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Adapting ethical impact assessment methodology to needs of innovative companies

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Impact Alliance Live

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Adapting EIA to needs of innovators



About me:

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- Consultant in ethics and responsible innovation for sustainable development
- Physics graduate, PhD in Philosophy
- Thesis topic: ethics & international governance of nanotechnology (Radboud University, 2011)

Info: <https://ethicschool.nl/en-gb/home>



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Aims of this session:



- 1) Demonstrate the Ethical Impact Assessment methodology based on CEN CWA 17145-2:2017
 - Case: H2 storage in salt caverns in Zuidwending
 - Highlights of the EIA of this case are presented to illustrate how the methodology works
- 2) Solicit suggestions for matching needs of research organizations developing innovations in ethically sensitive domains (e.g., health, food, sustainability)



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**CEN
WORKSHOP
AGREEMENT**

CWA 17145-2

June 2017

ICS 03.100.02; 03.100.40

English version

Ethics assessment for research and innovation - Part 2:
Ethical impact assessment framework

What is an Ethical Impact Assessment?

A procedural ethical analysis methodology to

- Identify and evaluate ethical issues and value conflicts
- Co-create recommendations to remediate expected ethical concerns and promote expected benefits
- In dialogue with stakeholders

Fitting in the context of H2020 / Horizon Europe
funded projects and EU requirements for
Responsible Research and Innovation

The methodology is based on the CEN Workshop Agreement CWA 17145-2-2017 developed in the SATORI project (<https://satoriproject.eu/>):
https://www.cencenelec.eu/media/CEN-CENELEC/CWAs/RI/cwa17145-2_2017.pdf



Ethical Impact Assessment methodology

– based on CEN Workshop Agreement CWA17145-2-2017 (E)- developed in SATORI project:

- Screening ethical impacts
- Create an Ethical Impact Assessment plan
- Identification of Ethical Impacts
- Evaluation of found ethical impacts and conflicts of values
- Recommendations and dialogue with stakeholders
- Audit by external ethicist

Online tools developed in RiskGONE guide you through the procedure:

<https://www.enalosccloud.novamechanics.com/riskgone/EIA/>

More info: <https://open-research-europe.ec.europa.eu/articles/3-170/v3>

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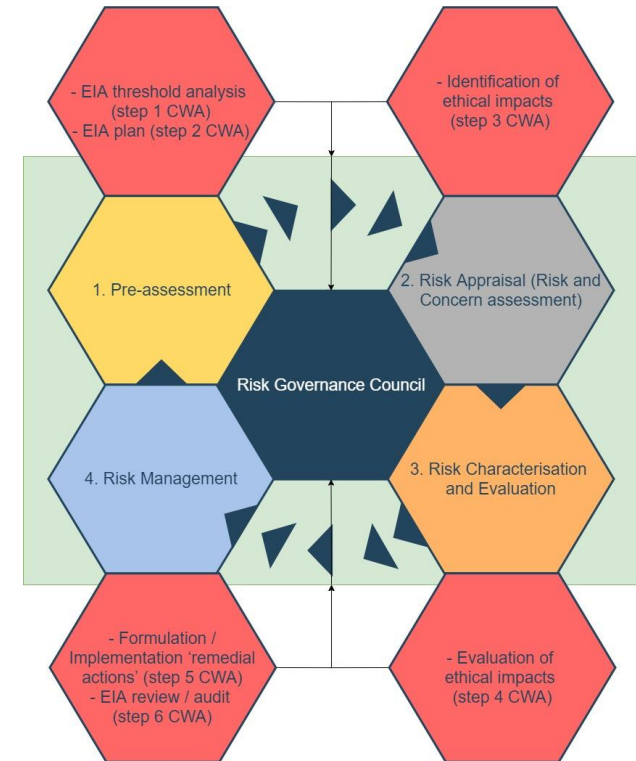


Figure 2 in Malsch, I., Isigonis, P., Dusinska, M., Bouman E. A., Embedding Ethical Impact Assessment in Nanosafety Decision Support. Small 2020, 2002901, <https://doi.org/10.1002/sml.202002901>



