in addressing human health and environmental safety aspects of manufactured nanomaterials, the OECD has developed a global resource which collects research projects that address environmental, human health and safety issues of manufactured nanomaterials. This database holds details of completed, current and planned research projects on safety, which are to be updated (electronically) by delegations. This database is also intended to be an inventory of information on research programs to help the other projects of the WPMN by identifying relevant research projects or storing information derived from the projects of the WPMN, including the sponsorship program on the testing of manufactured nanomaterials.
NIOSH Nanoparticle Information Library[39]	NIOSH - National Institute for Occupational Safety and Health	US	The goal of the NIL is to help occupational health professionals, industrial users, worker groups, and researchers organize and share information on nanomaterials, including their health and safety-associated properties. The information incorporated into the searchable online database includes: nanomaterial composition; method of production; article size, surface area, and morphology; demonstrated or intended applications of the nanomaterial; availability for research or commercial applications; associated or relevant publications; points of contact for additional details or partnering.
NHECD Intelligent Search[40]	NHECD Project Consortium	EU	A free access, robust and sustainable web based information system including a knowledge repository on the impact of nanoparticles on health, safety and the environment. It includes a robust content management system (CMS) as its backbone, to hold unstructured data (e.g., scientific papers and other relevant publications). It also includes a mechanism for automatically updating its knowledge

[38] https://nhecd.jrc.ec.europa.eu/
[39] http://nanoparticlelibrary.net/
[40] http://icon.rice.edu/advancedsearch.cfm

			repository, thus enabling the creation of a large and developing collection of published data on environmental and health effects following exposure to nanoparticles.
Project on Emerging Nanotechnologies[41]	Woodrow Wilson International Center for Scholars	US	An inventory of current research involving nanotechnology health and environmental implications has been developed. It catalogs global government-funded research into the human health, safety and environmental implications of nanotechnology. While not comprehensive, it is designed to serve as a resource for researchers, policy makers and others engaged in ensuring the success of nanotechnologies through understanding and reducing potential risks. It also includes some research projects supported by industry, foundations and others.
ICON Environmental, Health and Safety (EHS)[42]	Rice University Center for Biological and Environmental Nanotechnology	US	The Database Analysis Tool offers a way for researchers at universities, nongovernmental organizations, government and industry worldwide to analyze a database of citations to peer-reviewed publications addressing nanomaterials environmental, health and safety impacts. The tool enables research comparisons, with every database entry assigned nine indices and each index including a trend across time.
NANOhub[43]	European Commission Joint Research Centre	EU	A database and information platform developed to address and host nano-specific information and methodology. It is based on IUCLID, which provides a common accepted basis for regulatory use of data, such as in the OECD context. It complements the repository of nanomaterials for test method development and assessment. The hub covers application areas such as cosmetics, food and medical. It hosts a number of collections of research project data as well as study results from the OECD Working Party on Manufactured Nanomaterials (WPMN).
DaNa[44]	Federal Ministry of	DE	The database contains information about products and applications

[41] http://www.nanotechproject.org/inventories/ehs/
[42] http://icon.rice.edu/advancedsearch.cfm
[43] http://napira.jrc.ec.europa.eu

	Education and Research		with nanomaterials including aspects of applied nanomaterials on health and environment; facts on risk management and safety aspects of synthetic nanomaterials. It provides detailed information about nanomaterials and their behavior in biological or physiological analytical systems.
Nanomaterial Registry[45]	US National Institutes of Health	US	A data-driven tool whose purpose is to enable researchers to close the knowledge gap that currently exists in the nanotechnology field. The goal of is to archive a sufficiently large, accessible, and centralized body of integrated information to enable researchers in gaining knowledge from accumulated data. As computational tools and researchers interact with the information in the central data repository, knowledge will be extracted and used to guide new research and the safe use of nanomaterials.
caNanoLab[46]	National Institutes of Health	US	A data sharing portal designed to facilitate information sharing in the biomedical nanotechnology research community to expedite and validate the use of nanotechnology in biomedicine. caNanoLab provides support for the annotation of nanomaterials with characterizations resulting from physico-chemical and in vitro assays and the sharing of these characterizations and associated nanotechnology protocols in a secure fashion.
InterNano[47]	National Science Foundation	US	A searchable and openly accessible database of nanomanufacturing research, government reports on nanomanufacturing, and federally-funded education and outreach efforts for nanomanufacturing. It also contains information related to EHS issues.
Nanomaterial Biological Interactions (NBI) Knowledgebase[48]	Oregon State University	US	The NBI Knowledgebase serves as a repository for annotated data on nanomaterial characterization, synthesis methods, and nanomaterial-biological interactions defined at multiple levels of biological

[44] http://nanopartikel.info/cms/Wissensbasis#material=material/21
[45] https://www.nanomaterialregistry.org
[46] https://cananolab.nci.nih.gov/caNanoLab
[47] http://www.internano.org

			organization. Computational and data mining tools are currently being developed and incorporated into it to provide a logical framework to conduct species, route, dose, and scenario extrapolations and identify key data required to predict the biological interactions of nanomaterials.

