SCIENCE-BASED RISK GOVERNANCE
OF NANO-TECHNOLOGY

RISK GONE

# Demonstration of the RiskGONE Cloud Platform through selected case studies

## DELIVERABLE 2.4

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## Abstract

The deliverable describes the selection of case studies for the demonstration of the RiskGONE Cloud Platform. The demonstration aims to showcase the ease-of-use and usefulness of the various components of the platform for supporting the processes of the Risk Governance of nanomaterials, within the various stages of the risk governance framework and the implementation paradigm.



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## List of Abbreviations

BMDL - Benchmark Dose Level

CBA - Cost Benefit Analysis

CIF - Crystallographic Information Files

D - Deliverable

DB - Database

EIA - Ethical Impact Assessment

ENMs – Engineered Nanomaterials

FAIR - Findable, Accessible, Interoperable and Reusable

LCA - Life Cycle Assessment

NOAEL - No Observed Adverse Effect Level

NMs - Nanomaterials

PEC - Predicted Environmental Concentration

PNEC - Predicted No Effect Concentration

POD - Point Of Departure

RG - Risk Governance

SOP - Standard Operating Procedure

SSbD - Safe- and Sustainable by-Design

TGs - Test Guidelines



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# 1. Introduction – RiskGONE Cloud Platform

The RiskGONE Cloud platform (http://www.enaloscloud.novamechanics.com/riskgone.html) is an interoperable IT system, which has been designed with the purpose of providing easy access and guidance to the processes and materials that are considered relevant for an effective and scientific based Risk Governance (RG) of nanomaterials (NMs) and nano-enabled products. It has been designed to cater the needs of various types of stakeholders, from citizens to industry representatives, scientists and regulators. It is modular, to allow easy update and addition of resources, processes and tools that may become relevant in the future.

The main sections of the RiskGONE Cloud Platform are the following (Figure 1):

- Services: A collection of services and tools developed by the RiskGONE partners.
- Decision trees: List of the various decision trees and links to the respective pages.
- TGs – Guidelines: A collection of information from the experimental work packages of the project, as well as guidelines for risk-benefit assessment, including socio-economic assessment, ethics, LCA and more.
- Project Deliverables: List of RiskGONE deliverables.
- Data and DBs: Access to the RiskGONE eNanoMapper instance and other relevant databases.
- Regulatory information: An overview of nanosafety definitions and regulatory information.
- RG framework overview / Library of tools: An overview of the RiskGONE risk governance framework and the library of relevant tools.
- Safe-and-Sustainable-by-Design (SSbD): An overview of the state-of-the-art of scientific literature and information on Safe-and-Sustainable-by-Design (SSbD).

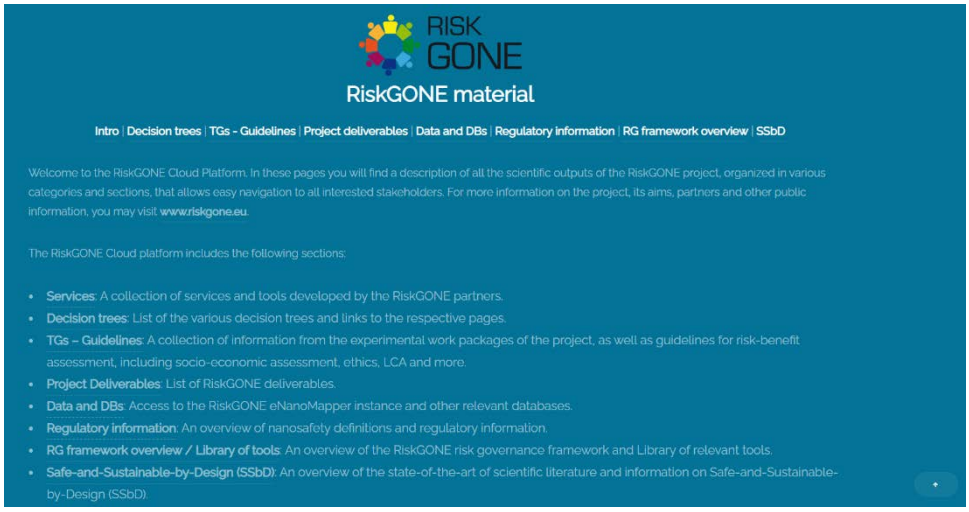


*Figure 1. RiskGONE Cloud Platform material page. Stakeholders can browse the different pages and access the RiskGONE material.*



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The RG framework of the RiskGONE project is available within the RiskGONE cloud platform with a user-friendly interface and operationalised via a set of decision trees implemented into a modular decision support tool providing instruments, guidance and guidelines for different aspects of the RG of NMs, such as:

- Characterisation, Fate, and Dosimetry of NMs
- Human Hazard Assessment
- Environmental Hazard/Effect Assessment
- Exposure Assessment
- Risk Assessment
- Life Cycle Analysis
- Economic Assessment
- Ethical Impact Assessment

The framework is complemented with resources, materials and information on standardisation activities, databases and tools for RG, regulatory information related to nanomaterials RG and introduction to the concept of Safe-and-Sustainable-by-Design (SSbD) for NMs.

In this deliverable, a demonstration of the usability, user-friendliness and relevance of the RiskGONE Cloud Platform for RG of NMs is shown through selected case studies for various components of the platform.

A technical description of the RiskGONE Database and Cloud Platform is available in D2.5 (The final version of RiskGONE Database and Cloud Platform).

# 2. Demonstration through selected case studies

## RiskGONE services

The RiskGONE Cloud platform, as described in Section 1 of the deliverable, incorporates content that can be useful for different processes and activities related with the RG of NMs.

The first accessible content is the list of RiskGONE services, allowing direct access of experienced users to the various tools that have been developed within the project. In that sense, the NanoConstruct tool, the RiskGONE *In Vitro* dosimetry tool and the complete set of decision trees as standalone services are presented, as seen in Figure 2.