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Step 1: Screening ethical issues with checklist of 9 ethical categories:

<https://www.enalosccloud.novamechanics.com/riskgone/EIA/thresholdanalysis/index.zul>

RiskGONE Threshold Analysis

Niet beveiligd | enalosccloud.novamechanics.com/riskgone/thresholdanalysis/

Apps Bookmarks Web Slice-galerie Geïmporteerd uit In... Black Google™ bla... nmpdela campings SUN » Andere bookmarks Leeslijst

RISK GONE Screening potential ethical impacts and their severity - 'Threshold analysis'

Screening ethical issues

Via this screen, you can access a decision tree for screening potential ethical issues related to the manufacturing, transport or use of a product incorporating nanomaterials. This screening tool should be used during the pre-assessment step of the Risk Governance process. You will be asked to assess the extent to which your product incorporating nanomaterials gives rise to nine categories of ethical issues. At this stage, you should just make your best estimate of the severity of each issue. In addition, you should include a specification on each identified potential ethical issue in the comment box.

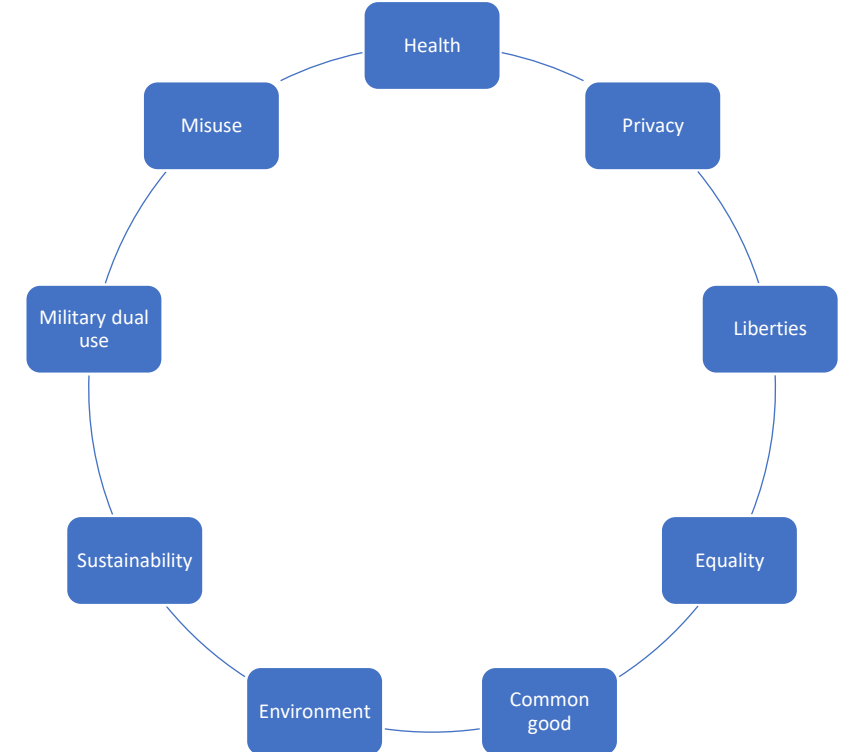
Main question: To what extent will the nanomaterials and products give rise to the following issues?

