**SCIENCE-BASED RISK GOVERNANCE
OF NANO-TECHNOLOGY**

Draft guidelines on Identification of regulatory and ethical risk thresholds

DELIVERABLE 3.6

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0.1	12-11-2020	Ineke Malsch (MALSCH)	First Draft Action: sent to task 3.5 partners	Panagiotis Isigonis (UNIVE), Ineke Malsch (MALSCH)
0.2	25-11-2020	Ineke Malsch (MALSCH)	Second Draft sent to WPL, PMB and Advisory Board Members	Khara Grieger (EAB)/ Ineke Malsch (MALSCH)
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Abstract

The present deliverable D3.6 starts in chapter 2 with a brief report on the work done in the first two years of task 3.5 of the RiskGONE project, on "Identification of regulatory and ethical risk thresholds". During this period, guidelines were drafted supporting members of the nano Risk Governance Council (RGC) and other stakeholders to self-assess regulatory compliance and to identify possible ethical impacts of nanomaterials (ENMs) or nano-enabled products. While the focus of the work in task 3.5 is on supporting the Risk Governance Council in considering ethical issues in their deliberations on governance of nanomaterials, compliance with existing democratically adopted legal requirements is arguable a form of ethics. However, ethics of emerging science and technology is more encompassing than merely following existing rules, if only because the new technologies may have properties and introduce impacts which were unforeseen at the time the laws were adopted. Therefore, guidelines for checking regulatory compliance are introduced separately from guidelines for performing an ethical impact assessment.

In chapter 3, the first set of guidelines are presented, supporting the user in self-assessment whether manufacturing, use or transport of a particular nanomaterial or product containing nanomaterials complies with legal requirements in the EU or specific Member States.

In chapter 4, guidance on performing an Ethical Impact Assessment as described in the CEN Workshop Agreement part 2 CWA 17145-2:2017 (E) was adapted to fit the needs of members of the nano Risk Governance Council and other stakeholders interested in exploring ethical impacts of nanomaterials and nano-enabled products. These 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.

The overall aim of Workpackage 3 of the RiskGONE project is to support risk-benefit assessment of nanomaterials, balancing positive and negative impacts on ethical, social, economic and ecological sustainability. This implies that potential risks as well as benefits must be identified. While the ethical impact assessment procedure proposed in the CEN CWA 17145-2:2017 focuses on ethical risks such as negative impacts on health, privacy, civil and socio-economic rights, sustainability and security, it can also be adapted to support the identification and evaluation of ethical benefits, contributing to better health, privacy, respect for civil and socio-economic rights, sustainability and security. To illustrate the usefulness for supporting risk-benefit assessment, an adaptation of the guidelines for screening ethical impacts to self-assess benefits as well as risks is explained in chapter 5.

In the coming period, the guidelines in the present deliverable D3.6 will be tested in case studies. This will also feed into the overall RiskGONE effort for responsible research and innovation

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LIST OF ABBREVIATIONS

BPR - Biocidal Products Regulation

caLIBRAte – H2020 project, risk Governance framework for assessment and management of human and environmental risks of ENM

CEN - European Committee for Standardisation

CLP - Classification, Labeling and Packaging Regulation

CWA - CEN Workshop Agreement

DSS - Decision support systems

EIA - Ethical Impact Assessment

ENMs – Engineered nanomaterials

EUON - European Union Observatory for Nanomaterials

GMO - genetically modified organism

GOV4NANO – one of the other projects funded under the NMBP-13 call

iNTeg-Risk – FP7 project in the area of "Nano-sciences, Nano-technologies, Materials and new Production Technologies"

KPI - Key Performance Indicator

NANORIGO - one of the other projects funded under the NMBP-13 call

NIA – Nanotechnology Industries Association

nRGF - nano Risk Governance Framework

OECD - Organisation for Economic Co-operation and Development

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

RGC - Risk Governance Council

SUNDS - Sustainable Nanotechnology DSS

UNESCO - United Nations Educational, Scientific and Cultural Organization

WHO - World Health Organization

1. Technical and Scientific progress

During the first two years of the project, guidelines have been developed for embedding Ethical Impact Assessment (EIA) in the broader Nano Risk Governance Framework. Already in the first year, the concept of embedding EIA in nanosafety has been discussed with peers at Nanotech 2019 in Boston. This presentation was subsequently developed further into a concept paper published by SMALL in July 2020. The draft guidelines formed the basis for online decision support tools which were included in a broader toolbox in the RiskGONE Cloud platform by partners in WP2, as part of task 2.2. Comments from project partners and external experts were received and used to improve the design of the tool.

1.1. Developing guidelines for Ethical Impact Assessment

The guidelines for EIA were mainly based on the CEN Workshop Agreement part 2 CWA 17145-2:2017 (E). Developing this pre-standard into guidelines for performing an EIA followed a stepwise approach. To address the need to consider regulatory thresholds influencing the marketing and use of nanomaterials, guidelines were developed for collecting information from online regulatory databases relevant to nanotechnology governance. These guidelines are distinct from the EIA guidelines, because the former address formal legal requirements, whereas the latter target the exploration of potential ethical risks (and benefits) of nanomaterials.

Step	Action	Risk Governance Framework stage
1	Screening Ethical Impacts	Risk pre-appraisal stage
2	Drafting EIA plan	Risk pre-appraisal stage
3	Identifying ethical impacts	Risk perception and concern assessment
4	Evaluating the ethical impacts	Evaluating risks
5	Formulating and implementing remedial actions	Risk management
6	Reviewing and auditing the EIA	Monitoring and feedback

Table 2.1 Overview of steps in the Ethical Impact Assessment procedure

The guidelines for performing an EIA follow a six-step approach (c.f. table 2.1). In the first step, guidelines were developed for 'screening ethical impacts.' In the second step, guidelines for 'preparing the Ethical Impact Assessment plan' were developed. The third step consisted of developing guidelines for embedding 'identification of the ethical impacts' in the risk perception and concern assessment phase of the(nano) Risk Governance Framework (nRGF). In the fourth step, guidelines were developed for embedding 'evaluation of ethical impacts' in evaluation of risks in the nRGF. The fifth step consisted of preparing guidelines for embedding the planning of 'remedial actions in risk management' in the nRGF. The final sixth step resulted in guidelines for embedding 'review and audit of EIA' in the monitoring feedback phase of the risk governance process.

Finally, all EIA draft guidelines were reviewed, and any errors or inconsistencies were corrected. This resulted in the finalisation of the EIA guidelines and beta version of the first decision trees by 31-12-2020.

1.2. Presenting and publishing the concept of embedding Ethical Impact Assessment in nanosafety

Co-creation has been at the core of the development of the guidelines for ethical impact assessment from the beginning of the RiskGONE project. To begin with, the concept of embedding EIA in nanosafety was discussed at the Environmental Health and Safety of Nanomaterials symposium, Nanotech 2019 Conference and Expo, June 17-19, 2019, Boston, MA, USA. The aims and scope of this presentation were as follows.

Industrial companies manufacturing nano-enabled products and regulators responsible for risk governance of nanomaterials must balance a wide range of aspects, including traditional risk assessment and risk management as well as sustainability. Decision support systems (DSS) are in development that can present all available data in one dashboard. In an earlier project, we developed a modular Sustainable Nanotechnology DSS (SUNDS), addressing industrial and regulatory stakeholder needs (Malsch et al, 2015a, 2015b, 2017, 2018). Ethics and national differences in regulatory systems are not included in the resulting beta-version of SUNDS. In RiskGONE 'Science-based Risk Governance of Nanotechnology', the present draft guidelines have been developed for an ethical impact assessment, based on the current guidance given by the CEN Workshop Agreement part 2 CWA 17145-2:2017 (E). In addition, EU and member states level regulations were mapped, allowing the Risk Governance Council and stakeholders to identify which thresholds should be considered in evaluating estimated risks and benefits. In subsequent case studies, thresholds identified for acceptability of risks will be applied in selected nanotechnology sectors, to test the guidelines we developed.

This presentation was subsequently developed further into a concept paper published by SMALL in July 2020. The scope of this concept paper focused more on the Ethical Impact Assessment guidelines, by outlining a strategy for developing one innovative part of a modular decision support system, designed to support the work of a new Risk Governance Council for nanomaterials which will be established through the combined efforts of the GOV4NANO, NANORIGO and RiskGONE H2020 projects. This new module consists of guidelines for ethical impact assessment for nanomaterials and nano-enabled products. This article offered recommendations for adapting the CEN (European Committee for Standardisation) pre-standard on Ethical Impact Assessment CWA (Workshop Agreement) 17145-2:2017 (E), to fit into the more-encompassing decision support system for risk governance of nanomaterials within the RiskGONE project.

1.3. Feeding the guidelines into the Nano Risk Governance Framework

The developed draft guidelines formed the basis for online decision support tools which were included in a broader toolbox in the RiskGONE Cloud platform by partners in WP2, as part of task 2.2. A Beta version of the first screening tool was first tried out by partners in RiskGONE on 25 June 2020, and improved versions were then demonstrated to peers outside the project during the virtual NanoSAFE 2020 conference, 16-23 November 2020. The received comments were used to improve the tools.

