A Common Framework for Ethical Impact Assessment

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Annex 1

A reasoned proposal for a set of shared ethical values, principles and approaches for ethics assessment in the European context

Deliverable D4.1

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1.1 EXECUTIVE SUMMARY

1.1.1 Context and purpose of this report

This report presents a comprehensive methodology for conducting an ethical impact assessment (EIA) in research and innovation (R&I) projects. Because of the increasing potential of R&I outcomes such a novel technologies to impact people's lives and society as a whole, there is an increasing need for not only assessing the ethics of the research procedure (as is done in conventional research ethics) but also for anticipating, determining, evaluating and, if possible, overcoming ethical impacts of research outcomes. Incorporating a procedure called ethical impact assessment in the R&I process can assist in doing so.

Thus far, no harmonised framework for conducting EIA has in practice been agreed upon or implemented. Different academic approaches for EIA exist (see Annex A) and for conducting foresight studies which are crucial elements of any EIA (see Annex B). Also, ethics assessment is increasingly becoming a requirement for obtaining funding for an R&I project. The lack of having a structured and harmonised approach in conducting EIAs makes it harder to assess the effectiveness and quality of the current EIAs.

The purpose of this document is to propose a structured methodology for conducting an EIA, which reflects both the existing literature and the R&I practice, tailoring it to the way R&I projects are organised. The methodology is both structured, by laying down clear steps and criteria and dynamic, by providing options for structuring EIAs for different scales of R&I projects and for different contexts of these projects (e.g. both for publicly funded and privately funded projects). Eventually, this document can be used by the following organisations in the following ways:

- For governance bodies to set up new regulations with regards to ethics assessment in R&I
- For research funding organisations to set up new procedures for conducting EIAs in the projects they fund
- For local research organisations and companies for setting up internal procedures for conducting an EIA in the R&I projects they organise

1.1.2 Outline of the report

The report comprises two parts: the main report in which the methodology for EIA is presented in a detailed manner and the annexes, which include overviews of the academic literature on EIAs and foresight studies.

The first part of the report deals with the EIA methodology in six steps that represent the different stages of the EIA: (i) the threshold analysis, (ii) the preparation of the EIA plan (iii) the ethical impact identification stage, (iv) the ethical impact evaluation stage, (v) the remedial actions stage and (vi) the review and audit stage. For each of these stages, a comprehensive list of procedural steps, a list of the involved stakeholders and recommendations for implementing the stages are provided.

The annexes of the report deal with the context in which the proposed EIA methodology is embedded, by presenting academic literature on EIA methodologies and foresight studies. It discusses and compares different established methods for EIA and foresight studies are presented, discussed and compared.

1.2 DEFINITIONS

Applied ethics:
Applied ethics is a branch of philosophy that examines practical cases or particular settings in public or private life that require moral deliberation. It aims at determining relevant ethical issues for particular settings and to offer theoretical frameworks to mitigate these issues in a responsible way.

Assessor:
Assessors are "agents (organisations or individuals) that engage in ethics assessment, usually on a professional basis. Sometimes, this term is used more broadly, to include agents that engage in any type of ethics assessment, guidance, awareness raising or advisement"[1]. In the ethical impact assessment (EIA) process, assessors are usually members of an R&I project. However, they can also be external experts working on an EIA or coming from organisations reviewing the EIA (e.g. funding organisations).

Reviewer:
Reviewers are those agents that are responsible for reviewing and auditing the entire EIA process. First, they are responsible for the evaluation of the threshold analysis, determining whether it is conducted correctly or needs to be amended. Second, they are responsible for conducting the review and audit stage together with the assessor.

Research & Innovation (R&I):
Research and innovation comprises basically all human activities that aim at formulating structured knowledge that can be used to explain or modify aspects of the world. More specifically, the SATORI project looks at such activities in the institutional context of research institutions such as universities or companies with research and development activities.

Emerging technology:
Emerging technologies are technologies being developed in a R&I context, that "are at an early stage of development and have not yielded many applications and societal consequences. They are still largely, or fully, at the research and development (R&D) stage, meaning that they are still at the stage of research into basic techniques, or at an early stage of development which at most has resulted in lab prototypes and experimental applications but little or no serious products that are being used by ordinary users."[2]

[1] Definition taken from SATORI Deliverable 1.1.
[2] Brey, P. Anticipatory Ethics for Emerging Technologies. NanoEthics, 6(1), 2012. 1–13. http://doi.org/10.1007/s11569-012-0141-7

Ethical impact:
An ethical impact is an activity (e.g. fraudulent conduct of research), event (e.g. environmental damage), outcome (e.g. knowledge about cloning humans) or an artefact (e.g. a nuclear weapon) in the context of R&I that can be identified as having normative implications. An ethical impact can be identified by moral intuition, consultation and participation.

Ethical impact assessment (EIA):
"An ethical impact assessment can be defined as a process during which an organization, together with stakeholders, considers the ethical issues or impacts posed by a new project, technology, service, program, legislation, or other initiative, to identify risks and solutions"[3].

Ethical impact identification:
Ethical impact identification uses the findings of the foresight studies to describe the ethical impacts that relate to the future applications of R&I activities. At this stage of the EIA, a description is provided of the relevant R&I outcomes as well as an explanation of the ethical character of these outcomes, using ethical frameworks.

Policy:
Policy can be understood from the definition given by Campbell in "Writing Effective Policies and Procedures for Step-by-Step Resource for Clear Communication." "Policies are guidelines that regulate organizational action. They control the conduct of people and the activities of systems. A policy is actually a type of position statement. It explains the organisation's stand on a subject and why there's a rule about it. It tells the reader how the organization intends to operate."[4]

Stakeholder:
A stakeholder is either a group or an individual who potentially affects or is affected by[5] an ethical impact and/or has a vested interest in the R&I context to which the ethical impact is ascribed. One can identify stakeholders by conceptualising the roles of actors in R&I processes[6]. Some of these roles are explicitly mentioned in some parts of the methodology (e.g. experts, policy makers). In those cases, 'stakeholders' refers to the non-standard roles that have to be identified on a case-to-case basis for R&I projects. For instance, elderly people as *clients* might be a stakeholder group in health-care projects, though they would probably not be in a project aimed at developing nuclear energy technologies.

1.3 LIST OF ABBREVIATIONS

- EI: Ethical impact
- EIA: Ethical Impact assessment

[3] Wright, D. Ethical Impact Assessment. Ethics, science, technology and engineering (2nd ed.). Gengage Learning. 2014.
[4] Campbell, N. J. (1998). Writing Effective Policies and Procedures for Step-by-Step Resource for Clear Communication. New York: American Management Association.
[5] Achterkamp, M. C., & J.F.J. Vos, Investigating the use of the stakeholder notion in project management literature, a meta-analysis. International Journal of Project Management, 26(7), 2008. 749–757. http://doi.org/10.1016/j.ijproman.2007.10.001
[6] Ibid. p.754.

- EU: European Union
- ICT: Information and Communication Technology
- R&I: Research and Innovation
- SME: Small and Medium-sized Enterprise(s)
- TRL: Technology Readiness Level

1.4 INTRODUCTION TO THE EIA FRAMEWORK

This report presents a practical, policy-oriented document that can guide researchers and ethics assessors through the different stages of the ethical impact assessment (EIA) process. It also incorporates findings of the SATORI reports on shared ethical principles and issues and on ethics assessment procedures. In the main report, we present the practical steps that can guide researchers and ethics assessors through the EIA process. In the annexes, we present the findings in the literature on which the main report is based.

In line with the overall aim of the SATORI project, this report can be seen as a first step towards a harmonised framework for conducting EIA of R&I activities in the EU.

We combine the insights from the literature on methods for EIA, as mentioned in the comparison of methods for foresight and EIA[7], and considerations of practicality of research innovations projects, as has been discussed in the SATORI Deliverable 1. As such, both a plurality of methods has been integrated in the proposal and a consideration of limitations of R&I projects, in terms of funding, scope, resources, etc.

1.4.1 Why conduct an ethical impact assessment

The increasing pace of technological advancements and societal impacts of resulting innovations in the contexts of genetic technologies, geo-engineering, ICTs, complex innovations, and financial technologies "have catalysed an increasing willingness at a policy level to discuss, challenge and rethink linear models of science policy and the social contract for science"[8]. Thus, EIA is meant both to help ethicists to investigate ethical challenges and researchers, policy makers and relevant stakeholders to deal with the ethical impacts of R&I.

The need for methods for EIA arises out of the increasing focus on responsible R&I in policy contexts and in collaborative efforts of researchers, as well as from new legal regulations for R&I at the European level. Moreover, the increasing impact of R&I on society and the increasing pace of technological advancements call for a reflection on the impacts of these transformations on society. The EU, and notably the European Commission, has been a driving force behind the development of impact assessment practices, by incorporating the need for responsible R&I in its framework programmes.

Research funding agencies such as the European Commission and funders at the national level could advocate the use of the EIA process proposed here as a good practice in research projects. Moreover, they could make having an ethical impact assessment built into an R&I project a condition of a project's successful funding. Academies of science could, as part of their role in promoting excellent science, help advocate the use of ethical impact assessment and also actively promote its use and

[7] See Annexes A & B
[8] Owen, R., Macnaghtan, P., Stilgoe, J. Responsible research and innovation: From science in society to science for society, with society. Science and Public Policy, 39(6). 2012.

encourage discussion about it. Policy makers and regulators could also help support the use of EIA by supporting them as a good practice measure in legislation and policy (as exemplified in the case of how data protection impact assessments are incorporated into the EU General Data Protection Regulation)[9].

1.4.2 Who can use this report?

The following, non-exhaustive list presents types of stakeholders that can make use of this report:

- **Policy makers:** Policy makers at different governmental levels (e.g. the EU level, the national level or regional level such as in the German Länder) can use this document as guidance for setting up policies for ethical impact assessment procedures for R&I projects.
- **Research funding organisations:** Public funders of public and private R&I projects can use this document to set requirements for the funding process and to inform funding recipients about the procedures for EIA they either should (in the case of regulatory guidance) or can (in the case of consolatory guidance) follow.
- **Public R&I performing organisations:** Organisations that perform R&I such as universities or research institutes can use this document to inform the procedures that their researchers might or should adhere to while performing an EIA for their R&I projects.
- **Private entities:** Private entities such as companies that perform R&I can use this document to either to follow the requirements of bodies providing public funding or to set up a responsible R&I policy as part of the organisations' corporate responsibility efforts.
- **Standards, accreditation and certification bodies:** Organisations providing for standards or accrediting and certifying third parties can use this document to set certain standards for EIA procedures in R&I and to inform the requirements for accrediting or certifying an organisation that performs EIA as part of their R&I processes.

1.4.3 Defining responsibilities in EIA

In conducting an EIA, roughly two main categories of tasks can be distinguished: *executing* the EIA and *reviewing and auditing* the EIA. For each of these tasks, responsibilities of the stakeholders for the respective processes can be defined as follows:

[9] Council of the European Union. Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), Inter-institutional File: 2012/0011 (COD), (OR. en) 15039/15, Brussels, 15 December 2015.

- **Executing the EIA:** The assessor will ultimately be responsible for executing the EIA in a proper and timely fashion. This assessor is usually a member of the R&I project team. For small-scale EIAs[10], the assessor can be researcher who has only limited experience in ethics. For medium-scale and large-scale EIAs the researcher needs to be sufficiently trained in ethics. However, for certain contexts, such as for commercial R&I projects, the assessor might be someone external to the organisation such as an external consultant[11].
- **Reviewing and auditing the EIA:** The responsibility of reviewing and auditing the EIA can lie with different people, depending of the context in which the EIA is conducted. However, the following rule of thumb applies here:
    - *If* the EIA is funded by a research performing institution (e.g. a university), the local ethics committee is responsible for conducting the review and audit of the EIA
    - *If* the EIA is funded by a research funding organisation (e.g. the European Commission), an ethics committee belonging to this organisation is responsible for conducting the review and audit of the EIA
    - *If* the EIA is funded by a commercial organisation, an internal body (e.g. the ethics board of a company) might review and audit the EIA, as well as an external body (e.g. a consultancy). External review and audit is to be preferred over internal review and audit.
    - *If* the EIA is part of an R&I project with mixed funding, the highest level public funding organisation should review the EIA. For instance, if a project is funded by a research-funding organisation, a research performing organisation and a commercial organisation, the research funding organisation is responsible for reviewing and auditing the EIA.

1.4.4 The role of stakeholder engagement in EIA

An ethical analysis can be done in two ways: either with or without stakeholder involvement. These two types of analysis are called *principle-driven* and *stakeholder-driven* ethical analysis. They are alternatively called traditional ethical analysis and ethical analysis with stakeholder involvement.

Ethical analysis without stakeholder engagement, or traditional ethical analysis, usually does involve the identification of stakeholders, which are then attributed certain interests, rights and responsibilities. These attributions are however made without their input. In ethical analysis with stakeholder involvement, stakeholders are consulted about their values, interests, and beliefs and may even have an active role in shaping the analysis. These two types of analysis may be called *principle-driven* and *stakeholder-driven* ethical analysis.

[10] For a discussion on EIA Scales, see SATORI Deliverable 4.1, A Framework for Ethical Impact Assessment
[11] See section 1.3.6.3. for the definitions of small-scale, medium-scale and large-scale EIAs.

In principle-driven analysis, the assessor identifies the stakeholders and attributes to them interests, rights and responsibilities. He or she then comes up with reasoned proposals of how these should be balanced against each other. The most immediate advantages of this approach are that it is the most efficient and inexpensive one. Also, if done properly, it avoids certain forms of bias, subjectivity and an undue emphasis on interests that may result from stakeholder-driven approaches. The disadvantages are that this approach rests on less reliable data because values and interests are projected onto stakeholders, it is less democratic, and it can introduce biases and preference of the analyst that remain unchecked by others.

Despite the advantages of principle-driven analysis, it will usually be preferable to engage in stakeholder-driven ethical analysis, because it gives stakeholders a chance to express their interests, values and opinions.

One can develop criteria for identifying stakeholders for an EIA from a representative or interest-driven perspective (by defining interests first, and base the selection of stakeholders on these interests). If one's stakeholder group was the wider public, then a representative sample would be one that has a good spread in relation to e.g. categories of: age, gender socio-economic, status, and background. If one was using interest as a criterion for identifying stakeholders, then a sample from 'publics' stakeholder group would focus on publics or groups engaging already engaging with a topic/issue or publics/groups directly affected. These two approaches to developing criteria for a sample of stakeholders can be referred to as the Habermasian and Dewian approach to publics, stakeholder involvement and democratic dialogue. If a choice is made for stakeholder-driven analysis, it can be done in two ways:

Consultative assessment:
In this process, stakeholders are consulted about their values, interests, beliefs and views, which are then used by the analyst to do a principle-driven ethical analysis. This can be as a one-off exercise or repeatedly as required. In order to avoid a "check-box" mentality, a feedback mechanism should be in place, which engages stakeholders in the decision-making process by showing how their values, interests and beliefs are taken into account.

Participatory assessment:
In this process, stakeholders participate directly in the EIA process. They get to determine in a more direct way what values and interests are at stake, how they should be weighed against each other, what their impacts are and might be, and what ethical recommendations result from this. The assessor has a more subordinate role in this process, as someone who helps shape the process and safeguards its integrity, but not as someone who gets to decide what values are at stake and how they should be balanced. This process requires a level of sophistication in the stakeholders, and may require prior training. It also requires considerable skill from the assessor who has the task of accompanying this process and ensuring its integrity and quality. Stakeholder-driven assessments can take place in mid-level and large EIAs.

Interests versus ethical principles
When stakeholders are considered in ethical impact assessments, or when they participate in such assessments, it is likely that at some point, the analysis turns to a

consideration of their interests. However, interests are not moral values or principles. Someone's financial interests in a new technology, for example, are quite distinct from moral considerations with respect to this technology, such as whether it may violate privacy or autonomy. Ethics is about what is the morally right thing to do, not about what best advances the interests of individuals, groups and organisations. Any ethical impact assessment that is reduced to balancing the interests of individuals and groups misses the point.

At the same time, any ethical impact assessment that does not consider the relevant interests of stakeholders is likely to be inadequate. A large part of ethics is concerned with respecting the rights of others and avoiding harms to others. Both rights and harms are dependent on interests. Harm can only occur if someone has a certain interest that can be harmed. For example, a disease is harm because individuals have an interest in being healthy. Similarly, individual rights can arguably be analysed in terms of fundamental interests that individuals have, such as interests to act, think, work and associate without interference or retribution by others. Such interests are so fundamental to people and so essential for a consideration of people as equals with an inherent worth that they are recognized as rights. Ethics is also concerned with human flourishing (i.e., well-being and happiness), and people therefore also have ethically relevant interests that do not concern harms or rights, but rather positive interests in their own well-being.

So interests are important to consider in an ethical impact assessment, but for it to be an ethical impact assessment, rather than a mere balancing of interests, these interests have to be analysed from the point of view of the ethical categories of harms, rights and well-being. Effectively, this means that interests will be framed and identified in terms of these ethical categories. A balancing of interests then translates into a balancing of ethical principles, which determine when, if ever, certain harms can be justified or rights can be violated, and how rights should be balanced against each other and against harms and benefits for well-being.

1.4.5 Overview of procedural steps

Below, both a schematic overview of the main procedural steps of the EIA can be found as well as a table that explicated what the procedural steps entail in more detail. The figure depicts the order of the different steps of the EIA, although some of these steps might chronologically overlap (e.g. the ethical impact anticipation and determination stage and the ethical impact evaluation stage). The review and audit stage runs separate from the other four stages, for it applies to the entirety of the EIA process.

The table provides a summarised overview of the concrete steps of each of the stages of the EIA. All these steps will be further clarified in the following sections.

