

## **Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework**

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## **European foreword**

### **Introduction**

The increasing pace of technological developments such as genetic technologies, geo-engineering, ICT and synthetic biology has been raising questions and discussion on the desirability and governance of the societal impacts. Ethics assessment and ethical impact assessment help ethicists to investigate ethical challenges. Ethics assessment and ethical impact assessment help researchers, policy makers and relevant stakeholders to deal with the ethical impacts of research and innovation.

The need for methods for ethics assessment and ethical impact assessment arises out of the increasing focus on responsible research and innovation in policy contexts and in collaborative efforts of researchers, as well as from new legal regulations for research and innovation at the European level. The European Commission, has been a driving force behind the development of ethics assessment and impact assessment practices, by incorporating the need for responsible research and innovation in its framework programmes.

The SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation, [www.satoriproject.eu](http://www.satoriproject.eu)) research project, funded by the European Commission, developed a framework for common basic ethical principles and joint approaches and practices with the objective to harmonize and improve ethics assessment practices of research and innovation.

Some of the SATORI project reports have been further developed into a CEN Workshop Agreement (CWA) on Ethics assessment for research and innovation. This CWA consists of two parts.

Part 1 sets recommendations for the composition, role, functioning and procedures of an Ethics Assessment Unit. Organisations can use part 1 to strengthen and or improve the ethics assessment of their research and innovation projects. Ethics Assessment Units include, but are not limited to, research ethics committees, institutional review boards, ethical review committees, ethics boards, and units consisting of one or more ethics officers. Part 1 of the CWA is applicable to all Ethics Assessment Units, regardless of their size scope or research and innovation area.

Part 2, outlined here, provides researchers with guidance on ethical impact assessment. Ethics assessors and ethical assessment units will find this information useful as it describes ethical impact assessment in different stages of the ethical assessment. Part 2 is applicable to all researchers, regardless of the context they are working in, or research and innovation area.

## 1 Scope

This CEN Workshop Agreement (CWA) sets requirements and provides guidelines for ethics assessment of research and innovation.

The CWA aims to improve the quality of ethics assessment and harmonize ethics assessment practices.

The CWA consists of two parts:

- part 1 Ethics assessment units; Part 1 provides recommendations for the ethics assessment units on practices and procedures;
- part 2 Ethical impact assessment framework. This part provides a practical, policy-oriented guidelines for researchers and ethics assessors on the different stages of the ethical impact assessment.

Both parts of the CWA are of interest to organisations or agents involved in performing, commissioning or funding research and innovation, and therefore have a responsibility to address ethical issues.

The focus of the CWA is on ethics assessment, not on ethical guidance.

## 2 Terms and definitions

For the purposes of this document the following terms and definitions apply.

### 2.1

#### **Delphi survey**

method for 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

[SOURCE: Global Foresight Glossary, 2013]

### 2.2

#### **design intervention**

changes in the design of the R&I project and outcomes in order to resolve identified ethical impacts

### 2.3

#### **ethical impact**

impact that concerns or affects human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good

### 2.4

#### **ethical impact anticipation**

use of foresight methods to describe different future applications of research and innovation (R&I)

[SOURCE: SATORI deliverable 4.3.1.2]

### 2.5

#### **ethical impact assessment (EIA)**

process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both means for a contextual identification and evaluation of these ethical impacts and translation to a set of guidelines or recommendations for remedial actions aiming at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders

## **draft CEN CWA SATORI-2:2016 (E)**

Note to entry: Ethical impact assessment is a means of actioning social responsibility in research and innovation.

[SOURCE: adapted from Wright, D. Ethical impact assessment, 2015]

### **2.6**

#### **ethical impact determination**

description of the ethically relevant aspects of the possible applications of research and innovation

[SOURCE: SATORI deliverable 4.3.1.2]

### **2.7**

#### **ethics**

moral principles that govern a person's behaviour or the conducting of an activity; The branch of knowledge that deals with moral principles

Note to entry The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy in [http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf).

[SOURCE: Oxford English Dictionary]

### **2.8**

#### **ethics assessment**

institutionalized assessment, evaluation, review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ethical principles or criteria

[SOURCE: SATORI D1.1, 2015]

### **2.9**

#### **ethics assessment unit**

institution or committee that performs ethics assessment

Note to entry Ethics assessment units may assess research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc. and their work may be performed before, during, and after the implementation of the projects they assess.

[SOURCE: adapted from SATORI Deliverable 1.1, 2015]

### **2.10**

#### **ethical issues**

issues that may be relevant for evaluating the ethical implications of maxims, principles, or particular courses of action

### **2.11**

#### **ethical principles**

general principles that may be relevant for making ethical evaluations

Note to entry: Such principles include beneficence, non-maleficence, autonomy, justice, and dignity

### **2.12**

#### **foresight**

action-oriented, multidisciplinary and participatory strategic intelligence focused on alternative futures

Note to entry Foresight aims 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.

[SOURCE: Eerola, A. and B.H. Jørgensen Technology Foresight in the Nordic Countries]

### 2.13

#### **futures, alternative**

idea that there is not a single future, but a range of possible futures, which are influenced by human choice today

[SOURCE: Adapted from Global foresight – glossary]

### 2.14

#### **futures wheel**

instrument for graphical visualization of direct and indirect future consequences of a particular change or development

[SOURCE: Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

### 2.15

#### **horizon scanning**

process of reviewing and analysing current literature, web sites, and other media to identify and describe noteworthy trends and their possible development and future

[SOURCE: adapted from Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

### 2.16

#### **impact of research and innovation**

influence or effects, e.g. societal, ethical, legal, political, economic, environmental, of research and innovation

EXAMPLE Environmental consequences of technological innovations resulting from research in the chemical sciences.

### 2.17

#### **innovation**

development, based on new ideas or inventions, of new products, services, processes and methods believed to create added value for society

[SOURCE: SATORI Deliverable 1.1, p 17]

### 2.18

#### **personal data**

information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person

[SOURCE: General Data Protection Regulation]

**2.19**

**remedial action**

follow-up activity aimed at overcoming ethical impacts

Note to entry: Remedial actions can be aimed at intervention into the design of the research and innovation project and at recommendations for future R&I efforts.