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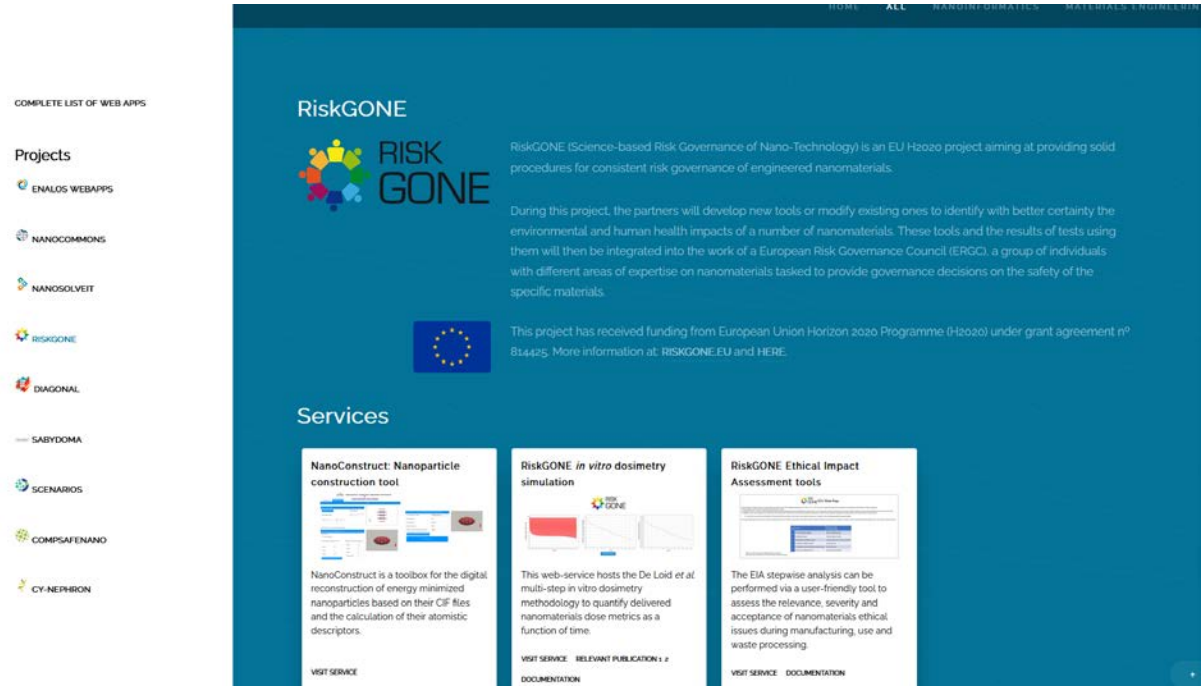


*Figure 2. The RiskGONE Cloud platform frontpage, allowing access to RiskGONE services.*

The selection of a service, which is complemented from relevant documentation and links to scientific publications, redirects to a user-friendly interface, which allows the use of the service, as described in the following paragraphs.

## RiskGONE generic decision tree

The 2nd level of access is focused on the guidance of users, which has been a pivotal and very important aspect of the project. For this purpose, a dedicated decision tree has been implemented, that is following the expertise of intended users. It provides step-by-step guidance to the sections of the RiskGONE Cloud platform, in order to facilitate the browsing of the scientific outputs of the project to each type of user and preferences, as seen in Figure 3.

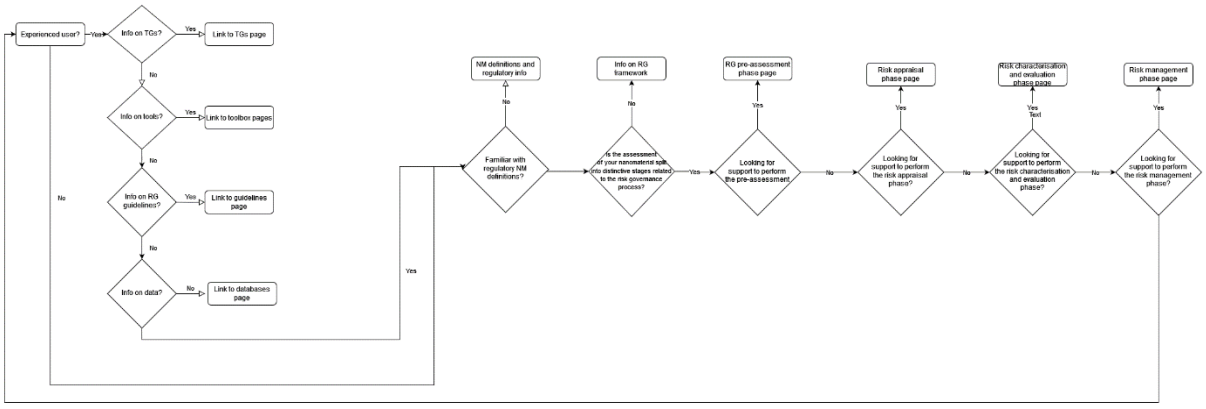


*Figure 3. The Novice vs Experienced user decision tree*



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To demonstrate the functionality of the experience level decision tree (http://www.enaloscloud.novamechanics.com/riskgone/decisiontrees/noviceexperience/) for three different types of users, three hypothetical scenarios are explored:

- An inexperienced user that would like to find i) information on the state-of-the-art on RG of NMs, ii) is not familiar with RG frameworks, and iii) would be interested in Risk Assessment methodologies will provide the following answers to the questions (Figure 4):
    - "*Are you an experienced user?*" → No, redirection to question 2
    - "*Are you familiar with the most recent regulatory definitions of NMs?*" → No, redirection to the RiskGONE page on definitions and regulation. (http://www.enaloscloud.novamechanics.com/riskgone%20-%20material.html#definitions)
    - "*Is the assessment of your nanomaterial split into distinctive stages related to the risk governance process?*" → In case of 'Yes' will be taken to the next question, in case of 'No' will be taken to the RG framework page of the Cloud platform. (http://www.enaloscloud.novamechanics.com/riskgone%20-%20material.html#RG)
    - "*Looking for support to perform the pre-assessment phase?*" → No, next question
    - "*Looking for support to perform the risk appraisal phase?*" → Yes, taken to the page on risk appraisal information (http://www.enaloscloud.novamechanics.com/riskgone%20-%20material.html#RG)
- An experienced user 1 that would like to find all the information on the standardisation activities of the RiskGONE project will provide the following answers to the questions (Figure 5):
    - "*Are you an experienced user?*" → Yes, redirection to question 1A
    - "*Looking for information on TGs?*" → Yes, redirection to the Technical guidance page of the RiskGONE Cloud Platform (http://www.enaloscloud.novamechanics.com/riskgone%20-%20material.html#TGs)
- An experienced user 2 that would like to find all the information on i) the standardisation activities of the RiskGONE project and ii) is interested to find the RiskGONE database and data templates will provide the following answers to the questions (Figure 6):
    - "*Are you an experienced user?*" → Yes, redirection to question 1A
    - "*Looking for information on TGs?*" → Yes, redirection to the Technical guidance page of the RiskGONE Cloud Platform (http://www.enaloscloud.novamechanics.com/riskgone%20-%20material.html#TGs)
    - "*Looking for the library of tools?*" → No, next question
    - "*Looking for Risk Governance guidelines?*" → No, next question
    - "*Looking for data sources and databases?*" → Yes, redirection to the databases page of the RiskGONE Cloud Platform (http://www.enaloscloud.novamechanics.com/riskgone%20-%20material.html#data)