2. Guidelines for identifying legal requirements

The following guidelines are intended to aid the Risk Governance Council in determining compliance of a nanomaterial under scrutiny with existing legislation and ethical norms. The following computer support is developed in task 2.2:

1) Add a list of links to online databases of relevant legislation with instructions how to use them to answer the question:
   a. EUON Website: Regulation: https://euon.echa.europa.eu/regulation
   b. NIA Regulatory Monitoring Database. http://nanotechia.org/activities/regulatory-monitoring-database (only for subscribers)
2) Check compliance with EU regulations via https://euon.echa.europa.eu/regulation
   a. In which country will the nanomaterial be produced, used or transported (use the tool separately for each country)?
      i. If non-EU: contact the authorities of the country in question to check compliance
      ii. If EU: is it a chemical substance under REACH? Is it covered by CLP? Is it a Biocide under the BPR? Is it food? Is it cosmetics? Is it a medical device? Is worker protection in accordance with EU occupational health and safety regulations?
      iii. If France, Belgium, Denmark, Norway or Sweden: is national reporting required? If so, is the nanomaterial reported?

The visual representations of the decision tree in the next pages are translated in instructions included in a table which can be used by programmers to develop an online tool.
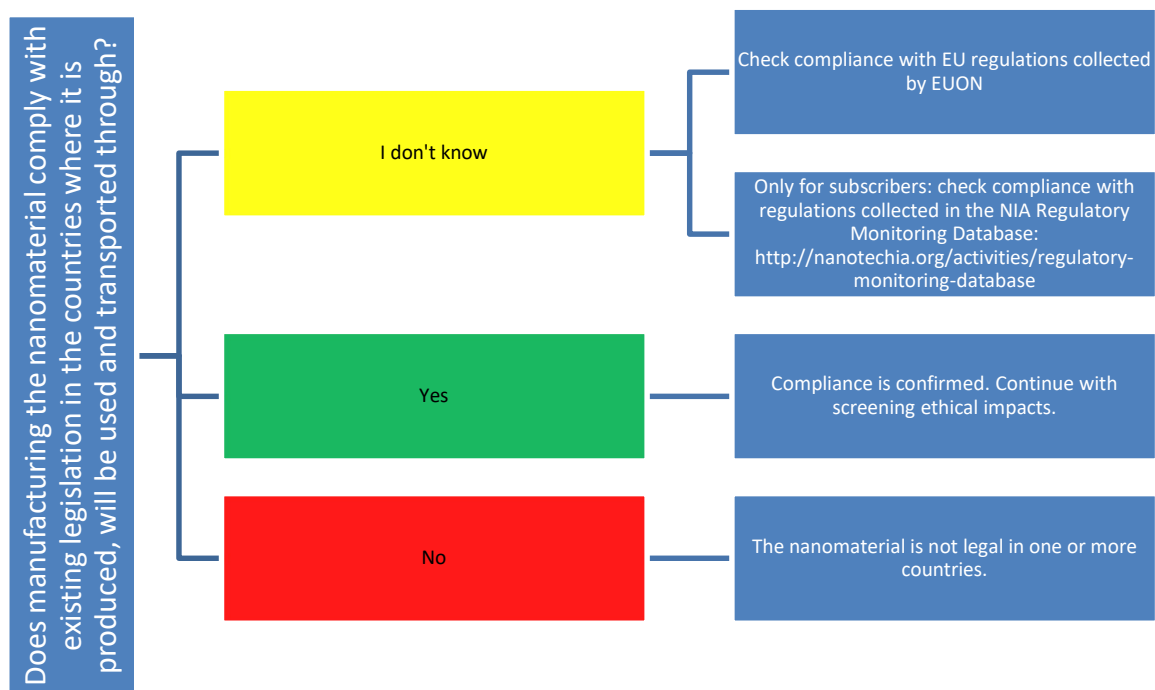
Figure 3.1: Preliminary question to self-assess awareness of legal requirements.
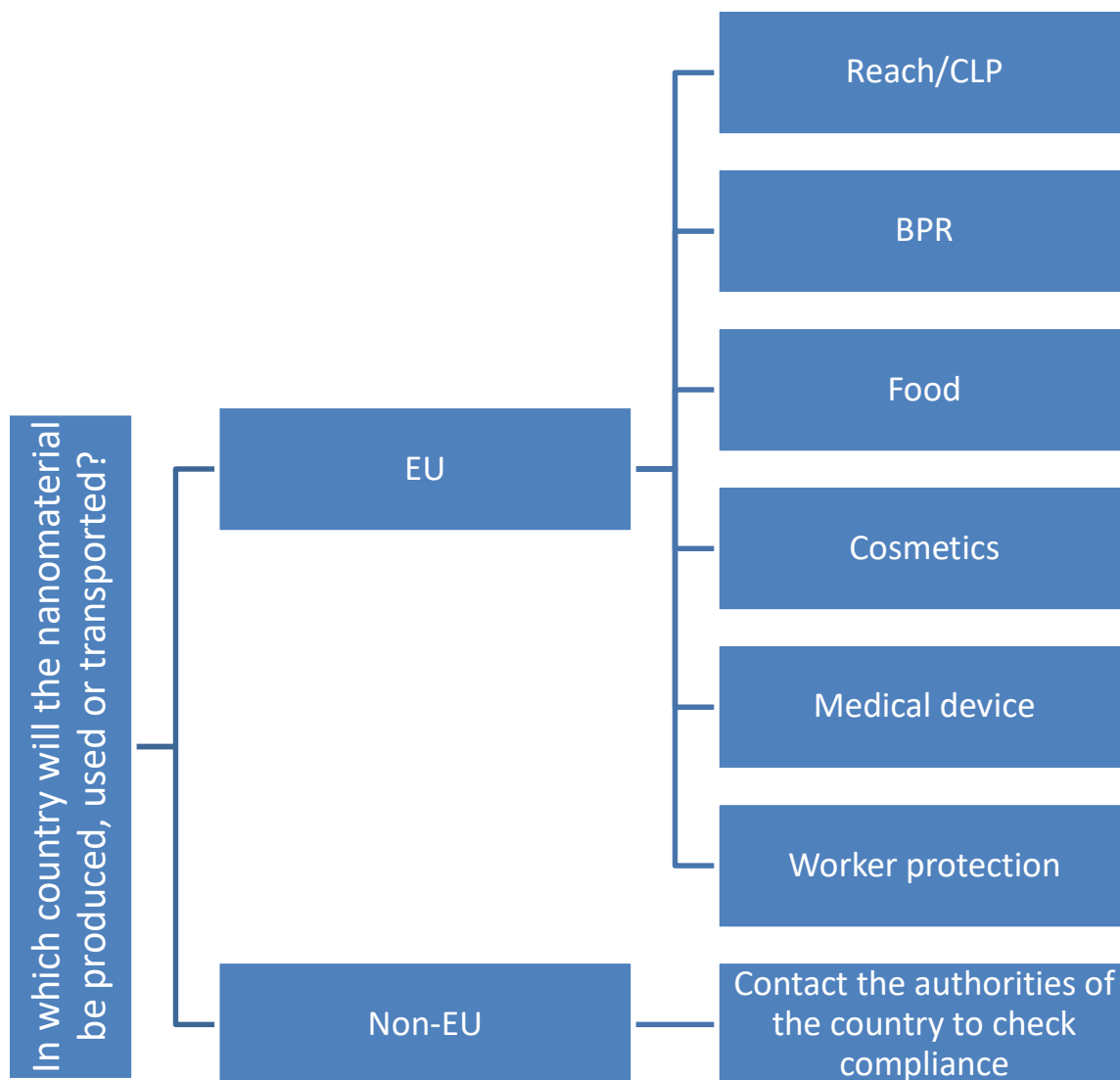
Figure 3.2: The scope of the tool to check legal compliance is limited to nanomaterials manufactured, used or transported through the EU.
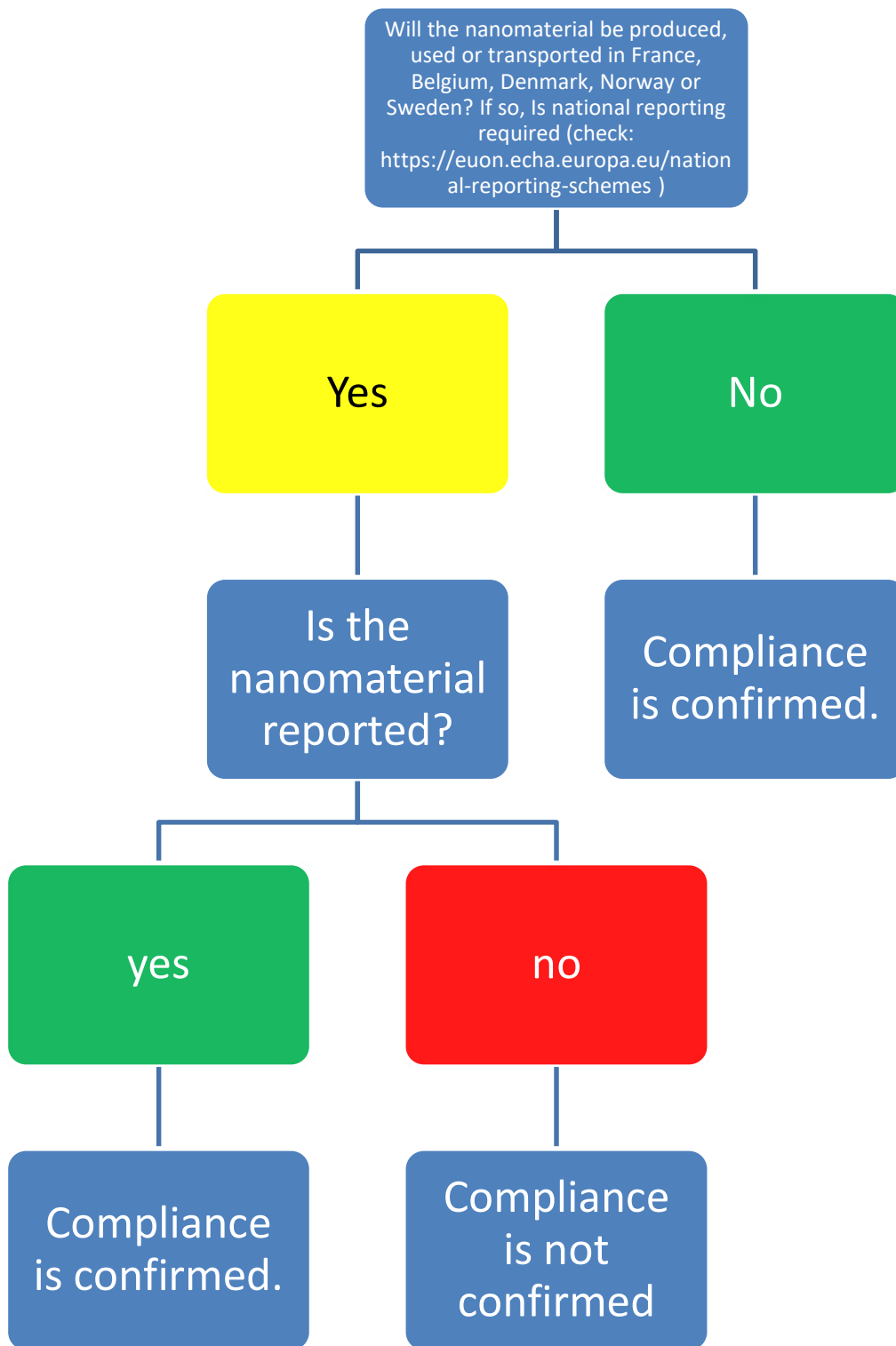
Figure 3.3 In addition to EU legislation, some countries impose additional reporting requirements.