**2.20**

**research**

form of disciplined inquiry that aims to contribute to a body of knowledge or theory

**2.21**

**responsible research and innovation (RRI)**

transparent, interactive process by which societal actors and innovators become mutually responsive to each other with view on the acceptability, sustainability and societal desirability of the innovation process and its marketable products, in order to allow a proper embedding of scientific and technological advances in society

**2.22**

**roadmapping**

vision driven tool for presenting the path from the current state to the desired future state. It provides a graphical presentation 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

Note 1 to entry The tool is often combined with vision building and participatory methods.

Note 2 to entry Strategic roadmapping is emerging.

**2.23**

**scenario**

predicted sequence of events that might possibly occur in the future

[SOURCE: Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

**2.24**

**scenario planning**

strategic planning method that e.g. organisations use to make flexible long-term plans.

[SOURCE: Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

**2.25**

**social responsibility**

principle for raising awareness of the societal impacts of the research and innovation, including taking appropriate remediate actions if deemed necessary

**2.26**

**technology assessment (TA)**

systematic evaluation of properties, effects and or impacts of technology.

Note to entry It may address the direct intended consequences of technologies as well as their indirect, unintended consequences

**2.27**

**trend**

tendency or direction that is evident from past events, it usually suggests a pattern

Note to entry A trend can be increasing or decreasing in strength or frequency of observation.

[SOURCE: adapted from Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

**2.28**

**vision**

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

[SOURCE: van der Helm, R. The vision phenomenon: towards a theoretical underpinning of visions of the future and the process of envisioning]

**2.29**

**weak signal**

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

[SOURCE: Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

**2.30**

**wild card**

unpredictable event or situation; event that has a low probability but a high impact

Note to entry: Wild cards are often recognized and known, but discounted, even when the event is relatively certain over a period of years.

[SOURCE: Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary]

### **3 Ethical impact assessment framework**

The framework presents a comprehensive methodology for conducting an ethical impact assessment (EIA) in research and innovation (R&I) projects.

The EIA framework consists of the following steps:

- 1. conduct an EIA threshold analysis;
- 2. prepare an EIA plan if the threshold analysis concludes that ethical issues are involved;
- 3. ethical impact foresight;
- 4. evaluate the ethical impacts;
- 5. formulate and implement remedial actions within and external to the project;
- 6. review and audit the EIA.

## 4 Conduct an ethical impact assessment threshold analysis

### 4.1 Objective

The purpose of the EIA threshold analysis is to determine whether or not ethical issues are involved in the R&I project that demand an EIA.

### 4.2 Who performs the threshold analysis

The institutional context indicates who should conduct the EIA threshold analysis. The responsible person most likely is:

- **designated administrator at a public research institute or a company** for larger institutions or companies. For universities, this could be the person that is responsible for coordination of research funding proposals. For larger companies, this could be the corporate responsibility manager;
- **researcher within the R&I project team** in case the institution or company, such as an SME, does not have a designated administrator who could perform the threshold analysis;
- **third party’s representative** in case several organisations cooperate in a R&I project, the threshold analysis could be performed by an independent consultant that is impartial about whether or not the R&I project is initiated.

### 4.3 Design and fill in the threshold analysis questionnaire

The threshold analysis typically consists of a questionnaire. The questionnaire should include the relevant ethical impacts for the R&I project, as described in the R&I project plan, and its expected outcomes. Annex A provides an overview of ethical impacts for a threshold analysis questionnaire that could be used for comparison and inspiration.

Table 1 provides a basic format for an ethical impact threshold analysis questionnaire. The questionnaire should be amended to include project- or scientific field specific ethical issues.

The threshold analysis should run in parallel with the writing of a project proposal. The EIA threshold analysis should be done timely and efficiently and should not unnecessarily hinder the planning of the R&I project.

**Table 1 — Basic format for an ethical impact 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.

1	Which of the following activities are within the scope of your project?	Yes	No
A	The development of fundamental scientific knowledge?		
B	The development of knowledge that can be used to develop technologies?		
C	The development of technologies, such as prototypes, models?		

	<b>D</b>	The development of models that can influence political decision-making, such as climate models or economic models?		
	<b>E</b>	None of the above, explain why		
<b>2</b>	<b>Does or could the project lead to the conceptualisation, design or development of technologies that:</b>		<b>Yes</b>	<b>No</b>
	<b>A</b>	Can be implemented in some form in a health-care setting?		
	<b>B</b>	Allow for the genetic modification of organisms?		
	<b>C</b>	Have to adhere to certain safety regulations?		
	<b>D</b>	Make use of personal data collection and/or processing?		
	<b>E</b>	Will not be accessible to certain people?		
	<b>F</b>	Interfere in some way with the environment?		
	<b>G</b>	Are likely to be targeted at vulnerable groups, such as elderly people, children?		
	<b>H</b>	Can be used to modify economic systems (e.g. resource distribution, finance)		
	<b>I</b>	Could be used for military or other non-civilian purposes?		
<b>3</b>	<b>In the event that the technologies in question could have a distinctly different use other than the ones listed above, please indicate this and explain briefly the alternative use(s).</b>			
<b>4</b>	<b>Does or could the project lead to the conceptualisation and implementation of intangible research outcomes, such as models, theories, intellectual or property right materials, that:</b>		<b>Yes</b>	<b>No</b>
	<b>A</b>	Include uncertainties that can have decisive impact on possible decisions based on these research outcomes?		
	<b>B</b>	Deal with culturally sensitive materials or acknowledged aspects of cultural heritage, e.g. endangered languages?		
	<b>C</b>	Could introduce bias or in some form obstruct freedom of speech or opinion?		
	<b>D</b>	Include aspects that impact intellectual property rights?		
<b>5</b>	<b>In the event that the research outcomes in question could have a distinctly different outcomes than the ones listed above, please indicate this and</b>			

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	<b>shortly explain the alternative use(s).</b>		