No = not applicable, 1 = minor, 2 = moderate, 3 = medium, 4 = high, 5 = severe

#	Question	Answer	Severity - (scale 1 (minor) to 5 (severe))	Guidance
1	Are the nanomaterials and nanoproducts either used in a health-care context or are ethically sensitive impacts on public health and safety expected?	No		Healthcare is defined in a broad sense, including pharmaceuticals, medical devices, dentistry, cosmetics and other products used in hospitals, at home, and in other locations for improving the health and well-being of people. Ethically sensitive impacts on health are defined as infringements of human rights to life and well-being guaranteed in international human rights law, including the Universal Declaration on Human Rights, International Covenant on Economic, Social and Cultural Rights, Council of Europe Convention for the protection of human rights and fundamental freedoms, Council of Europe Convention on human rights and biomedicine (Bioethics or Oviedo Convention, EU Charter of Fundamental Rights, UNESCO Declaration on the human genome and human rights and UNESCO Declaration on bioethics and human rights.
2	Does the application of nanomaterials involve the collection, processing, storing and/or transfer of personal data?	No		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. Consider whether sensitive personal data are collected relating to health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.
3	Could the value chain and application of nanomaterial have a negative impact on the rights and liberties of individuals and groups?	No		Consider effects on freedom, autonomy, authenticity, identity, privacy, human dignity, human bodily integrity, intellectual property, among others. When in doubt, check international human rights law, including the Universal Declaration on Human Rights, International Covenant on Civil and Political Rights, Council of Europe Convention for the protection of human rights and fundamental freedoms, EU Charter of Fundamental Rights.
4	Could the value chain and application of nanomaterial have a negative impact in terms of social justice and equality?	No		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

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Screening ethical issues - calibration of the scale:

NB: this calibrated scale is only relevant for deciding on whether a full-scale Ethical Impact Assessment is needed and how time and resources-consuming this should be

#	Severity	Calibration
1	Minor	Very unlikely and/or very low potential severity – examples: the frequency of this ethical impact is less than once in 100 years, or only few people are likely to be affected temporarily and reversibly, or the new technology does not significantly worsen ethical impacts caused by existing alternatives
2	Mode- rate	Unlikely and/or mild potential severity - examples: this ethical impact may happen a few times in a lifetime, or few people are likely to be affected mildly for a long time or irreversibly, or many people are likely to be affected temporarily and reversibly, or the new technology noticeably worsens ethical impacts caused by existing alternatives
3	Me- dium	Substantially likely and/or substantial potential severity – examples: this ethical impact is expected to occur several times in a lifetime, or at least a few people are likely to be affected substantially for a long time or irreversibly, or the new technology substantially worsens ethical impacts caused by existing alternatives
4	High	Likely and / or serious potential severity: this ethical impact will occur frequently, or many people are likely to be affected seriously for a long time or irreversibly, or the new technology seriously worsens ethical impacts caused by existing alternatives
5	Severe	Very likely and/or very high potential severity – examples: the serious ethical impact occurs permanently, or many people are affected severely and irreversibly, or fundamental human rights are violated, or largescale societal disruption is expected



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Ethical risk-benefit assessment

RISK GONE Screening potential risks and benefits

Screening ethical issues

Via this screen, you can access a decision tree for screening potential ethical issues risks and benefits related to the manufacturing, transport or use of a product incorporating nanomaterials. This screening tool should be used during the pre-assessment step of the Risk Governance process. You will be asked to assess the extent to which your product incorporating nanomaterials gives rise to nine categories of risks or benefits ethical issues. At this stage, you should just make your best estimate of the likelihood and magnitude/severity of each issue. In addition, you should include a specification on each identified potential risk or benefit in the comment box. Access the checklist here.

Main question: To what extent will the nanomaterials and products give rise to the following risks or benefits?

No = not applicable, 1 = minor; 2 = moderate; 3 = medium; 4 = high; 5 = severe

#	Question	Answer	Guidance
1	Are the nanomaterials and nanoproducts either used in a health-care context or are negative or positive impacts on public health and safety expected?	No	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. Relevant impacts on health include strengthening or infringing on human rights to life and well-being guaranteed in international human rights law, including the Universal Declaration on Human Rights, International Covenant on Economic, Social and Cultural Rights, Council of Europe Convention for the protection of human rights and fundamental freedoms, Council of Europe: Convention on human rights and biomedicine (Bioethics or Oviedo Convention, EU Charter of Fundamental Rights, UNESCO Declaration on the human genome and human rights and UNESCO Declaration on bioethics and human rights.
2	Does the application of nanomaterials involve or affect the	No	The privacy and data protection risks and benefits are caused by

The checklist of 9 ethical categories can also be used to set a baseline for **stakeholder dialogue** on relevant issues and differences in perception on the importance of each.