2.1. Results Interpretation

#	Question	Answer	Output
1	Does manufacturing the nanomaterial comply with existing legislation in the countries where it is produced, will be used, and transported through?	Yes	The intended activities comply with existing legislation.
		No	At least one of the intended activities is not legal in at least one country.
2A	After checking the NIA regulatory monitoring database, does manufacturing the nanomaterial comply with existing legislation in the countries where it is produced, will be used, and transported through?	Yes	The intended activities comply with existing legislation.
		No	At least one of the intended activities is not legal in at least one country.
3	Will the nanomaterial be manufactured, used or transported through an EU-Member State?	No	The scope of the tool is limited to the EU and its member states. If the intended activities will take place outside the EU, the user should contact the authorities of the country or countries to check compliance.
4A	Is the nanomaterial already registered under REACH/CLP?	Yes	The intended activities comply with REACH/CLP.
		No	Submit a dossier for REACH/CLP registration.
5A	Does the product comply with the Biocidal Products Regulation?	Yes	The intended activities comply with BPR.
		No	The intended activities do not comply with BPR.
6A	Does the product comply with the EU Food and Food Contact regulations?	Yes	The intended activities comply with food and food contact.
		No	The intended activities do not comply with food and food contact.
7A	Does the product comply with EU cosmetics legislation?	Yes	The intended activities comply with EU cosmetics legislation.
		No	The intended activities do not comply with EU cosmetics legislation.
8A	Does the product comply with EU legislation for medical devices?	Yes	The intended activities comply with EU medical device legislation.
		No	The intended activities do not comply with EU medical device legislation.
9A	Does the manufacturing, transport and professional use comply with Worker protection legislation?	Yes	The intended activities comply with worker protection legislation.

		No	The intended activities do not comply with worker protection legislation.
10	Will the nanomaterial be produced, transported, used or subject to waste processing in France, Belgium, Denmark, Norway or Sweden?	No	The national reporting requirements in France, Belgium, Denmark, Norway and Sweden are not relevant to the activity.
11	Is national reporting required?	No	The national reporting requirements in France, Belgium, Denmark, Norway and Sweden are not relevant to the activity.
12	Is national reporting already done?	Yes	The intended activities comply with national reporting requirements in the relevant countries.
		No	Submit a dossier for national reporting to the relevant authorities.

3. Guidelines for performing Ethical Impact Assessment

Members of the Risk Governance Council and other stakeholders can use the following sets of guidelines to assess the relevance, severity and acceptance of ethical issues related to specific nanomaterials and nano-enabled products during manufacturing, use and waste processing.

The procedure for performing the EIA consists of six steps, which will be explained in the following sections:

1) Screening Ethical Impacts,
2) Preparing the EIA plan,
3) Identifying Ethical Impacts,
4) Evaluating Ethical Impacts,
5) Proposing Remedial Actions Addressing Ethical Impacts and
6) Review and Audit of the EIA.

Obviously, ethical concerns and perception of impacts are not the same across different stakeholder groups or cultures. Therefore, the engagement of a representative group of stakeholders is needed, at least in the evaluation of ethical impacts and in discussion of the proposed remedial actions. In some cases, stakeholders will have to be involved also in approving the EIA plan and contribute to the identification of ethical impacts. In each section below, it will be clarified how stakeholders will be engaged in performing or evaluating the ethical impact assessment.

3.1. Screening potential ethical Impacts and their severity – 'Threshold analysis'

This screening phase is part of the **pre-assessment** step of the overall Risk Governance process. A member of the Risk Governance Council or other stakeholder can use an online self-assessment tool to estimate the presence and severity of potential ethical issues. An opening screen offers a brief explanation of the purpose of the tool and how it should be used. This opening screen gives access to a checklist of ethical impacts of nanomaterials and nanoproducts, included in table 4.1 below. Guidance helping the user to understand each question is programmed as an explanation box next to the question. The guidelines also include an explanation how the results of the screening tool should be interpreted. The technical implementation results in the online tool in (RiskGONE 2020a)[1].

To what extent will the nanomaterials and products give rise to the following issues?	No	1	2	3	4	5	Comment on your answer / specify briefly any potential ethical issues, including information on who has the concern:

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[1] http://enaloscloud.novamechanics.com/riskgone/thresholdanalysis/

Are they used in a health-care context?[2] If not: tick No. If yes, estimate the severity of expected ethical health-related issues, between minor (1) and severe (5).							
Does the application of nanomaterials involve the collection, processing, storing and/or transfer of personal data?[3] If not: tick No. If yes, estimate the severity of expected personal data protection issues, between minor (1) and severe (5).							
Could the value chain and application of nanomaterial have a negative impact on the rights and liberties of individuals and groups?[4] If not: tick No. If yes, estimate the severity of expected impacts on human rights and liberties, between minor (1) and severe (5).							
Could the value chain and application of nanomaterial have a negative impact in terms of social justice and equality?[5] If not: tick No. If yes, estimate the severity of expected impacts on social justice and equality, between minor (1) and severe (5).							

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[2] Healthcare is defined in a broad sense, including pharmaceuticals, medical devices, dentistry, cosmeceuticals and other products used in hospitals, at home, and in other locations for improving the health and well-being of people.

[3] The privacy and data protection issues are caused by the product in which the nanomaterials are used. Examples include sensors and monitoring devices, data storage devices etc.

[4] Consider effects on freedom, autonomy, authenticity, identity, privacy, human dignity, human bodily integrity, intellectual property, among others.

[5] Consider effects on the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks and hazards, and have special consideration for effects on vulnerable, disadvantaged, and under-represented individuals, groups, or communities in society, including future generations and individuals, groups and communities in low income and lower-middle income countries.

Could the value chain and application of nanomaterial have a negative impact on the well-being of individuals or groups, and/or on the common good, including cultural heritage?[6] If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5).						
Could the value chain and application of nanomaterial have a negative impact on the environment, animals and/or plants through the use of genetically modified organisms (GMOs) or any biological, chemical, radiological, nuclear or explosive elements used, as well as any effects in terms of human encroachment on natural habitats and environmental policy? If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5).						
Could the value chain or application of nanomaterial raise concerns for the 17 Sustainable Development Goals?[7] If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5), and specify which goals are concerned.						