For the following questions, please indicated the expected severity of risks of impact, on a scale 1 to 5; where 1 implies no risk and 5 implies severe risk:

<b>6</b>		<b>Please indicate the expected severity of risks of the following ethical impacts from your R&amp;I project or from its applications:</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	<b>A</b>	Health risks					
	<b>B</b>	Risks for unwarranted genetic modifications					
	<b>B</b>	Safety risks					
	<b>D</b>	Privacy risks					
	<b>E</b>	Risk of social exclusion					
	<b>F</b>	Risks of environmental damage					
	<b>G</b>	Risks for vulnerable groups					
	<b>H</b>	Risks of unfair distribution of means					
	<b>I</b>	Risks of dual use					
	<b>J</b>	Risks of fundamental uncertainties in the models or theories that are used					
	<b>K</b>	Risks for violation of culturally sensitive materials					
	<b>L</b>	Risks of obstruction of the freedom of speech/opinion					
	<b>M</b>	Risks for the violation of intellectual property rights					
<b>7</b>		<b>Can you reasonably expect any other risk of ethical impacts that might be involved in the R&amp;I but that is not listed above, please explain the possible other risk(s) and indicate the severity</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	<b>A</b>						
	<b>B</b>						
	<b>C</b>						

NOTE Parts of the questionnaire are based on the “Ethics issues table” of the European Commission: European Commission. *Ethics Issues Table – Checklist*. 2014.

## 5 Ethical impact assessment plan

### 5.1 Objective

The outcome of the threshold analysis [4] determines whether an EIA is required. When the threshold analysis has not identified ethical issues, no EIA is required. When the threshold analysis has identified ethical issues the project should prepare an EIA plan. The EIA plan should include the following sections:

- **Assess the level of scale of the EIA;**
- **Budget allocation;** in line with the level of EIA scale;
- **Team composition;** in line with the level of EIA scale;
- **Review criteria:** The EIA should be submitted for review. This review can be part of the overall project review, or it could be done separately if deemed necessary by the ethics assessment unit, funding body or company responsible. Certain review criteria could be agreed upon:
  - Milestones: deadlines for reports in which the completed stages of the EIA are presented;
  - Quality assurance: certain standards with regards to the form and content of the reports that need to be met;
  - Original research: in the event that either mid-range or full-scale EIA original research might be expected, this could be reflected in for instance a publication target;
- **(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;
- **(Optional) Stakeholder consultation:** In case the threshold analysis demands a mid-range or full-scale EIA, the project should consult with stakeholders at the start of the project. This consultation should aim for:
  - mapping the different relevant stakeholders;
  - raising awareness amongst stakeholders that the project will take place;
  - gathering more details about possible ethical impacts from stakeholders.

### 5.2 Assess the level of scale of the EIA

The outcomes of the threshold analysis guides the selection of the level of scale of the EIA; the level of scale has implications for the EIA team composition and budget:

- **Level of EIA:**
  - **Small-scale:** When a limited number (1or2) 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);
  - **Mid-range:** When a substantial number (3or4) 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 deemed substantially severe (3or4 on the 5-point scale);

- **Full-scale:** When a large number (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 one of them is deemed serious (4 or 5 on the 5-point scale).

— **Team composition:** The considerations for team composition are derived from different types of academic researchers that might be involved in the EIA. The following minimum considerations apply to the different levels of EIA:

- **Small-scale** EIA mostly requires deskwork and little anticipation and analysis of ethical impacts. The EIA team consists of a research assistant who is member of the R&I project team, for instance a PhD candidate. This is a part-time position;
- **Mid-range** EIA requires setting up consultative and participatory processes and asks for a more thorough anticipation and analysis of ethical impacts. The EIA team consists of a research fellow in the R&I project. This is a full-time position;
- **Full-scale** EIA requires the use of a variety of participatory efforts, involving multiple stakeholders, and calls for a deep and thorough anticipation and analysis of ethical impacts. The EIA team consists of a professor in the R&I project. This is a full-time position.

— **Budget composition:** The different levels of EIA may depend on the budget that is available. An EIA should preferably require 1-10% of the budget of an R&I project, with a maximum of 20%. The following estimations guide considerations for budget composition:

- **Small-scale** EIA has a budget of approximately 90% direct personnel costs and 10% other costs;
- **Mid-range** EIA has a budget of approximately 80% direct personnel costs and 20% other costs;
- **Full-scale** EIA has a budget of approximately 70% direct personnel costs and 30% other costs.

NOTE Budget and team composition are roughly based on the H2020 budget document of EU Research: EURESEARCH. (2014). Horizon 2020 – How to Budget My Project Costs.

Table 2 provides a categorisation of the level of EIA based on the size of a yearly budget and a 4 years budget, taking into account the maximum of 20% of the research budget.

**Table 2 — Categorisation of level of EIA based on yearly and 4 years budgets of the R&I project**

Level of EIA	Yearly budget (YB)	4years budget (4YB)
Small-scale	€ 135,000 < YB < € 600,000	< € 2,4 million
Mid-range	€ 600,000 , < YB < €1,3 million	€ 2,4 million < 4YB < € 4,9 million
Full-scale	>€1,3 million	> 4,9 million

NOTE A technology-scale EIA might be considered in addition to regular levels of EIA. A technology-scale EIA is a dedicated EIA for a new technological paradigm that is not tied to a specific R&I project. Annex B provides additional information for the technology-scale EIA.

## 5.3 Review of the EIA plan

### 5.3.1 Who reviews the EIA plan

The assessor reviewing the EIA plan depends on the funding source for the R&I project and could be:

- **Ethics assessment unit:** 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, should be in charge of reviewing the threshold analysis as part of the project proposal;
- **Funding body:** In the event that a research funding organisation funds, or partly funds, an R&I project. This could be the European Commission or a national research funding body. As many projects have several funders the review could be delegated;
- **Responsible department in a company:** In the event of a commercial entity funding an R&I project, different options exist. The company may assign an internal department, company association or consultant to review the EIA plan.