In RiskGONE, we added an extra risk-benefit assessment tool:

<https://enaloscloud.novamechanics.com/riskgone/EIA/riskbenefit/index.zul>

Exercise: trying the risk-benefit assessment tool



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Exercise:

- a) Individual: screen the case of H2 storage in salt caverns near Zuidwending with your personal estimates of relevant ethical categories (5 minutes)
- b) Group discussion on similarities and differences in the responses (10 minutes)



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EIA of H2 storage in salt caverns



- **Introduction to the case of H2 storage in salt caverns - 1:**
- EU ambition: Europe will become the first climate-neutral continent by 2050
- The development of a hydrogen economy with green hydrogen is part of the solution
- Large-scale storage of hydrogen is needed between production with renewable energy sources and use in industry and households
- Salt caverns under land or sea offer promising storage options
- The Netherlands' government Hydrogen storage targets (2022-2025: 1 salt cavern), 2025-2030: 3-4 salt caverns, after 2030: 10? (National Hydrogen Program. Roadmap Hydrogen. November 2022)



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EIA of H2 storage in salt caverns



- **Introduction to the case – 2:**
- The existing natural gas infrastructure/future hydrogen network is located at a relatively short distance from the location Zuidwending in the province of Groningen, which means that the length of the pipeline to be constructed can be limited.
- The salt structure and quality are known. That is why EnergyStock realized the natural gas buffer in Zuidwending around 2010. The local residents are familiar with salt extraction and with EnergyStock.
- **Alternative locations for salt caverns are too far away: Haaksbergen and offshore under the North Sea.**
- Source: Established NRD Zuidwending, p 14 (RVO).



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Exercise:

- a) Individual: screen the case of H2 storage in salt caverns near Zuidwending with your personal estimates of relevant ethical categories (5 minutes)
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Step 2: Drafting an EIA-plan with this tool:

<https://www.enalosccloud.novamechanics.com/riskgone/EIA/eiaplan/index.zul>

RiskGONE EIA Main Page x RiskGONE EIA Plan x +

Niet beveiligd | enalosccloud.novamechanics.com/riskgone/eiaplan/index.zul

Apps Bookmarks Web Slice-galerie Geïmporteerde uit In... Black Google™ bla... nmpdela campings SUN » | Andere bookmarks Leeslijst

Drafting EIA plan / Planning

Drafting an Ethical Impact Assessment Plan

The screening of the Ethical Impact, performed in the preceding step, results in one of four possible outcomes: no EIA or a small, medium, or large EIA. An external ethicist should check the self-assessment report if no EIA is deemed necessary. If a medium or large EIA is needed, the present tool only supports the preparation of an EIA plan. After this plan is checked by an external ethicist, professional ethicists should be engaged to perform the EIA. If a small EIA is needed and the EIA plan is checked by an external ethicist, the present tool is designed to guide the user through the procedure.

Screening outcome	Next Step
Small Scale EIA	Review and approval of EIA plan by independent body

Aspect	Content
Required budget (1-10% of research budget for the risk governance assessment of the nanomaterial and its applications)	90% personnel, 10% other
Team composition	Leader: part time research assistant Optional members: should have relevant expertise to the identified ethical issues
Formulating review criteria	Yes
Consult with stakeholders before starting the EIA 1	No
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 exploit issues through ethical checklists, and empirical analysis through online consultations with experts and stakeholders; document the 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 EIAs to on-site events in large scale EIAs.	Desk research: literature research of existing evaluation of ethical impacts in related projects. Use 5 rules of thumb2 to identify and resolve value conflicts. Present and discuss the ethical impact evaluation online 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
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.

Guidance text

Title of EIA:

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.]

Title

Abstract

Budget

Team composition

Review criteria

Identification of ethical impacts

Evaluation of ethical impacts

Remediation

Review of EIA



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Step 3: Identify Ethical impacts:

<https://www.enaloscloud.novamechanics.com/riskgone/EIA/idethimpact/index.zul>

The online tools support desk research to identify more detailed ethical issues:

- ✓ Search online (open access) ethics literature discussing comparable cases
- ✓ Analyse this literature by a more detailed checklist, estimate severity (1-5) and timescale (short-long)
- ✓ Discuss the results of the analysis with stakeholders or experts

Finalise the list of relevant literature analysing comparable cases to the nanomaterials and products under assessment.