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[6] Consider effects on the well-being and interests of individuals and groups in society, including the quality of work, and effects on social institutions and structures, democracy and important aspects of culture and cultural diversity. Cultural heritage includes physical artefacts and intangible attributes of a group or society, such as sites, monuments, artefacts, texts, archives, remains and information about the past.

[7] Check the goals via this link: https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals

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Could the nanomaterial or its application have significant military purposes (dual use)?[8] If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5).							
Could the nanomaterial or nano-enabled product become subject to misuse?[9] If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5).							

Table 4.1: checklist for screening ethical impacts (source CWA17145-2:2017 (E)).

3.1.1. Results Interpretation

The interpretation of the results of the self-assessment of ethical impacts is visualised in figure 4.1.

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[8] Consider, amongst others, any effects in terms of the development of weapons of mass destruction, military surveillance systems and autonomous weapons systems.

[9] Consider, amongst others, whether [information about] harmful biological, chemical, radiological, nuclear, or explosive materials, and/or the means of their delivery, can easily [or accidentally] be misused and whether it may easily fall into the hands of terrorists or criminals, and whether it may be abused by governmental and other institutional actors in non-military contexts.
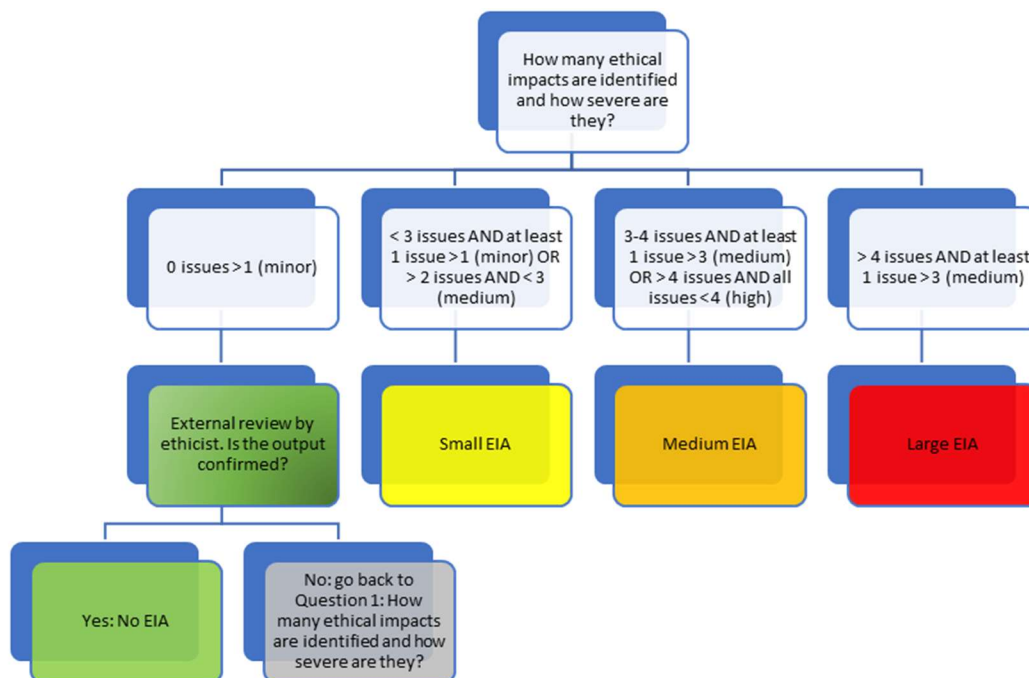
Figure 4.1. Interpretation of the results of the self-assessment of ethical impacts.

Table 4.1 below summarises how the self-assessment tool supports the user in determining if an ethical impact assessment will be needed and if so, how large it should be.

Yes/No answers	Scale	External reviewer	Agrees	Result	Comment
NO = 9	-	Yes	Yes	No EIA	
NO = 9	-	Yes	No	Go back to Question 1	
Yes ≥ 1	All Yes = 1	Yes	Yes	No EIA	
Yes ≥ 1	All Yes = 1	Yes	No	Go back to Question 1	
Yes ≤ 2	One Yes > 1	No	-	Small scale EIA	The output of the decision tree states the minimum requirements. A medium scale EIA may be performed if deemed appropriate
Yes > 2	All Yes ≤ 2	No	-	Small scale EIA	
Yes = 3	One Yes ≥ 3	No	-	Medium scale EIA	

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 814425.

Yes = 4	One Yes ≥ 3	No	-	Medium scale EIA	The output of the decision tree states the minimum requirements. A large-scale EIA may be performed if deemed appropriate
Yes > 4	All Yes < 4	No	-	Medium scale EIA	
Yes ≥ 5	One Yes ≥ 4	No	-	Large scale EIA	

Table 4.1 Connection between input and output of the Ethical Impact Assessment screening tool.

3.2. Guidelines for preparing the EIA plan

After the step of screening the Ethical Impacts to determine the size of the EIA, the preparation of the EIA plan is also part of the **pre-assessment** phase of the Risk Governance process. The CWA is modelled on a research project. In the EIA module supporting the work of the RGC, some adaptations are made to accommodate the work of the council. The module gives guidance for the EIA research team composition, budget and methods used to perform the small, medium, or large-scale EIA. Assuming that most members of the Risk Governance Council or other users of the EIA module are not professional ethicists, the tools will be limited to supporting the drafting of the EIA plan for all three EIA-sizes, but then only be sufficient to support the performance of a small scale EIA. If medium or large scale EIAs are needed, the user should employ or contract at least one professional ethicist to lead it.

The module can give access to a range of software tools supporting the performing of the small-scale EIA, through a decision tree, consisting of four additional steps:

- Identifying ethical impacts (in risk perception and concern assessment),
- Evaluating the ethical impacts (in evaluating risks),
- Formulating and implementing remedial actions (in risk management)
- Reviewing and auditing the EIA (in monitoring and feedback).

For more information, follow this link to the CWA.

3.2.1. Prepare EIA plan

The screening of the Ethical Impact, performed in the preceding step, results in one of four possible outcomes:

Screening outcome:	No EIA needed[10]	Small EIA[11] / Medium EIA[12] / Large EIA[13]
Next step:	Review[14] of EIA screening by independent body or person to check if no significant ethical impacts are expected	Review and approval of EIA plan by independent body

Screening outcome:	Small EIA[15]	Medium EIA[16]	Large EIA[17]
Required budget (1-10% of research budget for the risk governance assessment of the nanomaterial and its applications)	90% personnel, 10% other	80% personnel, 20% other	70% personnel, 30% other
Team composition	Leader: part time research assistant Optional members: should have relevant	Leader: full time researcher Optional members: should have relevant expertise to the	Leader: full time senior researcher or independent consultant

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[10] No significant Ethical Impacts were identified

[11] Some Ethical Impacts were identified

[12] Considerable Ethical Impacts were identified

[13] Many severe Ethical Impacts were identified

[14] This external review is not necessary if the Risk Governance Council is performing the EIA. The review presupposes that the organisation performing the EIA has an interest in the outcome of the assessment, which presumably is not the case if the RGC includes assessment of ethical issues in their discussions of potential risks of nanomaterials and appropriate governance measures. In accordance with the "four-eyes" principle, a review by a council member who was not involved in preparing the Ethics screening, preparing the EIA plan, or implementing it may be sufficient.

[15] Some Ethical Impacts were identified

[16] Considerable Ethical Impacts were identified

[17] Many severe Ethical Impacts were identified

	expertise to the identified ethical issues	identified ethical issues	Optional members: should have relevant expertise to the identified ethical issues
Formulating review criteria	Yes	Yes	Yes
Consult with stakeholders before starting the EIA [18]	No	Optional	Optional
Planning identification ethical impacts. Objective: to identify and describe the ethical impacts of the nanomaterial and its applications and places these impacts in a temporal perspective, anticipating short, medium and long-term impacts. To cover differences in perception of ethical issues between different stakeholder groups, stakeholder consultations are included in all cases. However, in small EIAs this may be limited to online consultations, while large scale EIAs may require the organisation of on-site stakeholder events.	Desk research: literature research; foresight through horizon scanning, and online expert and stakeholder consultation; Ethical Impact conceptual analysis of explicit issues through ethical checklists, and empirical analysis through online consultations with experts and stakeholders; document the outcomes.	Literature research: foresight through horizon scanning, trend analysis, expert and stakeholder consultation, brainstorming, futures wheel, and roadmapping; Ethical Impact conceptual analysis of explicit issues through ethical theories, and empirical analysis through consultations with experts and stakeholders; document outcomes.	Literature research: foresight through horizon scanning, trend analysis, expert and stakeholder consultation, delphi interviews, brainstorming, futures wheel, citizen panels, roadmapping and scenario writing; Ethical Impact conceptual analysis of explicit issues through ethical theories, of intuitive issues through situational approaches, and empirical analysis of explicit issues through expert and stakeholder consultations, of intuitive issues through techno-ethical scenarios; document outcomes.
Planning evaluating ethical impacts. Objective: assess the relative importance, the likelihood of occurrence and the possible value conflicts of identified ethical impacts. Stakeholders will in all cases be involved in the evaluation, ranging from online consultations for small scale	Desk research: literature research of existing evaluation of ethical impacts in related projects. Use 5 **rules of thumb**[19] to identify and resolve value conflicts. Present and discuss the ethical impact evaluation online with stakeholders.	Desk research and expert consultation. Methods: Delphi, interviews and workshops. Use 5 **rules of thumb** to identify and resolve value conflicts. Present and discuss the ethical	Desk research, expert consultation, and participatory approaches focusing on stakeholder engagement. Use 5 **rules of thumb** to identify and resolve value conflicts. Present and discuss the ethical impact evaluation with stakeholders.

