



RECIPES
Precaution • Innovation • Science

WP2 Methodological framework for the case study analysis

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List of abbreviations

CA	Consortium Agreement
CC	Consortium Committee
DOA	Description of Action
GA	Grant Agreement
PCG	Project Coordination Group
PO	Project Office
WP	Work Package

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1 Explanation

The following document is developed in RECIPES task 2.2 and details the methodological framework for carrying out the RECIPES case study research task (task 2.3). This document has a dual role as the methodological framework – an explanation of what to consider in each section – and the actual template for delivering the completed research at the end of task 2.3. Much of the background information relevant to this document is found in report for the RECIPES WP2.1, the *Conceptual framework for comparative multiple case study analysis* (D2.1). Researchers should also refer to the RECIPES WP1 report for further background information to the various sections of the methodology.

Note: While all RECIPES outputs from WP1 and the D2.1 constitute relevant background information, the final version of this document should be considered the template in terms of expectations for the output of the case studies themselves (task 2.3).

1.1 WP2 in Summary

The overall aim of WP2 is to understand both the actual and possible application of the precautionary principle in eight different cases, and explain potential commonalities and differences in the application of the precautionary principle in the cases. This analysis should reflect the particular context of the case and reveal the arguments that have been used for invoking the precautionary principle and/or adopting precautionary measures (even without mentioning the precautionary principle).

The multiple case study component of the RECIPES project is one of the key analytical phases of the project. Within the scope of the entire RECIPES project, WP2 builds on aspects of WP1, in particular the final WP1 report taking stock of the precautionary principle since 2000. The outputs of WP2 will feed directly into WP3, with the aim of the development of new tools and approaches to the PP in a co-creation approach.

This document is intended for the individual case study analysis, and does not directly inform the cross-case comparison analysis which will take place in task 2.4.

1.2 Case study research: background information

All considerations regarding the theoretical underpinnings of the case study methodology and their connection to the WP2 case study task are found in section 3 of the conceptual document, D2.1.

This includes information on:

- The unique nature of the RECIPES cases
- How WP1 is linked to WP2
- The full set of research questions to be addressed in WP2
- Background on the case study research methodology
- Case selection
- The relationship between the case studies and the cross-case comparison
- Deviating from the case study methodology
- Analyzing the data

1.3 Research Questions

As stated in the conceptual document, at the individual case study level (task 2.3) the main research goal is to:

Understand the complexities and controversies around the potential application of the precautionary principle for the case study topic. Where the PP has not been explicitly invoked, the goal is to analyze if the conceptual core of the PP, and in particular scientific uncertainty, is present to invoke the PP.

Secondary research questions/goals are:

Describe the specific context of the case study: legal and/or policy discussions (environmental, economic, risk policy), as well as social and cultural context.

How have/do precaution and innovation interact in the case study? Are they in tension?

How do the risk properties of complexity, ambiguity, and especially uncertainty add to this understanding, and how have they been understood by various relevant actors (legal, policy makers, the risk community, NGOs, industry, the public)?

How does this case challenge the innovation/PP juxtaposition?

1.4 Input materials for the case study research task

The following input materials will be distributed to the case study teams:

- 1) This document as both the practical explanation of the different components of the case study research methodology and a template for the final case study reports.
- 2) An excel file for providing concise answers / input to all relevant questions will be provided.
- 3) A 2-page template for easily sharing the key results of the case study analysis may be developed for completion at the end of the finalized analysis in task 2.4.

1.5 Output from the case study research task

The following outputs should be submitted at the end of task 2.3:

- 1) The final report (estimated to be 25-40 pages).
- 2) The methodology excel sheet. This will be used to both concisely summarize the research and help facilitate the cross-case comparison (task 2.4).
- 3) The 2-page summary of the case study.