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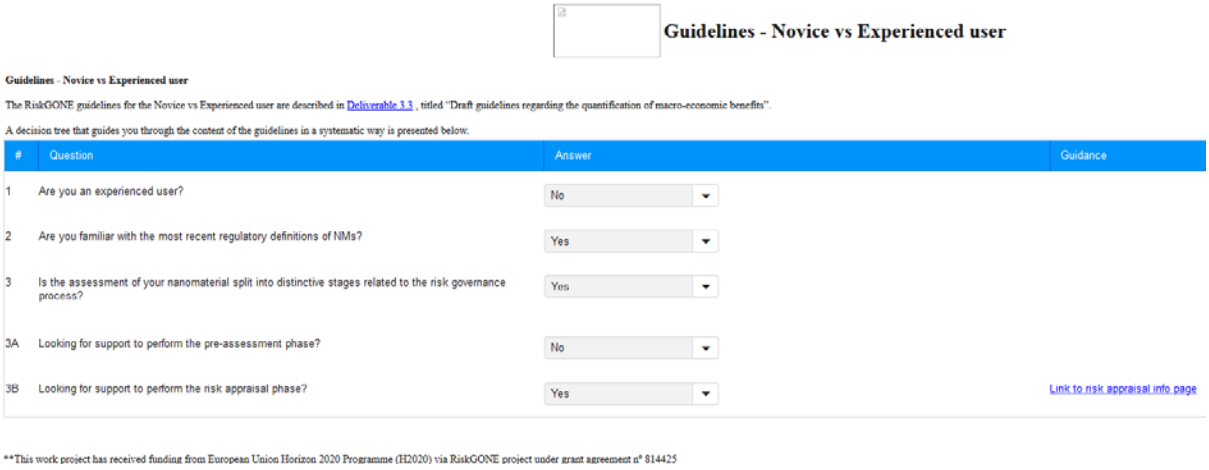

**Guidelines - Novice vs Experienced user**

**Guidelines - Novice vs Experienced user**

The RiskGONE guidelines for the Novice vs Experienced user are described in Deliverable 3.3 , titled "Draft guidelines regarding the quantification of macro-economic benefits".

A decision tree that guides you through the content of the guidelines in a systematic way is presented below.

| # | Question | Answer | Guidance |
|---|---|---|---|
| 1 | Are you an experienced user? | No | |
| 2 | Are you familiar with the most recent regulatory definitions of NMs? | Yes | |
| 3 | Is the assessment of your nanomaterial split into distinctive stages related to the risk governance process? | Yes | |
| 3A | Looking for support to perform the pre-assessment phase? | No | |
| 3B | Looking for support to perform the risk appraisal phase? | Yes | Link to risk appraisal info page |

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*Figure 4. Example of inexperienced user on the use of the generic decision tree of the RiskGONE Cloud platform*

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A decision tree that guides you through the content of the guidelines in a systematic way is presented below.

| # | Question | Answer | Guidance |
|---|---|---|---|
| 1 | Are you an experienced user? | Yes | The aim is to guide the different types of users to find t looking for within the Risk Governance Cloud Platform.. |
| 1A | Looking for information on TGs? | Yes | Link to TGs page [To be defined] |

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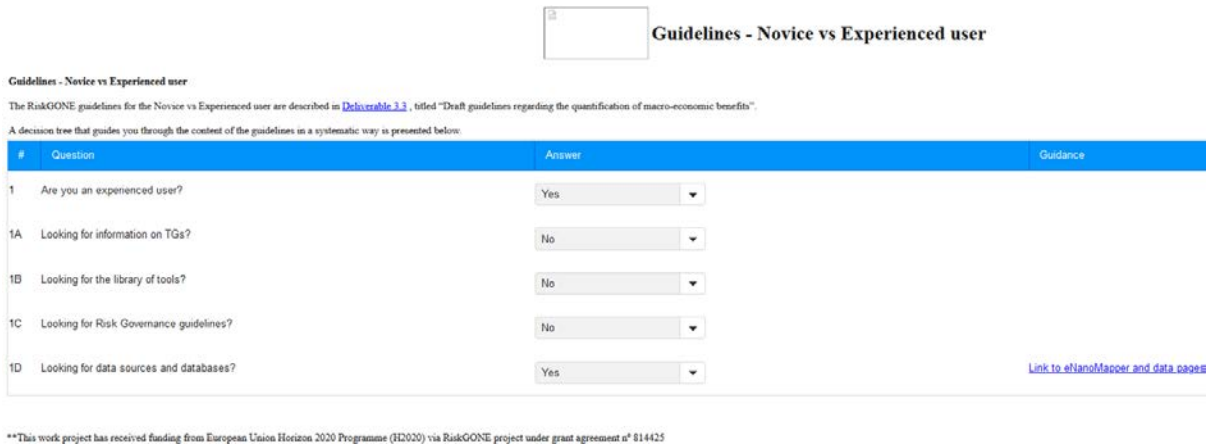
*Figure 5. Example of experienced user 1 on the use of the generic decision tree of the RiskGONE Cloud platform*



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A decision tree that guides you through the content of the guidelines in a systematic way is presented below.

| # | Question | Answer | Guidance |
|---|---|---|---|
| 1 | Are you an experienced user? | Yes | |
| 1A | Looking for information on TGs? | No | |
| 1B | Looking for the library of tools? | No | |
| 1C | Looking for Risk Governance guidelines? | No | |
| 1D | Looking for data sources and databases? | Yes | Link to eNanoMapper and data pages |

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*Figure 6. Example of experienced user 2 on the use of the generic decision tree of the RiskGONE Cloud platform*

## RiskGONE decision trees

Moving forward to the content of the RiskGONE Cloud Platform, eight (8) decision trees are offered to the users on distinctive topics of interest related to the scientific activities of the RiskGONE project and four (4) on contiguous topics of interest:



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- Characterisation, Fate, and Dosimetry of NMs
- Human Hazard Assessment
- Environmental Hazard/Effect Assessment
- Exposure Assessment
- Risk Assessment
- Life Cycle Analysis
- Economic Assessment
- Ethical Impact Assessment
- Risk Governance
- SSbD, new methodologies and general innovation governance
- Technical guidance and standardisation
- Data quality, Open data and FAIR principles

As the options for the use of each decision tree are numerous and cannot be all practically described in detail within the scope of this deliverable, representative examples have been chosen to showcase the usability of the Cloud Platform section:

- Risk Assessment
- Economic assessment
- Ethical Impact assessment

## Risk Assessment

The Risk Assessment decision tree (Figure 7) is based on the content of RiskGONE Deliverable 3.1 (Draft guidelines for risk assessment), which is a highly valuable document that incorporates knowledge on the state-of-the-art on risk assessment from experts of the RiskGONE consortium and combines it with guidelines and recommendations on assessing the safety of NMs.