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[18] To map relevant stakeholders; raise awareness amongst stakeholders that the project will take place; gather more details from stakeholders about possible ethical impacts.

[19] 1: Fundamental values take precedence over non-fundamental values; 2: Assess the degree of violation and choose the action that least compromises a fundamental value; 3: project moral values into situations when two fundamental values seem to be equally violated to determine which value appears more important in the particular situation; 4: negotiate conflicts of moral values between different parties, who constitute or represent stakeholders in the situation; 5: avoid the value conflict by reconfiguring the situation.

EIAs to on-site events in large scale EIAs.		impact evaluation with stakeholders.	
Planning ethical remediation: Review remediation in other projects, formulate and implement remediation, formulate and present recommendations to stakeholders.	Desk research: formulate societal and organisational recommendations	Formulate design, societal, organisational, regulatory and policy recommendations.	Formulate design, societal, organisational, regulatory and policy recommendations.
Planning the review of the EIA by an independent member of the RGC or external body. External reviewer provides feedback and guidelines for improving the EIA process and guards milestones and KPI.	At start: review and approve EIA plan. During: evaluate conduct and documentation. At end: review EIA process.	At start: review and approve EIA plan. During: evaluate conduct and documentation. At end: review EIA process	At start: review and approve EIA plan. During: evaluate conduct and documentation. At end: review EIA process

3.2.2. Output: template for EIA plan

The preparation for the three types of EIA can be supported by decision trees (online forms), which support the user in preparing a document containing a well-structured EIA plan. The input consists of a completed online questionnaire. The output is a pdf document including the EIA plan, with the following table of content:

Title of EIA:	
Authors:	
Abstract:	[This includes information on the nanomaterial and applications which will be assessed, the identified ethical issues, the scale of the EIA and who will be responsible for performing the EIA.]
Budget:	
Team composition:	
Review criteria:	
Optional: preliminary stakeholder consultation:	
Identification of Ethical Impacts:	
Evaluation of Ethical Impacts:	

Remediation:	
Review of EIA plan:	

3.3.   Guidelines for identifying ethical impacts

These guidelines are meant to assist the Risk Governance Council in identifying the ethical impacts of nanomaterials and nano-enabled products. The identification of ethical impacts is part of the **risk perception and concern assessment** phase of the Risk Governance process. It consists of three elements:

1. Literature review on potential ethical impacts preferably by an ethicist
2. Identify ethical impacts using foresight- and ethical impact analysis methods
3. Document the identified ethical impacts

3.3.1. Introduction

Identifying ethical impacts is the next step after preparing the EIA plan. The guidelines are offered in three versions, ranging from light, for a small EIA, to heavy, for a large EIA. The guidelines include brief explanations of the procedure for performing the identification of ethical impacts as well as tools supporting the implementation. To support the literature review, the Risk Governance Framework includes the following types of tools:

- Links to journals on ethics of science and technology, including: Nanoethics, Science and Engineering Ethics, Journal of Responsible Innovation, etc.
- Checklists of relevant keywords for searching literature databases
- Adapting the nano Risk Radar using ethics-related keywords (IntegRisk and caLIBRAte)[20]

To support the foresight- and ethical impact analysis, a shortlist of methods for identifying emerging ethical issues is explained. The identified ethical impacts should finally be documented in a report with the following contents. The reports that will be prepared for the RiskGONE case studies could be proposed as template:

- Introduction
- Description of methods used
- Results of expert consultations and/or stakeholder engagement
- Description of identified potential ethical impacts, short, medium, and long term
- Summary

3.3.2. Sources and tools for identifying ethical issues in a small-scale EIA

Finalise the list of sources for literature research, by updating the default list of science and technology ethics sources.

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[20] Accessible via: https://www.risk-technologies.com/home.aspx?lan=230&tab=1&itm=1&pag=12#bl58

Literature databases	Journals	Grey literature repositories, other
General academic literature databases include nanoethics literature	NanoEthics[21]	WHO Global Health Ethics[22]
	Journal of Responsible Innovation[23]	UNESCO Global Ethics Repository[24]
	Science and Engineering Ethics[25]	European Group on Ethics in Science and New Technologies[26]
	International Journal of Ethics Education[27]	European Data Protection Supervisor[28]
	Sustainability[29]	Ethics in H2020[30]
	Nature Nanotechnology[31]	

Finalise the overview of sources for foresight through horizon scanning, by updating the default list.

Online horizon scanning software	Other sources
Nano Risk Radar[32]	OECD overview of futures methodologies[33]

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[21] https://www.springer.com/journal/11569

[22] https://www.who.int/health-topics/ethics

[23] https://www.tandfonline.com/toc/tjri20/current

[24] https://en.unesco.org/themes/ethics-science-and-technology/geobs

[25] https://www.springer.com/journal/11948

[26] https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/ege_en

[27] https://www.springer.com/journal/40889

[28] https://edps.europa.eu/

[29] https://www.mdpi.com/journal/sustainability

[30] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics

[31] https://www.nature.com/nnano/

[32] Accessible via: https://www.risk-technologies.com/home.aspx?lan=230&tab=1&itm=1&pag=12#bl58

[33]

http://www.oecd.org/site/schoolingfortomorrowknowledgebase/futuresthinking/overviewofmethodologies.htm

Finalise the list of sources for online expert and stakeholder consultation, by updating the default list of tools:

Consultation tools	Target group	# respondents	Timing
Online survey			
Social media			
Webinar			
E-mail			
Other			

3.3.3. Perform the identification of ethical impacts

3.3.3.1. Ethical Impact conceptual analysis of explicit issues through ethical checklists (literature and foresight).

The ethical checklist of the EIA screening tool forms the core of this ethical checklist. Users can extend the list with specific ethical principles they consider relevant to the nanomaterial and its application which is the topic of the Ethical Impact Assessment. The original estimates of the severity of the identified issues are confirmed or revised based on the information collected through literature review and horizon scanning. The analysis of the reviewed information is documented and will be incorporated in the final report on the identification of ethical issues. General sources of ethical principles and concepts which can be used as inspiration are:

Stanford Encyclopaedia of Philosophy: https://plato.stanford.edu/index.html

UNESCO Global Ethics Observatory: https://en.unesco.org/themes/ethics-science-and-technology/geobs

What is known on the ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Description of the issue and severity, and whether it is a short, medium, or long-term concern	Reference to the source
Health-related issues of the manufacturing and use of the materials and products.	Applied in a healthcare context		
	Public health or safety issues		
Issues related to the application of nanomaterials involving the collection, processing, storing and/or transfer of personal data.			
	Freedom		

What is known on the ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Description of the issue and severity, and whether it is a short, medium, or long-term concern	Reference to the source
Impacts on the rights and liberties of individuals and groups of the value chain and application of nanomaterial.	Autonomy		
	Authenticity		
	Identity		
	Privacy		
	Human dignity		
	Human bodily integrity		
	Intellectual property		
Could the value chain and application of nanomaterial have a negative impact in terms of social justice and equality?	The distribution of opportunities, powers and capabilities		
	Civil and political rights		
	The distribution of economic resources and income		
	The distribution of risks and hazards		
	Effects on vulnerable, disadvantaged, and under-represented individuals, groups, or communities in society, including future generations		
	Effects on individuals, groups and communities in low income and lower-middle income countries		

What is known on the ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Description of the issue and severity, and whether it is a short, medium, or long-term concern	Reference to the source
Could the value chain and application of nanomaterial have a negative impact on the well-being of individuals or groups, and/or on the common good, including cultural heritage?	effects on the well-being and interests of individuals and groups in society, including the quality of work		
	effects on social institutions and structures, democracy and important aspects of culture and cultural diversity		
	Cultural heritage includes physical artefacts and intangible attributes of a group or society, such as sites, monuments, artefacts, texts, archives, remains and information about the past		
Could the value chain and application of nanomaterial have a negative impact on the environment, animals and/or plants?	the direct and long-term effects on the environment, animals and plants of any biological, chemical, radiological, nuclear or explosive elements used		
	the direct and long-term effects on the environment, animals and plants of GMOs		
	human encroachment on natural habitats and environmental policy		
Could the value chain or application of nanomaterial raise concerns in terms of sustainable development?	In terms of the use of resources		
	In terms of the generation of harmful waste products		
	effects in terms of the development of weapons of mass destruction		

What is known on the ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Description of the issue and severity, and whether it is a short, medium, or long-term concern	Reference to the source
Could the nanomaterial or its application have significant military purposes (dual use)?	military surveillance systems		
	autonomous weapons systems		
Could the nanomaterial or nano-enabled product become subject to misuse?	Can [information about] harmful biological, chemical, radiological, nuclear, or explosive materials, and/or the means of their delivery, easily [or accidentally] be misused		
	May such materials easily fall into the hands of terrorists or criminals		
	May such materials be abused by governmental and other institutional actors in non-military contexts		

3.3.3.2.   Ethical impact empirical analysis through online consultations of experts and stakeholders.

Use the same checklist as basis for a survey of views on identified ethical issues and add some open questions inviting respondents to add any other issues they are aware of.