[48] http://nbi.oregonstate.edu/

Annex 2

Table 1: Metadata for US and European databases

US Life Cycle Inventory Database	**European Reference Life Cycle Database (ELCD)**	
Activity	*Process information*	
• Name • Category • Location • Geography Comment Infrastructure process • Quantitative reference	Key Data Set Information	• Location • Geographical representativeness • Reference year • Name • Use advice for data set • Technical purpose of product or process • Classification • General comment on data set • Copyright • Owner of data set (contact data set)
	Quantitative reference	• Reference flow(s)
	Time representativeness	• Data set valid until: • Time representativeness description
	Technological representativeness	• Technology description including background system • Flow diagram(s) or picture(s) (source data set)
Modelling	*Modelling and validation*	
• LCI Method • Modelling constants • Data completeness • Data selection • Data treatment • Reviewer • Other evaluation • Sources	LCI method and allocation	• Type of data set • LCI method principle • Deviation from LCI method principle / explanations • LCI method approaches • Deviations from LCI method approaches / explanations • Modelling constants • Deviation from modelling constants / explanations • LCA methodology report (source data set)
	Data sources, treatment, and representativeness	• Data cut-off and completeness principles • Data selection and combination principles • Deviation from data selection and combination principles / explanations • Data treatment and extrapolations principles • Deviation from data treatment and extrapolations principles / explanations • Data source(s) used for this data set (source data set) • Percentage supply or production covered
	Completeness	• Completeness product model
	Validation	• Review • Data Quality indicators • Reviewer details • Reviewer name and institution (contact data

		set)
	Compliance declarations	• Compliance
Administrative information		
• Intended Applications • Copyright • Restrictions • Data Owner • Data Generator • Data Documentor • Project • Version • Created • Last Update	Commissioner and goal	• Commissioner of data set (contact data set) • Intended applications
	Data set generator / modeller	• Data set generator / modeller (contact data set)
	Data entry by	• Time stamp (last saved) • Data set format(s) (source data set) • Converted original data set from: (source data set) • Official approval of data set by producer/operator: (contact data set)
	Publication and ownership	• UUID of Process data set • Data set version • Permanent data set URI • Workflow and publication status • Unchanged re-publication of: (source data set) • Owner of data set (contact data set) • Access and use restrictions
Exchanges	*Inputs and Outputs*	
• Input: flows or/and processes • Output: flows or/and processes	• Input: flows or/and processes • Output: flows or/and processes	

Table 2: Scheme for a third party report and a report on comparative studies to be disclosed to the public

Third party report (ISO 14044:2009)	**Report on comparative studies to be disclosed to the public (ISO 14044:2006)**
a) *General aspects:* 1) LCA commissioner, practitioner of LCA (internal or external); 2) date of report; 3) statement that the study has been conducted according to the requirements of this International Standard.	
b) *Goal of the study:* 1) reasons for carrying out the study; 2) its intended applications; 3) the target audiences; 4) statement as to whether the study intends to support comparative assertions intended to be disclosed to the public.	
c) *Scope of the study:* 1) function of the system; 2) functional unit; 3) system boundary description: including omissions of life cycle stages, processes or data needs; 4) assumptions and cut-off criteria for initial inclusion of inputs and output.	
d) *Life cycle inventory analysis:* 1) data collection procedures; 2) qualitative and quantitative description of unit processes; 3) sources of published literature; 4) calculation procedures; 5) validation of data; 6) sensitivity analysis for refining the system boundary; 7) allocation principles and procedures.	
f) *Life cycle impact assessment:* 1) the LCIA procedures, calculations and results of the study; 2) limitations and relationship of the LCIA results relative to the defined goal and scope of the LCA and to the LCI; 5) impact categories and category indicators considered, including a rationale for their selection and a reference to their source, including all assumptions and limitations; 7) descriptions of or reference to all value-choices used in relation to impact categories, characterization models, characterization factors, normalization, grouping, weighting and, elsewhere in the LCIA, a justification for their use and their influence on the results, conclusions and recommendations; 8) a statement that the LCIA results are relative expressions and do not predict impacts on category endpoints, the exceeding of thresholds, safety margins or risks.	
e) *Life cycle interpretation:* 1) the results; 2) assumptions and limitations associated with the interpretation of results, both methodology and data related; 3) data quality assessment; 4) full transparency in terms of value-choices, rationales and expert judgments.	
g) *Critical review, where applicable:* 1) name and affiliation of reviewers; 2) critical review reports; 3) responses to recommendations.	
	h) analysis of material and energy flows to justify their inclusion or exclusion;
	i) assessment of the precision, completeness and representativeness of data used;
	j) description of the equivalence of the systems being compared
	k) description of the critical review process;
	l) an evaluation of the completeness of the LCIA;
	m) a statement as to whether or not international acceptance exists for the selected category indicators and a justification for their use;
	n) an explanation for the scientific and technical validity and environmental relevance of the category indicators used in the study;
	o) the results of the uncertainty and sensitivity analyses;
	p) evaluation of the significance of the differences found.
	q) if grouping is included in the LCA, add the following: 1) the procedures and results used for grouping; 2) a statement that conclusions and recommendations derived from grouping are based on value-choices; 3) a justification of the criteria used for normalization and grouping (these can be personal, organizational or national value-choices); 3) an explanation for the scientific and technical validity and environmental relevance of the category indicators used in the study; 4) the results of the uncertainty and sensitivity analyses; 5) evaluation of the significance of the differences found.