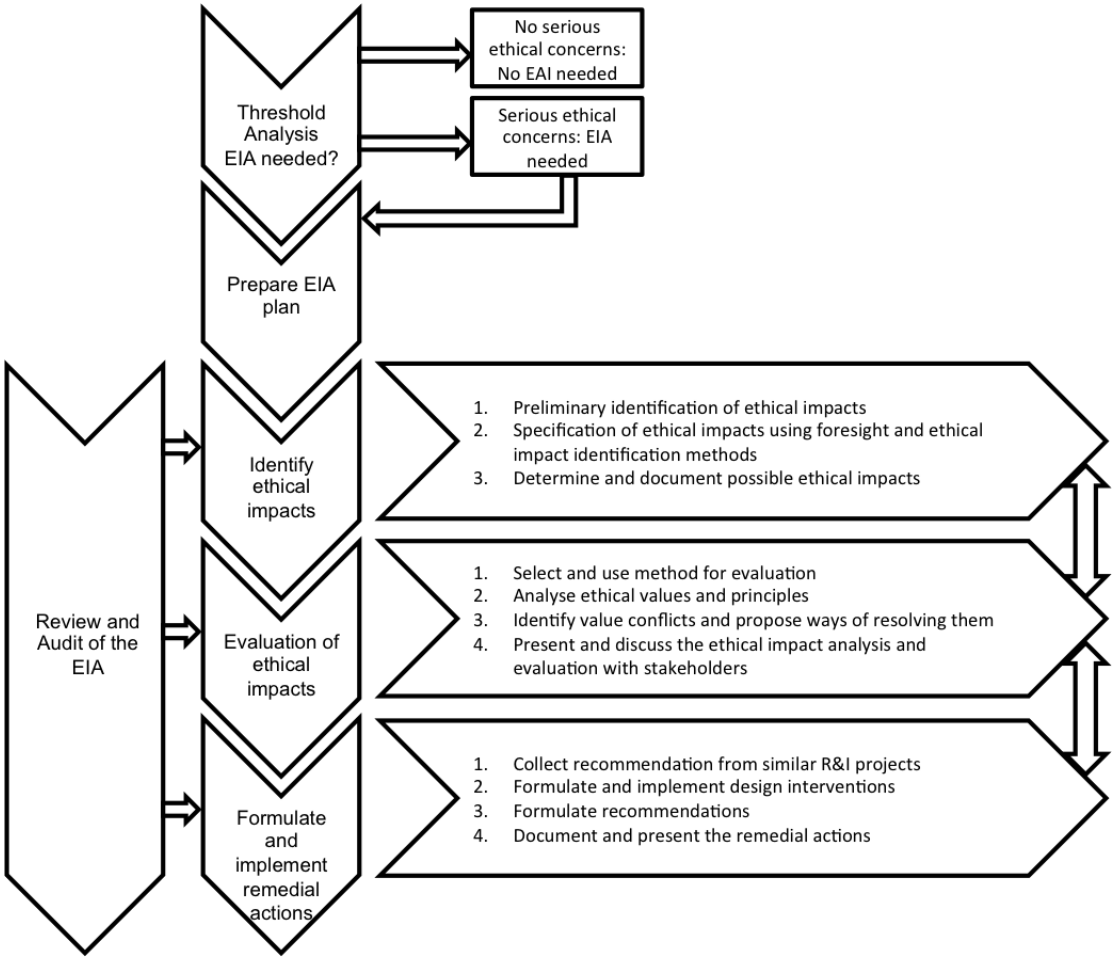

Figure 1: The six steps of the Ethical Impact Assessment (EIA)

1. **Conduct an EIA threshold analysis** i. Complete the EIA questionnaire ii. Send the finished documentation to the ethics assessor or conduct a self-assessment iii. The threshold analysis is either accepted, rejected or there will be a request for amendments
2. Prepare and EIA plan i. Assess the scale of the EIA ii. Allocate a budget to the EIA iii. Compose a team for the EIA iv. Review and approval of the EIA plan v. (Optional) Repeat the threshold analysis at different stages of the project, critically when there are significant changes in the project vi. (Optional) Consult with relevant stakeholders to raise awareness of the project taking place and gather more details about possible ethical impacts

3. Set up and execute an ethical impact identification assessment i. Assess the Technology Readiness Level (TRL) of the R&I project's outcomes ii. Review existing work in the relevant R&I field iii. Select appropriate methods for conducting the ethical impact identification based on the TRL and the threshold analysis iv. Gather relevant data (evidence based, by consulting experts, by interacting with stakeholders, based on creativity) v. Determine possible, probable and/or preferable ethical impacts vi. Document and present the ethical impacts
4. Evaluate the ethical impacts i. Decide which methods should be used (desk research, expert consultation or participatory method) ii. Conduct a contingency analysis to evaluate the likelihood of ethical impacts to occur iii. Assess the relative importance of ethical impacts iv. Identify potential or actual value conflicts and, if possible, aim at resolving these v. Formulate workable conceptualisations of the relevant ethical impacts vi. Document and present the ethical impacts evaluation
5. Formulate and implement remedial actions i. Gather relevant information about remedial actions proposed by other R&I projects ii. Formulate and implement design interventions iii. Formulate different types of recommendations iv. Document and present the remedial actions
6. Review and audit the EIA outcomes i. At the beginning of the EIA: set the milestones and criteria for the review and audit process ii. During the EIA: evaluate the EIA documentation and the agreed upon criteria and milestones iii. At the end of the EIA: ensure proper documentation, follow-up and signing off of the EIA iv. Document and present the review and audit outcomes

Table 1: Procedural steps of the Ethical Impact Assessment process

1.5 THE THRESHOLD ANALYSIS

The threshold analysis stage of an EIA is aimed at determining whether an EIA is necessary in a research and innovation (R&I) project. The determination could be done at the start of an R&I project but, if appropriate, also after the initiation of an R&I project. The purpose and setup of a threshold analysis will depend on the type of institution (public/private), the means of the institution initiating the project and the requirements of the oversight body (e.g. a funding body). Below, we outline specific practical steps and requirements for the threshold analysis of an EIA procedure i.e., its function, method, who performs it, who reviews it, and certain criteria.

1.5.1 Function

The two functions of the threshold analysis in the EIA process can be described in terms of their purposes in assessing the expected:

- Variety of ethical impacts
- Severity of ethical impacts

On the basis of this assessment, the analysis is to determine:

- What ethical impacts can be expected
- Whether or not an EIA is needed

1.5.2 Method

If followed correctly, a sequence of six procedural steps should lead to a successful threshold analysis of an EIA for an R&I project. The following table outlines these procedural steps:

Summary of key procedural steps[12]:
1. Design a questionnaire for the threshold analysis
2. Fill in the questionnaire to determine the variety and severity of expected ethical impacts of the R&I project
3. Send the threshold analysis to the reviewer (e.g. funding agency, science academy)
4. The reviewer either accepts, asks for amendments or rejects the threshold analysis: a. Acceptance: requirements for resource allocation and review are communicated b. Amendments: the project team is given feedback on the threshold analysis and is requested to revise it within a designated timeframe c. Rejection (optional[13]): the ethics assessor deems the severity and variety of ethical impacts too great for conducting an EIA within the

[12] Modeled on the EU's impact assessment guidelines: European Commission. Impact assessment guidelines. 2009. Retrieved from http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

means of the project; the entire R&I project ought to be revised
5. For some R&I projects, the ethics assessor should require to have the threshold analysis conducted in the course of the project. Specifically when: a. The project works with emerging technologies, the character of which is likely to change rapidly within the project timeframe (such as ICTs) b. The R&I project goals itself might be changed, depending on the research outcomes

Table 2: Procedural steps for a threshold analysis

1.5.3 Who performs a threshold analysis?

Depending on the type of entity that engages in an R&I project, different types of people could perform the threshold analysis of an EIA. Three types of people are most likely to conduct a threshold analysis, depending on the institutional context. They are a third party's organisational representative, a designated administrator or a researcher within the R&I research team:

Third party's organisational representative: In the event that the threshold analysis is performed by an independent body that is principally impartial with regards to whether or not a certain R&I project is initiated (such as a research funding organisation or a science academy), a representative of such a body could be made responsible for conducting the analysis. In such a case, the contact person of the project is requested to deliver the relevant information (project proposal, budget) and the independent institution performs the threshold analysis.

Designated administrator at a public research institute or a company: For larger institutions or companies a designated administrator might be in charge of conducting the threshold analysis. For universities, this could be the person who is responsible for coordination of research funding proposals. For larger companies, this could be the corporate responsibility person.

A researcher within the R&I project team: In the event that an institution or a company (especially an SME) does not have a designated administrator who could perform the threshold analysis, a member of the R&I project team might be appointed to be responsible for it. It is recommended that public institutions provide the necessary funds so that researchers can apply for a grant that covers their activities while working on the threshold analysis.

1.5.4 Who could review a threshold analysis?

Depending on the funding source for an R&I project, the following stakeholders could be responsible for reviewing the threshold analysis:

[13] Rejection of a threshold analysis is only applicable in case an ethics assessor has the mandate to do so. In some cases, for instance when dealing with R&I projects in the private section, ethics assessors often lack the mandate to do so.

An ethics committee of public institution: In the event that a public research institution, such as a university, funds the R&I project, the body that is responsible for conducting the existing ethics assessment activities (e.g. for ethics clearance of experiments) should be in charge of reviewing the threshold analysis as part of the project proposal.

Research funding organisation: In the event that a research funding organisation (partly) funds an R&I project (this could be the European Commission or a national research funding body), this organisation should review the threshold analysis.

Reviewers for commercial parties: In the event that commercial entity funds an R&I project, different options exist. The company could assign an internal department, with sufficient conflict of interest protocols, to review the threshold analysis. Also, company associations or consultancies might be asked to review the threshold analysis.

1.5.5 Essential elements of a threshold analysis

Here, we present essential elements of *any* threshold analysis to be conducted for an EIA, disregarding the type of organisation that conducts it or the nature of the EIA. We discuss the most important ethical impacts that need to be taken into account, the questionnaire that should be completed for a threshold analysis, and the criteria that can be used for assessing it.

1.5.5.1 A three-item taxonomy of ethical impacts

This section presents a brief, three-item taxonomy of ethical impacts, based on the findings in the SATORI report on shared ethical principles and issues[14]. The purpose of the taxonomy is to permit the construction of an outline for a questionnaire that enables the determination of the level of EIA that is required and, at the same time, includes sufficiently the types of possible ethical impacts.

Here, three types of ethical impacts are outlined. They include impacts during the research itself, impacts from the technologies being developed, and impacts from intangible research outcomes.

It is important to note at this point that the impacts that need to be taken into account in an EIA are impacts of R&I that can occur *even if the researchers stick to their ethical codes of conduct.* For instance, even though a nuclear researcher might stick to his/her professional ethical code and present his/her research results honestly and while limiting harm to the animals s/he uses in his/her experiments, the *outcomes and applications* of the research nonetheless might have severe ethical impacts.

1. *Impacts during research:*

The first sub-category of impacts mostly has to do with research ethics, including the ethical impacts that the practice of research can have, such as harm to human subjects, or scientific fraud. These impacts of an R&I project are usually taken into account during conventional ethics assessment procedures (through, for example, an ethics

[14] See Deliverable 4.1 of the SATORI project.

clearance for the use of human subjects in experiments) and are therefore of less importance for the threshold analysis of the EIA and the EIA itself.

2. *Impacts from technologies (innovation):*

The second sub-category of impacts has to do with new or emerging technologies that result from R&I projects, or tangible research outcomes. This category can be divided into the following nine, broad sub-categories. They are impacts that due to:

a. Application in the context of human healthcare
b. Genetic modifications
c. Safety risks
d. Collection/processing of personal data
e. Accessibility restrictions
f. Interference with the environment
g. Targeting of vulnerable groups
h. Modification of distribution of means
i. Dual use

3. *Impacts from intangible research outcomes*

The third sub-category of impacts has to do with intangible research outcomes of R&I projects that can have real life impacts. For example, climate models, though intangible, can have a strong impact on energy policies; new findings in the field of social psychology can have strong impacts on the value systems of certain cultures. This third category of impacts can be divided into the following sub-categories of impacts that due to:

a. Unpredictability of scientific models
b. Misuse or misrepresentation of cultural heritage
c. Restriction of free speech/ freedom of opinion
d. Violation of intellectual property rights

1.5.5.2 The questionnaire

Below, we present three types of questions that could be posed in a questionnaire used for conducting a threshold analysis. Following this list of three sample question types, a series of ways of handling the questions is listed i.e., tick box responses or closed (yes/no) responses.

The following criteria should apply to any questionnaire for an EIA threshold analysis:

- *Questionnaires should be guided by the concept of reasonable expectation:* "Reasonable expectation" is a notion that fits the context-dependent[15] nature of R&I projects and can be defined in contract law as "the objectively justified

[15] Mitchell, C. Leading a Life on its Own? The Roles of Reasonable Expectation. Oxford Journal of Legal Studies, 23(4). 2003. P. 640.

belief in the likelihood of some future event or entitlement"[16]. However, as a justification of *normative* beliefs, reasonable expectations can be derived from "previous experience and probability"[17]. When requesting researchers to perform a threshold analysis, an appeal is made to their ability to deal with uncertainties. (After all, at the stage of conducting a threshold analysis, the R&I project has yet to commence and, therefore, any ethical impact that might be at stake is hypothetical in nature.) In order to deal with the kinds of uncertainty that are at stake, reviewers of a threshold analysis can appeal to the concept of reasonable expectation. Thus, any threshold analysis is based on the presumption that researchers can hold reasonable expectations with regards to the ethical impacts of their planned R&I project. Questions should therefore be aimed at asking about concrete aspects of the R&I project about which any researchers should have reasonable expectations. Sometimes, therefore, performing a threshold analysis might require a certain level of previous experience with applied ethics.

- *Questionnaires should be as short and simple as possible, while still being comprehensive:* Since a threshold analysis will be part of the overall process of writing an R&I project proposal and should not unnecessarily burden this process, its questions should be short and simple to complete.
- *Questionnaires should be specific but also leave room for free interpretation:* Certain types of ethical impacts should be specifically mentioned in the questionnaire, in order to make it as inclusive as possible. However, in order to account for ethical impacts that arise with the development of novel innovations and emerging technologies, the questionnaire should also leave room for open-ended questions.

Below, we present an example of a possible EIA threshold analysis questionnaire:

For each of the following questions, please indicate to what extent your proposed R&I project might be reasonably expected to involve the following risks of ethical impacts. If there are no ethical impacts to be expected, explain why[18]**.**

1.5.5.3 Example questionnaire for an EIA threshold analysis

Please provide an answer between 1 (i.e., very unlikely and/or very low potential severity) and 5 (i.e., very likely and/or very high potential severity) to the following questions.						
Does the R&I project include, or could its results easily be used for, the	**1**	**2**	**3**	**4**	**5**	**Comment on your answer / specify briefly**

[16] Ibid. P.644.
[17] Ibid. P.646.
[18] Parts of the questionnaire are based on the "Ethics Issues Table" of the European Commission: European Commission. *Ethics Issues Table – Checklist*. 2014.

design or development of technologies, policies or protocols, that:		**any potential ethical issues:**
1. are used in a health-care context, *or* could have a negative impact on public health or safety?		
2. involve the collection, processing, and/or storing of personal data? *(Consider, in particular, whether sensitive personal data is collected relating to health, sexual lifestyle, ethnicity, political opinion, religious, or philosophical conviction.)*		
3. could have a negative impact on the rights and liberties of individuals and groups? *(Consider effects on freedom, autonomy, authenticity, identity, privacy, human dignity, human bodily integrity, [intellectual] property, amongst others.)*		
4. could have a negative impact in terms of social justice and equality? *(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 underrepresented individuals, groups, or communities in society, including future generations and individuals, groups, and communities in low income and lower-middle income countries.)*		
5. could have a negative impact on the well-being of individuals or groups, and/or on the common good, including cultural heritage? *(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.)		
6. could have a negative impact on the environment, animals, and/or plants, including through the use of GMOs? *(Consider, amongst others, the direct and long-term effects on the environment, animals, and plants of any biological, chemical, radiological, nuclear, or explosive elements used, including GMOs [genetically modified organisms], as well as any effects in terms of human encroachment of natural habitats, and environmental policy.)*		
7. could raise concerns in terms of sustainable development? *(Consider whether the R&I project is compatible with sustainable development in terms of the use of resources, the generation of harmful waste products, et cetera.)*		
8. could have significant military purposes (dual use)? *(Consider, amongst others, any effects in terms of the development of weapons of mass destruction, military surveillance systems, and autonomous weapons systems.)*		
9. could become subject to misuse? *(Consider, amongst others, whether [information about] harmful biological, chemical, radiological, nuclear, or explosive materials, and/or the means of their delivery, can easily [accidentally] be misused and whether it may easily fall into the hands of terrorists or criminals, and whether the R&I project may result in abuses by governmental and other institutional actors in non-military contexts.)*		

1.5.5.4 Review of the EIA threshold analysis

Because the threshold analysis is set up to be simple and should require little time to complete, the review should be straightforward in a similar fashion. The only purpose of the review is to see whether the threshold analysis has been completed in a fair and

reasonable way, to avoid for instance that researchers on purpose fail to report on crucial potential ethical impacts in order to avoid having to do an EIA.

The review of the threshold analysis focuses on the following aspects:

- Whether some ethical impacts that can be reasonably expected have not been taken into account
- Whether the likelihood of ethical impacts has been underestimated in the threshold analysis

For both these aspects, reviewers will have to provide reasons for their comments, explicitly stating which impacts could be expected, why they should have been included and what their likeness to occur would be.

1.5.6 Recommendations

- Certain R&I projects could be exempt from conducting a threshold analysis, especially projects that are based on a research funding call that already includes substantive requirements for ethics.
- An occasional peer-review process should be institutionalised, which means that independent researchers review on an periodic basis the threshold analyses of their peers in order to guarantee the independence of the reviewing institution (the university, funding organisation, etc.).
- The requirement for a threshold analysis should be included in research funding calls.

1.6 PREPARATION OF THE EIA PLAN

Once a project team receives an acceptance of its threshold analysis, it will have to take care of the following three mandatory and two optional, preparatory steps. On a mandatory level, they relate to budget allocation, team composition, and review criteria; on an optional level, they refer to periodical threshold analyses and stakeholder consultations:

1.6.1 Function

The drafting of the EIA plan has the following functions:

- To ensure that the EIA is well structured
- To ensure that the EIA will have sufficient institutional support

On the basis of this plan, the following will be determined:

- The budget of the EIA
- The team composition of the EIA
- The review and audit criteria for the EIA

1.6.2 Method

If followed correctly, a sequence of six procedural steps should lead to a successful formulation of an EIA plan for an R&I project. The following table outlines these procedural steps:

Summary of key procedural steps[19]:
1. Assess the scale of the EIA: small-scale, medium-scale or large-scale
2. Allocate a budget to the EIA, based on the scale and on the resources available to the overall R&I project
3. Compose a team for conducting the EIA, based on the scale of the EIA and the expertise and seniority of assessors
4. The EIA plan is reviewed,
5. For some R&I projects, the ethics assessor should require to have the threshold analysis periodically conducted in the course of the project. Specifically when: a. The project works with emerging technologies, the character of which is likely to change rapidly within the project timeframe (such as ICTs) b. The R&I project goals itself might be changed, depending on the research outcomes
6. For some R&I projects (notably those having medium- and large-scale EIAs), the ethics assessor should require organising preliminary stakeholder consultations.

Table 3: Procedural steps for the preparation of the EIA plan

1.6.3 Essential elements of the preparation of the EIA plan

Here, we present essential elements of *any* formulation of an EIA plan, disregarding the type of organisation that conducts it or the nature of the EIA. We discuss the most important ethical impacts that need to be taken into account, the questionnaire that should be completed for a threshold analysis, and the criteria that can be used for assessing it.

1.6.3.1 Determination of scale of EIA

The EIA plan is based on the idea that an EIA can have different *scales.* For reasons of simplicity, the SATORI project proposes three scales for an EIA procedure. These three are small-scale, medium-scale and large-scale EIAs. The different levels for an EIA guide the assessment criteria.

The following three aspects need to be taken into consideration: outcome of the threshold analysis, resources of the R&I project and possible team composition.