How severe do you consider the following ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Estimate of the severity of the issue (not at all to severe)	Please give a reason for your estimate
Health-related issues of the manufacturing and use of the materials and products.	Applied in a healthcare context		
	Public health or safety issues		
Issues related to the application of nanomaterials involving the collection, processing, storing and/or transfer of personal data.			
	Freedom		

How severe do you consider the following ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Estimate of the severity of the issue (not at all to severe)	Please give a reason for your estimate
Impacts on the rights and liberties of individuals and groups of the value chain and application of nanomaterial.	Autonomy		
	Authenticity		
	Identity		
	Privacy		
	Human dignity		
	Human bodily integrity		
	Intellectual property		
Could the value chain and application of nanomaterial have a negative impact in terms of social justice and equality?	The distribution of opportunities, powers and capabilities		
	Civil and political rights		
	The distribution of economic resources and income		
	The distribution of risks and hazards		
	Effects on vulnerable, disadvantaged, and under-represented individuals, groups, or communities in society, including future generations		
	Effects on individuals, groups and communities in low income and lower-middle income countries		
Could the value chain and application of nanomaterial have a negative impact on the well-being of individuals or groups,	effects on the well-being and interests of individuals and groups in society, including the quality of work		

How severe do you consider the following ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Estimate of the severity of the issue (not at all to severe)	Please give a reason for your estimate
and/or on the common good, including cultural heritage?	effects on social institutions and structures, democracy and important aspects of culture and cultural diversity		
	Cultural heritage includes physical artefacts and intangible attributes of a group or society, such as sites, monuments, artefacts, texts, archives, remains and information about the past		
Could the value chain and application of nanomaterial have a negative impact on the environment, animals and/or plants?	the direct and long-term effects on the environment, animals and plants of any biological, chemical, radiological, nuclear or explosive elements used		
	the direct and long-term effects on the environment, animals and plants of GMOs		
	human encroachment on natural habitats and environmental policy		
Could the value chain or application of nanomaterial raise concerns in terms of sustainable development?	In terms of the use of resources		
	In terms of the generation of harmful waste products		
Could the nanomaterial or its application have significant military purposes (dual use)?	effects in terms of the development of weapons of mass destruction		
	military surveillance systems		
	autonomous weapons systems		

How severe do you consider the following ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Estimate of the severity of the issue (not at all to severe)	Please give a reason for your estimate
Could the nanomaterial or nano-enabled product become subject to misuse?	Can [information about] harmful biological, chemical, radiological, nuclear, or explosive materials, and/or the means of their delivery, easily [or accidentally] be misused		
	May such materials easily fall into the hands of terrorists or criminals		
	May such materials be abused by governmental and other institutional actors in non-military contexts		
Is there any other ethical issue related to the manufacturing or use of the selected nanomaterial and its product you are aware of? Please explain the issue, how severe it is and why you think it is an issue.			

3.3.4. Document the outcomes of the identification of ethical impacts

Complete the sections in the online template (c.f. default below). This should be supported by an online report writing tool and the output should be a downloadable pdf.

Title:	
Authors:	
Abstract:	
Introduction:	
Description of methods used:	
Results of expert consultations and/or stakeholder engagement:	

Description of identified potential ethical impacts, short, medium, and long term:	
Summary:	
References:	
List of consulted persons:	

3.4. Guidelines for evaluating Ethical Impacts

The fourth step of the small-scale Ethical Impact Assessment addresses the evaluation of the ethical impacts of the use of nanomaterials and products. This step is part of the **evaluation and characterisation of risks**, the third step in the Risk Governance process. The EIA team should perform the evaluation of ethical impacts identified in the preceding step. This evaluation consists of four elements:

1. Select and use method for evaluation
    a. Desk research
    b. Expert consultation (optional)
    c. (Online) participatory approaches
2. Analyse ethical values and principles
    a. Clarify the ethical principles and values at stake.
    b. Assess the likelihood and intensity of violation of ethical values.
3. Identify value conflicts and propose ways of resolving them
    a. Balance trade-offs between conflicting ethical values and principles.
    b. Proposing ways to resolve value conflicts should follow five rules of thumb.
4. Present and discuss the ethical impact analysis with stakeholders. This can make use of online tools included in D2.5. The final version of RiskGONE Database and Cloud Platform.

3.4.1. Select and use method for evaluation

Desk research and online stakeholder consultations form the basis and are used in any case. If the EIA team considers it appropriate, expert consultations and/or on-site participatory approaches can also be used.

3.4.1.1. Desk research

The identified ethical issues related to the manufacturing and use of the nanomaterial and product under study should be compared with ethical issues identified for other comparable materials and products in earlier studies. In addition, the relative importance of different identified ethical issues must be ranked.

The EIA team can perform this comparison by itself in desk research, collecting and analysing literature and internet resources. Before finalising the evaluation report, online stakeholder consultation must be performed.

3.4.1.2. Expert consultation

If deemed appropriate external experts with additional expertise, which is not available in the EIA team may be asked to review the identified ethical issues and give their expert opinion on the severity and relative importance of the different identified issues, and make suggestions for balancing different values and principles at stake. Consultation can take the form of interviews, workshops or even Delphi studies.

3.4.1.3. Participatory approaches

If deemed appropriate, stakeholder representatives may also be consulted through on-site focus groups, citizen panels or similar approaches. The consulted stakeholders should be asked to comment on the relative importance of different principles and values at stake and make suggestions for balancing them.

3.4.2. Analyse ethical values and principles

The analysis of the relevant ethical values and principles which were identified in the preceding step of the Ethical Impact Assessment includes conceptual analysis by an ethicist of these principles and values and a semi-quantitative assessment of the likelihood and intensity of violations or benefits of the identified principles and values.

3.4.2.1. Clarify the ethical principles and values at stake

An ethicist should clarify these principles and values using conceptual analysis and the application of ethical theories.

Identified principle or value	Which ethical theory is applied	What does it mean in the case under study?

3.4.2.2. Assess the likelihood and intensity of violation of ethical values

The ethicist should assess the degree to which the ethical value or principle is likely to be violated or benefited in the expected ethical impact. This analysis can be supported by a decision tree as illustrated in the next table.

Degree of violation (1 = minor; 2 = moderate; 3 =medium; 4= high; 5=severe)	Identified principle or value	Degree of benefit (1 = minor; 2 = moderate; 3 =medium; 4= high; 5=extreme)

3.4.3. Identify value conflicts and propose ways of resolving them

In practice, value conflicts are likely between the identified principles, e.g. measures to protect safety at work can lead to infringements of privacy rights of employees. The ethicist should identify sets of conflicting values and principles and propose options for striking trade-offs between measures to remediate the identified ethical impacts. Then, five rules of thumb should be followed to propose ways to resolve value conflicts.

3.4.3.1. Balance trade-offs between conflicting ethical values and principles

Some of the identified ethical values and principles are conflicting, and trade-offs between measures to remediate them should be balanced.

Identify sets of conflicting values and principles	Describe the alternative remediation measures
e.g. privacy and safety	

3.4.3.2. Proposing ways to resolve value conflicts should follow rules of thumb

1. "Fundamental values including basic human rights such as the right to life, civil liberties, justice, security, etc. take precedence over non-fundamental values …

2. Assess the degree of violation and choose the action that least compromises a fundamental value …

3. Project moral values into situations when two fundamental values seem to be equally violated to determine which value appears more important in the particular situation …

4. Negotiate conflicts of moral values between different parties, who constitute or represent stakeholders in the situation …

5. Avoid the value conflict by reconfiguring the situation." (CEN, 2017, p23)

This can be programmed as a set of decision trees:

Rule of thumb 1: Fundamental values take precedence over non-fundamental values.