NOTE Research funding organisations are recommended setting up an independent body that is responsible for conducting the review and audit of EIA plans and EIAs.

### 5.3.2 Communication of the review

Based on the outcome of the threshold analysis the reviewer should accept, amendment, or reject the EIA plan and communicate the outcome:

- **The reviewers accept the EIA plan:**
  - Selection of review criteria, scale, budget and team composition are approved.
- **The reviewers ask for amendments to the EIA plan,** for example including:
  - 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 reasonably have been expected;
  - Additional requirements for budget team composition and or scale.
- **The reviewers reject the EIA plan** in the following cases:
  - When the threshold analysis calls for an EIA scale that does not fit the size of the project;
  - When some ethical impacts are deemed too severe for the means available to the project team.

The outcome of the review of the EIA plan should be kept confidential and can only be accessed by the reviewing organisation.

## 6 Ethical impact foresight

### 6.1 Objective

Ethical impact foresight maps the ethical impacts that might occur in the context of the R&I project and places these impacts in a temporal perspective, anticipating short, medium and long-term impacts.

The ethical impact foresight stage:

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

## **6.2 Procedure**

The ethical impact foresight stage has the following steps:

- 1. Adjust the EIA to the technology readiness level of the outcomes of the R&I project;
- 2. Identify possible ethical impacts: Select the methods and perform the activities for ethical impact anticipation;
- 3. Compare identified ethical impacts with literature on the analysis of ethical impacts of similar R&I projects;
- 4. Determine and document possible or probable ethical impacts.

The ethical impact foresight stage should start early in the R&I project to ensure that possible ethical impacts can be timely evaluated and translated into recommendations and remedial actions.

The ethical impact foresight activities are highly intertwined. Some of these steps can be carried out simultaneously, as the findings in one step might benefit work in another.

**Example** When stakeholders during the ethical impact anticipation activities point out that unexpected monitoring of their activities by data processes is problematic, the ethical impact determination will conclude that privacy is an ethical principle that is at stake. This could inform further ethical impact anticipation activities.

## **6.3 Adjust the EIA to the technology readiness level**

The Technology Readiness Level (TRL) methodology could be used to assess the technology readiness of the expected outcomes of an R&I project.

In a TRL assessment the EIA team should use the prospective outcomes of its research activities as the input for determining the TRL level.

**Example** 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.

Table 3 provides stipulates nine distinct levels for conducting a TRL assessment:

**Table 3 — Technology Readiness Levels (TRLs)**

<b>TRL level</b>	<b>Criterion</b>
TRL 1	Basic principles observed
TRL 2	Technology concept formulated

TRL level	Criterion
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
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)

NOTE Source: European Commission Decision C (2014)4995, 22 July 2014; General Annexes

The outcomes of a TRL assessment should guide the selection of activities for ethical impact anticipation[6.4] and ethical impact determination[6.5]. With a TRL of 1, 2 or 3, more attention will be paid to the ethical impact anticipation activities whereas, with a TRL of 6 or 7, more attention will be paid to the ethical impact determination activities. These activities are often intertwined and can be conducted at the same time.

**EXAMPLE** When impacts on privacy are considered a predominant area of concern in an R&I project, this influences the stakeholder involvement during the EI anticipation, by choosing experts on privacy in the expert consultation, or focusing on privacy issues in a citizen panel.

#### 6.4 Select methods and perform activities for ethical impact anticipation

Based on the TRL assessment [6.3] the EIA team should identify potential ethical impacts by selecting the ethical impact anticipation methodologies and performing the activities.

The methods for ethical impact anticipation differ in their reliance on sources of knowledge: *evidence, expertise, interaction and creativity*. Methods can be classified based on their degree of reliance on expertise vs. interaction and on creativity vs. evidence. The selection of methods should combine methods that rely on different sources of knowledge in order to obtain the most accurate and widest range of analysis.

The selection of methods for ethical impact anticipation also depend on the levels of EIA; small-scale, mid-range and full-scale.

Table 4 provides and overview of different ethical impact anticipation methods according to the level of EIA.

**Table 4 — Overview of ethical impact anticipation methods, according to the EIA level**

EIA level	Evidence	Expertise	Interaction	Creativity
Small-scale (basic )	Horizon scanning	Expert consultation		Roadmapping

Mid-range	Trend analysis		Brainstorm/futures wheel	
Full-scale		Delphi interviews	Citizen panel	Scenario writing

NOTE 1 Expertise-based methods, such as roadmapping and expert surveys, are helpful in determining the most likely futures, as well as the probabilities of possible futures.

NOTE 2 Creativity-based methods, such as wildcard workshops and scenario writing, are useful in identifying wild card events that may challenge the occurrence of “highly probable” situations in the future.

NOTE 3 Interaction-based methods, such as expert and citizen panels, expertise often gains considerably from being brought together and challenged to articulate with other expertise, and indeed with the views of non-expert stakeholders.

NOTE 4 Evidence-based methods, such as a literature review and trend analysis, are helpful for understanding the actual state of development of the field to which the R&I project belongs.

Annex C provides additional information on ethical impact anticipation methods.

## 6.5 Select methods and perform activities for ethical impact determination

The EIA team should compare and analyse the identified potential ethical impacts [6.4] with ethical impacts of similar R&I projects in order to describe the potential ethical impacts for the R&I project and its outcomes. For the comparison and analysis of ethical impacts from the R&I project the EIA team should select methods and perform activities for ethical impact determination.

This selection of methods and activities for ethical impact determination depend on the level of the EIA [5], type of analysis, and type of ethical issues.

- Ethical impact determination can be conducted by a *conceptual* analysis, for instance based on explicit ethical principles, or by an *empirical* analysis, for instance by consulting experts;
- During ethical impact anticipation the EIA team may identify two types of ethical issues; *explicit ethical issues*, where a technological or social option potentially violates a moral principle, value or norm, or *intuitive ethical 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 ethical principle.

EXAMPLE The ethical impact anticipation may conclude that developments in robotics may result in certain types of robots that violate people’s autonomy or privacy.