The decision on the level of EIA that is required rests with the body or person responsible for the review of the EIA plan. However, the outcome of the threshold analysis guides this decision in the following ways:

- If a limited number (for example, simply 1-2) of the ethically significant uses of the activities and outcomes of the R&I project are identified (question 2) and the risk of *at least one of them* is seen as only mildly severe (2 on the 5-point scale), then a small-scale EIA should be considered.
- If a substantial number (for example, 3-4) of the ethically significant uses of the activities and outcomes of the R&I project are identified

[19] Modelled on the EU's impact assessment guidelines: European Commission. Impact assessment guidelines. 2009. Retrieved from http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

(question 2) and the risk of *at least* one of them is deemed substantially severe (3-4 on the 5-point scale), then a medium-scale EIA should be considered.

- If a large number (for example, 5 or more) of the ethically significant uses of the activities and outcomes of the R&I project are identified (question 2), and the risk of *at least* on of them is deemed severe (4-5 on the 5-point scale), then a large-scale EIA should be considered.

1.6.3.2 Budget composition for an EIA

The different levels of EIA will especially depend on the budget that is required. We roughly base possible team compositions on the H2020 budget document of EU Research[20]. Almost all costs of an EIA will be direct personnel costs and some additional cost will be spent on other direct costs (e.g. workshop rooms, trainings). However, the more substantial an EIA is, the larger the percentage of other direct costs will be. Accordingly, the following estimations guide considerations for budget composition:

- An EIA should preferably require 1-10% of the budget of an R&I project, and maximally 20%
  - A small-scale EIA will be based on a budget of approximately 90% direct personnel costs and 10% other (in)direct costs
  - A medium-scale EIA will be based on a budget of approximately 80% direct personnel costs and 20% other (in)direct costs
  - A large-scale EIA will be based on a budget of approximately 70% direct personnel costs and 30% other (in)direct costs

1.6.3.3 Team composition for the EIA

Considerations of team composition are derived from the different types of academic researchers that might be involved in the EIA. This allotment may not be in line with the personnel costs of companies conducting an EIA, but we are not able to provide a realistic estimate of personnel costs for commercial entities here.

- The team composition is based on three main types of researchers who are involved in R&I proposals: research assistants, senior fellows and professors.
- The following minimum considerations apply to the different levels of EIA:
  - **Small-scale:** EIA mostly requires deskwork. The EIA team is led by a(research) assistant who is member of the R&I project team. This is a part time position.
  - **Medium-scale:** EIA requires setting up consultative and participatory processes. The EIA team is led by a (research) member (research fellow) in the R&I project. This is a full-time position.
  - **Large-scale:** EIA requires the use of a variety of participatory efforts, involving multiple stakeholders. The EIA team is led by

[20] EURESEARCH. (2014). Horizon 2020 – How to Budget My Project Costs.

a senior member (a professor) in the R&I project. This is a full-time position.

1.6.3.4 Formulating review criteria

The EIA will be submitted to a regular review, usually conducted or organised by the funding organisation. This review can be part of the overall project review, or it could be done separately if deemed necessary by the funding organisation. Certain review criteria could be agreed upon:

- Milestones: deadlines for reports in which the completed stages of the EIA are presented.
- Quality assurance standards: certain standards with regards to the form and content of the reports that need to be met.
- Original research: in the event that either medium-scale or large-scale EIA original research might be expected, this could be reflected in e.g. a publication target.

1.6.3.5 Review of the EIA plan

After the EIA plan has been reviewed, three different outcomes can be communicated (rejection, amendment, or acceptance):

- The reviewers might accept the EIA plan:
  - Definite requirements for budgeting and, if necessary, additional team composition are communicated to the project team.
- The reviewers might ask for amendments, including e.g.,:
  - Identification of additional ethically sensitive uses of research activities and outcomes.
  - Different assessment(s) of the level of severity of ethical impacts.
  - The addition of ethical impacts that the project team did not include in their threshold analysis but that nonetheless could have been reasonably expected.
- The EIA plan might be rejected in the following cases:
  - When the plan calls for an EIA scale that does not fit the size of the project.
  - Some ethical impacts are deemed too severe for the means available to the project team.

1.6.3.6 (Optional) Agreeing on a periodic threshold analysis

In the event that an R&I project deals with emerging technologies that change rapidly and could have different risks for ethical impacts throughout the duration of the project (such as certain types of ICTs or brain technologies), the funding body and the project team might agree on a periodic threshold analysis (to take place e.g. two or three times during the entire length of the project).

1.6.3.7 (Optional) A stakeholder consultation

Especially in the event that a project needs a medium-scale or large-scale EIA, it might need to consult with stakeholders before starting the R&I project. This consultation should be aimed at (a) mapping the different relevant stakeholders, (b) raising awareness amongst stakeholders that the project will take place, (c) gathering more details about possible ethical impacts that stakeholders perceive.

1.6.3.8 "Technology scale" EIA

In addition to the regular types of EIAs, a "technology-scale" EIA might be required. This implies that a new technological paradigm is established that calls for a dedicated EIA that is not tied to a specific research project.

A technology-scale EIA will accompany developments in research and innovation that set the stage for a new scientific or technological paradigm that does not belong to a single project but can apply to a great variety of R&I projects in different fields. An example of such a situation has been the paradigm of nano-research that has instigated a separate discussion about the ethical impacts of any technological application at the nano-scale. Technology-scale EIAs are set up in such a way that they can inform the individual EIAs of projects that incorporate the novel type of R&I.

For the abovementioned reasons, in contrast to the other types of EIAs, the initiation of a technology scale EIA does not lie in the range of responsibilities of R&I projects but rather, it follows on from more general observations made by policy or standard-setting bodies. For instance, if an academy of sciences observes that there is the need for ethical assessment of a new technological paradigm across a scientific field (such as the nano-technologies paradigm), it might initiate a technology-scale EIA.

Organisations that are likely to be initiators of technology-scale EIAs include:

- National ethics committees
- Funding organisations
- Science academies
- Standard setting bodies

A technology-scale EIA would follow the same procedure as the large-scale EIAs, with the following differences:

- A technology-scale EIA should be carried out by a dedicated team that is not tied to a specific R&I research project
- A technology-scale EIA would include the following activities that are not necessarily part of a large-scale EIA:
    - Development of new conceptual frameworks capable of dealing with the new technological paradigm
    - Development of new methodological frameworks capable of dealing with the new technological paradigm
    - Recommendations for, and potentially development of, policy and law for dealing with new technological paradigms.

1.6.4 Recommendations

Based on the above description of doing a threshold analysis as part of an EIA, we present a number of recommendations for implementing a threshold analysis in an appropriate way. It is recommended that:

- Public institutions should provide the necessary funds so that researchers can apply for a grant that covers their activities while working on the EIA plan.

This would ensure that the EIA plan is not an unnecessary financial or resource burden for a project team working on an R&I project proposal.

- A ready-made format for EIA plans could be provided by R&I institutions, to speed up the process of setting it up.

1.7 ETHICAL IMPACT IDENTIFICATION

Once the threshold analysis has been completed and the EIA plan has been formulated, the first stage of an EIA as part of the R&I project that is conducted is the ethical impact identification stage. At this stage, the researchers involved in the EIA aim at mapping the ethical impacts that might occur in the context of the R&I project and at putting these in a temporal perspective (anticipating short/medium/long-term impacts). Researchers can gain knowledge about possible ethical impacts by consulting existing literature or ethical impact assessments of similar R&I projects. However, often a multitude of perspectives will be needed to assess both what kind of impacts of the R&I project can be deemed ethically problematic and to know what the likelihood of those impacts to actually occur. For this reason, the ethical impact identification stage often includes approaches for stakeholder involvement and consultation and for involvement of experts.

1.7.1 Function

The function of the ethical impact identification stage can be explained as follows:

- Describe possible and probable futures regarding the ethical impacts of the R&I project.
- Describe the relevant research outcomes that can lead to ethical impacts.
- Identify ethical values and principles and relevant stakeholder interests regarding these impacts.

1.7.2 Method

In order to complete the ethical impact identification stage, several procedural steps have to be followed. However, these steps can be carried out simultaneously, especially since findings in one step might benefit the work done in another. The following table depicts the procedural steps of the ethical impact identification stage:

Summary of key procedural steps:
1. Assess the technology readiness level of the outcomes of the R&I project. For this, the widely used Technology Readiness Level (TRL) method can be used.
2. Review existing literature on foresight and determination (ethical analyses) of R&I projects with similar outcomes
3. Decide on which methods should be used a. Based on the technology readiness level and the EIA scale b. Methods can be chosen according to their focus on *expertise, interaction, creativity and evidence*.

Summary of key procedural steps:
4. Data gathering for the analysis of probable or possible ethical impacts of the R&I project. This can be done through: a. Evidence based methods (e.g. horizon scanning) b. Methods that involve experts (e.g. Delphi survey) c. Methods that involve interaction among stakeholders (e.g. citizen panels) d. Methods that revolve around creative methods (e.g. scenario building)
5. Determination of possible ethical impacts a. Based on conceptual methods (e.g. ethical checklists) b. Using empirical methods (e.g. executing consultation activities)
6. Documentation and presentation of the ethical impacts

Table 4: Procedural steps for the ethical impact identification stage

1.7.3 Who conducts the ethical impact identification?

The following types of people can be responsible for conducting the ethical impact identification stage.

Researchers working within the R&I projects: Commonly, R&I projects appoint researchers that are part of the project (they appointed according to the team composition as a result of the threshold analysis) to conduct the ethical impact identification stage. However, under certain circumstances it might be possible that people outside the project conduct it.

External experts: For R&I projects that produce outcomes that change rapidly and that can be implemented within a short-term timeframe, it can be desirable that external experts who have experience with managing rapid technological changes in societal settings assist the researchers in the R&I project with the ethical impact identification.

Designated consultants: For commercial entities, it can be valuable to involve consultants who have experience in conducting ethical impact identifications. These consultants could work on a commercial basis or they can be provided by public organisations (e.g. by research funding bodies).

1.7.4 Essential elements of the ethical impact identification stage

The ethical impact identification stage should preferably start early in the R&I project so as to ensure that possible ethical impacts can be evaluated in a timely manner, and be translated into recommendations and/or remedial actions. Below, we discuss the three essential steps of every ethical impact identification stage:

- Adjusting the EIA to the technology readiness levels applicable to an R&I project
- Determining requirements and selection of EIA methods

- Determining requirements and possible approaches for ethical impact identification

1.7.4.1 Assessing the technology readiness level of R&I project outcomes

The first step in any ethical impact identification stage is the assessment of the technology readiness of the expected outcomes of an R&I project. For this, the Technology Readiness Level (TRL) methodology can be used.

This sub-section describes why a TRL assessment should be conducted, how this should be done and what the follow-up involves.

Why conduct a TRL assessment?

A TRL assessment should be conducted because the level of applicability of the outcomes of a R&I project influences significantly the extent to which concrete impacts can be anticipated. Therefore, for each EIA, the tentative rule applies that *the closer R&I outcomes are to being applied; the more the EIA should focus on ethical impact identification compared foresight studies.*

EIA can be done in an R&I project in *applied science*: in the natural and life sciences, and the social sciences. An EIA for applied science is conducted in the same manner as an EIA is conducted for technological research and innovation. This means that it uses the same threshold analysis and stages of the EIA. EIAs can also be conducted for *fundamental science* in natural, life and social sciences. An EIA for fundamental science is always done at the *level of research programs* for new fields.

EIAs in fundamental science will often face the challenge of missing knowledge about potential applications and impacts of fundamental research. As a solution to this problem, the foresight stage is significantly expanded and allocated more financial and time-based resources relative to the EIA scales for technological research and innovation. Nonetheless, in conducting EIA for fundamental science, no matter how much time and effort are put into foresight, speculating on potential future applications and impacts of fundamental research has an increased likelihood that the predictions are wildly off the mark.

How to conduct a TRL assessment

The European Commission provides a blueprint for conducting a TRL assessment, stipulating nine distinct levels defined by certain criteria[21]:

TRL level	Criterion
TRL 1	Basic principles observed.
TRL 2	Technology concept formulated.
TRL 3	Experimental proof of concept.
TRL 4	Technology validated in lab.
TRL 5	Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies).
TRL 6	Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies).
TRL 7	System prototype demonstration in operational environment.

[21] European Commission Decision C (2014)4995, 22 July 2014; General Annexes

TRL level	Criterion
TRL 8	System complete and qualified.
TRL 9	Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space).

Table 5: The different Technology Readiness Levels (TRLs)

To do a TRL assessment, the R&I project team should use the prospective outcomes of its research activities as the input for determining the TRL level. For instance, an R&I project that aims at developing a demonstrator application for smart grid technologies probably ends up as TRL 6 or 7. However, a nano-technology R&I project that investigates the topology of certain materials would probably end up with a TRL that is based at either levels 1, 2 or 3.

Follow-up of the TRL assessment
The outcomes of a TRL assessment should lead to a tentative and reasoned balancing of activities of foresight and ethical impact identification. No strict guidelines for this balancing are given. The reviewing organisation (e.g. the research funding organisation) can, however, expect that, with a TRL of 1, 2 or 3, more attention will be paid to the foresight activities whereas, with a TRL of 6 or 7, more attention will be paid to the ethical impact identification activities.

1.7.4.2 Methods for foresight studies

Once the TRL assessment has been completed, both the foresight studies and the overall ethical impact identification activities can start. These activities are often intertwined and therefore can be conducted at the same time. For instance, if in the ethical impact identification impacts on *privacy* are seen as a predominant area of concern in an R&I project, this probably directly influences the stakeholder involvement during the foresight studies (by choosing experts on privacy in the expert consultation, or focusing on privacy issues in a citizen panel).

We outline the different foresight study methods that can be used. These methods can be categorised according four explicit features: focusing on expertise, interaction, creativity or evidence.

Methods involving evidence, expertise, creativity and interaction
The different methods are categorised according to their reliance on *evidence, expertise, creativity* and *interaction*. Methods can be classified based on their degree of reliance on expertise vs. interaction and on creativity vs. evidence. In order to obtain the widest range of analysis, it is helpful to combine methods that are different from one another in terms of these sources of knowledge. On the one hand, expertise-based methods (such as roadmapping and expert surveys), for example, may be helpful in determining the most likely futures, as well as the probabilities of possible futures. Creativity-based methods (such as wildcard workshops and scenario writing), on the other hand, can be useful in identifying wild card events that may challenge the occurrence of "highly probable" situations in the future. With interaction-based methods (such as expert and citizen panels), participants often gain considerably from being brought together and challenged to articulate ideas and exchange them with their peers (and indeed with the views of non-expert stakeholders). Evidence-based

methods (such as a literature review and trend analysis) are particularly helpful for understanding the actual state of development of the field to which the R&I project belongs.

1.7.4.3 Basic methods for foresight studies

The basic methods for foresight studies are structured activities or approaches that need to be followed in any EIA. Therefore, these basic methods are the minimum ones to be applied in a small-scale EIA (as established in the threshold analysis). Application of these basic methods can be stipulated as requirements for the conduct of any EIA by a reviewing body (e.g. a research funding organisation).

- (Evidence) Exploration of existing work – horizon scanning

The EIA process should always start with an analysis and an assessment of existing foresight studies in the field or in related fields. This can be done in the form of a structured literature review or a bibliometrical analysis. Horizon scanning is a suitable approach for exploring existing work. Horizon scanning clarifies the big picture behind the issues to be examined. It is often carried out by doing desk research, which should involve data coming from a wide variety of sources, such as Internet repositories, research communities, online and offline databases and journals, ministries and agencies, non-governmental organisations, and publications of international organisations and companies. Also, a small group of experts who are at the forefront in the area of concern can undertake horizon scanning by sharing their perspectives and knowledge with each other. A horizon scan can provide the background for strategic planning and decision-making.

- (Expertise) An expert consultation

As the simplest and most basic level of stakeholder engagement, an expert consultation should be conducted in an EIA. An expert consultation can take the form of a number of interviews, a short workshop or a small survey. Experts are to be selected on the basis of their expertise with the specific ethical impacts at hand or the particular R&I field.

- (Creativity) Roadmapping

A basic way in which the future development of the outcomes of the R&I project can be captured is by constructing a roadmap. This consists of collecting, synthesising and validating information about the expected R&I outcomes, and representing the trends within graphical displays associated with support documents. The approach should be based on a light and modular process by using a “toolbox”. The toolbox should contain different modules, depending on the roadmapping areas, issues, context and objectives. Roadmapping consists of three distinct steps: (1) defining the focus and timescale of the roadmap, (2) building the vision, (3) creating the roadmap contents (R&I outcomes).

1.7.4.4 Methods for medium-scale foresight studies

For medium-scale EIA procedures, expensive and time-consuming methods such as Delphi interviews and scenario writing will not be feasible. However, there are alternatives to these methods that require less time and resources so that comprehensiveness of the forecasting methods can be maintained in terms of knowledge sources used.

Thus, in addition to the basic methods the following may be a sequence of methods for a medium-scale EIA:

- (Evidence) Trend analysis

To investigate possible future impacts of R&I outcomes, researchers can aim to identify a trend in their area of R&I activities. A trend is a general tendency or direction that is already evident from past events, and hence is increasing or decreasing in strength of frequency of observation; it usually suggests a pattern. Three distinct features define the outlines of a trend analysis: (1) a specific time horizon, (2) the reach of impacts (regional/global, specific field/more general field) and (3) intensity of expected impact(s).

- (Interaction) Stakeholder brainstorming/futures wheel

As a form of stakeholder engagement focused on interaction, structured brainstorms can be organised in which specific aspects of the R&I project are discussed among stakeholders. The Futures Wheel is one way of organising thinking and questioning about the future. It produces a graphical visualisation of the direct and indirect future consequences of a change or development.

1.7.4.5 Methods for large-scale foresight studies

For a large-scale EIA, the financial and time resources to be used for foresight studies are the greatest. There is room for methods that are organisationally difficult and time-consuming but offer high quality information, such as the Delphi method or scenario writing. Stakeholder involvement, and especially *citizen* engagement or participation, will be important at this level to identify public concerns about the future and to establish legitimacy of the foresight process. This means that it is useful to include citizen panels within the mix of methods. The following four sets of methods may act as a sequence of methods in which the four sources of knowledge (i.e., expertise, interaction, creativity and evidence) are well represented:

- (Expertise) Delphi interviews

The Delphi method is a survey technique that involves repeated polling of the same individuals, feeding back anonymised responses from earlier rounds of polling. The underpinning concept is that this feedback loop will allow for better judgements to be made without there being undue influence from forceful or high-status advocates. There are three phases to conducting a Delphi. These are: (1) selection of the topic, (2) designing the questionnaire, and (3) selection of the panel of experts. Guidance on each of these phases is available at the European Foresight Platform[22].

[22] EFP (2012). European Foresight Platform.
<http://www.foresight-platform.eu/community/forlearn/what-is-foresight/> accessed on October 2015.