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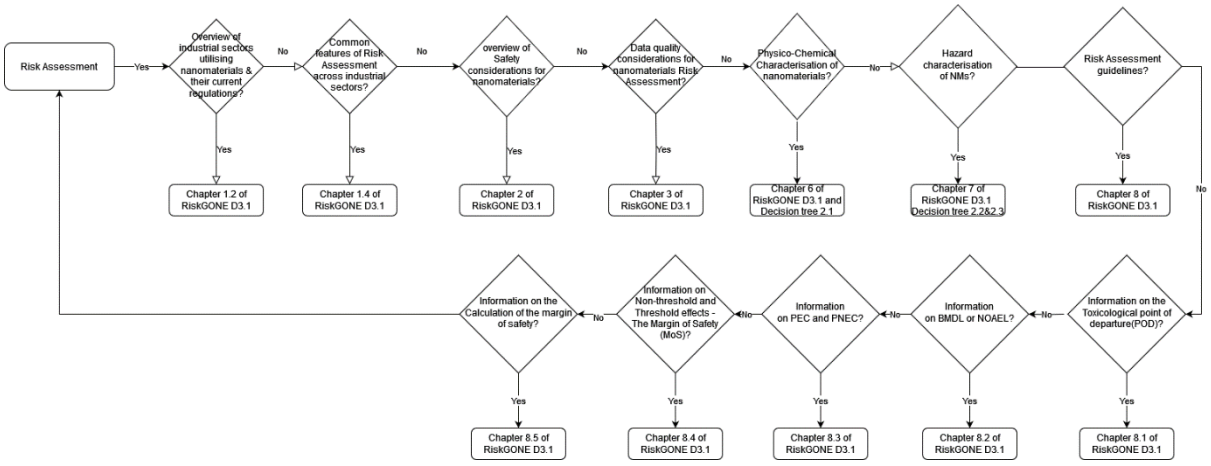


*Figure 7. The Risk Assessment decision tree*

To demonstrate the functionality of the decision tree (http://www.enaloscloud.novamechanics.com/riskgone/decisiontrees/riskassessment/) for two different types of users, two hypothetical scenarios are explored:

- An experienced user 1 that would like to find i) information on the Safety considerations for performing risk assessment of NMs, ii) information on the state-of-the-art on 'Hazard characterisation of NMs', and iii) guidelines on PEC and PNEC estimation will provide the following answers to the questions (Figure 8):
    - "*Looking for an Overview of industrial sectors utilising nanomaterials & their current regulations?*" → No, next question
    - "*Looking for an overview of Common features of Risk Assessment across industrial sectors?*" → No, next question
    - "*Looking for an overview of Safety considerations for nanomaterials?*" → Yes, redirection to Chapter 2 of RiskGONE D3.1 (http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.1.pdf). Then next question
    - "*Looking for an overview of Data quality considerations for nanomaterials Risk Assessment?*" → No, next question
    - "*Looking for an overview of Physico-Chemical Characterisation of nanomaterials?*" → No, next question
    - "*Looking for an overview of Hazard characterisation of NMs?*" → Yes, redirection to Chapter 7 of D3.1 that includes the state-of-the-art on the topic. (http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.1.pdf) and then suggestion to follow the dedicated decision trees on the 'Human Hazard Assessment' (http://www.enaloscloud.novamechanics.com/riskgone/decisiontrees/humanhazard/) and 'Environmental Hazard/Effect Assessment'



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(http://www.enaloscloud.novamechanics.com/riskgone/decisiontrees/environmentalhazard/)

The Decision trees on Human Hazard Assessment and Environmental Hazard/Effect Assessment of NMs supports the user with dedicated questions on the two topics and allows an easy navigation of the technical guidance of the RiskGONE project, the SOPs and tailored information from deliverables of WP5 and WP6.

- "*Looking for an overview on Risk Assessment guidelines?*" → No, next question
- "*Looking for information on the Toxicological point of departure (POD)?*" → No, next question
- "*Looking for information on BMDL or NOAEL?*" → No, next question
- "*Looking for information on PEC and PNEC?*" → Yes, redirection to Chapter 8.3 of RiskGONE D3.1 (http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.1.pdf).

- An experienced user 2 that would like to find all the information on i) data quality considerations for NMs RA and ii) on the state-of-the-art on 'Physico-Chemical Characterisation of NMs' will provide the following answers to the questions (Figure 9):
  - "*Looking for an Overview of industrial sectors utilising nanomaterials & their current regulations?*" → No, next question
  - "*Looking for an overview of Common features of Risk Assessment across industrial sectors?*" → No, next question
  - "*Looking for an overview of Safety considerations for nanomaterials?*" → No, next question
  - "*Looking for an overview of Data quality considerations for nanomaterials Risk Assessment?*" → Yes, redirection to Chapter 3 of D3.1 that includes the state-of-the-art on the topic. (http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.1.pdf). Once informed, move to the next question.
  - "*Looking for an overview of Physico-Chemical Characterisation of nanomaterials?*" → Yes, redirection to Chapter 6 of D3.1 that includes the state-of-the-art on the topic. (http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.1.pdf) and then suggestion to follow the dedicated decision tree on the 'Physico-Chemical Characterisation of nanomaterials' (http://www.enaloscloud.novamechanics.com/riskgone/decisiontrees/cfd/)

    The Decision tree on Physico-Chemical Characterisation of NMs supports the user with dedicated questions on the topic and allows an easy navigation of the technical guidance of the RiskGONE project, the SOPs for phys-chem characterisation and tailored information from deliverables D4.2-4.9 of WP4.

It is considered evident that the decision trees are designed so that users can navigate very easily between the options, so that all the relevant materials become available in few seconds, in a structured and organised way.



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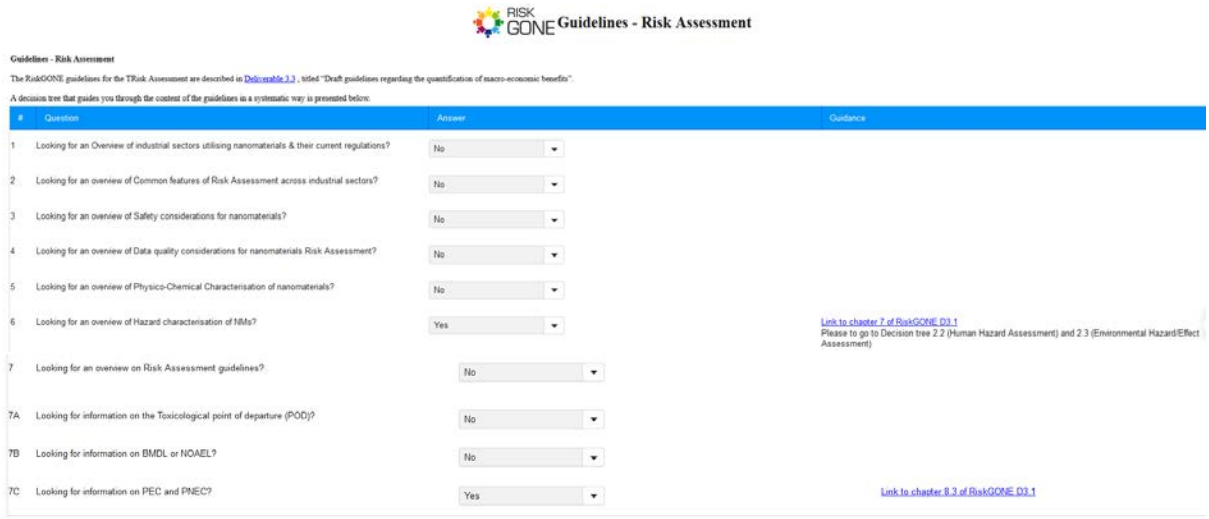