Table 3: Overview on Current (nano-specific) Life Cycle Assessment Methodologies

Methods	Organisation	Country	Description
ISO 14040 – 14044; Environmental Management – Life Cycle Assessment	International Standardization Organisation	International	A life cycle assessment (LCA) is the assessment of the environmental impact of a given product throughout its lifespan. The goal of LCA is to compare the environmental performance of products in order to be able to choose the least burdensome. The term 'life cycle' refers to the notion that for a fair, holistic assessment the raw material production, manufacture, distribution, use and disposal (including all intervening transportation steps) need to be assessed. This then is the 'life cycle' of the product. The concept can also be used to optimize the environmental performance of a single product (eco-design) or that of a company. ISO 14040:2006, Environmental management – Life cycle assessment – Principles and framework, provides a clear overview of the practice, applications and limitations of LCA to a broad range of potential users and stakeholders, including those with a limited knowledge of life cycle assessment. ISO 14044:2006, Environmental management – Life cycle assessment – Requirements and guidelines, is designed for the preparation of, conduct of, and critical review of, life cycle inventory analysis. It also provides guidance on the impact assessment phase of LCA and on the interpretation of LCA results, as well as the nature and quality of the data collected.
Analysis and Strategic Management of Nanoproducts with Regard to their Sustainability Potential (Nano-Sustainability Check)	Oeko-Institut, Institute for Applied Ecology	Germany	The aim of the Nano-Sustainability Check is to examine the sustainability of products and applications involving nanomaterials in terms of their practical advantages. The most important feature in this context is an evaluation grid by means of which nano-products (i.e. products that are produced with nanomaterials) can be analysed by comparison with an existing reference product that has been manufactured without the use of nanomaterials. In addition, the evaluation grid is able to address any possible threats. The aspects investigated within the Nano-Sustainability Check are represented in the form of a total of 14 key performance indicators. The focus is on aspects of environmental and climate protection, which are – as far as possible – considered from a quantitative point of view. The Nano-Sustainability Check offers users the facility of an early warning system and thus provides an important indication as to what direction should be taken in the innovation process of nano-products.
Guidelines for collecting data and comparing benefit and risk aspects of nanoproducts	NanoCommission	Germany	This is a guideline for collecting data and comparing benefit and risk aspects of nano-products throughout their life cycle and tested these on the basis of example products. Owing to constraints on time and resources, as well as difficulties in developing objective, broadly applicable methods of assessing the parameters, this guideline is unable to fulfil its remit to produce a “comprehensive assessment methodology” including evaluation indicators. The list of criteria should therefore not be viewed as a (definitive) evaluation tool , but rather

			as an aid for preliminary appraisal of the benefit and risk aspects of nano-products and as a tool for promoting transparent, objective stakeholder discourse.
Sustainability indicators for nanotechnology (Prosuite project)		Netherlands	The objectives of the nanotechnology task within work of the EU-PROSUITE-Project were (1) to gather data and conduct case studies about several nano-enabled products, (2) to perform a sustainability assessment for each of these case studies applying the economic assessment methods, environmental assessment methods and social assessment and participative methods, weighting factors, and (3) to provide feedback and suggest improvements to the overall method developers. These objectives were fully achieved and the results are included in the report entitled "Nanotechnology – Final sustainability assessment" – see http://www.prosuite.org/c/document_library/get_file?uuid=13d10bd8-170f-4504-8d1e-5f2facdfdb63&groupId=12772 or via http://www.prosuite.org/web/guest/project-case-studies.
Guidance to Facilitate Decisions for Sustainable Nanotechnology	Environmental Protection Agency	U.S.A.	The aim of this work is not to make decisions for stakeholders, but help frame the pertinent issuesthat must be addressed to properly assess emerging nanotechnology and to provide information on various tools that may be used to address them. The foundation of this approach is to consider existing standards and methods for environment, economic, and social assessments using a life cycle perspective and offer guidance by relaying first-hand knowledge of applying assessment tools to nanotechnologies, whenever possible.