References

What is known on the ethical issues raised by the nanomaterials and products under assessment?	Sub-criterion	Description of the issue and severity (short, medium, long)	EIA team estimate of the severity of the issue (not at all (0) to severe (5))	Timing (short, medium, long)	Reference to the source	Stakeholder estimate of the severity of the issue (not at all (0) to severe (5))	Stakeholder reason for their estimate
Health-related	Applied in a healthcare context						



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EIA of H2 storage in salt caverns

Identification of Ethical Impacts. What is known about the expected ethical impacts? – **example**

<https://www.enaloscloud.novamechanics.com/riskgone/EIA/idethimpact/index.zul>

Criterion and Sub-criterion	Description	Risk estimate (0-5)	Time scale	Reference
Health – Health and Safety	The proposed storage of hydrogen in salt caverns at Zuidwending in Groningen may pose risks to the safety and health of local residents . These risks are expected to be comparable to those of the current storage of natural gas, but the risks are being investigated.	1	medium	KEM-28 – FINAL REPORT. RISK ASSESSMENT OF HYDROGEN STORAGE IN A CONGLOMERATE OF SALT CAVERNS IN THE NETHERLANDS. 3 april 2024
Social justice and equality – risk-benefit division	The socio-economic benefits of storing hydrogen in the salt caverns benefit companies, the Dutch state and Dutch citizens . The risks to safety, health and the environment are mainly borne by local residents , comparable to the effects of natural gas extraction and storage in Groningen.	2	medium	E.g.: Vinkenvleugel, S. Twee keer Drents 'nee' tegen kernaafval in zoutkoepels. RTV Drenthe 18 October 2024



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Step 4: The online tools support desk research by an ethicist to evaluate the identified ethical issues:

<https://www.enalosccloud.novamechanics.com/riskgone/EIA/evethimpact/index.zul>



- Search additional online (open access) ethics literature
- Apply ethical theories to the analysis of the identified ethical issues
- Assess the degree to which the ethical value or principle is likely to be violated or benefited in the expected ethical impact
- Check whether there are value conflicts between the relevant ethical values or principles and resolve these conflicts with up to 5 rules of thumb
- Propose technological, organisational or regulatory solutions



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Evaluation of found ethical impacts and conflicts of values – example 1:

Principle	Social justice: sharing of opportunities and risks
Ethical theory	Equity: procedural, distributive, recognition, energy justice
Meaning in this case	<p>In decision-making about large-scale interventions in the living environment, such as the storage of hydrogen in salt caverns in the Dutch soil, justice traditionally takes the form of procedural justice. Laws and regulations lay down which organizations and citizens are allowed to give their opinion on plans that are available for inspection at what time, and how this should be dealt with by the government and the companies involved. These procedures have recently changed due to the introduction of the new Environment and Planning Act: https://www.rijksoverheid.nl/onderwerpen/omgevingswet . In addition to changing interpretations of procedural justice theory, the concept of distributive justice is also becoming more important. Distributive justice is important in decision-making about hydrogen storage in salt caverns, because the choice fell on a location in the province of Groningen, which has already been disproportionately confronted with the risks of natural gas extraction in the past, while the benefits benefited the economy, companies and Dutch society as a whole. It is therefore important to explicitly take distributive justice into account when deciding on the storage of hydrogen in salt caverns or other forms of storage.</p> <p>Another form of justice, recognition, is also sometimes mentioned as relevant to decision-making on the energy transition (Correlje in Weijen et al).</p>