*Figure 8. Example of experienced user 1 on the use of the Risk Assessment decision tree of the RiskGONE Cloud platform*


*Figure 9. Example of experienced user 2 on the use of the Risk Assessment decision tree of the RiskGONE Cloud platform*

## Economic Assessment

The economic assessment guidelines are demonstrated through a case study on engineered nanomaterials (ENMs) coated textiles that can be used for preventing Healthcare-associated infections, such as copper nanoparticles (CuNP), silver nanoparticles (AgNP), Zinc oxide nanoparticles (ZnNP) and more. Based on the Economic Assessment decision tree (Figure 10 - http://www.enaloscloud.novamechanics.com/riskgone/decisiontrees/economicassessment/), the user is guided through the various proposed methodologies for performing the analysis of the economic aspects.



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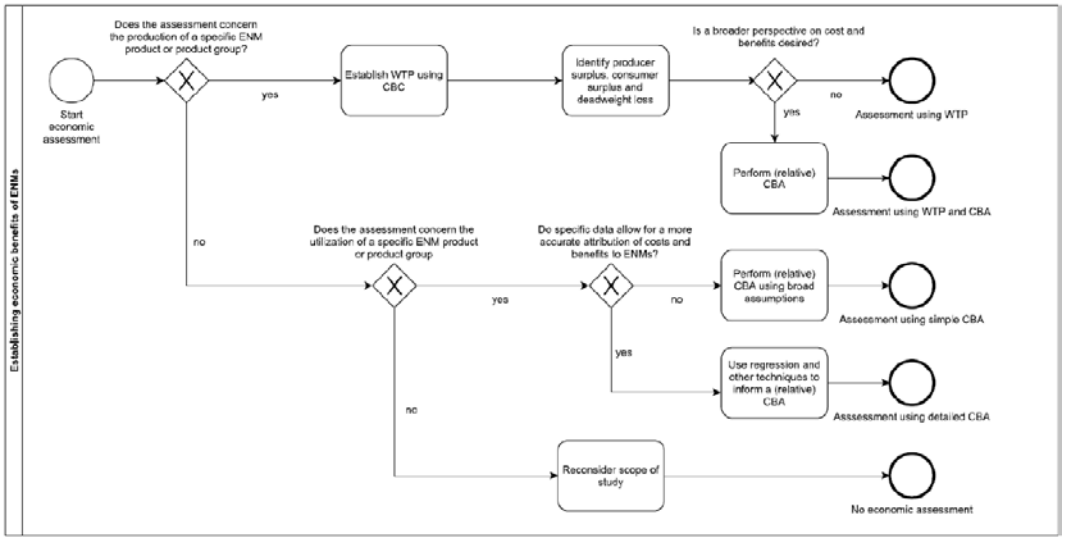


*Figure 10. The economic assessment decision tree*

Specifically, the case study does "*not concern the production of a specific ENM product or product group*", therefore the user is guided to the next branch where it is possible to identify that the assessment "*concerns the utilisation of a specific ENM product or product group*", i.e., ENMs coated textiles that can be used for preventing Healthcare-associated infections. Based on "*availability of data for attributing costs and benefits to ENMs*", the user is guided to perform either an "*assessment using detailed Cost Benefit Analysis (CBA)*" in presence of available data (Figure 11) or an "*assessment with broad assumptions*" in a typical example with scarcity of data (Figure 12), as often in real case studies.

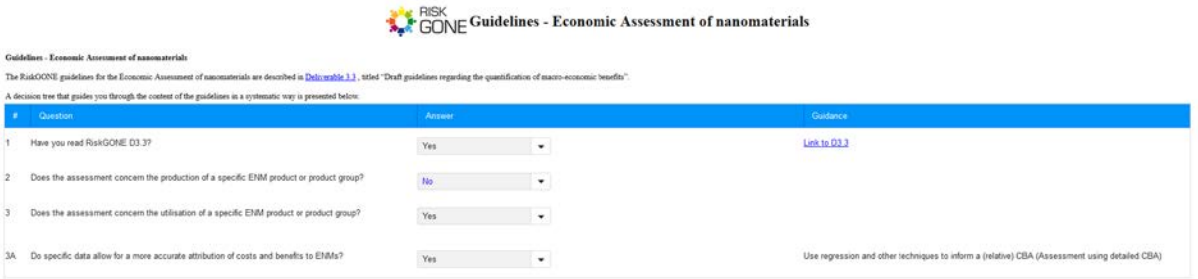


*Figure 11. Example of case study with data availability on the use of the Economic Assessment decision tree of the RiskGONE Cloud platform*


*Figure 12. Example of case study with data scarcity on the use of the Economic Assessment decision tree of the RiskGONE Cloud platform*



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For both cases, a detailed description of the case study and the relevant outcomes are presented in Deliverable D3.3 (Draft guidelines regarding the quantification of macro-economic benefits - http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.3.pdf)

## Ethical Impact Assessment

During the course of the RiskGONE project, the Ethical Impact assessment guidelines have been utilised for assessing ethical impacts of ENMs in nanomedicine (Malsch, 2023), water purification, dental products, rubber tyres (Malsch et al., 2022) and ZnO for combatting citrus greening. In addition, the ethics of publishing nanosafety data and the ethics on nano risk governance have been assessed by the consortium (Malsch et al., 2023a).

For the purposes of D2.4, an ethical impact assessment of nanosafety data sharing is summarised to demonstrate through the case study the use of the draft guidelines (http://www.enaloscloud.novamechanics.com/deliverables/RiskGONE-D3.6.pdf), the decision tree (Figure 13) and the relevant RiskGONE service (http://www.enaloscloud.novamechanics.com/riskgone/EIA/).