Table 5 provides an overview of ethical impact determination methods, according to types of analysis and types of ethical issues.

**Table 5 — Overview of ethical impact determination methods**

Method type	Conceptual analysis	Empirical analysis
Explicit ethical issues	Ethical principles checklist, Use of ethical theories	Consolatory approaches

Intuitive ethical issues	Situational approaches	Techno-ethical scenario building
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Annex D provides additional information on the ethical impact determination methods.

## 6.6 Determine the ethical values and principles for the given impacts

The EIA team should document the outcomes of ethical impact foresight activities. The report typically has the following structure:

- Introduction;
- Overview of methods used;
- If applicable, outcomes of expert consultations and or stakeholder engagement;
- Identified possible ethical impacts;
- Discussion on the perceived short, medium and long term ethical impacts;
- Conclusion with determined ethical impacts.

As the EIA progresses, the EIA team, and possibly stakeholders who participate, may identify additional values and principles impacted by the proposed R&I technology.

## 7 Ethical impact evaluation

### 7.1 Objective

In ethical impact evaluation the EIA team should assess the relative importance, the likelihood of occurrence and the possible value conflicts of ethical impacts that have been determined in the ethical impact foresight stage (6).

**EXAMPLE** In a proposed project on the Internet of Things (IoT) the ethical impact foresight stage determined that behavioural profiling by IoT systems presents privacy issues. In the evaluation stage, the assessor determines the threats, vulnerabilities and risks, advantages and disadvantages, their impacts, 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.

### 7.2 Procedure

The ethical impact evaluation stage has the following steps:

- 1. Select the methods and perform the activities for ethical impact evaluation
- 2. Conduct a contingency analysis to evaluate the likelihood of ethical impacts to occur;
- 3. Assess the relative importance of ethical impacts;
- 4. Identify potential or actual value conflicts and, if possible, aim at resolving these. If value conflicts cannot be solved, this should be explicitly recognised;
- 5. Clarify the ethical impacts and the related ethical values or principles and formulate workable conceptualisations.

### **7.3 Select methods and perform activities for ethical impact evaluation**

The EIA team should select the methods for the ethical impact evaluation. The choice of these methods depends on the scale of the EIA. The methods can be distinguished in three types of inquiries:

- **Desk-research** forms the basis of all activities undertaken to conduct the ethical impact evaluation. These include literature reviews and reviews of existing evaluation of ethical impacts in related R&I projects and the deployment of certain conceptual frameworks, for instance, when trying to resolve conflicts of values;
- **Expert consultation** calls for ethical expertise or expertise in other specific areas, such as field-specific expertise. Similar methods as those mentioned in the ethical impact foresight stage can be selected, such as Delphi. The focus of the consultation is about the relevant importance of already determined ethical impacts;
- **Participatory approaches** are preferred if the scale of the EIA and the available resources allow the selection. These focus on stakeholder engagement, for instance in the form focus groups or citizen panels.

### **7.4 Conduct 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.

In the contingency analysis the EIA team should focus the different aspects of the context in which the ethical impact occurs.

**EXAMPLE** In a privacy-related project an assessor might first anticipate the ethical impact of the violation of a person's privacy. However, whether and to what extent internet cookies violate user privacy depends on many factors, such as the type of information contained in the cookie, policies that regulate the use of such cookies, the browser's support of privacy settings or the behavioural patterns of internet users. A contingency analysis makes explicit such contingencies.

A contingency analysis can be conducted by:

- extensive desk-review in which certain factors derived from the context of an ethical impact are made explicit;
- horizon scanning for each of the factors identified, determining the likelihood of the factors changing in the future, for instance technologies which are at the development stage and will be put on the market;
- short scenarios for the ethical impacts that have been determined in the ethical impact foresight stage.

### **7.5 Assess the relative importance of ethical impacts**

The EIA team should assess the relative importance of the potential ethical impacts under study based on the contingency analysis, and with additional desk research, expert consultations or participatory processes. The relative importance of these ethical impacts depends 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.

**EXAMPLE** In neuro-technology the technology may be massively deployed in the future, which would radically undermine the ethical principles of human autonomy. By arguing that autonomy is an essential value, we could conclude that the ethical impacts raised by this technology are very significant.

The relative importance of ethical impacts results in a ranking in scales:

- scale on the importance, which is, however, bound to be controversial;
- scale on the risks of occurrence, that a value or principle is violated;
- intensity scale which assesses the expected strength and scope of the violation, if it were to occur.

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

- **basic EIA procedures:**
  - conduct a literature review to evaluate the relative importance of the ethical impacts identified by (1) assessing which ethical principles and values are brought into consideration for an ethical impact and (2) evaluating them by using an ethical theory, such as consequentialism, deontology or virtue ethics;
  - use the contingency analysis to assess the likelihood of the ethical principles or values being violated;
  - consider factors of scale and intensity to assess the severity of impacts by 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 and time, for instance considering the speed at which impacts can occur.
- **mid-range or full-scale EIA procedures**, in addition to the basic procedures:
  - conduct an expert consultation or organise participatory stakeholder engagement, through methods such as focus groups or citizen panels, to gather opinions on the relative importance of the ethical principles and values at stake;
  - conduct an expert consultation to obtain 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;
  - use 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.

Table 6 provides an overview of methods for evaluating the relative importance of ethical impacts.

**Table 6 — Overview of procedures for evaluating the relative importance of ethical impacts**

<b>EIA scale</b>	<b>Normative importance ethical impact</b>	<b>Risk of violation of ethical principles/values</b>	<b>Severity of impacts</b>
<b>Small-scale or basic</b>	Desk review	Outcomes of the contingency analysis	Analysis of factors of scale and intensity of

	Ethical theories		ethical impacts
<b>Mid-range or full-scale</b>	Expert consultation  Stakeholder engagement	Expert consultation for input on the contingency analysis	Expert consultation for input on severity of ethical impacts

### 7.6 Identify and resolve value conflicts

The EIA team should identify and resolve value conflicts based on the relative importance of the ethical impacts. The relationships between these ethical principles and values should be evaluated by identifying possible value conflicts and aiming to overcome them.