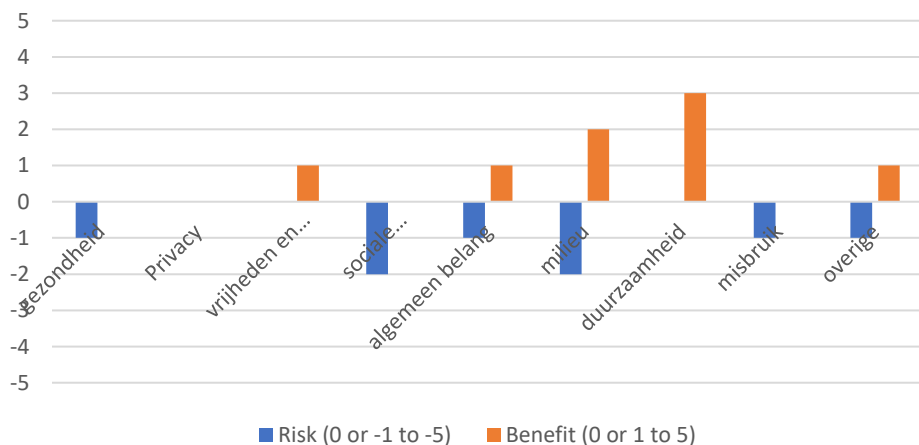
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Evaluation of ethical impacts and value conflicts – balance between opportunities and risks:

Use of risk-benefit analysis tool: <https://enaloscloud.novamechanics.com/riskgone/EIA/riskbenefit/index.zul>

Screening ethical risks and benefits of H2 storage in salt caverns



Risk	Ethical principle	Benefit
1	Public health and safety of residents	0
0	Civil rights and freedoms: consultations and public engagement	1
2	Social justice: division of benefits and risks	0
1	Common good: Risks to the environment, including fear of damage to monuments – but appropriate measures are provided	1
2	Benefits and risks to the environment are possible	2
0	Sustainability: storage in salt caverns of green hydrogen is part of the energy transition, intended to support the circular economy	3
1	Potential for abuse by malicious parties	0
1	Unknown Opportunities and Risks of Using AI and Innovations	1



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Evaluation of found ethical impacts and conflicts of values – example 2:

Balance social justice risk with opportunities for sustainability and climate change mitigation

5 Rules of thumb

Rule of thumb 1: Which of the conflicting values is fundamental? Give priority to that.

Both values are fundamental

Rule of thumb 2: Estimate the severity of the damage and choose an action that least threatens a fundamental asset. The current approach implements procedural justice, which does not address the call for distributive justice and recognition.

Rule of thumb 3: Project moral values in situations when two fundamental values seem equally threatened and determine which value is the most important in that situation.

Distributive justice and recognition are neither more nor less important than sustainable development.





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Evaluation of found ethical impacts and conflicts of values – example 2:

Balance social justice risk with opportunities for sustainability and climate change mitigation

Rule of thumb 4: Negotiate value conflicts between stakeholder representatives

The current negotiations are a form of **procedural** justice: Residents and other stakeholders already have a say and are regularly informed about the project

Questions about **distributive justice and recognition** do not fit well into this - as is evident from the question about recognizing and distributive justice and answer referring to procedural justice from the Memorandum of Response draft

NRD – Energy buffer Zuidwending: project Hystock hydrogen storage (see next sheet):

<https://www.rvo.nl/onderwerpen/bureau-energieprojecten/lopende-projecten/zuidwending>



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Question	Answer
<p>Residents of the province of Groningen have suffered a lot from gas extraction. Gas extraction has yielded billions to the state treasury and some multinationals but has left many residents with material and immaterial damage and misery. Make sure that this HyStock project does not lead to the same drama in miniature for the residents of Ommelandervijk and Zuidwending. It should not be the case that this relatively small group of residents of Groningen / the Netherlands will be the victims of a large project that will soon earn many millions and probably benefit many people/companies at home and abroad. You can therefore see this view as a pre-announcement of intended objections to any permit procedure that has to be conducted in the context of the HyStock project and related projects.</p>	<p>Everyone is free to make use of the objection and appeal procedures in accordance with the laws and regulations. EnergyStock is designing the project within the planning and legal frameworks that exist, and would like to do this in good harmony with local residents and stakeholders. EnergyStock is convinced that cooperation with local residents on the substantive characteristics of this project will have a positive effect on the end result.</p>

