SCIENCE-BASED RISK GOVERNANCE
OF NANO-TECHNOLOGY

RISK GONE

Training material for risk-benefit assessment

DELIVERABLE 3.8

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Abstract

This report summarizes the training material developed within the RiskGONE project in the context of risk-benefit assessment of engineered nanomaterials (ENMs) and nano-enabled products (NEPs). Training material may take on various forms – from written material to audio-visual presentation material and interactive tools. Starting from a summary of different elements of the risk-benefit process, different dissemination outlets are presented where individual training materials are made available. Recognizing the diversity of potential risk-benefit case studies on ENMs and NEPs, this deliverable and the examples therein must be viewed as a guide towards a growing repository of training material, with at its focal point the RiskGONE cloud platform currently under construction.

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List of Abbreviations

API - Application programming interface

CEN - Comité Européen de Normalisation, European Committee for Standardization

ENM - Engineered nanomaterial

LCA - Life cycle assessment

LCI - Life cycle inventory

MCDA - Multi-criteria decision analysis

NEP - Nano-enabled product

NGO - Non-governmental organisations

OECD - Organization for Economic Co-operation and Development

RA - Risk assessment

RBA - Risk-benefit assessment

REST - Representational state transfer

SME - Small and Medium Sized Enterprise

WTP - Willingness to pay

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1 Introduction

1.1 Risk-benefit assessment

RiskGONE supports the development, communication and dissemination of training materials regarding the draft guidelines for risk-benefits assessment created throughout the project in Work Package 3 (WP3). The risk-benefit assessment guidelines developed by the RiskGONE cover a wide range of potential use scenarios and address different stakeholder perspectives. Individual guidelines have been developed addressing 'traditional' toxicological risks, environmental risks using life-cycle indicators, economic risks and benefits, social risks, and ethical impacts. The (semi-)quantitative outcomes of one or several of these individual assessments can be used in a multi-criteria decision-making process, making use of multi-criteria decision analysis (MCDA), comparing engineered nanomaterials (ENMs) and their applications to each other or to a non-nano background scenario.

The risks and benefits associated with an ENM are not always confined to the material itself. In particular economic, environmental, social and ethical risks and benefits are comprised of a combination of the ENM, its application and (enabling) functionality in a nano-enabled product (NEP), as well as the environment the ENM and NEP are used in. This implies that for the individual (i.e. social, economic, environmental, etc.) elements of an risk-benefit assessment (RBA) different scopes may apply. For example, toxicological risk assessment may concern itself with the ENM and exposure during production and use, but for environmental assessment based on a life-cycle perspective, both the ENM and the product it is used in are relevant.

The numerous potential combinations of ENMs, their use in NEPs, and application areas make it very hard to generalise risk-benefit assessment for ENMs in a concrete way. The training material developed in WP3 are therefore casuistic in nature and highlight different elements of an RBA procedure, each with their own material, product and scope. In this report, we have therefore chosen to summarise the training material and indicate where training materials are, and will be, made available, with each case adding to a growing corpus of training material on RBA.

Within WP3 different activities have resulted in training material, aimed at describing, documenting and training potential users in application of the individual elements of RBA of ENMs and NEPs. As training material, we have included therefore different types of activities, such as:

- Written documents related to the draft guidelines
- Webinars and presentations
- Training videos

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- Interactive (web) tools

This training materials are made available to the general public via a diverse set of outlets, discussed in Chapter 3.

1.2 Target audience

RBA of ENMs is a methodology that is at a lower stage of maturity than e.g. OECD test guidelines on ENMs. Recognising the developmental nature of the different aspects of RBA, the prime intended audience for the training material is research scientists working in an academic or industrial environment. However, in developing the draft guidelines on RBA we have taken into account the perspective of SMEs and there are low entry level options available that may aid in the screening of risks and benefits from a variety of perspectives (i.e. economic, environmental, ethical, etc.). This screening acts as a basis for identifying points of attention (in the case of risks) and opportunities (in the case of benefits) early in a research and development process of an ENM and NEP. In a similar fashion, the guidelines and tools may be used by outside stakeholders (e.g. non-governmental organisations (NGOs)) for identifying risks and benefits associated with an ENM or NEP of interest, provided that they have sufficient access to required input data.

1.3 Structure

For the remainder of this report, we present shortly a summary of the individual RBA guidelines developed under WP3 in Chapter 2. Chapter 3 continues with a presentation of the different types of training materials and their dissemination outlets. Finally, we conclude this report looking forward to the future developments within the RiskGONE project and beyond.