Rarely a particular technological artefact or scientific application has impact on one value and is neutral to all the others. Normally a technological artefact 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.

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 EIA team can resort to the rules of thumb that explicate the different types of procedures that can be used:

— **first rule of thumb:** Fundamental values get precedence over non-fundamental values. Fundamental values are not reducible to other values and are important to uphold, considering public consensus;

EXAMPLE In the West, fundamental values include autonomy, freedom, dignity, including the right to life, justice, well-being, privacy, equality, security and bodily integrity.

- **Procedure:** Refer to fundamental values as they are discussed in ethical theories and/or are agreed upon in authoritative, widely accepted documents such as the law or the declaration of human rights.

— **second rule of thumb:** Assess the degree of violation and choose the action that least compromises a fundamental value;

EXAMPLE 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.

— **third rule of thumb,** project moral values into situations when two fundamental values seem to be equally violated to determine which value appears more important in the particular situation, and reason why giving priority;

EXAMPLE In an airport, the value of security is generally thought to be more important than the value of privacy.

- **Procedure:** Construct an ethical argument, based on moral intuition, to favour one value over another.
- **fourth rule of thumb:** negotiate conflicts of moral values between different parties. The different parties constitute or represent a representative sample of stakeholders in the situation:
- **Procedure:** Organise a stakeholder consultation and use stakeholder inputs for balancing the values at stake, for mid-range and full-scale EIA.
- **fifth rule of thumb:** Avoid the value conflict by reconfiguring the situation. It may be possible to avoid value conflicts by avoiding situations in which they occur.

## 7.7 Construct workable concepts

The EIA team should clarify the ethical concepts of the ethical principles and values at stake, if applicable.

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. 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 EIA team can:

- review literature definitions of the respective ethical principle or value;
- construct a definition of the respective ethical principle or value by drawing relationships with related concepts.

## 7.8 Present the ethical impact evaluation

The EIA team should document the outcomes of the impact evaluation activities with a frequency agreed in the EIA plan. The report typically has 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

Results of the ethical impact evaluation can be published and presented to the public.

NOTE A knowledge repository with documents, either in full or parts, relevant for ethical impact evaluation, such as lists with ethical principles and human rights declarations and ethical impact evaluation reports, would be very useful for assessors in order to reduce the amount of time spent on activities such as desk review.

## 8 Remedial actions

### 8.1 Objective

Based on the results of the ethical impact evaluation [7] the remedial action stage formulates and execute remedial actions. These remedial actions are recommendations and or design interventions to overcome the ethical impacts.

### 8.2 Procedure

The remedial action stage has the following steps:

- 1. Collect information about recommendations and design interventions proposed by other related R&I projects;
- 2. Formulate and implement design interventions;
- 3. Formulate recommendations at different levels;
- 4. Present the remedial actions.

### 8.3 Collect information about remedial actions

The EIA team should collect information on recommendations and design interventions proposed by related R&I projects. The list of ethical impacts in table 7 guides the selection of the type of remedial actions:

**Table 7 — Overview of remedial actions according to type of ethical impacts**

<b>Type of ethical impact:</b>	<b>Type of remedial action:</b>
Ethical impact due to technology being developed in the R&I project (e.g. big data applications)	Design interventions (mid-range, full-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. conflicts of interest risks)	Organisational recommendations (all types of EIA)
Impacts due to regulatory or conventional deficiencies (e.g. risk of corruption, legal opaqueness)	Regulatory recommendations (mid-range, full-scale EIA)
Impacts due to insufficient policy support (e.g. environmental risks)	Policy recommendations (mid-range, full-scale EIA)

## 8.4 Formulate and implement design interventions

The EIA team should formulate and implement design interventions. Design interventions are usually targeted at technical aspects of the project and innovation activity. Value sensitive design interventions are design interventions that resolve ethical impacts.

Value sensitive design employs an integrative and iterative methodology, consisting of conceptual, empirical, and technical investigations:

- **conceptual stage** conceptualises the values that ought to be addressed for the technology and its context of use into workable concepts. This stage can draw from conceptualisation work done during ethical impact evaluation [7.7];

EXAMPLE If trust ought to be addressed in an IT system, a philosophically informed working definition of trust is provided.

- **empirical stage** investigates the interactions between humans and the R&I outputs using methods for empirical research, such as interview methods, survey methods and ethnographic methods. This stage can draw from stakeholder engagement exercises in the ethical impact foresight stage [6];
- **technical stage:** formulates and implements design interventions. This stage can draw from the value conflicts identified in the evaluation stage [7.6]. The researchers, possibly with stakeholders, alter the design to do justice to each value that ought to be inscribed in the technology.

NOTE More information on value sensitive design is available from: Friedman, B., P.H. Kahn & A. Borning. Value Sensitive Design and Information Systems.

## 8.5 Formulate external recommendations

The EIA team should formulate recommendations that are to be implemented on a broader scale. The recommendations can address different levels, as applicable:

- **societal recommendations** 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** on how an organisation identifies, responds to, addresses, manages, avoids or minimises ethical issues. The organisation conducting the research or innovation activity is responsible for implementing the recommendations;
- **regulatory recommendations**, for two types of stakeholders: regulators need to put in place new regulations addressing particular ethical issues, and those subject to regulatory strictures. The recommendations offer guidance on how to meet legal and ethical obligations. The legislators and regulators are responsible for implementation;
- **policy and public policy recommendations** for decision making authorities. Politicians and public authorities are responsible for implementation.

## 8.6 Present the remedial actions

The EIA team should formulate remedial actions. It should be clear to whom the remedial actions are directed including the responsibility for implementing the remedial actions.

The remedial actions can be presented in different ways, according to the action type:

- **design interventions:** can be presented in the form of a report with the proposed design interventions and or surveys for stakeholders;

NOTE If the survey takes place before and after the design interventions, the effectiveness of the interventions can be assessed.