- (Interaction) Citizen panels

In order to gain the input from stakeholders during the foresight studies process, citizen panels or focus groups can be organised. These panels might take place during conferences, workshops or trainings at which stakeholders are invited to participate actively. The outcomes of citizen panels can take the form of written feedback on the R&I project setup, minutes of the meeting, or a collaborative report in which probable or preferable impacts of the R&I project are discussed.

- (Creativity) Scenario writing

Scenarios are used in a wide variety of ways as tools for foresight analysis, e.g., for developing strategies and pathways. Many of the scenarios are constructed from the past and present and head towards the future; they are therefore forward-looking. Backcasting scenarios instead look backwards from a desired future[23,24]. The major concern is not which futures are most likely to occur, but how to attain desirable futures. Multiple preferred futures can be taken as starting points for the backcasting exercise (pluralistic backcasting[25]). Three main classes of scenarios can be distinguished[26,27,28] that answer the following three questions: what will happen (trend extrapolations, business as usual scenarios, probable scenarios); what could happen (forecasting, foresighting, strategic scenarios); and what should happen (normative scenarios, like those used in backcasting).

1.7.4.6 Overview of methods for ethical impact identification

EIA level/Method type	Evidence	Expertise	Interaction	Creativity
Small-scale (basic methods)	Horizon scanning	Expert consultation		Roadmapping
Medium-scale	Trend analysis		Brainstorm/futures wheel	
Large-scale		Delphi interviews	Citizen panel	Scenario writing

[23] Robinson, J.B., Futures under glass: A recipe for people who hate to predict. *Futures*. 22, 1990. 820–842.
[24] Hirschorn, L., Scenario writing: A developmental approach. *Journal of the American Planning Association*. 46, 1980.172–182.
[25] Tuominen, Anu; R. Tapio, V. Varho, T. Järvi, D. Banister, Pluralistic backcasting: Integrating multiple visions with policy packages for transport climate policy. *Futures.* (2014) vol. 60, 2014. pp. 41 – 58.
[26] Vergragt, P.J., J. Quist, Backcasting for sustainability: Introduction to the special issue. *Technological Forecasting and Social Change*. 78, 2011. 747–755.
[27] Amara, R., The futures field. Searching for definitions and boundaries. *Futurist*. 15, 1981. 25–29
[28] Börjeson, L., M. Höjer, K. Dreborg, T. Ekvall, G. Finnveden, Scenario types and techniques: Towards a user's guide. *Futures.* 38, 2006. 723–739.

Table 6: Overview of foresight methods, according to the EIA level.

1.7.4.7 Steps for the ethical impact identification

The ethical impact identification activities take place in sequence with the foresight studies, meaning that both activities can and usually should be conducted at the same time. The ethical impact identification stage includes (1) a description of the R&I outcomes (e.g. the technologies that are being developed) and preliminary ideas of ethical impacts, (2) a description of the expected impacts of the R&I outcomes (in congruence with the foresight outcomes) and (3) a determination of ethical values and principles that are at stake for the given impacts.

1.7.4.8 Describing the technology and preliminary ethical impacts

In order to conduct the ethical impact identification, the assessor (and his/her team, if s/he has one) first prepares a description of the technology and an initial identification of ethical values and principles and, possibly, relevant interests of stakeholders. The assessor investigates if features of the technology are likely to impact moral values or principles negatively. In some analyses, identification of the interests of different stakeholders can be chosen and these can be related to ethical principles. This investigation results in a structured list of ethical issues that may emerge if certain future technological or social options are realised as a result of the project being conducted. As the EIA progresses, the assessor (and possibly stakeholders who may participate in the process) can identify additional values and principles impacted by the proposed technology.

1.7.4.9 Methods for ethical impact identification

After the preliminary investigation, methods for conducting the ethical impact identification need to be selected. This selection will depend on the level of the EIA (as established in the threshold analysis), but also on some additional factors.

First of all, the ethical impact identification can be conducted by a conceptual analysis (e.g. determining ethical impacts based on explicit ethical principles) or by an empirical analysis (e.g. determining ethical impacts by consulting experts).

Secondly, during the identification stage, ethicists may do two types of identification. A first type is that of *explicit moral issues*, where a technological or social option potentially violates a moral principle, value or norm. For example, in the identification stage, it may be concluded that developments in robotics may result in certain types of robots that violate people's autonomy or privacy. A second type is that of *intuitive moral issues*, where a technological option has certain characteristics or implications that intuitively feel morally problematic or controversial, even though it is not immediately clear how and whether the option violates any moral value or principle.

Below, the two different methods are presented according to their conceptual or empirical basis and according to whether they focus on explicit moral values or intuitive moral issues. Also, their relative advantages and disadvantages are outlined.

1.7.4.10 Ethical impact identification through conceptual investigations

Method(s) focusing on explicit moral values:

- Ethical checklist approaches (for a basic EIA)

Ethical checklist approaches offer practical and comprehensive ways to determine ethical impacts and can be used in any EIA. When using an ethical checklist approach, a list of ethical principles or values is cross-referenced with the technological options that were identified during the foresight studies. If the ethical checklist is drawn up adequately, this approach has the advantage of being thorough because it ensures that all relevant values or principles are checked upon. It also has a disadvantage, which is that it does not allow for the identification of intuitive moral issues. In addition, it is difficult for any checklist to be suitably comprehensive, so that it covers all moral values or principles that may be at issue with a certain technology[29].

- Use of ethical theories (for medium-scale and higher EIAs)

In the event that the assessors conducting the EIA have an expertise in ethics, they can use ethical theories to determine the ethical impacts of the R&I activities. The most frequently and well-known ethical theories are (a) consequentialism, (b) deontological ethics and (c) virtue ethics. Other approaches, such as care ethics or value-ethics, might be used, depending on the field of research under development (i.e. care ethics would be an appropriate approach for research related to healthcare).

Method(s) focusing on intuitive moral issues:

- Situational approaches (for a large-scale EIA)

Situational approaches are those in which the analyst does not start out with a list of moral principles or values, but screens the research and innovation options by drawing on his or her moral intuitions. This leads to a collection of technological options that are found to be morally problematic from an intuitive point of view.

1.7.4.11 ethical impact identification through empirical investigations

Method(s) focusing on explicit moral values:

- Consolatory / consultative approaches

Consolatory approaches are approaches in which the assessor reviews previous ethical analyses (and possibly other analyses that may contain ethical observations, such as policy analyses) in order to collect ethical issues that have been identified by others, or interviews experts to collect their opinions and evidence on possible ethical issues. The assessor does not identify any ethical impacts him- or herself in this approach, although he or she has to be able to recognise those issues identified by others and place them in order.

Method(s) focusing on intuitive moral issues:

[29] Note, additionally, that ethical checklists can be used explicitly or implicitly. An assessor may not use a written checklist at the identification stage, but may still apply the same set of ethical principles and therefore make use of an implicit checklist.

- Techno-ethical scenario building

By constructing descriptive narratives (scenarios) about the way a technological innovation might impact society, a more comprehensive analysis of the ethical impacts of research and innovation can be obtained. This method uses a three-step methodology: (1) it provides a descriptive account of the present situation (both regarding the technology and existing ethical controversies) to ground the analysis, (2) it explicates potential moral controversies by means of the ethics of New and Emerging Science and Technology (NEST) approach) that considers technological expectations, critical objections to the technology, and patterns of arguments among stakeholders, and (3) it permits closure by judging plausible resolutions of the ethical controversies.

1.7.4.12 Overview of methods and resources for ethical impact identification

Method type	Conceptual investigation	Empirical investigation
Explicit moral values	Ethical principles checklist, Use of ethical theories	Consolatory approaches
Intuitive moral values	Situational approaches	Techno-ethical scenario building

Table 7: Overview of ethical impact identification methods.

1.7.5 Presentation of ethical impact identification results

After the ethical impact identification and foresight studies have been initiated, the assessors need to make sure that the outcomes of their activities are documented frequently and in a comprehensive manner. In the event that a periodic review is conducted in the EIA, the reviewing bodies might set certain milestones with regards to the presentation of the results. The following types of presentations of results might typically be requested or required:

- For a small-scale EIA: a report, outlining the activities that have been undertaken in the Ethical impact identification stage, the R&I outcomes that can be expected and the consequent ethical impacts that have been identified is required. This report will generally have the following structure:
  - Introduction
  - Description of expected R&I outcomes (e.g. the technology being developed)
  - Overview of methods used and activities conducted
  - Overview of anticipated ethical impacts
  - Conclusion and Discussion
- For a medium-scale EIA: Additional to the report, a number of academic publications or public deliverables might be requested or required that explore

the ethical impacts that have been identified and share the findings with the broader (academic) community.

- For a large-scale EIA: Additional to the report and academic publications, it might be requested or required to present the outcomes of the EIA publicly, especially those resulting from stakeholder engagement.

1.7.6 Recommendations

Based on the above description of the ethical impact identification stage of the EIA, we present three recommendations for implementing this stage in an appropriate way:

- A repository of documentation of the ethical impact identification stages for R&I projects would be very useful, in order to avoid duplication of the same activities.
- If the impacts of an R&I project remain uncertain, more resources of the EIA should be allocated to the foresight studies and fewer resources to the ethical impact identification.
- In the event that periodic reviews of the EIA take place, the assessor(s) might be requested or required to work on certain milestones with regards to the presentation of the EIA outcomes (e.g. a report, publications or public presentation of the results).

1.8 ETHICAL IMPACT EVALUATION

The ethical impact evaluation stage of an ethical impact assessment (EIA) is aimed at evaluating the relative severity of ethical impacts that have been determined, as well as the likelihood of occurrence of these impacts and potential value conflicts that may be at stake.

Here we take the example of a proposed project on the Internet of Things (IoT). For instance, in the ethical impact identification stage, the assessor may have determined that behavioural profiling by IoT systems presents privacy issues. In the evaluation stage, the assessor determines the threats, vulnerabilities and risks, the advantages and disadvantages, their impacts, the permissibility of allowing the violation of privacy by these technologies, how privacy may conflict with other values in the use of IoT technologies (such as autonomy, security and well-being), and on what grounds such conflicts could, and should, be resolved.

1.8.1 Function

What is ethical impact evaluation?

- Ethical impact evaluation comprises the assessment of the relative importance, the likelihood of occurrence and the possible value conflicts of ethical impacts that have been determined earlier.

The function of the ethical impact evaluation stage in the EIA process can be explicated as follows:

- To assess the relative importance of ethical impacts, which have been identified.

- To locate potential value conflicts and, where possible, to resolve these.
- To find workable conceptualisations of the ethical impacts and the ethical values/principles, which apply to them.

1.8.2 Method

In order to complete the Ethical impact evaluation stage, five procedural steps have to be followed. The following table depicts the procedural steps of the Ethical impact evaluation stage:

Summary of key procedural steps:
1. Decide which methods should be used; base this decision on the EIA level
2. Conduct a contingency analysis to evaluate the likelihood of ethical impacts to occur
3. Assess the relative importance of ethical impacts a. Based on the contingency analysis b. Based on the methods applied
4. Identify potential or actual value conflicts and, if possible, aim at resolving these a. If value conflicts cannot be solved, this should be explicitly recognised
5. Clarify the ethical impacts and the related ethical values/principles and formulation of workable conceptualisations

Table 8: Procedural steps for the ethical impact evaluation stage

1.8.3 Who conducts the ethical impact evaluation?

To determine who should work on the ethical impact evaluation, roughly the same arrangement as in the ethical impact identification stage can be used. That is to say, ethical impact evaluation can be conducted by researchers within the R&I project, by external experts, or by designated consultants. Who will perform the ethical impact evaluation will ultimately depend on the desirability or an external review and on the resources available.

1.8.4 Essential elements

1.8.4.1 Deciding on methods for ethical impact evaluation

Similar to the ethical impact identification stage, the assessor will have to decide on the methods to deploy for working on the ethical impact evaluation. The choice of these methods will largely depend on the scale of the EIA that was decided upon by means of the threshold analysis. Basically, methods can be distinguished for three types of inquiries: methods in (1) desk-research approaches, (2) for conducting expert consultations or (3) in participatory approaches.

- **Desk-research approaches:** Desk-research approaches form the basis of all activities undertaken to conduct the ethical impact evaluation stage. These include reviews of existing evaluation of ethical impacts in related R&I projects and the deployment of certain conceptual framework, for instance when trying to resolve conflicts of values.
- **Expert consultation:** Because some activities in the ethical impact evaluation stage might call for ethical expertise or expertise in other specific areas (e.g. for field-specific expertise when conducting the contingency analysis), methods for expert consultation might be selected. For this, similar methods as those mentioned in the ethical impact identification stage can be selected (e.g. an ethical Delphi). However, the focus will be different (not inquiring about possible or probable ethical impacts, but about e.g. the relevant importance of already determined ethical impacts).
- **Participatory approaches:** If the scale of the EIA and the available resources allow this, then selecting participatory approaches for conducting parts of the ethical impact evaluation stage is preferred. These focus on stakeholder engagement, in the form of e.g. focus groups or citizen panels.

1.8.4.2 Conducting a contingency analysis

A contingency analysis is a detailed analysis of the way in which the very occurrence and strengths of occurrence of the ethical impact depends on various *factors*, such as the presence of certain technological features or configurations, aspects of the social and institutional context in which the technology is used, aspects of users or user groups, and particular ways of using the technology.

A contingency analysis can therefore be seen as a continuation of the foresight studies, but with a focus on different aspects of the context in which the ethical impact occurs instead of on determining the impact itself. For instance, an assessor might first anticipate the ethical impact of violation of someone's privacy. However, whether and to what extent internet cookies violate user privacy clearly depends on many factors: the type of information contained in the cookie, policies that regulate the use of such cookies, the browser's support of privacy settings, the behavioural patterns of internet users, and so forth. In a contingency analysis, many such contingencies are laid bare. A contingency analysis can be conducted in the following way:

- Conducting an extensive desk-review in which certain factors derived from the context of an ethical impact are laid bare
- Conducting a horizon scanning for each of the identified factors, determining the likelihood of it changing in the future (e.g. current technologies in the development stage being put on the market)
- Constructing short scenarios for the ethical impacts that have been determined in the ethical impact identification stage.

1.8.4.3 Assessing the relative importance of ethical impacts

Based on the contingency analysis, and additional desk-research, expert consultations or participatory processes, the relative importance of the ethical impact under study can be tentatively arrived at. This relative importance will depend on at least three factors: the normative importance of the value or principle that may be violated (either arrived at through the use of ethical theories or stakeholder consultation), the likelihood that it will be violated, and the intensity by which it may be violated.

For example, a new neuro-technology may be massively deployed in the future, which radically undermines the ethical principles of human autonomy. By arguing that autonomy is an essential value, we could conclude that the ethical impact raised by this technology is very significant. The three factors mentioned actually define different scales of importance of ethical impacts:

1. A scale on which moral values and principles could be ranked for their importance (which is, however, bound to be controversial)
2. A scale to assess risks of occurrence (that a value or principle is violate)
3. An intensity scale (which assesses the expected strength and scope of the violation, if it is to occur)

These three scales inform the methodologies that can be used for conducting the assessment of relative importance of ethical impacts:

- **For basic EIA procedures (in all cases):**
  1. Evaluate the relative importance of the ethical impacts identified by: (1) conducting a desk-review to assess which ethical principles and values are brought into consideration for an ethical impact in the literature, considering and identifying the appropriate contexts where certain principles may take priority (e.g. security and privacy when considering ethical impacts of an ambient technology) and (2) evaluate them by using an ethical theory (such as consequentialism, deontology or virtue ethics).
  2. Use the contingency analysis to assess the likelihood of the ethical principles or values to be violated.
  3. Assess the severity of impacts by considering factors of scale and intensity such as (1) the number of people that might be harmed, (2) the severity of the harm, (3) the spread of the impacts through space (e.g. considering the area being impacted) and time (e.g. considering the speed at which impacts can occur).
- **For medium-scale or large-scale EIA procedures (in addition to the basic procedures):**
  1. Evaluate the relative importance of the ethical impacts identified by: (1) conduct an expert consultation to gather opinions on the relative importance of the ethical principles and values at stake or (2) organise participatory stakeholder engagement such as focus groups or citizen panels to gather opinions.

2. Conduct an expert consultation to get additional inputs and feedback on the contingency analysis. Balance the opinions of the experts and the outcomes of the contingency analysis to determine the likelihood of the ethical principles and values to be violated.
3. Utilise the same expert consultation to gain additional opinions about the severity of possible ethical impacts, based on the same parameters as used for the basic EIA procedures.

EIA scale/Dimension of ethical impact:	Normative importance ethical impact	Risk for violation of ethical principles/values involved	Severity of impacts
Basic procedures	• Desk review • Ethical theories	• Outcomes of the contingency analysis	• Analysis of factors of scale and intensity of ethical impacts
Medium-scale/large-scale	• Expert consultation • Stakeholder engagement	• Expert consultation for input on the contingency analysis	• Expert consultation for input on severity of ethical impacts

Table 9: Overview of procedures for evaluating the relative importance of ethical impacts

1.8.4.4 Identification and resolution of value conflicts

Once the relative importance of the ethical impacts has been evaluated, the ethical principles and values that are at stake when considering these ethical impacts need to be evaluated as well. That is to say, especially the relationships between these ethical principles and values need to be evaluated, which can be done by identifying possible value conflicts and aiming to overcome them.

It will rarely or never be the case that a particular technological artefact or scientific application has an impact on one value and is neutral with respect to all the others. It will normally support, to a greater or lesser extent, certain values or principles, while violating or harming others. An attempt to mitigate the violation of one principle may result in the violation of another principle. This creates a value conflict. For example, CCTV cameras are intended to provide security, but in doing so, they potentially violate privacy. Removing the cameras protects privacy, but runs the risk of compromising security.

In order to identify and resolve value conflicts, the assessor can resort to the following five rules of thumb that also explicate the different types of procedures that can be used.

1. **A first rule of thumb** is to follow the conviction in many ethical theories that that some values are fundamental, in two senses. They (1) are fundamental in the sense of not being reducible to other values, and (2) in that it is normally very important (considering public consensus) to uphold them. At least in the West, fundamental values include autonomy, freedom, dignity (including the right to life), justice and well-being. There are other candidates as well, such as privacy, equality, security and bodily integrity. Normally, fundamental values will get precedence over non-fundamental values in value trade-offs. Often, however, value conflicts will occur between two or more values that are both considered to be fundamental. In such cases, people will often have different reasons or moral intuitions for giving priority for one value over the other. So how to proceed?
    - **Procedure:** Refer to (i) fundamental values as they are discussed in ethical theories and/or (ii) fundamental values as they are agreed upon in authoritative, widely accepted documents such as the declaration of human rights.
2. **A second rule of thumb** is that when fundamental values conflict, it is taken into account how severe the violation of one value is when the other is given priority to, and to choose that action that least compromises a fundamental value, understood in terms of the degree to which and scale at which a violation takes place. For example, if the choice is between a mild violation of autonomy, in which informed consent is partially but not fully realized, and a large injustice, in which thousands of people are denied opportunities that others have, then based on the degree of violation, the fundamental value is given priority that would be violated most. This kind of assessment requires an understanding of the circumstances in which the violations occur in order to assess the severity of violation.
    - **Procedure:** Take into account the evaluation of the severance of the ethical impact, looking at the values at stake in this evaluation.
3. **A third rule of thumb**, in cases in which two fundamental values seem to be equally violated, a solution is to project one's moral intuitions onto the situation to determine which value appears more important in the particular situation, and to also employ moral reasoning to explore pros and cons for giving priority for one value over the other. This is, however, a process for which there is no sure method. It can be taken into account, though, that particular types of situations or contexts favour some values more than others. For example, in an airport context, the value of security is generally thought to be more important than the value of privacy, since the stakes for security are so high.
    - **Procedure:** Construct an ethical argument, based on moral intuition, to favour one value over another.
4. **A fourth rule of thumb** is that conflicts of moral values can be resolved through deliberation and negotiation between different parties, who ideally

constitute or represent a representative sampling of stakeholders in the situation.
    - **Procedure:** (only for medium-scale and large-scale EIA processes): organise a stakeholder consultation to use their inputs for balancing the values that are at stake.
5. **A fifth rule of thumb** is that one can attempt to avoid the value conflict altogether by thinking up reconfigurations of the situation in which the value conflict will not occur. It is often possible to avoid value conflicts by avoiding situations in which they occur. Some examples will be discussed in the sections concerning the recommendation and the remedial action stages.