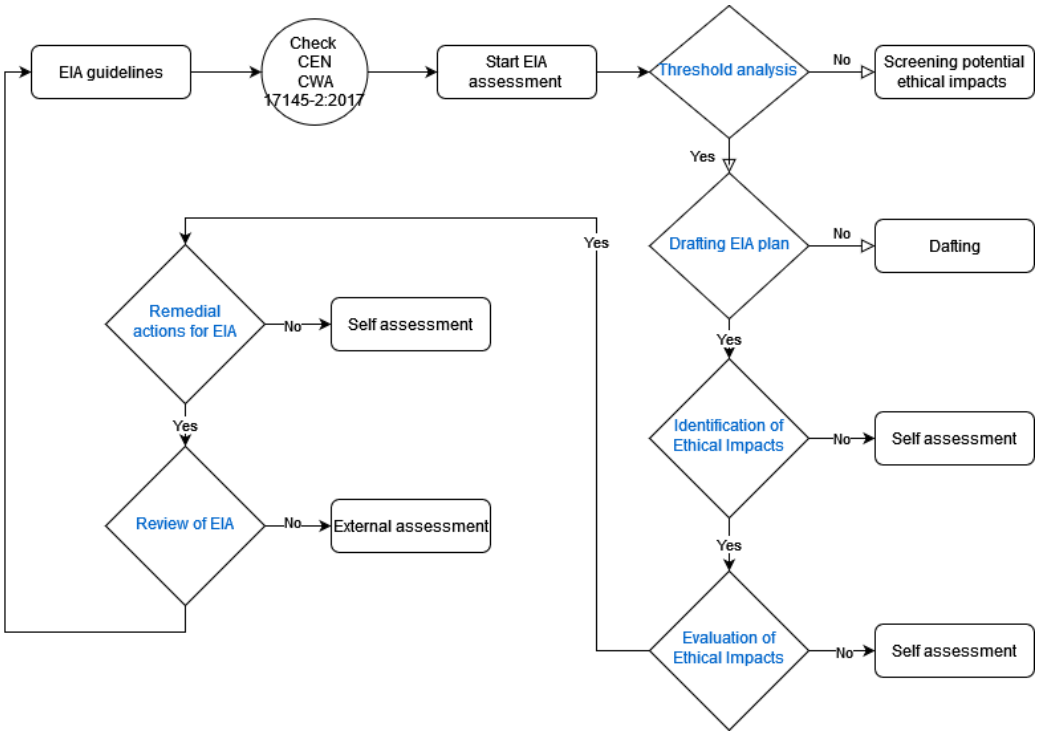


*Figure 13. The Ethical Impact assessment decision tree*

An experienced ethicist, in close collaboration with the RiskGONE consortium, performed an assessment of the ethical impacts, based on the EIA tool in order to explore the implications of the statement "*It is unethical not to share [nanosafety] data [needed by other researchers and for regulation*". The benefits and costs of sharing nanosafety data, in view of the statement have been analysed, as seen in Figure 14. The first step of the EIA assessment is a threshold analysis for the categories "health-related, privacy,



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liberties, equality, common good, environment, sustainability, military dual use and misuse", on the basis of which, a small EIA has been suggested to be performed for this case study.

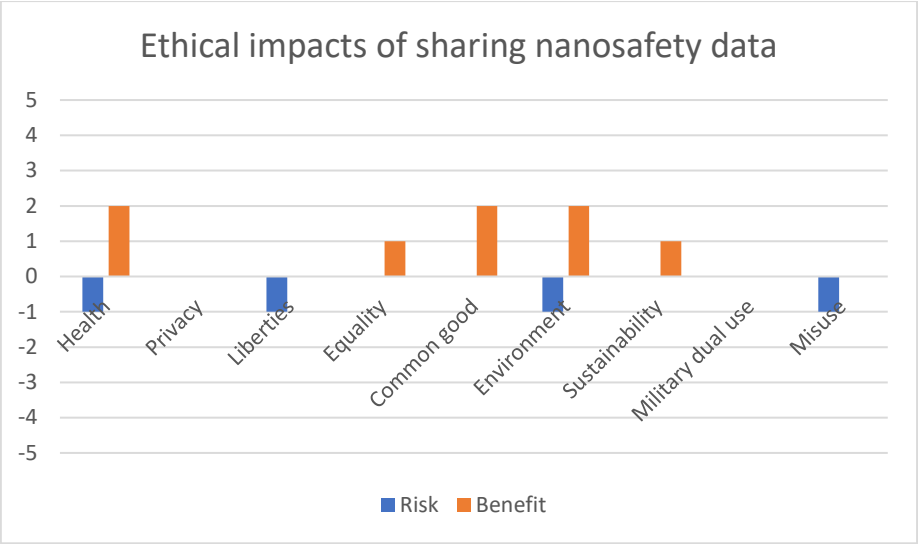


*Figure 14. Ethical risk-benefit screening of sharing nanosafety data.*

Based on the suggested scale of the EIA, an analysis has been performed following the remaining 5 steps of the EIA tool. An EIA has been planned based on the expertise of the consortium on ethics, LCA, informatics, software programming, risk assessment, nanosafety, and risk governance.

Following the planning, the ethical impacts of sharing nanosafety data have been identified and documented, while at the same time the ethical impacts of not sharing nanosafety data have been identified and documented as well. The ethical impacts have been evaluated based on the draft guidelines, specifically on "Intellectual property, Social justice, Public health ethics, Dual use and misuse, and Environmental and animal ethics". As expected, sharing nanosafety data has been found more likely to bring more significant benefits than raise ethical problems. A summary of the balance of ethical impacts for each category has been estimated and measures for remediation have been identified.

The complete description of the case study is currently included within a scientific paper under preparation (Malsch et al. 2023b).

## In vitro dosimetry tool

The *in vitro* dosimetry tool is based on the work of De Loid et al. (2017) who addressed issues with nominal doses in ENM toxicity testing using in vitro assays, through a multi-step *in vitro* dosimetry methodology to quantify delivered dose metrics as a function of time. A complete description of the functionality of the tool is described in D2.5 (The final version of RiskGONE Database and Cloud Platform) and Cheimarios et al. (2022). A case study from Cheimarios et al. (2022) is summarised below to demonstrate the use of the tool within the RiskGONE Cloud platform.

Six different NPs have been used as a case study for the demonstration and proof-of-concept of the "*in vitro* dosimetry" web application within RiskGONE. Namely, four different silver NPs (AgNP), and two different gold NPs (AuNP), with various coatings, were prepared and characterised to demonstrate the



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use of tool for NPs of the same size but with different surface coatings and surface charges. Six to eight nominal concentrations were considered for the NPs and 'user defined' parameters (e.g., distribution type, effective density) for the material, solvent and simulation have been used in the case study (Figure 15).

The case study provided a wealth of information on the NPs effective concentrations calculated at the bottom compartment of the cell culture plates in comparison with the nominal doses (Figure 16). Readers interested in further technical details, can check the relevant publication (Cheimarios et al. 2022).