- **societal and organisational recommendations** are presented in the form of a simple report. This report can be based on a short review of societal and organisation recommendations from other projects; complemented by the ones that are specific to the R&I project in which the EIA takes place;
- **regulatory recommendations** 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;
- **policy recommendations:** these are presented in the form of green- or whitepapers. 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 for implementation.

## **9 Review and audit**

### **9.1 Objective**

The review and audit stage of an ethical impact assessment (EIA) ensures independent evaluation of the EIA process and, if necessary, independent intervention. The review and audit stage:

- provides constructive feedback for improving the execution of the EIA process; provides guidelines for successfully finalising the EIA process;
- guards agreed milestones and key performance indicators of the EIA process.

### **9.2 Procedure**

The review and audit stage has the following steps:

- At the start of the EIA: set the key milestones and review criteria for the review and audit process;
- During the EIA process: evaluate the conduct and documentation of the EIA process;
- At the end of the EIA process: final review of the EIA process;

For each step the performer of the review and audit should present the findings. Review and audit procedures should be standardised as much as possible to decrease their administrative burden, for instance by providing for an online entry system in which the reviewer can present the EIA findings and upload documentation.

### 9.3 Who performs the review and audit

The assessor for review and audit of the EIA depends on the funding source for the R&I project; the ethics assessment unit, the funding body or a company responsible. The assessor performing the review and audit of an EIA and the person reviewing the EIA plan [5.3] could be the same.

NOTE Research funding organisations are recommended to set up an independent body that is responsible for conducting the review and audit of EIAs.

### 9.4 Review and audit planning and criteria

The assessor for review and audit, in cooperation with the EIA team should agree on review and audit planning and criteria at the start of the EIA.

Even though the planning and criteria are decided upon on a case-to-case basis, the following guidelines can assist in determining them:

#### — Review and audit planning:

- small-scale EIA has a final review and audit, a mid-term review is optional;
- mid-range EIA has a mid-term and a final review and audit, additional reviews are optional;
- full-scale EIAs has yearly reviews and audits as well as a final review and audit.

#### — Review and audit criteria:

- Review criteria are usually framed in terms of the necessary documentation that needs to be submitted;
- Audit criteria 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.

EXAMPLE These criteria might include requirements for the presentation of EIA outcomes, such as reports or publications, or requirements for stakeholder engagement.

### 9.5 Evaluation of the documentation of the EIA process

During the EIA the assessor should review and audit the documentation of the EIA process, depending on the scale and progress of the EIA:

#### — Intermediate review

- **Monitoring:** The reviewer requests the documentation of the different EIA steps to monitor the progress of the EIA process;
- **Evaluation:** The reviewer should convene a meeting with the EIA team during which the EIA is evaluated. Based on this evaluation, the reviewer will issue feedback and recommendations for the future EIA work;
- **Management:** The reviewer should evaluate the project management of the EIA, including issues such as division tasks and financial management;
- **Communication:** The reviewer should ensure that communication is established between the EIA team and the R&I project funding body.

#### — Intermediate audit:

- The reviewer should provide the EIA team an audit report, which states whether the agreed upon milestones and or deliverables have been met;
- The reviewer should 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: (1) acceptance of EIA without revisions, (2) acceptance of EIA with minor or major revisions and (3) rejection of current EIA progress with the need of re-initiating the EIA process.

## **9.6 Final review**

At the end of the IEA process the reviewer should organise a final review and audit. 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 EIA team to evaluate the EIA and document recommendations for future EIAs;
- the reviewer 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 mid-range and full-scale EIA: the reviewer conducts a short survey amongst the stakeholders that were involved in the EIA.

### **— Final Audit:**

- the reviewer makes a financial statement, with the cost of the EIA, and a portfolio of publications for the funding organisation of the R&I project;
- the reviewer convenes a final audit meeting with the EIA team at which leftover follow-up actions are agreed upon. These need to be performed in order to meet the audit criteria.

## **9.7 Presentation of the review and audit results**

Depending on the different steps in the review and audit stage, the reviewer should present the results 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 assessor and the EIA team. This contract can be part of the overall contract between 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. The reviewer should send the audit reports 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:
  - final EIA report, drafted by the EIA team;
  - final review document, drafted by the reviewer;

- financial statement;
- portfolio of publications related to the EIA.

## Annex A (informative)

### Ethical issues for the threshold analysis questionnaire

#### A.1 Select ethical impacts for the threshold analysis questionnaire

##### A.1.1 Overview of ethical impacts

The relevant ethical impacts guide the construction of the threshold analysis questionnaire. The performer of the threshold analysis selects relevant ethical issues from the different types.

The three types of ethical impacts are the following:

- **impacts during research** concern research ethics, including the ethical impacts that the practice of research can have, such as harm to human subjects, or scientific fraud. The impacts during research are usually taken into account during conventional ethics assessment procedures, and are therefore of less importance for the threshold analysis of the EIA;
- **impacts from technologies (innovation)** concern new or emerging technologies that result from R&I projects. This category consists of the following nine, broad sub-categories. They are impacts due to:
  - application in the context of human healthcare;
  - genetic modifications;
  - safety risks;
  - collection/processing of personal data;
  - accessibility restrictions;
  - interference with the environment;
  - targeting of vulnerable groups;
  - modification of distribution of means;
  - dual use.
- **impacts from research outcomes** concern with the research outcomes of R&I projects that can have real life impacts. For example climate models 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 due to:
  - unpredictability of scientific models;
  - misuse or misrepresentation of cultural heritage;
  - restriction of free speech/ freedom of opinion;
  - violation of intellectual property rights.

NOTE The impacts to be taken into account in an EIA are impacts of R&I. These impacts can occur despite *the researchers sticking to the ethical codes of conduct*. For instance, even though a nuclear researcher sticks to the professional ethical code, presents the research results honestly and limits harm to the animals used in the experiments, the *outcomes and applications* of the research nonetheless might have ethical impacts.

### A.1.2 Design and complete the threshold analysis questionnaire

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

- **guided by the concept of reasonable expectation:** Questions should be aimed at asking about concrete aspects of the R&I project;
- **as short and simple as possible, while still being comprehensive:** Since a threshold analysis is 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;
- **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.

