



Screening Nano-Ethical Issues

Ineke Malsch, Panagiotis Isigonis, Evert Bouman, Antreas Afantitis, Georgia Melagraki, Iseult Lynch, Mihaela Roxana Cimpan, Maria Dusinska



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

NanoSafe 2020
Online, 16-23 11 2020

Nano-Ethics - Intro



Aims of this presentation:

- Highlight how ethics may be addressed by the Risk Governance Council for Nanomaterials established by RiskGONE, Gov4Nano and NANORIGO
- Demonstrating the use of the screening tool for ethical impacts of nanomaterials developed in RiskGONE



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

Ineke MALSCH
Director, Malsch TechnoValuation
NanoSafe 2020 - Online, 16-23 11 2020

Nano-Ethics – Risk Governance Framework

<http://enaloscloud.novamechanics.com/riskgone/thresholdanalysis>



Incorporating ethics in the Nano Risk Governance Framework – the ethical impact assessment screening tool

RiskGONE Threshold Analysis

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

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, cosmeceuticals 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 fundamental freedoms (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



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

Ineke MALSCH
 Director, Malsch TechnoValuation
 NanoSafe 2020 - Online, 16-23 11 2020

Nano-Ethics – Risk Governance Framework

<http://enaloscloud.novamechanics.com/riskgone/riskbenefit/>



Incorporating ethics in the Nano Risk Governance Framework – the ethical risk-benefit assessment tool

A screenshot of a web browser displaying the RiskGONE application. The browser address bar shows the URL: enaloscloud.novamechanics.com/riskgone/riskbenefit/. The page title is "RiskGONE - Screening potential risks and benefits". The main content area has a heading "Screening ethical issues" and a sub-heading "Screening potential risks and benefits". Below this, there is a main question: "To what extent will the nanomaterials and products give rise to the following risks or benefits?". A legend indicates the severity levels: 0 = not applicable, 1 = minor, 2 = moderate, 3 = medium, 4 = high, 5 = severe. A table with 5 rows and 4 columns is shown. The columns are "#", "Question", "Answer", and "Guidance". The "Answer" column contains dropdown menus, all currently set to "No". The "Guidance" column contains detailed text for each question.

#	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 collection, processing, storing and/or transfer of personal data?	No	The privacy and data protection risks and benefits 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 or positive 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 or positive 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 communities in society, including future generations and individuals, groups and communities in low income and lower-middle income countries.
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?	No	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.



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

Ineke MALSCH
Director, Malsch TechnoValuation
NanoSafe 2020 - Online, 16-23 11 2020

Nano-Ethics – Risk Governance Framework

<http://enaloscloud.novamechanics.com/riskgone/thresholdanalysis>

And <http://enaloscloud.novamechanics.com/riskgone/riskbenefit/>



Demonstrating the EIA-screening tool on a case study of nanopharmacy (Timmermans et al, 2011: <https://link.springer.com/article/10.1007/s11569-011-0135-x>)

Issue:	Health	Privacy	Liberties	Equality	Common good	Environment	Sustainability	Military dual use	Misuse
Risk	Yes	Yes	No	Yes	No	Yes	Yes	No	No
Severity	2	1	0	4	0	2	2	0	0

Five ethical risks are identified, including one high, which requires a **large scale EIA**.

Issue:	Health	Privacy	Liberties	Equality	Common good	Environment	Sustainability	Military dual use	Misuse
Benefit	Yes	No	No	No	Yes	No	Yes	No	No
Strength	4	0	0	0	2	0	2	0	0



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

Ineke MALSCH
 Director, Malsch TechnoValuation
 NanoSafe 2020 - Online, 16-23 11 2020

Nano-Ethics – Risk Governance Framework

<http://enaloscloud.novamechanics.com/riskgone/thresholdanalysis>

And <http://enaloscloud.novamechanics.com/riskgone/riskbenefit/>



Demonstrating the EIA screening tool on a case study of nanovaccines in fish farming (Myhr & Myskja, 2011): <https://link.springer.com/article/10.1007/s11569-011-0112-4>

Issue:	Health	Privacy	Liberties	Equality	Common good	Environment	Sustainability	Military dual use	Misuse
Risk	Yes	No	No	No	No	Yes	Yes	No	No
Severity	2	0	0	0	0	3	3	0	0

Three ethical risks are identified, including two medium. This results in a **medium scale EIA**.

Issue:	Health	Privacy	Liberties	Equality	Common good	Environment	Sustainability	Military dual use	Misuse
Benefit	Yes	No	No	No	No	No	Yes	No	No
Strength	3	0	0	0	0	0	3	0	0



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

Ineke MALSCH
 Director, Malsch TechnoValuation
 NanoSafe 2020 - Online, 16-23 11 2020

Nano-Ethics – Risk Governance Framework

<http://enaloscloud.novamechanics.com/riskgone/thresholdanalysis>

And <http://enaloscloud.novamechanics.com/riskgone/riskbenefit/>



Demonstrating the EIA screening tools on a case study of nanoTiO₂ in sunscreens (Jacobs et al, 2010): <https://link.springer.com/article/10.1007/s11569-010-0090-y>

Issue:	Health	Privacy	Liberties	Equality	Common good	Environment	Sustainability	Military dual use	Misuse
Risk	Yes	No	Yes	No	No	Yes	Yes	No	No
Severity	1	0	1	0	0	2	2	0	0

Four negative ethical issues have been identified, including two moderate. This results in a **small scale EIA**.

Issue:	Health	Privacy	Liberties	Equality	Common good	Environment	Sustainability	Military dual use	Misuse
Benefit	Yes	No	No	No	No	No	Yes	No	No
Strength	3	0	0	0	0	0	3	0	0



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.

Ineke MALSCH
 Director, Malsch TechnoValuation
 NanoSafe 2020 - Online, 16-23 11 2020



RISK GONE

THANK YOU!

Ineke Malsch

Malsch TechnoValuation

malschtechnovaluation@xs4all.nl

www.riskgone.eu | riskgone@nilu.no



This project has received funding from the European Union's Horizon 2020 programme: grant agreement 814425.