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2 Summary of RBA guidelines

In the following sections we briefly summarize the various aspects of risk-benefit assessment in the context of the RiskGONE project.

2.1 Draft guidelines for risk assessment

The RiskGONE *draft Guideline for Risk Assessment of Engineered Nanomaterials* aims to provide solid procedures for science-based inter-disciplinary risk assessment (RA) of ENMs, that will be useful for scientific experts and stakeholders, such as regulatory authorities and industry from different sectors. The guideline covers all nanospecific aspects related to physicochemical characterization, hazard identification, dose-response characterization as well as environmental exposure and exposure assessment – including internal exposure (systemic exposure, accumulation in organs, tissues & uptake of ENMs by cells). It contains detailed protocols developed during realization of the project and provides an overview of the current state of the science and the advances made within the RiskGONE project. Divided in two parts, the first part contains a review of the state-of-the-art in relation to RiskGONE's nano-governance activities. The second part provides recommendations in terms of assessing the safety ENMs, including updates to existing tests and proposed new test approaches and assays (Dusinska et al. 2022).

2.2 Draft guidelines for life-cycle environmental indicators

The RiskGONE *draft guidelines regarding the quantification of lifecycle environmental and human health risk indicators* aims to provide an overview of environmental and human health risks and benefits as may be calculated through a Life Cycle Assessment (LCA) approach. It is based on an extensive review of LCA and impact assessment literature describing the state-of-the-art approaches in the field of LCA for ENMs as well as the CEN technical specification 17276:2018 – Application of EN ISO 14044:2006 to Manufactured Nanomaterials (Igos et al. 2020).

2.3 Draft guidelines regarding the quantification of macro-economic benefits

The RiskGONE *draft guidelines regarding the quantification of macro-economic benefits* describes benefit analysis of ENMs. Quantification of benefits (and costs) is described using various techniques. Willingness to Pay (WTP) is examined first. This approach is particularly effective when considering a specific product or product group and can capture risk, risk perception and the consumer price point for that product. A welfare economics approach, examined second, can capture the utility to a customer as the aggregate societal benefit of engineered nanomaterials using cost-benefit analysis techniques. Based on a decision tree scheme, various types of economic assessment are represented, depending on the scope of the study (i.e. assessment of a specific ENM production, utilisation, and

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availability of sufficient source data on costs and benefits for attribution to ENMs) (Murphy et al. 2020).

2.4 Draft guidelines on societal acceptance of ENMs

The RiskGone *Draft guidelines on the societal acceptance of nanomaterials considering risk and benefit perception* presents the main considerations for properly addressing social benefits and risks of ENMs. It covers social impact assessment frameworks and methodologies that can be used to identify and evaluate social benefits and risks of ENMs and provides an approach to include ENM risk perception assessment as part of social impact assessment. It concludes with a set of guidelines for performing more complete evaluations of Social Impact Assessment and for communicating benefits and risks of ENMs (Antunes et al. 2022).

2.5 Draft guidelines on ethical impact assessment

The RiskGONE *draft guidelines on identification of regulatory and ethical risk thresholds* main outcome in the context of this report is a framework for performing Ethical Impact Assessment and associated ethical impact assessment tool, made available through the RiskGONE cloud platform (http://www.enaloscloud.novamechanics.com/riskgone.html). The guidelines follow a six-step procedure, including screening ethical impacts, preparing an Ethical Impact Assessment plan, identifying ethical impacts, evaluating the identified ethical impacts, formulating and implementing remedial actions, and review and audit of the Ethical Impact Assessment procedure.

2.6 Draft guidelines on multi-criteria decision analysis

The RiskGONE *draft guidelines on Multi-Criteria Decision Analysis framework* presents the approach for effectively integrating the analyses of the lifecycle environmental, human health, macroeconomic, social, and ethical risks and benefits of ENMs and NEPs. The developed MCDA framework can support decision-makers by synthesizing multidimensional risk and benefits into a single measure of preference, in a comparative analysis of different ENM or NEP options with similar functionality. The MCDA framework was implemented as a web-service for use by stakeholders and incorporation in the RiskGONE cloud platform (Boero et al. 2022).

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3 Training material dissemination outlets

Training material under the RiskGONE project has been developed in several forms - As written material (e.g. the draft guidelines and associated cases presented in Chapter 2), as webinars or recorded presentations, and as interactive tools. The materials have been made available to the public on a variety of outlets, presented in the different sections of this Chapter.