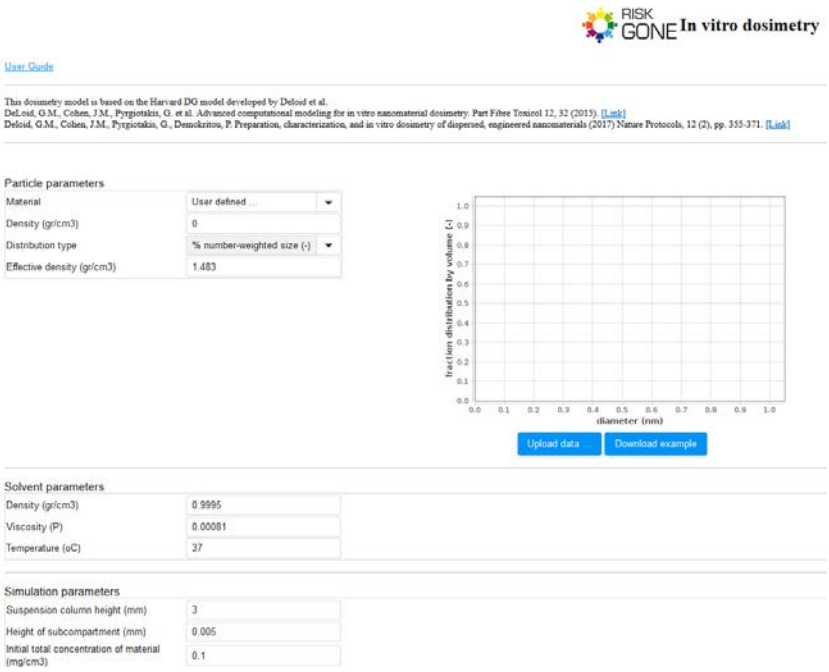


*Figure 15. Simulation of the In Vitro dosimetry tool*

| Calculated Value | Nominal conc. (mg/cm$^3$) | AOT-AgNP | PLL-AgNP | GSH-AuNP | GSH-AgNP | CYS AuNP | CYS AgNP |
|---|---|---|---|---|---|---|---|
| Mass concentration of NPs at well bottom (mg/cm$^3$) | 0.005 | 0.042 | 0.189 | 0.008 | 0.005 | 0.057 | 0.005 |
| | 0.01 | 0.084 | 0.378 | 0.017 | 0.010 | 0.114 | 0.010 |
| Mass per unit area of well (mg/cm$^2$) | 0.005 | $4.192 \times 10^{-5}$ | $1.891 \times 10^{-4}$ | $8.353 \times 10^{-6}$ | $5.019 \times 10^{-6}$ | $5.676 \times 10^{-5}$ | $5.034 \times 10^{-6}$ |
| | 0.01 | $8.384 \times 10^{-5}$ | $3.782 \times 10^{-4}$ | $1.671 \times 10^{-5}$ | $1.004 \times 10^{-5}$ | $1.135 \times 10^{-4}$ | $1.007 \times 10^{-5}$ |
| NPs number at well bottom (cm$^{-3}$) | 0.005 | $2.196 \times 10^{10}$ | $6.382 \times 10^{11}$ | $4.556 \times 10^{12}$ | $1.016 \times 10^{13}$ | $5.564 \times 10^{10}$ | $4.350 \times 10^{12}$ |
| | 0.01 | $4.392 \times 10^{10}$ | $1.276 \times 10^{11}$ | $9.112 \times 10^{12}$ | $2.031 \times 10^{13}$ | $1.113 \times 10^{11}$ | $8.701 \times 10^{12}$ |
| NPs number per unit area of well (cm$^{-2}$) | 0.005 | $2.196 \times 10^{7}$ | $6.382 \times 10^{7}$ | $4.556 \times 10^{9}$ | $1.016 \times 10^{10}$ | $5.564 \times 10^{7}$ | $4.350 \times 10^{9}$ |
| | 0.01 | $4.392 \times 10^{7}$ | $1.276 \times 10^{8}$ | $9.112 \times 10^{9}$ | $2.031 \times 10^{10}$ | $1.113 \times 10^{8}$ | $8.701 \times 10^{9}$ |
| NPs surface area at well bottom (cm$^2$/cm$^3$) | 0.005 | 2.656 | 4.482 | 2.967 | 5.550 | 2.024 | 4.223 |
| | 0.01 | 5.313 | 8.964 | 5.934 | 11.101 | 4.048 | 8.446 |
| NPs surface area per unit area of well (cm$^2$/cm$^2$) | 0.005 | 0.003 | 0.004 | 0.003 | 0.006 | 0.002 | 0.004 |
| | 0.01 | 0.005 | 0.009 | 0.006 | 0.011 | 0.004 | 0.008 |

*Figure 16. Comparison of median values of calculated dosimetric parameters for the tested AgNP and AuNP at the nominal concentrations of 0.005 and 0.01 mg cm–3 used in the toxicity experiments. All values correspond to the effective NPs concentrations calculated at the bottom compartment of the cell culture plates (cellular microenvironment). Cheimarios et al. 2022.*



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## NanoConstruct tool

The NanoConstruct tool uses Crystallographic Information Files (CIF) available on crystallographic databases as input to geometrically reconstruct crystalline NPs, while maintaining stoichiometry by removing excess atoms on the surface. It provides capabilities for importing structural information, performing stoichiometric adjustments, and conducting advanced simulations to obtain a highly accurate, energy-minimized digital replica of the nanoparticle. A complete description of the functionality of the tool is described in D2.5 (The final version of RiskGONE Database and Cloud Platform). A case study is summarised below to demonstrate the use of the tool within the RiskGONE Cloud platform, specifically the digital reconstruction of ZrO2 (rutile) ellipsoid Nanoparticle having started from TiO2 (rutile) CIF file (Figure 17). (Kolokathis et al., 2023)

While the tool performs a series of interconnected and advanced scientific calculations, the tool has a user-friendly interface that is intuitive and easy to use, where the user can:

- Load a CIF and visualise the unit cells
- Replace chemical elements of the CIF with other elements
- Insert ellipsoid axes and rotation vectors to digitally reconstruct the material
- Apply energy minimisation techniques
- Extract the results and related computational data
- Adjust the parameters and run the simulation for various different options