Annex 3

Table 1: LCA Publications containing LCI data for manufactured nanomaterials (updated, based on the original table from Hischier & Walser, 2012)

		Input		Output						
				emission to air		emission to water		emission to soil		
Reference	covered nanomaterial(s)	material input	energy input	- general	- nanomaterials	- general	- nanomaterials	- general	- nanomaterials	further aspects
Greijer et al. 2001	nanocrystalline dye (out of nano-TiO2 & carbon powder)	yellow	yellow							
Lloyd and Lave 2003	polymer nanocomposite (on nanoclay base)	yellow	green							
Steinfeldt et al. 2004a	(i) nano varnish / (ii, iii) carbon nanotubes / (iv) quantum dots	yellow	yellow							
Lloyd et al. 2005	nanoscale platinum-group metal (PGM) particles	green ■	green ■							
Osterwalder et al. 2006	nanoparticles of titanium dioxide (TiO2) & zirconia (ZrO2)		green ■	yellow ■						
Roes et al. 2007	polymer nanocomposite (on nanoclay base)	green ■	green ■							
Bauer et al. 2008	carbon nanotubes (CNT)	green	green							
Healy et al. 2008	single-wall carbon nanotubes (SWCNT)	green ■	yellow ■	yellow ■						yellow ■
Joshi 2008	nanoclay (OMMT, organically modified montmorillonite)	green ■	green ■	green ■		green ■				
Kushnir and Sanden 2008	carbon nanoparticles (CNP) - i.e. fullerenes and nanotubes		green ■							
Singh et al. 2008	single-wall carbon nanotubes (SWCNT)	green ■	green ■	yellow ■				yellow ■		
Khanna et al. 2008b	carbon nanofiber (CNF)	green ■	yellow ■							
Khanna and Bakshi 2009	carbon nanofiber polymer composite	green	yellow							
Fthenakis et al. 2009	nano CdTe, nanocrystalline-Si and nano-Ag contact PV systems	yellow ■	green ■							
Grubb 2010	titanium dioxide nanoparticles	green ■	green ■	yellow						
Roes et al. 2010	nanoscale silica (SiO2), [org. montmorillonite, CNTs]	green ■	green ■	green ■		green ■				
Walser et al. 2011	nano silver (coating)	green ■	green ■	green ■	green ■	green ■	yellow ■	green ■		

Reference	covered nanomaterial(s)	Input: material input	Input: energy input	Output: emission to air - general	Output: emission to air - nanomaterials	Output: emission to water - general	Output: emission to water - nanomaterials	Output: emission to soil - general	Output: emission to soil - nanomaterials	further aspects
Wender and Seager, 2011	single-wall carbon nanotubes (SWCNT)	green	green							yellow
de Figueirêdo et al. 2012	two different types of cellulose nanowhiskers	green ■	green ■			green ■				
Deorsola et al. 2012	Molybdenum sulfide (MoS2) nanoparticles	green ■	green ■							
Eckelman et al. 2012	single-wall carbon nanotubes (SWCNT)	green	yellow	yellow						yellow
Le Corre et al. 2012	starch nanocrystals (SNC) plus org. mod. nanoclay (OMMT)	green ■	green ■	yellow						
Manda et al. 2012	nano titanium dioxide	green ■	green ■	yellow						
Pascu et al. 2012	nano iron oxide particles	green ■	green ■							

Legend:
- green: good data coverage
- (grey): no data coverage / no such information
- yellow: partial data coverage
- ■: quantitative LCI information reported in publication

Annex 4

Table 1: LCA Publications on nano-product and nanotechnology containing sensitivity analysis

Authors	***Scope***	***Sensitivity analysis***
Kanna et al. (2008)	LCA on environmental impact of carbon nanofibers (CNFs) synthesis	varying cycle times and unreacted feedstock and carrier gas recycle rates on the life cycle energy consumption
Walser et al. (2011a)	to compare nanosilver T-shirts with conventional T-shirts with and without biocidal treatment	varying single parameter values, such as biocidal concentrations, different precursor production technologies, and altering assumptions of consumer behaviour, within realistic value ranges.
Li et al (2014),	LCA of a high-capacity LIB pack using SiNW prepared via metal-assisted chemical etching as anode material	on the effects of multiple factors, including the cathode material, the service life of battery pack, the electricity mix for battery charging, and the operating geographic region of the EVs
Pizza et al (2014),	Life cycle assessment of nanocomposites made of thermally conductive graphite nanoplatelet	on the electricity mix used during the GnP production process and composite production,
Barberio et al. (2014)	LCA of production of alumina nanofluid with two process	Varying the precursor material used to produce the nanofluid