Recognition

Procedural justice

Distributive
justice



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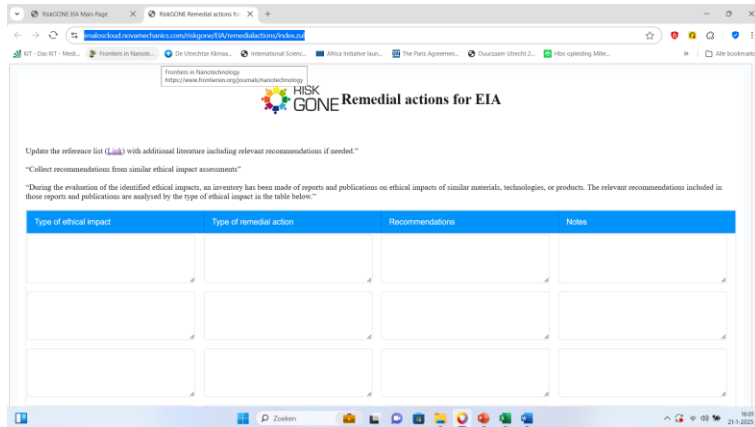
EIA of H2 storage in salt caverns

- **Evaluation of found ethical impacts and conflicts of values – example 2:**
- Balance social justice risk with opportunities for sustainability and climate change mitigation
- **Rule of thumb 5: Avoid the conflict of values by changing the situation**
- Option 1: broaden the dialogue with local residents and stakeholders and co-create acceptable solutions for distributive justice and recognition– also hire ethicists and social scientists to guide this dialogue
- Option 2: broaden the number of options for locations of salt caverns and, together with the stakeholders, weigh up Zuidwending, Haaksbergen and offshore storage. Is there really no other choice to be made? What are the pros and cons of the different options?



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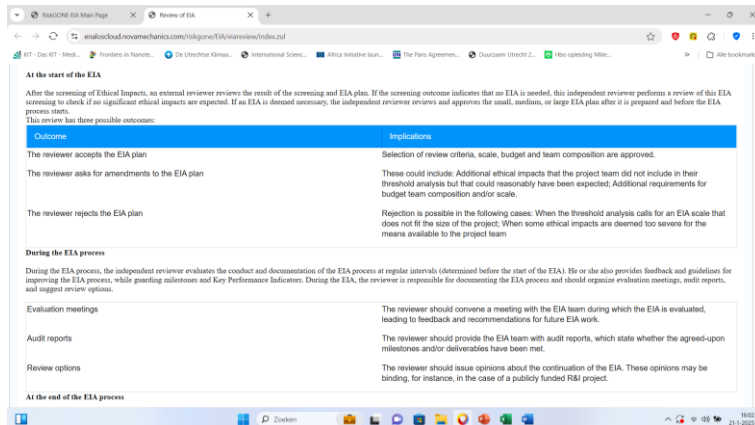
Step 5: Draft and implement solutions in dialogue with stakeholders:

<https://www.enaloscloud.novamechanics.com/riskgone/EIA/remedialactions/index.zul>

- ✓ The online tools support the drafting of recommendations for remediating the identified ethical issues:
- ✓ Search online (open access) ethics literature including recommendations for similar cases and list these recommendations
- ✓ Draft societal and organisational recommendations
- ✓ Discuss the recommendations with stakeholders or experts



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Step 6 - Audit by external ethicist:

- At the start: Review EIA plan
- Mid term: review interim reports and discuss possible changes with the EIA team
- Finally: audit the quality of the EIA by original review criteria



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Discussion



- To recapitulate: EIA aims to:
 - ✓ Identify and evaluate ethical issues and value conflicts
 - ✓ Co-create recommendations to remediate expected ethical concerns and promote expected benefits
 - ✓ In dialogue with stakeholders
- Would you consider using this EIA methodology in your work? If so, what for?
- Which adaptations could make the methodology more useful for you?



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References:

CEN Workshop Agreement CWA 17145-2-2017 developed in the SATORI project (<https://satoriproject.eu/>):

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