List all sets of two values at stake which conflict with each other
Examine the first set of conflicting values. Which of these values is a fundamental value? Refer to a list of fundamental values and human rights treaties[34]
If one value is fundamental and the other is non-fundamental, select the fundamental value. If both are fundamental, keep the value conflict marked as important. If both are non-fundamental, keep the value conflict marked as normal. Then compare the next set of conflicting values, until all sets of conflicting values are assessed. Then move to rule of thumb 2.

Rule of thumb 2: Assess the degree of violation of conflicting fundamental values and choose the action that least compromises a fundamental value.

Identify the value conflict	Describe likely scenarios where the value conflict occurs	For each scenario, identify alternative remediation actions	Estimate the degree of violation of the conflicting fundamental values in each alternative action (1 = minor; 2 = moderate; 3 =medium; 4= high; 5=severe)	Compare the degrees of violation in alternative actions and select the option with the lowest degree of violation of both fundamental values
Security versus transparency	Dual use nanomaterials are produced in a factory	Restrict access to factory to personnel with ID-card	1 versus 4	Not selected, because transparency is highly violated
Security versus transparency	Dual use nanomaterials are produced in a factory	Invite local communities during open days to the factory after registration	3 versus 2	Selected, because violation of security is medium

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[34] https://www.un.org/en/universal-declaration-human-rights/index.html and
https://treaties.un.org/Pages/Home.aspx?lang=en

Rule of thumb 3: Project moral values into situations when two fundamental values seem to be equally violated to determine which value appears more important in the particular situation.

Identify the value conflict	Describe likely scenarios where both fundamental values are equally violated	Which value appears more important in the particular situation and why?
Privacy versus safety of employees	Untested nanomaterials are produced in a factory and sensors are used to monitor release during production	From the perspective of the precautionary principle, safety appears more important in this case

Rule of thumb 4: (in medium or large scale EIAs) Negotiate conflicts of moral values between different parties, who constitute or represent stakeholders in the situation.

Identify the value conflict	Describe likely scenarios where the value conflict occurs	Identify the stakeholders	Let each stakeholder representative estimate the importance of each of the conflicting fundamental values (1 = minor; 2 = moderate; 3 =medium; 4= high; 5=extreme)	Organise dialogue and report any changes in perceived importance for each stakeholder representative
Security versus health	Dual use nanomaterials for essential medicine are produced in a factory	Factory owner	1 versus 4	
Security versus health	Dual use nanomaterials for essential medicine are produced in a factory	Employees	2 versus 4	
Security versus health	Dual use nanomaterials for essential medicine are produced in a factory	Patients	1 versus 5	
Security versus health	Dual use nanomaterials for essential medicine are produced in a factory	Local community	3 versus 3	
Security versus health	Dual use nanomaterials for essential medicine are produced in a factory	Government	5 versus 3	

Rule of thumb 5: Avoid the value conflict by reconfiguring the situation.

Identify the value conflict	Describe likely scenarios where the value conflict occurs	Describe technological options	Describe social or organisational options	Describe legal or regulatory options
Security versus health	Dual use nanomaterials for essential medicine are produced in a factory	Safe by design	Training to raise awareness of ethical issues among employees	Develop code of conduct

3.4.4. Present and discuss the ethical impact analysis with stakeholders

The draft results of the evaluation of identified ethical impacts are discussed with stakeholder representatives and the received comments and suggestions are included in the report of the EIA. In small EIAs, this consultation is held online. If deemed appropriate, the results or even the whole consultation can be made public. In any case, this discussion can make use of online tools included in D2.5. The final version of RiskGONE Database and Cloud Platform. The report on the evaluation of the ethical impacts should have the following table of contents:

Title	
Authors	
Abstract	
Introduction	
Method for evaluation	
Analysis of ethical values and principles	
Identified value conflicts and proposed ways of resolving them	
Outcome of discussion of the ethical impact analysis with stakeholders	
References and consulted persons	

3.5.   Guidelines for Proposing Remedial Actions Addressing Ethical Impacts

Planning remedial actions for the identified ethical impacts is part of the **Risk Management** phase in the Risk Governance process. It consists of four elements:

1. Collect recommendations from similar R&I projects
2. Formulate and implement design interventions
3. Formulate recommendations
   a. Societal
   b. Organisational
   c. Regulatory
   d. Policy
4. Document and present the remedial actions
   a. Design interventions: report
   b. Societal and organisational recommendations: report
   c. Regulatory recommendations: legal proposals
   d. Policy recommendations: green- or whitepapers.

3.5.1. Collect recommendations from similar ethical impact assessments

During the evaluation of the identified ethical impacts, an inventory has been made of reports and publications on ethical impacts of similar materials, technologies, or products. The relevant recommendations included in those reports and publications are analysed by the type of ethical impact in the table below.

Type of ethical impact	Type of remedial action
Broad social impacts due to R&I activities (e.g. changing economic paradigms)	Societal recommendations
Impacts due to malfunctioning of organisations (e.g. risks of conflicts of interest)	Organisational recommendations

3.5.2. Formulate recommendations

The EIA team formulates recommendations for different other actors and discusses these recommendations with the persons or organisations who should implement them. In small-scale EIAs, only societal and organisational recommendations are made.

3.5.2.1. Societal

Societal recommendations address identified conflicts between different stakeholder groups, including industry and civil society organisations. The following decision tree can support the formulation of societal recommendations.

Type of issue (drop down menu)	Specify the issue (text)	Involved stakeholders (drop down menu, several choices allowed)	Describe the value conflict	Draft preliminary recommendations of EIA team (bullet points)	Insert outcome of discussion of recommendations with stakeholders (text)	Formulate final recommendations (bullet points)
Societal values		Scientists				
Public trust		Industry				
Public concerns		Trade unions				
		NGOs (specify)				
		Media				
		Other (specify)				

3.5.2.2. Organisational

The EIA team addresses recommendations for organisational changes to public or private organisations involved in the manufacturing, selling, use, or waste processing of the nanomaterial and product under study. These recommendations are discussed with representatives of the addressed organisations. The following decision tree supports the formulation of organisational recommendations.

Name of the organisation (text)	Activity of organisation (drop down menu)	Draft preliminary recommended change in procedure to identify, respond to, address, manage, avoid, or minimize ethical issues (bullet points)	Insert outcome of discussion of recommendations with organisation (text)	Formulate final recommendations (bullet points)
	Manufacturing			

	Sales			
	Use			
	Waste processing			
	Other (specify)			

3.5.3. Document and present the remedial actions

The EIA team documents the recommended remedial actions in specific types of deliverables. For small scale EIAs, a report is prepared summarising the societal and organisational recommendations and explaining how and why these recommendations were made. In addition, brief explanations are added on how and why the recommendations were reached. Online templates can be used to fill in the reports.

3.5.3.1. Societal and organisational recommendations: report

The template for reporting on the societal and organisational recommendations is as follows.

Title	
Authors	
Date of preparation	
Abstract	
Summary of the societal and organisational recommendations	
Methodology	
Results of review of published recommendations	
Explanation of proposed recommendations	
References	
Consulted persons	
Annex: minutes of consultations	

3.6. Guidelines for Review and Audit of the EIA

The review and audit of the ethical impact assessment is part of the **Monitoring Feedback** phase in the Risk Governance process. The review and audit of the EIA focuses on whether the EIA is performed in compliance with its own stated objectives and whether its own milestones have been achieved as budgeted. Monitoring of the ethical impacts of the assessed project or technology is not covered.

3.6.1. At the start of the EIA

After the screening of Ethical Impacts, an external reviewer (who can also be a Risk Governance Council member who is not involved in the Ethical Impact Assessment) reviews the result of the screening and EIA plan. If the screening outcome indicates that no EIA is needed, this independent reviewer performs a review of this EIA screening to check if no significant ethical impacts are expected.

If an EIA is deemed necessary, the independent reviewer reviews and approves the small, medium, or large EIA plan after it is prepared and before the EIA process starts.

This review has three possible outcomes:

Outcome	Implications
The reviewer accepts the EIA plan	Selection of review criteria, scale, budget and team composition are approved.
The reviewer asks for amendments to the EIA plan	These could include: Additional ethical impacts that the project team did not include in their threshold analysis but that could reasonably have been expected; Additional requirements for budget team composition and/or scale.
The reviewer rejects the EIA plan	Rejection is possible in the following cases: When the threshold analysis calls for an EIA scale that does not fit the size of the project; When some ethical impacts are deemed too severe for the means available to the project team

3.6.2. During the EIA process

During the EIA process, the independent reviewer evaluates the conduct and documentation of the EIA process at regular intervals (determined before the start of the EIA). He or she also provides feedback and guidelines for improving the EIA process, while guarding milestones and Key Performance Indicators.

During the EIA, the reviewer is responsible for documenting the EIA process and should organize evaluation meetings, audit reports, and suggest review options.

Evaluation meetings	The reviewer should convene a meeting with the EIA team during which the EIA is evaluated, leading to feedback and recommendations for future EIA work.
Audit reports	The reviewer should provide the EIA team with audit reports, which state whether the agreed-upon milestones and/or deliverables have been met.
Review options	The reviewer should issue opinions about the continuation of the EIA. These opinions may be binding, for instance, in the case of a publicly funded R&I project.

