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# An integrated Life Cycle Assessment and Risk Assessment approach for assessing the environmental sustainability of nanoproducts

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## 1. Introduction

Engineered nanomaterials (ENM) are becoming an important part of our society and are used in a wide range of industrial applications and commercial products. However, the potential impacts and risks of these materials on human health and the environment are still poorly understood. Releases of ENMs (intentional or otherwise) into the environment may occur at any stage of the product life cycle, potentially resulting in human and environmental exposure to potentially toxic agents. Currently, the potential impact of such releases are scarcely addressed in Life Cycle Assessment (LCA) studies on ENM due to the gap of knowledge regarding the quantities and hazard of ENM releases [1]. Additionally, the production of ENM may be associated with high energy and water consumption, which results in negative environmental impacts. Given the potential for adverse effects and potential impacts, there is a need to investigate and understand the potential EHS risks and impacts of nanomaterials at an early stage in product development so that appropriate measures can be put in place to resolve any issues [2]. Such early stage assessments are typically based on the well-established risk assessment (RA) methodology. However, RA is solely focused on identifying and managing actual human and environmental risks and does not consider wider related potential environmental impacts, such as climate change; an issue that typically is covered by applying the LCA methodology. This latter, more comprehensive approach is essential in order to obtain a broader, more comprehensive picture of the sustainability of such new nanoproducts. In the context of the recently finished H2020 project NanoReg2, a new, comprehensive, integrated LCA and RA framework for assessing the environmental sustainability and human health risks of ENMs and related nano-enabled products has been developed. The H2020 project NanoReg2 ([www.nanoreg2.eu](http://www.nanoreg2.eu)) aims to address the challenge of how to couple safe by design principles into the regulatory process for ENM and has a core objective to develop supportive tools for safe by design based on regulatory oriented grouping approaches.

## 2. Framework development

Opposite to the work from the OECD Working Party of Manufactured Nanomaterials (WPMN) published in 2015 [3], representing a better linking between RA and LCA by e.g. guidance regarding the proper scoping of LCA studies on nano-enabled applications (functionality, system boundaries, etc.), and the for this purpose existing data sets (especially concerning human & eco toxicity), the new framework here represents an integration of the LCA and the RA methodologies in each each single stage of a ENM (or nano-enabled product) development cycle. The framework (summarized in Figure 1) is structured by following the standard stage-gate model i.e. as described in Cooper RG, 1990 [4]. In stage one where the core business idea is described (stage therefore called “business idea”), an initial qualitative scoping of possible potential impacts and risks is established and the main legislative requirements are identified. Then, in stage two (i.e. the stage of the “business concept”), simplified screening applications of LCA and RA, covering the potential benefits and risks (for workers, consumers and the environment) are applied, allowing a first rough evaluation of the sustainability of the product, based on a mix of qualitative and partly quantitative (e.g. estimated) data, using e.g. the LICARA approach [5] as supporting tool. At this stage, the toxicity of ENM is assessed by using literature data and technical reports only. Based on this information, a first qualitative assessment of the exposure can already be carried out. Then, in the third step (split into the steps 3a about “prototype ENM”, and 3b “prototype industrial setting”), all operating conditions are usually identified and known, and thus quantitative data – at lab scale and in an industrial setting – can be collected. In this stage, experimental studies to characterize the toxicity of the ENM are performed, with environmental, workers and consumers exposure being quantified through respective RA-based approaches. Additionally, relevant

process-based life cycle inventory (LCI) data (inputs and outputs of energy, water and materials, emissions to the environment) related to the ENM production can be collected and used to perform an initial LCA study. The data gained through the RA activities (especially the case specific workers exposure characterization) will be integrated into the LCA framework to provide a more detailed characterization of the potential human impacts [6]. In the fourth and final stage (“validation and market”), the requirements for the REACH regulations are integrated. As above, any revised or new outputs from the RA (i.e. case specific workers exposure characterization) related to human and environmental toxicity will be used to support the characterised life cycle impact assessment (LCIA) in the LCA. Notably, a variety of different tools (such as e.g. LICARA, NanoRiskCat, Nanosafer, the Swiss Precautionary matrix) are used at each stage to provide valuable insights into performance to support the company in the process of the evaluation of the risk and sustainability of their product. The Safe by Design Platform can integrate all these tools and more guiding the company in collecting and organizing regulatory and non-regulatory relevant information for each stage.

	Stage 1 Business idea	Stage 2 Business Concept		Stage 3a Prototype ENM		Stage 3b Prototype (industrial setting)		Stage 5 Validation/Market
<b>Data</b>	Provide a qualitative assessment of the potential impact and risk. The main legislative requirements are considered.	Physico-Chemical characterization ENM, Toxicity characterization; Exposure: identification of the main exposure route	Data quality: qualitative Data collection: Material Safety Data Sheet, Technical Data Sheet, literature	Physico-Chemical characterization ENM, Toxicity evaluation; Exposure characterization (workers, consumer, environment)	Data quality: quantitative data (experimental data & in situ), LCI: inventory data, LCA & RA: I) Toxicity experimental data (in vitro, literature data); II) Characterization of the exposure RA; III) Interim CF	Physico-Chemical characterization ENM, Toxicity evaluation; Exposure characterization (workers, consumer, environment)	Data quality: quantitative data (experimental data & in situ), LCI: inventory data, LCA & RA: I) Toxicity experimental data (in vitro, in vivo); II) Characterization of the exposure RA; III) CF development	REACH, product-related regulations/requirements, Labelling requirements (regulatory compliance)
<b>Tools</b>	NanoRiskCat, LICARA			Nanosafer, SPM, SUNDS; Revised used of LICARA; Lab -scale LCA & RA		LCA&RA -industrial setting; revised used of LICARA; SUNDS		
	SbD Implementation Platform							
	Qualitative				Quantitative			

Figure 1: A general overview of the RA&LCA integration framework is shown. The figure reports the key elements of the framework

### 3. Conclusions and Outlook

In the here described, integrated RA-LCA framework for assessing the environmental sustainability of ENM and nanoproducts RA and LCA are applied in each stage of the product development cycle, following a generally valid and well-known stage-gate model. The framework integrates the outcomes of the site-specific RA activities into the general LCIA framework for assessing toxicological impacts in order to allow a more accurate and more comprehensive evaluation of the potential impacts of nanoproducts in the toxicity-related impact categories. This framework is based upon to the Safe by Design approach developed within the NanoReg2 project and could be used as a basis for further integration with socio-economic analysis approaches for a yet more comprehensive overview of the sustainability of nanoproducts; an addition that will be discussed further here and that is the basis of further ongoing research.

### 4. References

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