Note: This document (D.2.2) should form the backbone of the case studies and provide their structure. Case study authors should take this document as starting point, and except for the explanation section (section 1) all other sections should be filled out. This will constitute the final case study report. Please remove the explanation section and the explanations found in the section throughout this document in the final document. All headings should remain.

1.6 Sources

Based on our research and the partner survey, we have identified a number of sources which should be used for the case study task.

Desk research should make up the majority of the research including sources such as

- Academic journals & book chapters
- Government and inter-governmental documents
- NGO publications and grey literature
- Newspapers & magazines
- Primary legal documents & case records
- Secondary interpretation of legal documents
- Industry publications and reports.

In addition, many partners expressed interest in using primary expert interviews to add to their investigation. This may include academics, policy & law makers, industry stakeholders, NGOs.

1.7 Final considerations

As a final note, the below methodological framework has been developed with a broad range of case study topics in mind. This means that not every section and point of consideration will apply to every case study topic. Researcher should aim to address every sub-section, and where this is not applicable, explain why it is not applicable and how they have otherwise addressed or considered the underlying point of that section. In addition, if several sub-sections would be more suitable as a single large section, researchers can merge them.

In particular, it is feasible that the core competencies, risk governance and legal sections of the PP consideration (section 3 of the methodology) may substantially overlap. This outcome is preferred to the reverse case, whereby an important component of the case is not covered. If this occurs, consideration will be given to amending the template to merge the risk governance component into the other components. This can be discussed during the bi-monthly tele-conferences between the case study research teams and the WP2 work package leads.

2 The Methodology

2.1 Introduction

Length: 2 pages

An executive summary and description of the case study topic.

This section is simply a summary of the research done in the case study. It should consist of:

- *A short description of the specific context of the case study: legal and/or policy discussions (environmental, economic, risk policy), as well as social and cultural context.*
- *The cases unit parameters, including geographic area, time frame.*
- *A brief explanation of the topic/threat/controversy.*
- *A brief explanation of why the topic is a precautionary principle candidate.*
- *Discussion of legal cases/frameworks/bodies who have dealt with the case.*
- *Describe any EU regulation which is relevant.*
- *A brief presentation of the innovation argument.*
- *A restatement of the research questions (tailored to the case topic).*

2.2 Key timeline

List a key timeline of scientific findings, legal cases/decisions, risk management, civil society activity, relevant trade treaties or other economics events. Include mainly your relevant geographic area. Landmark activity from the US, WTO, UN or other national regions can be provided to add context.

Note: A graphical template format will be provided for this at a later stage.

Notes/considerations for section 2

This section should provide a summary of the overall report.

3 Precautionary principle considerations

Length: 8-12 pages

The core section on the topic and the precautionary principle

3.1 Outline the 'risk/threat' of the case topic

Length: 1-2 pages

Outline the 'risk/threat' of the case topic: point to existing scientific evidence or reasons why it is a risk to people and the environment. This section makes it clear why the PP has or might be considered for this case.

Describe:

What is the overall risk(s) of the topic? Describe how different societal groups (individual health, local communities, the local environment, and future generations) are threatened or potentially harmed: what evidence of this has there been?

Notes/considerations for sub-section 3.1

The reader should come away from this section with a good understanding of why the case study topic is up for consideration as a risk to human and environmental health, and which groups are at risk.

However, this should not include a detailed discussion of the applicability of the PP, and the scientific uncertainty surrounding the evidence, etc. That will be covered in the next section.

3.2 Precautionary principle: conceptual core

Length: 5-7 pages

This section will assess how the case study topic has met the conceptual core requirements. Recall that while WP1 did not identify a single definition of the PP, it identified a conceptual core for invoking the PP. Each of these points should be addressed in this section. See WP1 Final Report section 8.2, and D2.2 section 6 for background information.

Describe if and how the above conceptual core has been met:

- ***Some form of scientific analysis has taken place***
- ***Scientific uncertainty***
- ***Threshold of damage is met***
- ***Cost effective/proportionality***
- ***Reversibility of the measure***
- ***Reversal of burden of proof***

3.2.1 Scientific analysis

Describe the scientific analysis of the risk which has taken place: studies, reports, task groups, government inquiries.