1.8.4.5 Constructing workable concepts for relevant principles and values

Once the relative importance of the ethical impacts has been evaluated and possible value conflicts have been identified and, if possible, resolved, all the needed information is present to proceed to the final stages of the EIA (the recommendation and the remedial action stages). However, the ethical principles and values that are at stake are ethical concepts that may require conceptual clarification. For example, what is freedom, what kinds are there, and what is the importance of and justification for each? These questions can be answered in a conceptual analysis. Conceptual analysis may also be used to clarify non-moral concepts that play an important role in an analysis. For example, in a moral evaluation of cloning, it may be necessary to clarify the concept of cloning, or that of genetic engineering.

To conduct this conceptual analysis, the assessor can follow the following steps:

- A literature review of definitions of the respective ethical principle or value
- Constructing a definition of the respective ethical principle or value by drawing relationships between its concept and related concepts

1.8.5 Presentation of ethical impact evaluation

After the ethical impact evaluation activities have been initiated, the assessors need to make sure that the outcomes of these activities are documented frequently and in a comprehensive manner. In case a periodic review is applied to the EIA, the reviewing bodies might set certain milestones with regards to the presentation of the results. The following types of presentations of results might typically be requested or required:

- For small scale EIA: a report, similar to the report written for the ethical impact identification stage with the following structure:
    - Introduction
    - Overview of methods used
    - (If applicable) outcomes of expert consultations and/or stakeholder engagement
    - Outcomes of contingency analysis
    - Discussion of the relative importance of ethical impacts
    - Discussion of the value conflicts and possible resolutions for these conflicts
    - Discussion and presentation of workable concepts

- Conclusion and Discussion

- For medium-scale and large-scale EIA: The same guidelines can be followed as for the ethical impact identification stage. Results of the ethical impact evaluation might be expected to be published and presented to the public.

1.8.6 Recommendations

Based on the above exposition of the ethical impacts evaluation as part of the EIA, we present a number of recommendations for implementing this stage in a proper way:

- Because of the controversial nature of deciding on the relative importance of ethical impacts, assessors should be required to be nuanced in conducting this evaluation.
- Since certain knowledge of ethical theories would be a prerequisite, it would be recommended to provide for sufficient training for the assessor in order to ensure the assessor's sufficient knowledge in this area.
- A knowledge repository with documents relevant for the ethical impact evaluation stage (such as widely acknowledged lists with ethical principles and human rights declarations) would be very useful for assessors in order to reduce the amount of time spend on activities such as desk review.

1.9 REMEDIAL ACTIONS

1.9.1 Introduction

The remedial actions stage of an ethical impact assessment (EIA) is aimed at formulating and executing so-called "remedial actions" that are based on the foresight and ethical impact evaluation stages. These remedial actions can take the form of (i) recommendations and (ii) design interventions. The purpose of remedial actions is to overcome the ethical impacts that have been identified and evaluated in earlier stages of the EIA. The evaluation stage lays the basis for remedial actions by identifying the importance of certain ethical principles and by proposing how they should be balanced against each other. However, the evaluation stage only contains general, de-contextualised recommendations. In the remedial actions stage, the assessor uses these, with other considerations, to arrive at practical recommendations for the involved stakeholders in the project or program and at design interventions to deal with ethical impacts at the technology level.

1.9.2 Function

What are remedial actions?

- Remedial actions are follow-up activities based on the earlier findings in the EIA process that are aimed at overcoming the relevant ethical impacts. These actions can both be aimed at internal intervention into the design of the R&I outcomes and at external recommendations for future R&I efforts.

The function of the remedial actions stage can be explicated as follows:

- To translate the earlier findings in the EIA into practical recommendations for the relevant stakeholders

- To translate the earlier findings in the EIA into design interventions at the project level
- To identify possible gaps between the earlier findings and practical possibilities for remedial actions and, if necessary, reiterate parts of the previous stages.

1.9.3 Method

We explicate the method of a remedial actions stage of an EIA by describing a sequence of procedural steps that, if followed correctly, should lead to successful formulation and implementation of remedial actions for an R&I project. The following table depicts these procedural steps:

Summary of key procedural steps:
1. Gather relevant information about recommendations and design interventions proposed by other related R&I projects
2. Formulate and implement design interventions, as appropriate regarding the earlier identified ethical impacts and according to three distinct steps: a. A conceptual stage, at which the relevant values are transformed into workable concepts b. An empirical stage, at which the interactions between humans and the R&I outputs are investigated c. A technical stage, at which the researchers, possibly together with stakeholders, formulate and implement design interventions
3. Formulate different recommendations, classified according to the following typology: a. Societal recommendations b. Organisational recommendations c. Regulatory recommendations d. Policy and public policy recommendations
4. Present the remedial actions in an appropriate manner: a. For design interventions: in the form of a report with the proposed design interventions or a survey for stakeholders b. For different types of recommendations: i. Societal & organisational recommendations: these are presented in the form of a simple report ii. Regulatory recommendations: these are presented in the form of legal proposals iii. Policy recommendations: these are presented in the form of green/white papers

Table 10: Procedural steps for the remedial actions stage

1.9.4 Who performs the remedial actions?

Who performs the remedial actions will depend largely on the type of remedial actions that are selected to be implemented in line with the earlier findings of the EIA. For each of the below mentioned types of remedial actions, the following people can work on them:

- **For design interventions:** Design interventions are usually undertaken by the researchers in the R&I project, in collaborations with the project's assessor(s). This implies that a coordinated effort needs to be made to think about the outcomes of the R&I project with assessors that have some knowledge of ethics and researchers that know about the technicalities of the R&I outcomes.
- **For societal and organisational recommendations:** The assessor(s) in the R&I project usually work on formulating societal and organisational recommendations.
- **For regulatory and policy recommendations:** The assessor(s) in the R&I projects usually collaborate with experts in the areas of law and policy making to formulate regulatory and policy recommendations.

1.9.5 Essential elements

Based on the findings in the earlier stages of the EIA, the assessor can engage in different types of remedial actions. The following checklist functions as a guide for determining which remedial actions are appropriate:

Type of ethical impact:	Type of remedial action:
Ethical impact due to technology being developed in the R&I project (e.g. big data applications)	Design interventions (Medium-scale, large-scale EIA)
Broad social impacts due to R&I activities (e.g. changing economic paradigms)	Societal recommendations (All types of EIA)
Impacts due to malfunctioning of organisations (e.g. risk for conflicts of interests)	Organisational recommendations (All types of EIA)
Impacts due to regulatory or conventional deficiencies (e.g. risk for corruption, legal opaqueness)	Regulatory recommendations (Medium-scale, large-scale EIA)
Impacts due to insufficient policy support (e.g. environmental risks)	Policy recommendations (Medium-scale, large-scale EIA)

Table 11: Checklist for the type of remedial actions to be chosen

1.9.5.1 Design interventions

Design interventions are *any kinds of changes in the design of the R&I outcomes in order to resolve identified ethical impacts.* Thus, unlike recommendations, design interventions are internal to the workings of the R&I project. They are usually targeted at technical aspects of the project and innovation activity. Since not many approaches have as yet been developed to organise and structure design interventions that are aimed at resolving ethical impacts, the EIA framework incorporates the most prominent existing approach: *value sensitive design.*

Value sensitive design

One of the main approaches to incorporate ethical concerns in the design of technologies is the "value sensitive design" approach, which was initiated by Batya Friedman[30] and consequently developed by scholars such as Jeroen van den Hoven[31]. It was initially developed specifically for information technologies, but has also been applied to different engineering sciences and can in principle be used for many kinds of technology development[32]. The method "employs an integrative and iterative tripartite methodology, consisting of conceptual, empirical, and technical investigations"[33].

The following three distinct steps can be followed in order to incorporate values in technology design:

1. *The conceptual stage:* At the conceptual stage, both the technology in question, the values that ought to be inscribed in it and its context of use (e.g. stakeholders involved) are conceptualised in a philosophically rigorous manner. For instance, if trust ought to be inscribed in a certain IT system, a philosophically informed working definition of trust is provided. For this stage, the assessor can extensively draw from earlier work done in the ethical impact evaluation stage (arriving at workable conceptualisations).
2. *The empirical stage:* Methods for empirical research such as can be found in the social sciences are used to inform the human context in which the technology at hand will be used. Such can be for instance interview methods, survey methods and ethnographic methods. This stage should establish how different stakeholders apprehend their values in an interactive context mediated by the respective technology. In conducting this stage, the stakeholder can therefore extensively draw from the stakeholder engagement exercises in the Ethical impact identification stage.

[30] Friedman, B., & P. Kahn. Value sensitive design: Theory and methods. *University of Washington Technical*, (December), 1–8. 2002. http://doi.org/10.1016/j.neuropharm.2007.08.009
[31] Hoven, J. Van Den. ICT and Value Sensitive Design. In *IFIP International Federation for Information Processing*. Boston: Springer. 2007.
[32] Cummings, M. L. Integrating ethics in design through the value-sensitive design approach. *Science and Engineering Ethics*, *12*(4), 701–715. 2006. http://doi.org/10.1007/s11948-006-0065-0
[33] Friedman, B., P.H. Kahn & A. Borning. Value Sensitive Design and Information Systems. In K. E. Himma & H. T. Tavani (Eds.), *Human-Computer Interaction and Management Information Systems: Foundations* (pp. 1–27). John Wiley & Sons, Inc. 2006. http://doi.org/10.1145/242485.242493

3. *The technical stage:* At the technical stage, trade-offs between certain values in the technology design (such as between privacy and security) are identified. To do so, the assessor can draw from the value conflicts as identified in the evaluation stage. Accordingly, the design should be altered in order to foster alternative designs that do more justice to each value that ought to be inscribed in the technology.

1.9.5.2 Types of recommendations

Next to undertaking remedial actions that are internal to the R&I project, in the sense of intervening in the design of the R&I outcomes, the EIA might be used to formulate recommendations that are to be implemented on a broader scale (e.g. as industry standards, regulations, policies). Assessors may make different types of recommendations (as applicable to the project, or innovation activity):

- **Societal recommendations**: these include advice on societal aspects such as impact on societal values, public trust, public concerns. Responsibility for implementation: research project team, in engagement with other societal actors such as non-profit and civil society organisations (NGOs and CSOs), media, representatives from industry trade associations and trade unions, and other special interest groups.
- **Organisational recommendations**: these include recommendations for how an organisation identifies, responds to, addresses, manages, avoids or minimises ethical issues. Responsibility for implementation: the organisation conducting the research or innovation activity.
- **Regulatory recommendations**: these are aimed at two types of stakeholders. The first are regulators who might need to put in place new regulations addressing particular ethical issues. The other types of stakeholders are those who would be subject to regulatory strictures. Such recommendations could offer specific guidance on how to meet legal, ethical obligations. They could specify how regulation might need to be put in place or revised to take into account the ethical impact of a particular research or innovation activity. Responsibility for implementation: legislators and regulators.
- **Policy and public policy recommendations**: these include policy advice for any group with decision-making authority and public policy influence. Responsibility for implementation: government organisations, politicians, and public authorities.

1.9.6 Presentation of the remedial actions

Firstly, as a general guideline, Wright recommends that "the assessor should be clear to whom his or her recommendations are directed"[34] – the responsibility for implementing the recommendations should be clearly demarcated and we have provided some examples of the responsibility for the different types of recommendations (these are by no means intended to be exhaustive).

[34] Ibid, p. 165.

Secondly, the remedial actions can be presented in different ways, according to the action type. These different ways of presenting remedial actions are categorised as follows:

- **For design interventions:** these are presented in the form of a report with the proposed design interventions and/or a survey for stakeholders. The survey would need to take place before and after the design interventions have been implemented, in order to assess the effectiveness of the interventions.
- **For societal and organisational recommendations:** these are presented in the form of a simple report. This report can be based on a short review of societal and organisation recommendations that resulted from other projects; complemented by the ones that are specific to the R&I project in which the EIA takes place.
- **For regulatory recommendations:** these are presented in the form of legal proposals. Such proposals generally consist of (i) an explanation of the context and rationale of the proposed regulations, (ii) an explanation of how the proposed regulations fit in with the existing relevant regulatory framework, (iii) a presentation and explanation of the proposed regulations.
- **For policy recommendations:** these are presented in the form of green/white papers. Such papers generally consist of (i) an explanation of the purpose and context of the policy, (ii) the function of the policy, (iii) the procedures involved in its implementation and (iv) a roadmap laying down the implementation trajectory.

1.9.7 Recommendations

Based on the above exposition of the remedial actions stage as part of the EIA, we present a number of recommendations for implementing this stage in a proper way:

- The value sensitive design approach would need to be developed further in order to make it fit with actual R&I practices. At this point, the framework offers only a fairly abstract groundwork on how to implement value sensitive design.
- Overall, recommendations should be viable and implementable. It would also be good to get experts or other external stakeholders to review draft recommendations before their finalisation.[35]
- More concrete frameworks for the way in which recommendations can be drafted should be proposed, primarily with the aim of increasing the communicability of the EIA outcomes as well as giving reviewers of the EIA better criteria for assessing the EIA's effectiveness.

[35] Wright, David, "Ethical Impact Assessment", in J. Britt Holbrook and Carl Mitcham (eds.), *Ethics, Science, Technology and Engineering: A Global Resource, 2nd edition*, Macmillan Reference, Farmington Hills, MI, USA, 2015, p 165.

1.10 REVIEW AND AUDIT STAGE

1.10.1 Introduction

The review and audit stage of an ethical impact assessment (EIA) aims at ensuring independent evaluation of the EIA process and, if necessary, of independent intervention. It especially focuses on the finalisation of the EIA, by reviewing and assessing whether the process has been successfully conducted and whether the assessor has ensured follow-ups of the relevant findings. However, the review and audit stage also plays a role during the entire EIA process, for it can steer the process in the right direction and help correcting mistakes if they occur. The extent to which reviewers are able to steer the EIA process will depend on the type of R&I project (public or private) and the EIA scale.

1.10.2 Function

What is the review and audit stage of an EIA?

- The review and audit stage evaluates and, if necessary, steers the EIA process. The review process entails an iterative evaluation of the process with the aim of generating feedback. The audit process entails the evaluation of certain measurable milestones that the assessor and the reviewer agreed upon.

The function of the review and audit stage in the EIA process can be explicated as follows:

- To provide constructive feedback for improving the execution of the EIA process.
- To provide guidelines for successfully finalising the EIA process.
- To guard agreed-upon milestones and KPIs (key performance indicators) of the EIA process.

1.10.3 Method

We explicate the method of a review and audit stage of an EIA by describing a sequence of procedural steps that, if followed correctly, should lead to a successful threshold analysis for an R&I project. The following table depicts these procedural steps:

Summary of key procedural steps:
1. At the beginning of the EIA process: set the key milestones and review criteria for the review and audit process, as part of the R&I project's proposal a. Agree upon review and audit moments during the project's execution b. Agree upon remedial actions that can be undertaken once certain review or audit criteria are not met
2. During the EIA process: at the agreed upon review and audit moments, the reviewer evaluates: a. The documentation of the EIA process

b. The agreed upon criteria and milestones
3. At the end of the EIA process: during the final review and audit moment, the reviewer ensures: a. Proper documentation of the findings of the EIA b. Proper planning of follow-up measures of the EIA c. Proper signing-off of the EIA at the appropriate level
5. Present the review and audit in an appropriate manner: a. In a "milestone report", which explains how the main criteria and milestones have been attained b. In a general final report, which reflects on the findings of the EIA, the remedial actions and which identifies recommendations for future EIAs

Table 12: Procedural steps for the review and audit stage

1.10.4 Who performs the review and audit of an EIA?

Depending on the funding source of an R&I project, the following stakeholders could be responsible for reviewing the threshold analysis:

When the research is funded by a public research institution: For R&I projects funded and executed at the level of a research institution, the review and audit can take place at the same level. This means that the local EAU (for instance, the university's ethics committee) should be made responsible for reviewing and auditing the EIAs that are conducted.

When the research is funded by a research-funding organisation: For R&I projects that are funded by external research-funding organisations, such as the European Commission, the responsibility for conducting the review and audit of the EIAs lies with these funding organisations.

When the research is funded by a company: For commercially funded research, the review and audit can be done by different organisations. Generally, an internal body within the commercial body can do the review and audit, or an external organisation such as a consultancy.

1.10.5 Essential elements of the review and audit stage

The review and audit process for EIAs that is described in this proposal is partially based on existing procedures and best practices as discussed for the follow-up, review and audit of environmental impact assessment[36][37]. The purpose of the review and

[36] Maltby, J. Environmental audit: theory and practices. Managerial Auditing Journal, 10, 15–26. 1995. http://doi.org/10.1108/02686909510147372

[37] Arts, J., P. Caldwell & A. Morrison-Saunders, "Environmental impact assessment follow-up: good practice and future directions" — findings from a workshop at the IAIA 2000 conference. Impact Assessment and Project Appraisal, 19(3), 175–185. 2001. http://doi.org/10.3152/147154601781767014

audit is to provide an assurance about the effectiveness of the EIA process and extent of the implementation of the recommendations. A review might also highlight new information that changes the basis of the original recommendations; this might necessitate repeating the EIA process or taking additional remedial actions, if necessary. The procedural steps focus on three distinct stages of the review and audit: at the start of the EIA, during the EIA and at the finish of the EIA.

1.10.5.1 At the start of the EIA

At the start of the EIA, after the threshold analysis has been completed, the assessor responsible for executing the EIA and the EIA reviewer need to reach a consensus regarding the review and audit planning as well as the review and audit criteria. Even though this planning and these criteria will be decided upon on a case-to-case basis, the following guidelines can assist in determining them:

- **Review and audit planning:**
  - For small-scale EIAs: only a final review and audit will be required; a mid-term review will be optional (the reviewer might initiate one if deemed necessary).
  - For medium-scale EIAs: A mid-term and a final review and audit will be required; additional reviews will be optional (the reviewer might initiate some if deemed necessary).
  - For large-scale EIAs: Yearly reviews and audits as well as a final review and audit are required.