## **Annex B** (informative)

### **Technology-scale ethical impact assessment**

A technology-scale ethical impact assessment (EIA) is a type of EIA in addition to the regular (small-, mid-range and full-scale) types. A technology-scale EIA is relevant when a new technological paradigm 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 full-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 full-scale EIA:
  - development of new conceptual frameworks to deal with the new technological paradigm;
  - development of new methodological frameworks to deal with the new technological paradigm;
  - recommendations for, and potentially development of, policy and law for dealing with new technological paradigms.

## Annex C (informative)

### Methods for ethical impact anticipation

The methods for ethical impact anticipation differ in their reliance on sources of knowledge: *evidence, expertise, interaction and creativity*. The methods for ethical impact anticipation also differ for the different levels of EAI; small-scale, mid-range and full-scale.

#### C.1 Basic methods for ethical impact anticipation

The basic methods for ethical impact anticipation are structured activities that should be followed in any EIA. These basic methods are the minimum activities and apply to a small-scale EIA:

- **(Evidence) Exploration of existing work – horizon scanning:** Analysis and assessment of existing ethical impact anticipation or foresight studies in the field or in related fields can be done in the form of a structured literature review or a bibliometric 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 the Internet, research communities, online and offline databases and journals, ministries and agencies, non-governmental organisations, and international organisations and companies. A small group of experts, at the forefront in the area of concern, could 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) Expert consultation** the simplest and most basic level of stakeholder engagement in an EIA. An expert consultation can take the form of a number of interviews, a short workshop or a small survey. Experts are selected on the basis of their expertise with specific ethical impacts or the R&I field;
- **(Creativity) Roadmapping** is a basic way to capture the future development of the outcomes of the R&I project. Roadmapping consists of collecting, synthesising and validating information about the expected R&I outcomes, and representing the trends within graphical displays and support documents. The approach is a light and modular process with the use of “toolbox”. The toolbox contains different modules, depending on the roadmapping areas, issues, context and objectives. Roadmapping consists of three steps: (1) defining the focus and timescale of the roadmap, (2) building the vision, (3) creating the roadmap contents, R&I outcomes.

#### C.2 Methods for mid-range ethical impact anticipation

In addition to the basic methods the following may be a sequence of methods for a mid-range EIA:

- **(Evidence) Trend analysis** is used to investigate possible future impacts of R&I outcomes. 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** discusses specific aspects of the R&I project among stakeholders. The Futures Wheel is tool for organising thinking and questioning

about the future. It produces a graphical visualisation of the direct and indirect future consequences of a change or development.

### C.3 Methods for full-scale ethical impact anticipation

For a full-scale EIA, the methods, such as the Delphi method or scenario writing, are organisationally difficult, time-consuming and offer high quality information. Stakeholder involvement, and especially *citizen* engagement or participation, is important to identify public concerns about the future and to establish legitimacy of the foresight process. The following four sets of methods may act as a sequence of methods in which the four sources of knowledge, expertise, interaction, creativity and evidence, are represented:

- **(Expertise) Delphi interviews:** This survey technique involves repeated polling of the same individuals and 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: (1) selection of the topic, (2) designing the questionnaire, and (3) selection of the panel of experts.;

Note The European Foresight Platform (EFP, 2012) provides guidance on each of these phases <<http://www.foresight-platform.eu/community/forlearn/what-is-foresight/>>.

- **(Interaction) Citizen panels** gain input from stakeholders during the ethical impact anticipation process. These panels might take place during conferences, workshops or trainings at which stakeholders are invited to participate. The outcomes of citizen panels 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 for foresight analysis, for instance, for developing strategies and pathways. The major concern is not which futures are most likely to occur, but how to attain desirable futures. Three main classes of scenarios can be distinguished<sup>1,2,3</sup> 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).

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<sup>1</sup> Vergragt, P.J., J. Quist, Backcasting for sustainability: Introduction to the special issue. *Technological Forecasting and Social Change*. 78, 2011. 747–755.

<sup>2</sup> Amara, R., The futures field. Searching for definitions and boundaries. *Futurist*. 15, 1981. 25–29

<sup>3</sup> Börjeson, L., M. Höjer, K. Dreborg, T. Ekvall, G. Finnveden, Scenario types and techniques: Towards a user's guide. *Futures*. 38, 2006. 723–739.

## Annex D (informative)

### Methods for ethical impact determination

The methods for ethical impact determination differ in the level of the EIA, type of analysis, and type of ethical issues.

#### D.1 Ethical impact determination through conceptual investigation

Conceptual investigation can make use of the following methods:

— **Method(s) focusing on explicit moral values:**

- **Ethical checklist approaches**, for a basic EIA, offer practical and comprehensive ways to determine ethical impacts. In the ethical checklist approach a list of ethical principles or values is cross-referenced with the technological options that were identified during the ethical impact anticipation. The ethical checklist ensures that all relevant values or principles are checked during the ethical impact determination. The ethical checklist does not identify intuitive ethical issues. In addition
- **Ethical theories**, for mid-range and higher EIAs, 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.

— **Method(s) focusing on intuitive moral issues:**

- **Situational approaches**, for a full-scale EIA: The EIA team does not start with a list of moral principles or values, but screens the research and innovation options by drawing on moral intuitions. The situational approach leads to a collection of technological options that are found to be morally problematic from an intuitive point of view.

#### D.2 Ethical impact determination through empirical investigation

Empirical investigation can make use of the following methods:

— **Method(s) focusing on explicit moral values:**

- **Consolatory or consultative approaches** are approaches in which the EIA team reviews previous ethical analyses (and possibly other analyses that may contain ethical observations, such as policy analyses) and collects ethical issues that have previously been identified by others, or interviews experts to collect their opinions and evidence on potential ethical issues;

— **Method focusing on intuitive moral issues:**

- **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) provides a descriptive account of the present situation (both regarding the technology and existing ethical controversies) to ground the analysis, (2) 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) permits closure by judging plausible resolutions of the ethical controversies.

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