3.2.2 Scientific uncertainty

In this section, the partner should describe the controversy and scientific uncertainty surrounding the evidence. The key risk properties of complexity, uncertainty and ambiguity should be considered here. See D2.1, section 4 for an in-depth discussion.

This is a key component of the report!

3.2.2.1 Complexity

Outline/describe the complexity inherent to the risk/threat of your topic (in particular as it relates to scientific uncertainty).

Is there evidence of feedback loops, tipping point, network effects, etc. which help describe the risk?

Are their non-linear effects present in the case study: at the level of potential harm, but also at the level of interaction between the PP and the case topic?

3.2.2.2 Uncertainty

Describe the scientific uncertainty or other key controversies in the evidence?

Link the presence of complexity to the uncertainty.

3.2.2.3 Ambiguity

Discuss where the ambiguity is found in the evidence and outcomes, which is relevant to the PP.

How do different societal groups value outcomes differently?

3.2.3 Threshold of damage

How has the threshold of damage been set, and met or not met, in existing legal cases or regulatory decisions?

What discussion of the threshold of damage has taken place?

What definition has been taken, or what threshold has been met?

Where no PP decisions have been made, is there a risk of damage which would satisfy the thresholds of damage discussed in the WP1 report?

3.2.4 Cost effective/proportionality

If the PP has been invoked, have both the cost-effectiveness of the measure, and the proportionality of the measure been considered in existing legal cases or regulatory decisions? Discuss.

3.2.5 Reversibility of the measure

If the PP has been invoked, is the measure reversible?

Have there been previous reversals of precautionary measures?

3.2.6 Reversal of burden of proof

Has a reversal of the burden of proof been specifically implied or requested in legal or regulatory decisions?

3.2.7 Further discussion

If it helps the analysis, discuss the normative arguments which have been put forth, or could be put forth? (See WP1 Final Report section 2.2 for background information.)

Notes/considerations section 3.2

This section should thoroughly describe if and how the above conceptual core has been met.

The debate surrounding the scientific uncertainty is of utmost importance in this section.

3.3 Governance and PP

This section on risk governance is a way to approach how the PP has been considered and debated in each of the case study topics. In particular, we draw on WP1's suggestion to use all components of the IRGC framework. See D2.1 section 5 for more information.

3.3.1 Risk governance

In the following section, we aim to understand the risk governance process. This entails a specific look into the 5 steps of the IRGC framework in order to see whether such phases can be identified in the case study topic at stake (see D2.1 Section 5).

Note: This is for inductive purposes and does not imply that RECIPES is adopting the IRGC framework. This section should be conceived of as a useful way to order case study findings. As such, there is appropriate freedom for research partners to deviate from the framework if the empirical data suggest that other aspects are also relevant to understanding the whole risk governance of a case.

3.3.1.1 Pre-estimation

How does society construct this risk problem? Take into account the views and agendas of all relevant stakeholders.

Has this risk been prioritized over other risks? What does that show about the risk politics?

3.3.1.2 Interdisciplinary risk estimation

Describe the risk assessment phase: look at how researchers from the natural, technical, and medical sciences have estimated the potential harm of a given threat.

Describe the concern assessment phase: look at how social science researchers have analysed the risk to society and individuals.

Comment on the way this has been done.

3.3.1.3 Risk characterization

Describe the decision process regarding whether a risk is acceptable, tolerable, or intolerable. Comment on the way this has been done.

3.3.1.4 Risk Evaluation

Describe risk evaluation phase then consider ranking or prioritizing risks according to probabilities and the consequences of the risk occurring. Comment on the way this has been done.

3.3.1.5 Risk management

This stage builds on the previous steps by systematically reviewing all relevant data and information generated in those steps. Various solutions are then considered.