- **Review and audit criteria:**
  - Review criteria: these are usually framed in terms of the necessary documentation that needs to be delivered before every review takes place. Criteria might include:
    - The types of documentation needed for each stage of the EIA
    - The minimum period of time before the review date before which the assessor needs to communicate the necessary documents with the reviewer
  - Audit criteria: these are usually framed in terms of the necessary minimum milestones or deliverables that need to be provided in order for the EIA process to be continued and funded. These criteria might include:
    - The finalisation of certain stages of the EIA at certain moments in time in the duration of the R&I project
    - Requirements for the presentation of the EIA outcomes, such as:
      - Reports of the EIA stages
      - A number of academic publications
    - Requirements for stakeholder engagement, such as:
      - A log with the stakeholders engaged in the EIA

- Stakeholder evaluation data

1.10.5.2 During the EIA

During the EIA the reviewer might conduct intermediate review and audit activities, depending on the scale of the EIA and the overall progress of the EIA. When the reviewer has the impression that essential activities in the EIA are delayed, an intermediate review and audit might be requested. The following activities might be part of the intermediate reviews and audits:

- **Intermediate review**
  - *Monitoring:* The reviewer will request the assessor to communicate the documentation of the current progress of the EIA. This documentation will be used as the basis of monitoring the progress of the EIA process.
  - *Evaluation:* The reviewer will convene a meeting with the assessor during which the EIA as a whole is evaluated. Based on this evaluation, the reviewer will issue certain feedback that can be incorporated in the future EIA work.
  - *Management:* The reviewer will also evaluate the project management of the EIA, including issues such as:
    - Proper division of tasks within the EIA team
    - Proper financial management
  - *Communication:* The reviewer will ensure that sufficient communication is established between the assessor and the R&I project funding body.

- **Intermediate audit**
  - The reviewer will request a short audit report from the assessor, which states whether the agreed upon milestones and/or deliverables have been met and which provides for proper evidence to support these claims.
  - Based on the intermediate audit, the reviewer will issue an opinion about the continuation of the EIA. This opinion might be binding, for instance in the case of a publicly funded R&I project, but is not necessarily so. The opinion can take the following forms: (i) acceptance of EIA without revisions, (ii) acceptance of EIA with minor or major revisions and (iii) rejection of current EIA progress with the need of re-initiating the EIA process.

1.10.5.3 At the finish of the EIA

Once all the steps of the EIA have been finished, a final review and audit will be organised. An EIA is complete after remedial actions have been taken, the review and audit stage has been completed and the EIA report is approved and signed off at a level appropriate to the project or innovation activity. The following activities might be part of the final review and audit of and EIA:

- **Final review**
  - The reviewer convenes a final review meeting with the assessor. During this meeting, the entire EIA is evaluated and recommendations for future EIAs are documented.
  - The assessor writes a final EIA report, which includes the main findings of the EIA and a description of the remedial actions.
  - The reviewer writes a final review document, which will be send to the funding organisation of the R&I project as well as to the relevant stakeholders.
  - For medium-scale and large-scale EIAs: the reviewer conducts a short survey amongst the stakeholders that were involved in the EIA.
- **Final Audit**
  - During the final audit, the reviewer makes sure that the following actions are undertaken:
    - A final financial statement is made, explicating the final cost of the EIA.
    - A final portfolio of publications (both internal and external) is presented and send to the funding organisation of the R&I project.
  - The reviewer convenes a final audit meeting with the assessor, at which:
    - Leftover follow-up actions are agreed upon. These need to be performed, even if they fall outside of the EIA budget, in order to meet the audit criteria.

1.10.6 Presentation of the review and audit

Depending on the different moments of the review and audit stage, it is presented in the following ways:

- **At the start of the EIA:** The review and audit criteria are documented in the form of a contract that needs to be signed by both the reviewer and the assessor. This contract can be part of the overall contract between the assessor, as part of the R&I project and the research funding organisation.
- **During the EIA:** Intermediate reviews and audits are presented as audit reports, that are put together by the reviewer; which are to be send to the research funding organisation.
- **At the finish of the EIA:** The review and audit at the end of the EIA process is presented in the following ways:
  - A final EIA report, drafted by the assessor
  - A final review document, drafted by the reviewer
  - A final financial statement
  - A final portfolio of publications related to the EIA

1.10.7 Recommendations

Based on the above exposition of the review and audit stage as part of the EIA, we present a number of recommendations for implementing a threshold analysis in a proper way:

- Research funding organisations should consider setting up a body that is responsible for conducting the review and audit of EIAs.
- An independent body might need to be installed for ensuring the independence of the review body. This might for instance be a watchdog organisation at the EU level.
- Review and audit procedures should preferably be standardised as much as possible to decrease their administrative burden, for instance by providing for an online entry system in which the assessor can present the necessary EIA outcomes.

1.11 SELECTED READINGS

Abrahams, D., & Y. Wyss, Y. Guide to Human Rights Impact Assessment and Management (HRIAM), 2010, 199. Retrieved from www.guidetohriam.org

Boenink, M., T. Swierstra, & D. Stemerding, D. Anticipating the Interaction between Technology and Morality: A Scenario Study of Experimenting with Humans in Bionanotechnology. *Studies in Ethics, Law, and Technology*, *4*, 1. 2010. http://doi.org/10.2202/1941-6008.1098

Brey, P. Method in computer ethics: Towards a multi-level interdisciplinary approach. *Ethics and Information Technology*, *2*, 2010, 125–129. http://doi.org/10.1023/A:1010076000182

Brey, P. Anticipatory Ethics for Emerging Technologies. *NanoEthics*, *6*(1), 2012, 1–13. http://doi.org/10.1007/s11569-012-0141-7

De Beco, G. Human Rights Impact Assessments. *Netherlands Quarterly of Human Rights*, *27*(2), 2009, 139–166.

Hasson, F., S. Keeney, & H. McKenna. Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing*, *32*(4), 2000, 1008–1015. http://doi.org/10.1046/j.1365-2648.2000.t01-1-01567.x

Kiran, A. H., N. Oudshoorn, & P.P. Verbeek. Beyond checklists: toward an ethical-constructive technology assessment. *Journal of Responsible Innovation*, (June 2015), 2015, 1–15. http://doi.org/10.1080/23299460.2014.992769

Manzeschke, A., K. Weber, E. Rother, & H. Fangerau, H. *Ethische Fragen im Bereich Altersgerechter Assistenzsysteme*. Druckerei Thiel Gruppe Ludwigsfelde. 2013.

Millar, K., E. Thorstensen, S. Tomkins, B. Mepham, & M. Kaiser. Developing the Ethical Delphi. *Journal of Agricultural and Environmental Ethics*, *20*(1), 2007, 53–63. http://doi.org/10.1007/s10806-006-9022-9

Owen, R., P. Macnaghten, & J. Stilgoe. Responsible research and innovation: From science in society to science for society, with society. *Science and Public Policy*, *39*(6), 2012, 751–760. http://doi.org/10.1093/scipol/scs093

Palm, E., & S.O. Hansson. The case for ethical technology assessment (eTA). *Technological Forecasting and Social Change*, *73*(5), 2006, 543–558. http://doi.org/10.1016/j.techfore.2005.06.002

Stahl, B. C., R. Heersmink, P. Goujon, C. Flick, J. van den Hoven, K. Wakunuma… M. Rader. Identifying the Ethics of Emerging Information and Communication Technologies. *International Journal of Technoethics*, *1*(4), 2010. 20–38. http://doi.org/10.4018/jte.2010100102

Wright, D. A framework for the ethical impact assessment of information technology. *Ethics and Information Technology*, *13*, 2011. 199–226.

2 ANNEX A: OVERVIEW OF METHODS FOR ETHICAL IMPACT ASSESSMENT

2.1.1 Introduction

In this section, we will first discuss different established methods for ethical impact assessment. These methods differ from one another in terms of their objective and focus, the kind of data they analyse, the stakeholders that participate in the process and the innovation they bring to the fore. The methods that we include in our analysis are the *Ethical Technology Assessment, the Techno-Ethical Scenarios, the ETICA, Ethical Impact Assessment proposed by Wright, the Anticipatory Technology Ethics, Human Rights Impact Assessment,* and the *MEESTAR* methods. Although a greater variety of methods exist – such as more general methods for technology assessment – the ones we discuss are widely recognised and used. We focus on these methods to construct a comprehensive ethical impact assessment procedure for the SATORI project.

Secondly, we will discuss different foresight methods that can be used in order to anticipate ethical impacts. The difference between methods for ethical impact assessment and foresight is that the first aim at analysing and overcoming ethical impacts, and the second aim at anticipating those impacts and looking at the long term ethical concerns in the context of research and innovation (R&I). Although some foresight methods are already integrated in the methods for ethical impact assessment, we discuss them separately to elucidate the structures of those approaches. The methods that we include in our analysis are *Trends, weak signals, wild cards, Horizon and technology scanning, Vision building, Scenarios, Delphi, Road mapping and Futures wheel.* Finally, we will present a reasoned proposal for a framework for ethical impact assessment for the SATORI project, which takes into account the major features of the existing methods.

The overall aim of this section is to provide an overview of the most prominent methods that are currently used for the purpose of ethical impact assessment in R&I. Moreover, we will discuss these methods in terms of their advantages and disadvantages. Eventually, the aim is to construct a SATORI framework for ethical impact assessment that is informed by the existing methods.

2.1.2 Choice of methods

The following sections provide an overview of methodologies in the field of ethical impact assessment and in the field of foresight studies. The selection of sources containing these methods was based on the following criteria during the search:

- An included source should not merely *use* a method for ethical impact assessment or foresight in the context of a case study, but give an *outline* of the method with the appropriate steps, definitions and procedures described.
- An included source should outline a method that is *innovative* in some way vis-à-vis other methods, with regards to its aims, procedures or participation methods.

- Most of the selected methods for ethical impact assessment were selected from an earlier study in SATORI that was part of Deliverable 1 (annex 1a).
- Some sources were derived from the review sections of the existing literature in of the primary sources we found.

Since our overview is based on searches according to these criteria, rather than on a full-fledged literature review, we believe that our overview is extensive but not exhaustive. Certain methods for ethical impact assessment or foresight might be missing from our overview though they should have been included. Nevertheless, by following the abovementioned criteria we argue that the most important aspects of existing ethical impact assessment methodologies will be covered in this report.

2.1.3 Methods used for Ethical Impact Assessment

Although academic endeavours that deal with issues of ethical impact assessment are still largely in a premature and exploratory state, because of the relatively novel nature of the field, several methodologies for ethical impact assessment have been developed. In this section, we discuss seven methodologies that deal with ethics in R&I. We briefly first identify their key elements and their main points of divergence vis-à-vis the other methodologies, then compare their approach, focus, participation and main innovation elements.

Ethical Technology Assessment

Palm and Hansson propose a method for ethical technology assessment that makes use of a checklist of crucial ethical aspects of technologies. This will serve as "a tool for identifying adverse effects of new technologies at an early stage"[38]. They argue that categories of these effects are "(1) Dissemination and use of information, (2) Control, influence and power, (3) Impact on social contact patterns, (4) Privacy, (5) Sustainability, (6) Human reproduction, (7) Gender, minorities and justice, (8) International relations, and (9) Impact on human values"[39]. A continuous dialogue between stakeholders should be set up to assess the ethical ramifications on the basis of the checklist. For instance, through a stakeholder dialogue certain privacy issues of a technological application might come to the fore. Hence, the steps in this approach are: (1) setting up a stakeholder dialogues, (2) identifying the ethical issues by using the checklist, and (3) evaluating the identified ethical issues.

Techno-ethical scenarios

The techno-ethical scenarios approach distinguishes itself by focussing on the "soft" impacts of technological innovations on human values, relations and identities instead of on "hard" impacts that generally relate to quantifiable risks (e.g. health risks)[40]. Moreover, it uses the well-established method of building scenarios as a phase in the process of ethical impact assessment. By constructing descriptive narratives

[38] Palm, E., & S. O. Hansson. The case for ethical technology assessment (eTA). *Technological Forecasting and Social Change*, *73*(5), 2006, 543. http://doi.org/10.1016/j.techfore.2005.06.002
[39] Ibid. p.543.
[40] Boenink, M., T. Swierstra, and D. Stemerding. Anticipating the Interaction between Technology and Morality: A scenario Study of Experimenting with Humans in Bionanotechnology. *Studies in Ethics, Law and Technology*, 4(2), 2010, p.2.

(scenarios) about the way a technological innovation might impact society, a more comprehensive analysis of the ethical impacts of R&I can be obtained. It uses a three-step methodology: (1) providing a descriptive account of the present situation (both regarding the technology and existing ethical controversies) to ground the analysis, (2) explicating potential moral controversies by means of the NEST-ethics (ethics of New and Emerging Science and Technology) approach that considers technological expectations, critical objections to the technology and patterns of arguments amongst stakeholders, and (3) constructing closure by judging plausible resolutions of the ethical controversies.

ETICA (Ethical Issues of Emerging ICT Applications)

The ETICA methodology comprises a number of steps that are aimed at identifying emerging technologies and subsequently analysing the ethical issues that these technologies might present. The first step of data analysis aimed at identifying emerging technologies is an examination of texts of two different discourses (a discourse analysis) about technology: discourse in the political realm and discourse in the research community[41]. In order to analyse the ethical impacts of emerging technologies, the ethical issues with regards to the defining features of technologies are assessed (e.g., that a system is dependent on personalisation). Secondly, the applications of the technology in different fields (e.g. health care, transportation) are analysed separately. Thirdly, a bibliometrical analysis is done to confirm that the most important ethical issues are discussed. These steps all come together in a conclusion that is meant to lead to policy recommendations.

Ethical Impact Assessment

The Ethical Impact Assessment method proposed by David Wright is aimed at constructing a comprehensive framework that can be practically used by policy-makers, technology developers, project managers, etc.[42] It starts by discussing the main ethical principles that underlie the assessment, which are borrowed from the well-established principlism approach of Beauchamp and Childress[43]. These are respect for autonomy (liberty), non-maleficence (no harm), beneficence and justice and the additional principles of privacy and data protection (added by Wright). Several questions are presented that can guide the assessors in doing the ethical impact assessment. Secondly, a number of tools for ethical impact assessment are presented: consultations and surveys, expert workshops, checklists of questions, the ethics matrix (which applies certain prima facie principles to certain groups of people), the ethical Delphi (exchange of arguments between experts), consensus councils aimed at resolving ethical conflicts and citizen panels. Thirdly, procedural aspects are discussed, which are aimed at consulting and engaging stakeholders. Wright proposes the following 14 steps for an ethical impact assessment process: determine whether an EIA is necessary (threshold analysis); identify the EIA team and set the team's terms of reference, budget, and time frame; prepare an EIA plan;

[41] Stahl, B. C., R. Heersmink, P. Goujon, C. Flick, J. van den Hoven, K. Wakunuma … M. Rader. Identifying the Ethics of Emerging Information and Communication Technologies. *International Journal of Technoethics*, *1*(4), 2010, 27. http://doi.org/10.4018/jte.2010100102

[42] Wright, D. A framework for the ethical impact assessment of information technology. *Ethics and Information Technology*, *13*, 2011, 199–226. http://doi.org/10.1007/s10676-010-9242-6

[43] Beauchamp, Tom L., and James F. Childress. *Principles of biomedical ethics*. Oxford university press, 2001.

describe the proposed project to be assessed; identify stakeholders; consult with stakeholders and analyse the ethical impacts; check that the project complies with legislation; identify risks and possible solutions; formulate recommendations; prepare and publish the report; implement the recommendations; third-party review and/or audit of the EIA; update the EIA if there are changes in the project; embed ethical awareness throughout the organisation and ensure accountability.[44]

Anticipatory Technology Ethics

The Anticipatory Technology Ethics (ATE) approach of Brey focuses mainly on the problems of dealing with emerging technologies in their premature design phase.[45] Brey distinguishes between the *technology* level as a collection of techniques (e.g. nuclear energy technologies), the level of functional *artefacts* and the *application* level (the specific context of use of an artefact). These levels are used to identify the ethical issues that can be of a very general nature at the technology level and of a very particular nature at the application level. The impacts of emerging technologies can be assessed by means of future studies in which engineers and ethicists cooperate. As a method to subsequently normatively evaluate the ethical impacts, Brey suggests using a checklist with four clusters of principles (harms and risks, rights, justice and well-being) that are basically similar to the ones used by Wright. The different steps presented are: (1) identify ethical impacts by performing future studies, (2) focus subsequently on the levels of technology, artefact and application and (3) evaluate the impacts by means of assessing the influences of technologies according to ethical principles.

Human rights impact assessment

Human rights impact assessment[46] does not exclusively focus on R&I but can nonetheless be deployed to deal with ethical impacts of R&I. It revolves around several distinct stages: (i) the preparation stage during which the societal context is established, (ii) the screening stage during which the range of technologies is narrowed down, (iii) the scoping stage during which options and scenarios are depicted, (iv) the evidence gathering stage during which data is gathered to support claims of impacts (v) the consultation stage during which stakeholders are consulted, (vi) the analysis stage aimed at verifying the depicted impacts, (vii) a conclusion and recommendation stage and (viii) a monitoring and evaluation stage during which the outcomes are juxtaposed with stakeholder expectations[47].

Model for the ethical evaluation of social technical arrangements (MEESTAR)

[44] Wright, David, "Ethical Impact Assessment", in J. Britt Holbrook and Carl Mitcham (eds.), *Ethics, Science, Technology and Engineering: A Global Resource, 2nd edition*, Macmillan Reference, Farmington Hills, MI, USA, 2015.
[45] Brey, P. Anticipatory Ethics for Emerging Technologies. *NanoEthics*, *6*(1), 2012, 1–13. http://doi.org/10.1007/s11569-012-0141-7
[46] De Beco, G. Human Rights Impact Assessments. *Netherlands Quarterly of Human Rights*, *27*(2), 2009, 139–166.
[47] Abrahams, D., & Y. Wyss. Guide to Human Rights Impact Assessment and Management (HRIAM), 2010, 199.

The MEESTAR method is a structured approach to engage stakeholders directly in the ethics assessment process[48]. It revolves around a seven dimensional model that includes both ethical principles (care, autonomy, safety, justice, privacy, participation and self-conception), the levels at which ethical issues are identified (individual, organisational, societal) and the level of severity of ethical issues. Along the lines of the dimensions of the model, specific questions can be formulated that can be discussed by relevant stakeholder target groups. Moreover, it allows for a "threshold analysis" to determine the severity of the ethical issues at hand. The decision-making process based on the ethical impact analysis is therefore grounded in both stakeholder engagement and theoretical rigour.

The following table provides an overview of the different methods for ethical impact assessment we discussed; comparing them according to their main focuses, approaches for gathering data for the EIA, the kind of participation and the main innovation each approach brings to the fore.