3.6.3. At the end of the EIA process

At the end of the EIA process, the independent reviewer reviews the EIA process. The following activities are typically part of this final review and audit:

Review meeting	The reviewer convenes a final review meeting with the EIA team to evaluate the EIA and document recommendations for future EIAs.
Review document	The reviewer writes a final review document, to be sent to the relevant stakeholders.
Financial statement	The reviewer makes a financial statement, with the cost of the EIA, and a portfolio of publications
Audit meeting	The reviewer convenes a final audit meeting with the EIA team at which leftover follow-up actions are agreed. These need to be performed to meet the audit criteria.

3.6.4. Output: template for review and audit of EIA

The review and audit of the Ethical Impact Assessment results in a document. The preparation of this document can be computer supported by completing an online form which can be downloaded as pdf. Depending on the different steps in the review and audit stage, the reviewer should present the results in the following ways:

Start	The review and audit criteria are documented in the form of a contract that needs to be signed by both the reviewer and the EIA team.
During	Intermediate reviews and audits are presented as audit reports.
End	The review and audit at the end of the EIA process should be presented as follows: • Final EIA report drafted by the EIA team. • Final review document, drafted by the reviewer • Financial statement. • Portfolio of reports and publications related to the EIA.

4. Bonus: convert EIA screening tool in Risk-Benefit assessment tool

An objective of WP3 is to develop guidelines for risk-benefit assessment of nanomaterials and nanoproducts. To address this, the feasibility of using a decision tree to screening potential risks as well as benefits is explored, by adapting the existing decision tree for screening Ethical Impacts to prompt the user to give estimates of benefits as well as risks. This screening phase is part of the **pre-assessment** step of the overall Risk Governance process. The guidance is programmed as an explanation box next to the question in (RiskGONE, 2020b).[35]

To what extent will the nanomaterials and products give rise to the following issues?	No	1	2	3	4	5	Comment on your answer / specify briefly any potential risks and benefits, including information on public perceptions:
Are the nanomaterials and nanoproducts either used in a health-care context or are negative or positive impacts on public health and safety expected?[36] If not: tick No. If yes, estimate the magnitude of expected ethical health-related risks as well as benefits, between minor (1) and large(5).							
Does the application of nanomaterials involve the collection, processing, storing and/or transfer of personal data?[37] If not: tick No. If yes, estimate the magnitude of expected personal data protection risks as well as benefits, between minor (1) and large (5).							
Could the value chain and application of nanomaterial have a negative or positive impact on							

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[35] http://enaloscloud.novamechanics.com/riskgone/riskbenefit/

[36] Healthcare is defined in a broad sense, including pharmaceuticals, medical devices, dentistry, cosmeceuticals and other products used in hospitals, at home, and in other locations for improving the health and well-being of people.

[37] The privacy and data protection issues are caused by the product in which the nanomaterials are used. Examples include sensors and monitoring devices, data storage devices etc.

the rights and liberties of individuals and groups?[38] If not: tick No. If yes, estimate the strength of expected impacts on human rights and liberties, between minor (1) and large (5).						
Could the value chain and application of nanomaterial have a negative or positive impact in terms of social justice and equality?[39] If not: tick No. If yes, estimate the strength of expected impacts on social justice and equality, between minor (1) and large (5).						
Could the value chain and application of nanomaterial have a negative or positive impact on the well-being of individuals or groups, and/or on the common good, including cultural heritage?[40] If not: tick No. If yes, estimate the strength of expected impacts, between minor (1) and large (5).						
Could the value chain and application of nanomaterial have a negative or positive impact on the environment, animals and/or plants through the use of genetically modified organisms (GMOs) or any biological, chemical, radiological, nuclear or explosive elements used, as well as any effects in terms of						

[38] Consider effects on freedom, autonomy, authenticity, identity, privacy, human dignity, human bodily integrity, intellectual property, among others.

[39] Consider effects on the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks and hazards, and have special consideration for effects on vulnerable, disadvantaged, and under-represented individuals, groups, or communities in society, including future generations and individuals, groups and communities in low income and lower-middle income countries.

[40] Consider effects on the well-being and interests of individuals and groups in society, including the quality of work, and effects on social institutions and structures, democracy and important aspects of culture and cultural diversity. Cultural heritage includes physical artefacts and intangible attributes of a group or society, such as sites, monuments, artefacts, texts, archives, remains and information about the past.

human encroachment on natural habitats and environmental policy? If not: tick No. If yes, estimate the strength of expected impacts, between minor (1) and large (5).						
Could the value chain or application of nanomaterial have negative or positive impacts on the 17 Sustainable Development Goals?[41] If not: tick No. If yes, estimate the strength of expected impacts, between minor (1) and large (5), and specify which goals are concerned.						
Could the nanomaterial or its application have significant military purposes (dual use)?[42] If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5).						
Could the nanomaterial or nano-enabled product become subject to misuse?[43] If not: tick No. If yes, estimate the severity of expected impacts, between minor (1) and severe (5).						

Table 5.1: checklist for risk-benefit assessment (adapted from CWA17145-2:2017 (E)).

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[41] Check the goals via this link: https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals

[42] Consider, amongst others, any effects in terms of the development of weapons of mass destruction, military surveillance systems and autonomous weapons systems.

[43] Consider, amongst others, whether [information about] harmful biological, chemical, radiological, nuclear, or explosive materials, and/or the means of their delivery, can easily [or accidentally] be misused and whether it may easily fall into the hands of terrorists or criminals, and whether it may be abused by governmental and other institutional actors in non-military contexts.

4.1. Output of risk-benefit screening tool

The output of the tool is a table representing the risks as well as benefits for each of the listed issues.

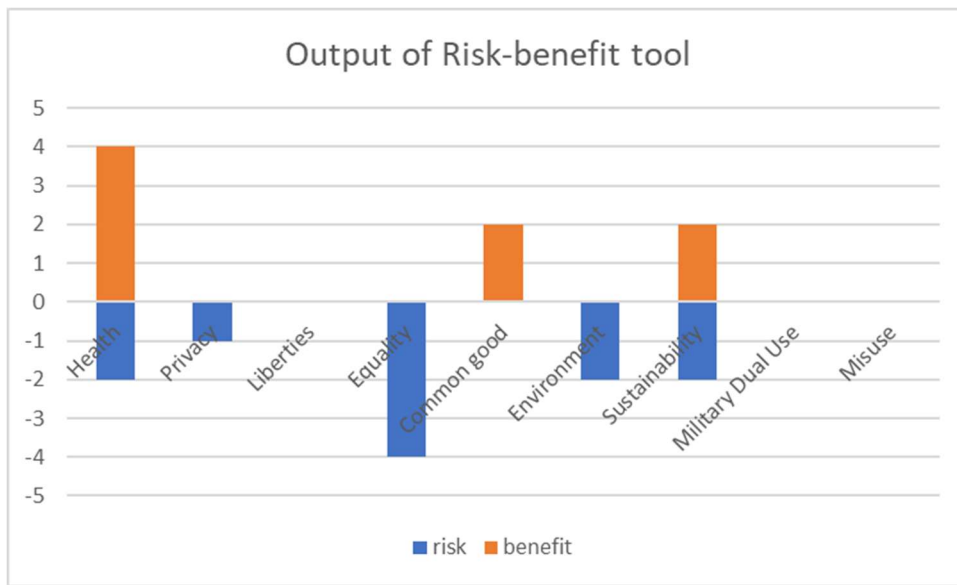| Issue	risk	benefit
Health	-2	4
Privacy	-1	0
Liberties	0	0
Equality	-4	0
Common good	0	2
Environment	-2	0
Sustainability	-2	2
Military Dual Use	0	0
Misuse	0	0

Figure 5.1 output of risk-benefit tool

5. Deviations from Description of Action – impact/how you cope with them

The work on task 3.5 has progressed according to plan. No deviations have occurred.

6. Conclusions

To support the work of the Nano Risk Governance Council under development in RiskGONE, GOV4NANO and NANORIGO, a Risk Governance Framework is constructed including a number of online tools and guidelines. This report explains how guidelines for assessing regulatory compliance and ethical impacts of nanomaterials and nanoenabled products were developed and discussed with peers and stakeholders in task 3.5 during the first two years of the RiskGONE project.

Subsequently, the guidelines for assessing compliance with existing legislation were included, followed by a six-step procedure for performing an Ethical Impact Assessment of nanomaterials and nanoenabled products. Finally, a first draft tool for supporting ethical risk-benefit assessment of the nanomaterials and nanoenabled products is added as a bonus. This can inspire further work on developing risk-benefit assessment in other tasks in WP3.

7. References

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RiskGONE (2020a) threshold analysis beta version:
http://enaloscloud.novamechanics.com/riskgone/thresholdanalysis/

RiskGONE (2020b) risk-benefit analysis beta version:
http://enaloscloud.novamechanics.com/riskgone/riskbenefit/

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