3.1 RiskGONE website

The RiskGONE project website has acted as a main repository for training materials developed within the project. In particular, webinars and training videos, as well as the guidelines developed in this work package can be accessed and viewed on the website (https://riskgone.eu/home-riskgone-project/resources/).

3.2 Interactive tools

Two interactive tools have been developed in conjunction with the work performed in WP3 – an ethical impact assessment tool and a tool aiding in multi-criteria decision analysis. The ethical impact assessment tool is made available on the RiskGONE cloud platform, together with its documentation. The RiskGONE cloud platform is developed under WP2 and receives input from the other WPs in the RiskGONE project. It is available here: http://www.enaloscloud.novamechanics.com/riskgone.html.

To support MCDA processes, the MCDA framework developed in WP3 was made available as a web-service with an Application Programming Interface (API). The code for the web-service is available under an open-source software license at https://git.nilu.no/impact/mca_service. As part of the software package, interactive training material is made available in the form of a Jupyter python notebook.

It is the ambition that all developed tools will be made available through the RiskGONE cloud platform in the remainder of the RiskGONE project, but this is still under development at the time of writing of this report.

3.3 Zenodo archive

To ensure maximum longevity of training materials, and more generally, all RiskGONE project output training material is backed up on Zenodo. Zenodo is an archiving platform aimed at facilitating Open Science, where any (research) output can be uploaded, irrespective of format or size. This aids dissemination as well as reproducibility of scientific work, as many (digital) materials required for scientific projects are not made available in 'traditional' written journal articles. Zenodo is an ideal

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dissemination platform for the training materials, with an anticipated longevity that is much larger than the RiskGONE website.

Uploaded material on Zenodo may be tagged to a specific community. The RiskGONE project does not have its own community, but rather RiskGONE materials are made available under the Nano Risk Governance (https://zenodo.org/communities/nanoriskgovernance) and EU NanoSafety Cluster (https://zenodo.org/communities/nsc) communities.

3.4 Overview

An overview of the different outlets discussed in this Chapter can be found in Table 1.

Table 1: Resources for training materials

Resources	Contains	Location
RiskGONE website	Webinars and videos	https://riskgone.eu
RiskGONE cloud platform	Ethical impact assessment tool	http://www.enaloscloud.novamechanics.com/riskgone.html
Nano Risk Governance portal	Links to RiskGONE materials	https://www.nanoriskgov.eu
Software	MCDA tool and training material	https://git.nilu.no/impact/mca_service
Archive	Posters, presentations, written, material, archived copies of some of the above	https://zenodo.org/ and the communities https://zenodo.org/communities/nsc and https://zenodo.org/communities/nanoriskgovernance

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Conclusions

This report summarizes the training material developed within the RiskGONE project in the context of risk-benefit assessment of ENMs and NEPs. It includes a summary overview of the different RBA guidelines developed and highlights the different types of training materials and the intended audience for the training material. Different dissemination outlets for the training materials were presented.

The RiskGONE cloud platform currently under construction in WP2 will be further developed to include the RBA guidelines developed in WP3 as well as (links to) associated training material. In addition, WP3 materials may be linked to from the community portal for Nano Risk Governance currently under development as a joint activity between the three European projects working on Nano Risk Governance, RiskGONE, GOV4NANO, and NANORIGO. The RiskGONE cloud platform, the nano risk governance portal and backups of output in the Zenodo archive ensure that training material can be added in the future, and that current and future material are preserved for the audience in accordance with current best practices – also after the formal end of the RiskGONE project.

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References

Antunes et al. (2022) *Draft guidelines on the societal acceptance of nanomaterials considering risk and benefit perception*. RiskGONE project deliverable 3.5

Boero et al. (2022) *Draft guidelines on Multi-Criteria Decision Analysis framework.* RiskGONE project deliverable 3.7

Dusinska et al (2022) *Draft Guideline for Risk Assessment of Engineered Nanomaterials.* RiskGONE project deliverable 3.1

Igos et al. (2020) D*raft guidelines regarding the quantification of lifecycle environmental and human health risk indicators.* RiskGONE project deliverable 3.2

Malsch et al. (2020) *Draft guidelines on identification of regulatory and ethical risk thresholds.* RiskGONE project deliverable 3.6

Murphy et al. (2020) D*raft guidelines regarding the quantification of macro-economic benefits.* RiskGONE project deliverable 3.3

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