Approach	**Focus**	**Data gathering**	**Participation**	**Main innovation**
Ethical Technology Assessment	Identify adverse effects of technologies at an early stage.	Checklist assessment by stakeholders	Stakeholders	Identification of ethical issues at an early stage.
Techno-ethical Scenarios	"Soft" impacts of R&I.	Scenario building	Stakeholders	Identification of ethical issues in use-scenarios.
ETICA	Ethical issues of emerging ICTs.	Text analysis of government and research community	Ethicists/policy makers	Structured identification and analysis of ethical issues.
Ethical Impact Assessment	Giving ethics assessors the tools to conduct an ethical impact assessment.	Surveys, workshops, checklists, ethics matrix	Experts and stakeholders	Providing a comprehensive toolkit for assessors.
Anticipatory Technology Ethics	Identifying ethical issues of emerging technologies in the design phase.	Checklist of ethical issues applied to different stages of technology development	Ethicists	A theoretical framework to deal with different levels of ethical analysis. Also adds a robust foresight approach.

[48] Manzeschke, A., K. Weber, E. Rother, H. & Fangerau. *Ethische Fragen im Bereich Altersgerechter Assistenzsysteme*. Druckerei Thiel Gruppe Ludwigsfelde, 2013.

Approach	Focus	Data gathering	Participation	Main innovation
Human Rights Impacts Assessment	Measuring the effects of R&I on human rights.	Analysis of records and regulations	Policy makers, stakeholders	A framework that is based on the well-established convention of human rights.
Model for the Ethical Evaluation of Social Technical Arrangements	Engage stakeholders in the ethics assessment process.	Stakeholder engagement meetings	Ethicists, stakeholders	A dynamic theoretical framework that guides stakeholder engagement.

Table 13: Comparative overview of the established methods for ethical impact assessment.

2.1.4 Comparing the methods

This section comprises a comparative analysis the abovementioned methods for ethical impact assessment, focusing on their main features. Instead of simply discussing the "advantages" and "disadvantages", we will discuss different points of divergence. We will examine how the methods are different from one another with regards to their main innovative aspects and theory use, their data gathering methods, their identification of relevant stages in the R&I process, and the ways they allow for participation in the assessment process.

Theory use

Three types of theory use can be distinguished in the above ethical impact methodologies. First, some approaches tend to offer a structured way to assess R&I impacts by considering "ethical checklists" containing different aspects of those impacts that are often grounded in theory. For instance, the Beauchamp and Childress list of ethical principles is frequently applied in the methods (e.g., Ethical Impact Assessment, Anticipatory Technology Ethics, and MEESTAR). However, such checklists are criticised for being insufficiently adaptable to the rapid technological changes in R&I.[49] The ethical principles remain static while they are argued to be themselves affected by technology changes. For instance, procreative technologies such as the pill have affected the principle of "autonomy" because they enabled women to make autonomous choices with regards to their procreation[50]. Secondly, the ETICA approach distinguishes itself from the others by offering a method grounded in discourse analysis. However, it is argued that the scientific rigour of the texts that are studies might be questionable.[51] A third type of theory use revolves around the "generation" of new ideas, which is notably the case in the techno-ethical scenarios approach and in the MEESTAR approach. However, it is argued that such approaches

[49] Kiran, A. H., N. Oudshoorn, & P.P. Verbeek. Beyond checklists: toward an ethical-constructive technology assessment. *Journal of Responsible Innovation*, (June 2015), 2015, 1–15. http://doi.org/10.1080/23299460.2014.992769

[50] For an elaborate version of this argument, see Verbeek, P.-P. What things do; philosophical reflections on technology, agency, and design. Pennsylvania: Pennsylvania University Press. 2005.

[51] Brey, P. Anticipatory Ethics for Emerging Technologies. *NanoEthics*, *6*(1), 2012, 1–13. http://doi.org/10.1007/s11569-012-0141-7

might leave out some important ethical issues for they depend to a large extent on non-expert, public opinion.[52]

Data gathering and analysis

With regards to the data gathering and analysis in the methods for ethical impact assessment, three different categories of data seem to be prominent: data from texts (policy papers, scientific articles, future studies), data from surveys (questionnaires for experts, stakeholder surveys) and data obtained from interaction (interviews with stakeholders, workshop outcomes). Some approaches only deal with gathering data from one single source (for example primarily data from *texts* for the ETICA method and data from *interaction* for the techno-ethical scenarios approach). However, some approaches combine data from different sources, as is the case in the Ethical Impact Assessment method. All discussed methods deal primarily with *qualitative* data analyses.

Stages in Research and Innovation

A distinctive feature of some of the methods concerns the way in which different *stages or levels* in R&I processes are distinguished. These stages can refer to the extent to which ethical impacts R&I projects are of a fundamental or rather of an applied nature, as for instance in the anticipatory technology ethics approach which tries to distinguish between the technology, artefact and application levels. They can also refer to the severity of the ethical impacts that are analysed; as for example is the case for the MEESTAR method. Moreover, they can refer to the level at which an ethical issue is identified (at the level of the individual, an organisation, or society at large); which is also notably applied in the MEESTAR method.

Participation

The methods for ethical impact assessment strongly diverge on the point of participation. Some methods focus primarily on the needs of ethicists or ethics assessors; which is for example the case in the anticipatory ethics methodology. Other methods, often the ones that are already in line with approaches to solving problems in policy circles, focus primarily on policy makers; as, for instance, is the case with the human rights impact assessment approach. The anticipatory technology ethics approach stands out as it explicitly tries to include researchers in the participation process, the argument being that they are vital to help identify ethical issues related to emerging technologies. Most of the analysed methods focus on the inclusion of "stakeholders" in the process of ethical impact assessment. The following table provides an overview of the different types of theory use, data gathering approaches, identification of stages or levels in and R&I projects and participation in the EIA:

Methodology feature	**Different types**
Theory use	• Checklists approach • Discourse analysis • Generation of ideas
Data gathering and analysis	• Texts • Surveys • Interaction

[52] Ibid.

Methodology feature	Different types
Stage identification	• Design-implementation • Severity • Individual-society
Participation	• Experts • Ethicists/Assessors • Policy makers • Researchers • Stakeholders

Table 14: Overview of different types of methodology features in methods for ethical impact assessment.

3 ANNEX B: OVERVIEW OF FORESIGHT METHODOLOGIES

3.1.1 Introduction

Foresight can be defined as action-oriented, multidisciplinary and participatory strategic intelligence focused on alternative futures. The aim is to produce knowledge interactively between multiple stakeholders with specific interests and differing perspectives towards the topic under exploration and to facilitate interaction between the relevant stakeholders and catalyse the desired developments and strategies[53]. Foresight is based on present knowledge about future options that are collected and ennobled with different methods in a systematic way. The aspect of alternative futures has traditionally been the key aim in scenario methodologies, but also linking of the past, present and future may bring relevant alternative views to the future potentials[54]. In the field of foresight, an action-oriented mode towards the future is also present[55] with the practical idea (innovation orientation) that the "idea is to look for options and opportunities for change before the business is forced to change"[56]. This separates it from a passive mode towards the future, in which the future is seen as something that is inescapably beyond the present actions. A holistic system perspective is the basis of foresight. Further, foresight has been envisaged as a triangle combining "Thinking the Future", "Debating the Future" and "Shaping the Future" (Figure below).

[53] Eerola, A. and B.H. Jørgensen Technology Foresight in the Nordic Countries. Risø National Laboratory, Roskilde. 2002.
[54] List, D. Multiple pasts, converging presents, and alternative futures. *Futures* 36 (2004) 2004. 23–43.
[55] Havas, A. Locating foresight. Presentation. 27 September 2007, Institute of Economics Hungarian Academy of Sciences, Budapest. 2007.
[56] Wilenius, M. Taming the dragon: how to tackle the challenge of future foresight. *Bus. Strategy* Ser. 9:2 (2008) 2008. 65-77.

Figure 2: Foresight triangle[57]

Foresight exercises are often complex and highly interactive processes. There is no "single" way of organising an exercise. Although each individual exercise will have its own specific characteristics, they should all have in common the following: a deep understanding of the context in which it is embedded, and a clear set of objectives.

A foresight exercise can be split into five general interconnected phases:[58]

1. *Feasibility assessment:* Is foresight appropriate in the context? Can it be linked to action?
2. *Defining the aim and scope of the exercise:* What is the objective of the exercise? What are the boundaries, what is taken into account, what is the general issue? What is the time scale and the spatial focus?
3. *Choosing the methods:* What are the suitable methods given the context, scope and aims?
4. *Running the exercise:* Managing time, people, participants, communications and most importantly the learning process itself.
5. *Follow up:* Did the exercise achieve its goals? Are the outcomes plausible, useful, and insightful? Has the process created new learning and networks? What is the relevance for policy making?

Foresight studies rely on a wide variety of methods, which can be classified in several ways. Some distinctions are:

- Quantitative versus qualitative
- Exploratory versus normative
- Predictive versus open

[57] JRC 2015. The FOR-LEARN Online Foresight Guide. Accessed October 19, 2015. http://forlearn.jrc.ec.europa.eu/guide/0_home/index.htm
[58] EFP (2012). European Foresight Platform. <http://www.foresight-platform.eu/community/forlearn/what-is-foresight/> Accessed on October 2015.

- Reliance on creativity vs. reliance on evidence

Important concepts that can be used to characterise methods include also:

- The level of participation (large involvement of citizen versus reduced number of experts)
- The degree of reliance on expertise
- The degree of interactivity

Figure 2 (Foresight Diamond) illustrates one way of classifying foresight methods based on the degree of reliance on expertise vs. interaction, reliance on creativity vs. evidence and also qualitative vs. quantitative nature[59].

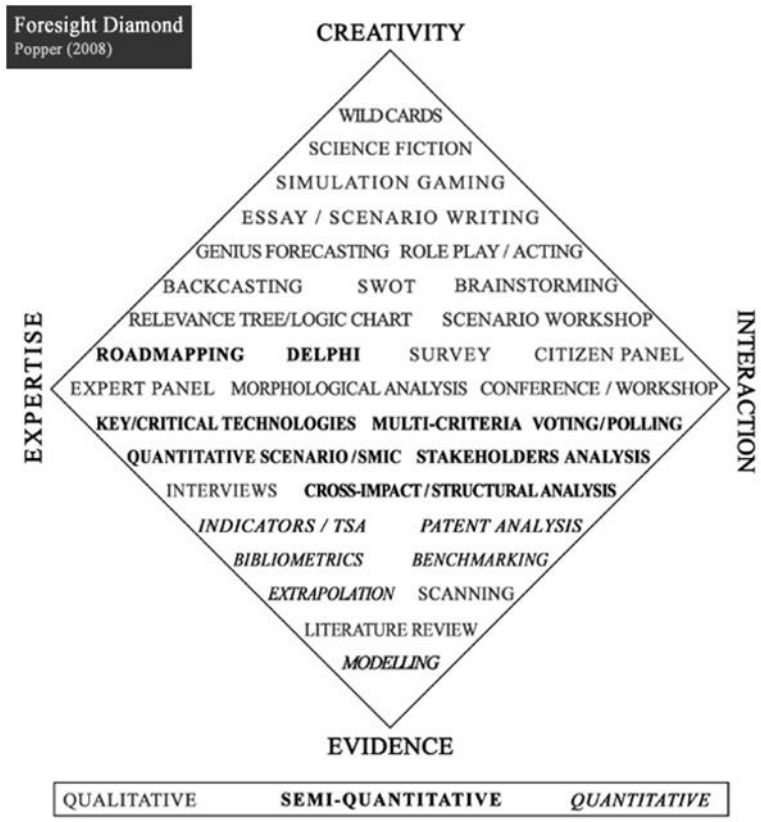

Figure 3: Foresight Diamond[60].

In a foresight exercise, different methods or sets of methods are employed at different stages of the process. Finding the appropriate sequence of methods is often one of the most delicate design steps. The following section briefly presents some typical foresight approaches. European Foresight Platform material[61], Antofagasta learning

[59] Popper, R. Foresight Methodology, in Georghiou, L., Cassingena, J., Keenan, M., Miles, I. and Popper, R. (eds.). The Handbook of Technology Foresight, Edward Elgar, Cheltenham, 2008, pp. 44-88.
[60] Ibid.
[61] EFP (2012). European Foresight Platform. <http://www.foresight-platform.eu/community/forlearn/what-is-foresight/> accessed on October 2015.

package for foresight[62] and some scientific articles (cited later in the text) have been used as the main sources for the methodological presentations below. A brief glossary of the selected foresight terms and definitions is presented below.

Delphi method: a way of estimating future measures by asking a group of experts to make estimates, recirculating the estimates back to the group, and repeating the process till the numbers/answers converge. [63]

Futures Wheel: an instrument for graphical visualization of direct and indirect future consequences of a particular change or development. [64]

Horizon scanning: the initial and continuing process of reviewing and analysing current literature, web sites, and other media to identify and describe noteworthy trends and their possible development and future.[65]

Megatrend: a long-term process of transformation with a broad scope and a dramatic impact. Megatreds are considered to be powerful factors, which shape future markets.

Roadmapping: a graphic representation showing key components of how the future might evolve. Usually applied to a new product or process, or to an emerging technology matching short and long term goals with specific solutions. Also strategic Roadmapping is emerging.

Scenario: a predicted sequence of events that might possibly occur in the future.

Scenario planning: a strategic planning method that e.g. organizations use to make flexible long-term plans.[66]

Trend: general tendency or direction evident from past events increasing or decreasing in strength of frequency of observation, it usually suggests a pattern.[67]

Weak signal: past or current development/issue with ambiguous interpretations of its origin, meaning and/or implications. Weak signals are unclear observables warning us about the probability of future events.

Wild card: an unpredictable event or situation; event that has a low probability but a high impact. Wild cards are often recognized and known, but discounted, even when the event is relatively certain over a period of years.[68]

Vision: a carefully formulated and clearly articulated description of a desired future state of affairs as stated by an individual or a group. The ambition of the vision is to motivate, inspire and give direction to those who are committed to the vision. [69]

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[62] Dufva, M., Kohl, J., Könnölä, T. and and Koivisto, R. (eds.) Learning package on foresight. ICI-Antofagasta project. 2012.
<https://antofagastaforesight.wordpress.com/overview-on-foresight/> accessed on November 2015.
[63] Global Foresight Glossary.< http://www.globalforesight.org/glossary> accessed on February 2016.Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary. Shaping Tomorrow. <http://www.shapingtomorrow.com/media-centre/pf-ch11.pdf> accessed on February 2016.
[64] Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary. Shaping Tomorrow. <http://www.shapingtomorrow.com/media-centre/pf-ch11.pdf> accessed on February 2016.
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Ibid.
[69] van der Helm, R. The vision phenomenon: towards a theoretical underpinning of visions of the future and the process of envisioning. Futures, Vol. 41 No. 2, 2009, pp. 96-104.

3.1.2 Foresight methods

The aim of this section is to provide an overview of the most prominent methods that are currently used for the purpose of foresight or forward-looking activities in R&I. We will discuss the key features of some frequently used methods that will indicate also their potential contribution to ethical impact assessment.

3.1.2.1 Trends, weak signals, wild cards

Trends and megatrends can help to anticipate the future by looking at the direction of current developments. Weak signals and wild cards, on the other hand, can be used to sense the possible but improbable events (Figure 3). Let us briefly explain these central concepts, which are often used in many foresight methods.

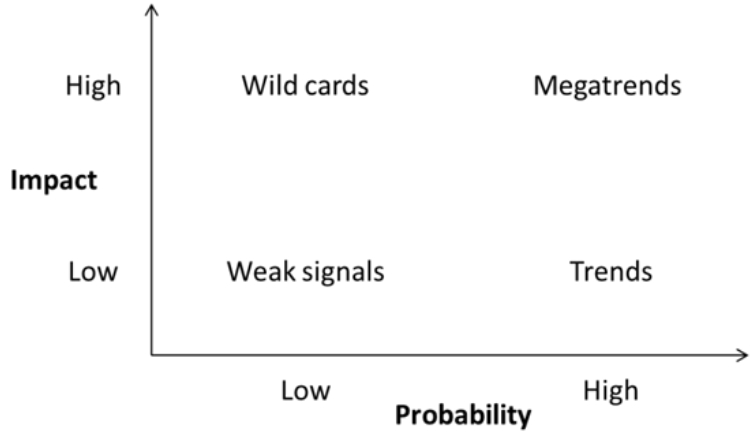

Figure 4: The impact and probability of wild cards, weak signals, trends and megatrends[70].

A trend describes a general direction in which a situation in changing or developing. Megatrends differ from other trends in three ways:

- Time horizon: Megatrends can be observed over decades.
- Reach: Megatrends have a comprehensive impact on all regions, and result in multidimensional transformations of all societal subsystems, whether in politics, society, or economy.
- Intensity of impact: Megatrends impact powerfully and extensively on all actors, whether it is governments, individuals and their consumption patterns, or corporations and their strategies.

Trends and megatrends are usually identified by carrying out desk research, which uses recent statistics, scientific literature, policy and business documents as source material. Interviews and surveys can also be used.

[70] Dufva, M., Kohl, J., Könnölä, T. and and Koivisto, R. (eds.) Learning package on foresight. ICI-Antofagasta project. 2012.

Weak signals can be described as early signs of currently small changes. When searching for weak signals, one does not really know what one is looking for. The search encompasses the identification of things that do not seem to have a strong importance or impact in the present but may bring about major events in the future. Finding weak signals is one of the most challenging tasks in foresight and their proper analysis may lead to the identification of wild cards.

Wild Cards are high-impact events that seem too incredible or unlikely to happen, yet many do.[71] An example of a wild card is the 2011 attack on the World Trade Center on 9/11. A collection of wild cards and weak signals as well as trends can be found on the iKnowFutures website.[72]

3.1.2.2 Horizon scanning

Horizon scanning clarifies the big picture behind the issues to be examined. It is often carried out by doing desk research, which should involve data coming from a wide variety of sources, such as the Internet, research communities, online and offline databases and journals, ministries and agencies, non-governmental organisations, and international organisations and companies. Also, a small group of experts who are at the forefront in the area of concern can undertake horizon scanning by sharing their perspectives and knowledge with each other. A horizon scan can provide the background for strategic planning and decision-making.

3.1.2.3 Long-term vision building

There are several definitions for the term 'vision' in the foresight communities. Often it has been used interchangeably with the term 'image of the future'. Nanus[73] defines the term 'vision' as a carefully formulated and clearly articulated description of a desired future state of affairs as stated by an individual or group. Correspondingly, Van der Helm[74] suggests that all visions involve the aspects of the future, the ideal and the desire for a deliberate change. For our purposes, we have adopted the definition by Van der Helm. According to Van der Helm, a vision is aimed at motivating, inspiring and giving direction to those who are committed to the vision. A vision is hence not just an instrument for exploration or analysis. Instead, images are like learning environments. By drafting images, several ideas and their interaction can be tested. Hence, it is possible to develop many different images of the future, compare them and assess their potential benefits.