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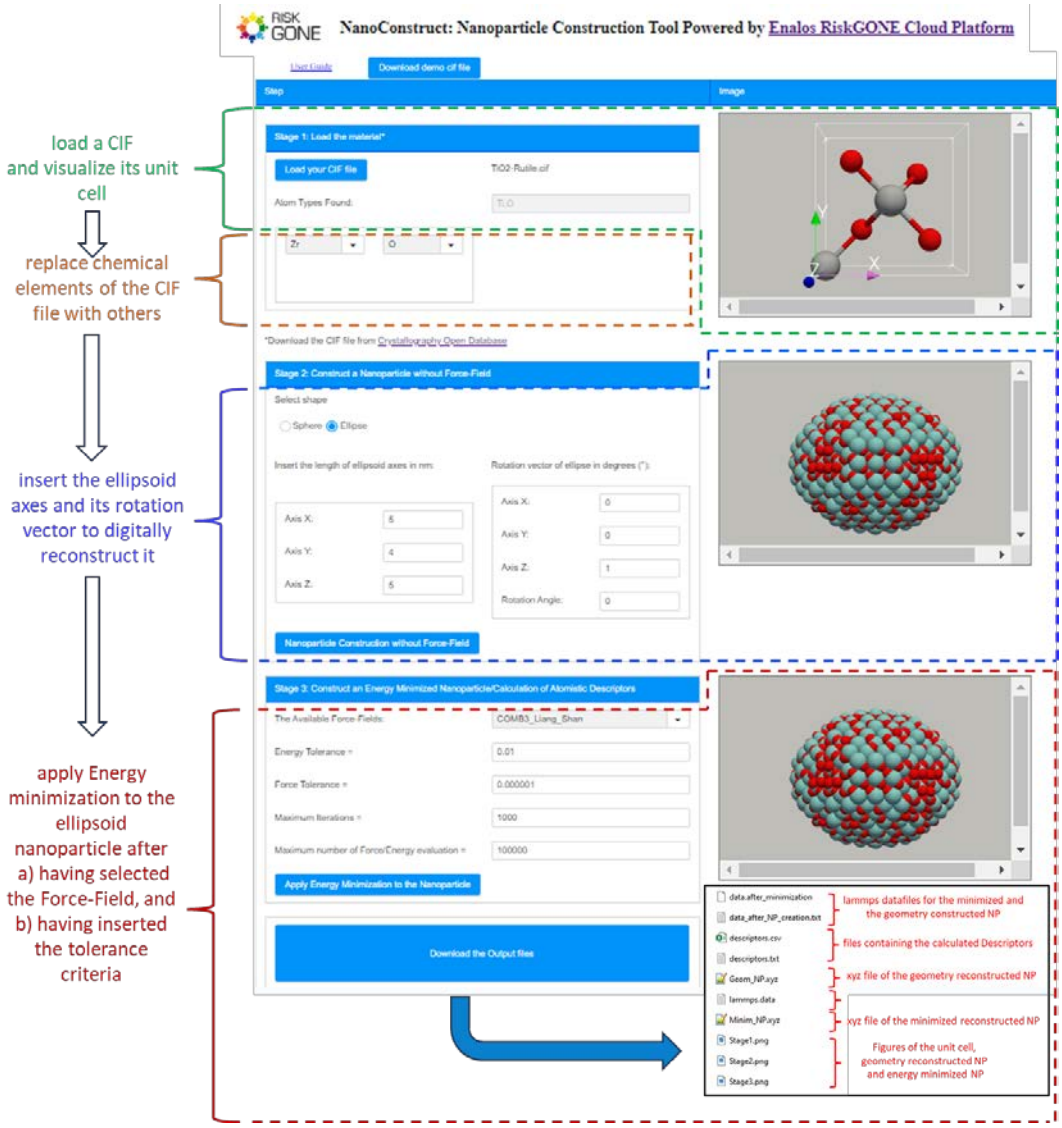


*Figure 17. Graphical User interface (GUI) of the NanoConstruct tool and its application for the digital reconstruction of ZrO2 (rutile) ellipsoid Nanoparticle having started from TiO2 (rutile) CIF file.*

## Tyre wear nanoparticles as test for a nano risk governance framework

Within the frame of the NMBP-13 collaboration, a joint case study on the assessment of "tyre wear nanoparticles" based on the RG frameworks has been performed. The joint case study was led by the NANORIGO project and partner Bureau KLB that performed a literature review and collected data on tyre wear nanoparticles. The results of the review are presented in Van Broekhuizen (2022). The topic of tyre wear nanoparticles was framed based on the stages of the RG frameworks of RiskGONE and NANORIGO and the literature review was used to evaluate the suitability of available tools, the inherent uncertainty and the identification of data gaps that may influence the assessment.

Within RiskGONE, an evaluation of LCA, ethical impacts, social impacts and macro-economic benefits has been explored on the basis of the developed draft guidelines within WP3. The results of the RiskGONE assessment are reported in detail in Van Broekhuizen et al. (2022) and summarised below.



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Guidelines for performing an LCA, as developed by the RiskGONE project (Igos et al., 2020), have been examined for application in the rubber tyre case study. However, the amount of data needed to perform such an assessment is very high, and not fully covered by the data collected in the technical reference document. Data are required on material and energy consumption during production, and on the emissions to air, water and soil.

Ethical impacts of the use of NMs in rubber tyres have been explored by Malsch et al. (2022) through the ethical impact assessment decision tree and the related RiskGONE tool. Possible ethical risks and benefits have been reported, through self-assessment of available literature, but a more thorough assessment should be performed for assessing possible ethical impacts from tyre wear particles.

Guidelines for assessing social impacts and macro-economic risks and benefits, developed in the RiskGONE project was hampered by the complexity of the topic of tyre wear particles, various uncertainties and data gaps.

In relation to the application of existing tools for the various stages of the RG frameworks (i.e., risk pre-assessment, risk appraisal, risk evaluation, risk management) it has been concluded that many of the tools selected for risk assessments within this case study test highlight the significant lack of data that makes the tools unsuitable for direct use (Van Broekhuizen et al., 2022). Table 1 summarizes the main data gaps that have been identified through the case study and their potential severity in hampering the RG processes.

Table 1. Main identified data gaps and their potential severity in hampering the risk governance processes. (Van Broekhuizen et al., 2022)

| Identified data gaps | Importance/Severity |
|---|---|
| Exposure data | High |
| Hazard data | Medium |
| Realistic concentrations | High |
| Ecotox and occupational scenarios | High |
| Estimation/Separation of particles types and related concentrations in the matrix (NMs from tyre wear, microplastics, nanoplastics, exhaust piper particles, other types of particles) | High |

## 3. Conclusions

Deliverable 2.4 presents the demonstration through case studies of the modular RiskGONE Cloud platform, which has been developed by the RiskGONE consortium for operationalising the RiskGONE RG framework and the related tools and services. The case studies showcase the ease-of-use and suitability of the developed services, tools and materials of the RiskGONE project towards RG of NMs, based on scientific outputs and methodologies, that provide stakeholders an easy-to-follow pathway through the, often perplexed, state-of-the-art.

The decision trees and the RiskGONE framework are described in detail in D2.3 (Report on the RG framework and decision trees), while the overall architecture of the RiskGONE Cloud Platform is described in D2.5 (The final version of RiskGONE Database and Cloud Platform).



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## 4. Deviations

No deviation from DoA.

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