Several approaches, from very detailed to cursory, exist to build a vision. One rather detailed alternative is to use a three-step vision building process, which includes a selection of futures methods and tools[75], accompanied by step-by-step instructions on how to formulate the vision. The three consecutive steps of the process are (1) horizon scanning, (2) constructing futures tables and visions and (3) describing visions.

[71] Ibid.
[72] http://wiwe.iknowfutures.eu/scan/easy/wild-card/
[73] Nanus, B. Leading the vision team. *The Futurist*. May-June, 1996. pp. 21-3.
[74] van der Helm, R. The vision phenomenon: towards a theoretical underpinning of visions of the future and the process of envisioning. *Futures*. Vol. 41 No. 2, 2009. pp. 96-104.
[75] Auvinen, H., A. Tuominen, and T. Ahlqvist, Towards long-term foresight for transport: envisioning the Finnish transport system in 2100. *Foresight*. Vol. 14 Iss: 3, 2012. pp. 191 - 206.

The vision building process starts with horizon scanning: a survey of the forces of change. At this stage, all relevant emerging forces of change are identified. For details of the process, see Auvinen et al.[76].

3.1.2.4 Scenarios

Scenarios are used in a wide variety of ways as tools for foresight analysis, e.g. for developing strategies and pathways. Many of the scenarios are constructed from the past and present towards the future, and are therefore forward looking. Backcasting scenarios instead look backwards from the desired future[77,78]. The major concern is not which futures are most likely to occur, but how to attain desirable futures. Also, multiple preferred futures can be taken as starting points of the backcasting exercise (pluralistic backcasting[79]).

In a classical classification of scenarios, three classes of future scenarios have been distinguished[80,81,82] answering the questions: what will happen (trend extrapolations, business as usual scenarios, probable scenarios); what could happen (forecasting, foresighting, strategic scenarios) and what should happen (normative scenarios like those used in backcasting). Normative scenarios can also be called desirable futures or visions of the future. All of the three scenario classes can be constructed in a forward- and backward-looking way (see Table 4).

Future type	**Starting from**	
	Past and present: Forward-looking	Future: Backward-looking
Probable (What will happen)	Searching the probable course of development, e.g. trend extrapolation, deterministic scenarios. Useful in stable situations when making short term forecasts.	Estimating the probability of a specific future image, e.g. traditional consensus Delphi with timing estimates. Useful in volatile situations, where a decision-maker is strongly dependent on external drivers.

[76] Ibid.
[77] Robinson, J.B., Futures under glass: A recipe for people who hate to predict. *Futures*. 22, 1990. 820–842.
[78] Hirschorn, L., Scenario writing: A developmental approach. *Journal of the American Planning Association*. 46, 1980.172–182.
[79] Tuominen, Anu; R. Tapio, V. Varho, T. Järvi, D. Banister, Pluralistic backcasting: Integrating multiple visions with policy packages for transport climate policy. *Futures.* (2014) vol. 60, 2014. pp. 41 – 58.
[80] Vergragt, P.J., J. Quist, Backcasting for sustainability: Introduction to the special issue. *Technological Forecasting and Social Change*. 78, 2011. 747–755.
[81] Amara, R., The futures field. Searching for definitions and boundaries. *Futurist*. 15, 1981. 25–29
[82] Börjeson, L., M. Höjer, K. Dreborg, T. Ekvall, G. Finnveden, Scenario types and techniques: Towards a user's guide. *Futures.* 38, 2006. 723–739.

Future type	Starting from	
Possible (What could happen)	Using data driven variety of options, e.g. what...if modelling of factors external to decision-making. Useful in stable situations where the relationships between key drivers are well-known.	Creating heuristic images of the future, e.g. scenario workshops, non-consensual Delphi studies Useful in volatile situations where great changes could happen.
Preferred (What should happen)	Performing incremental measure driven scenarios, e.g. what...if modelling of factors internal to decision-making Useful in stable situations where relationships between measures and their impact are well-known.	Envisioning the desirable future, e.g. backcasting, brainstorming, futures workshops Useful in volatile situations, where strategic changes are necessary or highly desired.

Table 15: Various ways to make scenarios[83].

In the following text, we take the typology of van Notten et al. as a starting point for describing the various ways in which scenarios can be used to think about the future.[84] Generally, there are three themes that can be used to classify a scenario: *project goal*, *process design* and *scenario conten*t (Table 3).

According to van Notten et al., the project goal can range from explorative to scenarios as tools in decision-making processes. In an explorative process, scenario development can be used to stimulate creative thinking about the future, to discover pathways and connections and to raise awareness. At the other end of the spectrum, scenarios for decision support are strategic tools used to examine specific paths to a desirable future. Depending on the project goal, van Notten et al. identify a number of characteristics of scenarios: inclusion of norms, vantage point, subject of the scenario study, time scale and spatial scale.

The project design process of scenario development can range from intuitive to formal (Table 3). Often the intuitive approach depends on qualitative data and stakeholder involvement in the process of developing the scenario. At the other end of the spectrum, the formal approach takes as starting point quantitative data and computer simulations to develop scenarios. Finally, the design process can also draw on both an intuitive and formal approach. The project design process also includes a

[83] Tuominen et al. op. cit., p. 16.
[84] van Notten, P.W.F., J. Rotmans, M.B.A. van Asselt, and D.S. Rothman, An updated scenario typology. *Futures*. 35, 2003. pp. 423-433.

number of choices in terms of: the nature of data, method of data collection, nature of resources and the nature of institutional conditions[85].

With regards to the content of scenarios, it can range from simple to complex (Table 3). Generally, one can say that a scenario that illustrates the situation or development of one actor or organisation can be seen as simple in terms of content. Scenarios that describe relations between actors, developments and illustrate developments across various time and space scales can be seen as complex in terms of content. The following additional choices will need to be made between: temporal nature, nature of variables, the nature of dynamics, level of deviation and level of integration[86].

Overarching themes	**Characteristics**
Project goal: Exploration vs. decision support	Inclusion of norms Vantage point Subject Time scale Spatial scale
Process design: Intuitive vs. Simple	Data Method of data collection Resources Institutional conditions
Scenario content: Complex vs. Simple	Temporal nature Variables Dynamics Level of deviation Level of integration

Table 16: Scenario typology[87]

As we have also seen in the previous section, scenario development and use has been taken up in ethics and science and technology studies (STS), to develop ethics assessment of emerging technologies[88,89,90]. Ethical impact assessment of emerging science and technology faces the challenge of assessing developments which have yet to occur[91]. The assessor must take as a starting point promises, visions and future scenarios of what different actors say a scientific development or emerging technology will be able to perform in our societies. In fact the challenge is double: not only is the promised technology not there yet, but promises and expectations about the future are fickle.

[85] Ibid.
[86] Ibid.
[87] Ibid.
[88] Boenink, M., T. Swierstra, and D. Stemerding, Anticipating the Interaction between Technology and Morality: A scenario Study of Experimenting with Humans in Bionanotechnology. *Studies in Ethics, Law and Technology*. 4(2), 2010. pp. 1941-6008
[89] Stemerding, D., T. Swierstra and M. Boenink, Exploring the interation between morality and technology in the field of genetic susceptibility testing: A scenario study. *Futures*. 42, 2010. pp. 1133-1145.
[90] Nordmann, A. and A. Rip, Mind the gap revisited. *Nature Nanotechnology*. 4(5), 2010. pp. 273-274.Lucivero, F., Swierstra, T. and M. Boenink 2011. Assessing Expectations: Towards a Toolbox for an Ethics of Emerging Technologies. *Nanoethics*. 5, pp. 129-141.
[91] Lucivero, F., T. Swierstra and M. Boenink, Assessing Expectations: Towards a Toolbox for an Ethics of Emerging Technologies. *Nanoethics*. 5, 2011. pp. 129-141.

An ethical impact assessment would therefore also have to assess the promises made about a certain technology or technological development. Lucivero et al.[92], suggest that such an assessment must consist of three steps: 1) a check of claims to technological feasibility, 2) A check of societal usability and finally 3) an assessment of ethical desirability. Scenarios can be used to develop and illustrate so-called 'thick' descriptions in step 2 and 3. In the second step scenarios can be used to explore future use, how will the envisioned use of a technology play out, who will have to do what and how does that match with what we know of social routines and preferences? In the third step, scenarios can be used to explore how morality might be affected or might influence a technological development. What controversies can be imagined? What constrictions might happen or what changes might occur in what we deem morally acceptable or desirable? An ethics impact assessment of an emerging technology or scientific development could therefore use scenarios, but in a way that takes into account the uncertain and strategic nature of the technology or science itself and the promised associated with it.

3.1.2.5 Delphi method

Delphi is survey technique that involves repeated polling of the same individuals, feeding back anonymised responses from earlier rounds of polling, with the idea that this will allow for better judgements to be made without undue influence from forceful or high-status advocates.

There are three phases in conducting a Delphi. These are: selection of the topic; designing the questionnaire; and selection of the panel of experts. Guidance on each of these phases is available at the European Foresight Platform[93]

The aim of a Delphi method is in many cases to organise a debate, to collect and synthesise opinions and to achieve a degree of convergence. Sometimes, however, differing opinions are also a valuable result. Delphi method is useful for longer-term assessments where extrapolations are not useful or make no sense. For example, in fields where there is not a lot of evidence about the developments and where experts do not dare to explain their real opinion, it can help to gather the opinions. Delphi method is conducted anonymously and designed to avoid domination by particular individuals.

3.1.2.6 Roadmapping

The Roadmapping process can be implemented in many ways. The method is often combined with vision building and participatory methods.[94]

The construction of the roadmap consists of collecting, synthesising and validating the information, and representing the trends within graphical displays associated with support documents. It is neither practical nor desirable to attempt to develop a single, standardised methodology. Rather, the approach should be based on a light and modular process using a "toolbox" with different modules depending on the Roadmapping areas, issues, context and objectives. The following steps can, however, be identified.

[92] Ibid.
[93] EFP (2012). European Foresight Platform.
<http://www.foresight-platform.eu/community/forlearn/what-is-foresight/> accessed on October 2015.
[94] Ibid.

1. Defining the focus and time scale of the roadmap. The time scale depends on the focus of the roadmap:

- One year may be good for a specific rapidly changing technology in product development,
- Five years for existing larger technology or business concepts,
- Ten years for emerging technology fields, and
- Longer than 10 years for studying changes in infrastructure, e.g. buildings or traffic systems.

2. Building the vision. A vision is a plausible and desired state of the future. It should cover the technical goal as well as information about products and solutions, actors, markets and drivers.

3. Creating roadmap content. What are the technologies, products and solutions, markets and drivers in the present, intermediate goal and in the vision. These are placed on the timeline and structure presented in Figure 5. After filling the roadmap it can be reflected with the following questions:

- Does the roadmap contain relevant elements?
- Is the roadmap future-oriented? Can it be used to identify future challenges?
- Is there enough interaction between technologies and business model?

Roadmaps can be applied

- In definition and embedding of R&D targets
- In characterisation of development and competence needs
- As a strategic tool to combine different temporal perspectives and aims of a firm
- As a tool to map the changes in the markets
- As a tool plan business activities and networks
- In the anticipation of the long-term changes in the environment
- As a tool raise awareness of technological and environmental changes, especially in combination with scenarios

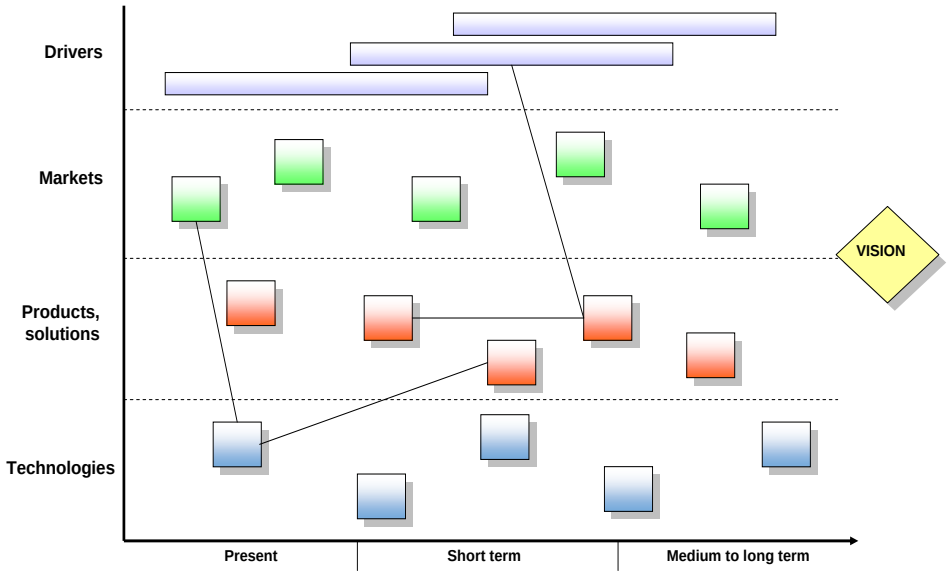

Figure 5: Roadmap structure[95]

3.1.2.7 Futures Wheel

The Futures Wheel is a way of organizing thinking and questioning about the future—a kind of structured brainstorming. It produces a graphical visualization of direct and indirect future consequences of a change or development.

Dufa et al provide guidance on how to construct a futures wheel[96]. The steps are as follows and presented also in Figure 5.

First, the subject under consideration (e.g. an idea or value) is written in the middle of a piece of paper (blue oval in Figure 5) and participating stakeholders are asked to say what necessarily goes with this item. Primary impacts or consequences offered by the group are then written around the central item forming a wheel-like illustration (red ovals).

Next, the group will identify the most likely impacts for each of the primary impacts of the first ring and place them around the primary impacts to form a second ring (green ovals).

The process continues with participants listing third, and even fourth order consequences with very little evaluation. After the group feels its views are represented on the wheel, they can evaluate and edit the wheel.

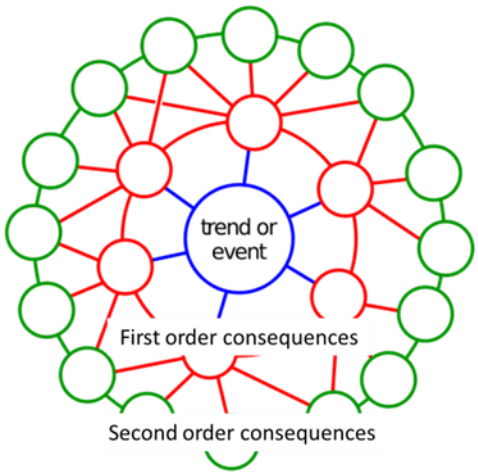

Figure 6: Futures Wheel[97].

The Futures Wheel is most commonly used to:

- Think through possible impacts of current trends or potential future events

[95] Ahlqvist, T., VTT Backpocket roadmap: rubric. Slide set. VTT Technical Research Centre of Finland. 2007.
[96] Dufa et al. op. cit., p. 12.
[97] Dufa et al. op. cit., p. 12.

- Organize thoughts about future events or trends
- Create forecasts within alternative scenarios
- Show complex interrelationships
- Display other futures research
- Develop multi-concepts
- Nurture a futures-conscious perspective
- Aid in group brainstorming

3.1.3 Comparing the methods

This section shows and discusses how the foresight approaches presented above diverge in relation to their focus, data gathering, impact, participation, and the challenges they face. Table 5 presents the key findings.

Approach	Focus	Data gathering	Impact/ Innovation	Participation	Challenges
Trends, weak signals, wild cards	Systematic trend and megatrend analysis, search for weak signals and wild cards	Literature, interviews, surveys, observation	Knowledge on factors which will shape the future agenda of the field under consideration	Future oriented seniors & gurus in the field and other fields	Finding and analysing weak signals (and based on them wild cards) is very challenging
Horizon and technology scanning	Systematic examination of potential threats and opportunities	Internet, ministries, agencies, non-governmental organisations, international organisations and companies, research communities, databases and journals	Detecting early signs of potentially important developments	Experts (and all sources involved in data gathering)	Effectively exploring the margins of current thinking and accurately identifying the matters that challenge past assumptions.
Vision building	Building a consensus on the future state of affairs and changes required	Literature, interviews, surveys, work shops	A common vision, which motivates, inspires and gives direction to those who are committed to it. Vision building provides a learning environment	Experts, all stakeholders the vision concerns	Deducing several different alternative futures from the most relevant forces of change may be challenging.
Scenarios	Identification of possibilities future contexts offer and limitations they set for coming	Future workshops, literature, interviews, surveys	Awareness of future business and policy opportunities in various external contexts	Stakeholders, experts	Choosing defining quality for a vision

Approach	Focus	Data gathering	Impact/ Innovation	Participation	Challenges
	actions				
Delphi	Consensus building amongst experts	Surveys	Organisation of debate, clarification of opinions	Large group of experts	Creative thinking about the future and imagining alternative, yet plausible pathways of development
Road-mapping	Presentation of the path from the current state to the desired future state	Workshops, literature, interviews	Graphical presentation of the key elements which link the current development trends to the desired future, and their inter-linkages	Experts, stakeholders	Finding a representing sample of experts
Futures Wheel	A way of organizing thinking about the future	Brainstorming, workshops	Graphical visualization of direct and indirect future consequences of a change or development	Experts, stakeholders	It is challenging to establish a useful level of interrelatedness of the elements in the four domains, and to effectively use this in creating vision strategy

Table 17: Foresight methods and their specific features.

Participation

Foresight exercises are primarily highly interactive processes. Knowledge is produced interactively between multiple stakeholders with specific interests and differing perspectives towards the topic under exploration. Some of the methods, such as the Delphi, consider only one type of participants (experts), but in many foresight approaches a wide range of potential stakeholders is present. A further aim in some of the approaches, such as vision building and strategic Roadmapping, is to facilitate interaction between the relevant stakeholders and catalyse the desired developments and strategies.

Focus and Impact

The foresight methods reviewed in the previous sections present three types of foci in approaches. The first one is a systematic collection and analysis of future related information (e.g. trends and weak signals). This type of activity increases knowledge on potential key factors shaping the future agenda e.g. within a certain field and helps therefore the stakeholders to prepare for future developments. The second type focuses on building consensus among experts (Delphi), or wider groups of

stakeholders (Vision building). In the best case, the process provides a learning environment for the participants and helps in structuring the complexity of future. The third type presents a more complex approach where the focus is, firstly, on illustration of possibilities future contexts may offer and limitations they may set. Secondly, focus is on presenting future paths from present to the desired future illustrating actions we can do to succeed in alternative future contexts. Scenarios and Roadmaps present examples of this type. The methods help to build the knowledgebase and commit to future actions. They also increase awareness of future business and policy opportunities. In some cases, the method itself may act as an effective policy instrument.

Data gathering

Data gathering and analysis in the foresight methods can be categorised in the same three groups as have been identified for ethical impact assessment methods. These three groups are: data from texts (policy papers, scientific articles, news, professional and topical literature), data from surveys (questionnaires for experts, stakeholder surveys) and data obtained from interaction (interviews with stakeholders, workshop outcomes). Most of the approaches combine data from different sources, and use both qualitative and quantitative data.