Who is engaged in invoking and applying the precautionary principle?

- *Who is involved in the decision making and at what level?*
- *At what stage of the process are the different parties involved?*
- *What influence or power do the involved parties have in the decision-making process?*

3.3.1.6 Other considerations

Assess how risk governance frameworks might address Responsible Research and Innovation (RRI) considerations.

How are gender differences present in PP-innovation-IP considerations in the case study? Further bilateral input on gender aspects will be provided to the research partners by K & I.

Notes/considerations section 3.3

This section studies the case studies from a risk governance perspective. It should incorporate the 5 IRGC framework components into the case study methodology.

3.4 Legal and Regulatory history

Length: 2-5 pages (depends on legal history)

This section looks into the legal case history and framework surrounding the case study topic.

Sources: primary legal documents (legislation, case law), interpretations of those documents (e.g. in the literature), Interviews with legal/risk scholars to interpret legal findings where needed.

3.4.1 Legal history

What is the legal status of the PP in your case and jurisdictions?

List relevant court cases (if applicable)

If applicable, describe all legal cases/frameworks/bodies who have dealt with the case in your geographic area (country of analysis) and the EU overall (time / relevance permitting, refer to other jurisdictions i.e. US)

If relevant, has a definition of the PP has been used in legal cases/acts pertaining to your case?

Please also consider whether an impact assessment has been made prior to the adoption of precautionary measures.

Analysis:

What controversies were found in the legal discussion of the scientific uncertainty covered in the above section (3.2.2)?

Summarize how the other conceptual core components were handled in the legal history.

3.4.2 Other regulations

This section is optional and should be considered in as much as it increases the understanding of your case topic

Consider how other regulatory policies (i.e. ISO, EU bodies, standards, voluntary regulations, research policies) have been used in regards to your topic:

Have other regions or international bodies considered the PP for your topic (optional)?

Notes/considerations for section 3.4

This section looks into the legal case history and framework surrounding the case study topic.

If no legal history is available, use your discretion to consider the case for the PP, including how other stakeholders have advocated for the PP

If very little advocacy of the PP is available *at all*, consider why, and make the case for the PP in response to the potential threat described in section 3.1.

3.5 Criticism of the PP

Describe criticism of the present use and application of the precautionary principle and any alternative proposals for the application and use of the precautionary principle with regards to the case study topic (i.e. from stakeholders, authorities or academia)?

Describe other stakeholders exhibiting ideological opposition to the PP or regulation in your particular case topic (i.e. who are not directly doing so on behalf of industry)?

Outside of direct industry interest in the given innovation: What other economic forces may be at play (i.e. trade treaties or other trade negotiations, international law, WTO, CETA) in the larger context of the case study topic?

Have stakeholders called for the revision of the PP in the case? If so, which stakeholders and what is the nature of the complaint?

Notes/considerations for section 3.5

This section looks into the criticisms expressed in relation to the PP in the specific case study topic.

4. Innovation

Length: 5 pages

This is the core section on the topic and innovation and the IP.

4.1 Intro

Length: 2 pages

Describe the general benefit that your technological case provides (innovation argument) for the case study topic:

A brief description of the innovation/benefit: Why has this product/technology been developed? What problems will it / does it solve? Provide a balanced assessment of the benefits this product brings.

Describe the economic, social, environmental benefits.

Are these benefits themselves debatable? What is the evidence/uncertainty discussion?

What do the different stakeholders say about the benefits? Outline this debate.

4.2 Innovation pathways

Length: 2-3 pages

How was the technology developed? Describe the complex interplay between market forces (demand), research, competition, regulation, and other technological advancements.

What alternative innovation pathways can and has the PP opened up, if any?

Is there evidence of regrettable substitution, whereby the banning of one substance leads to the adoption of a potentially worse substance?

*Please consider **complexity, uncertainty and ambiguity** in this portion of the analysis as well: what uncertainty and complexity do companies and researchers developing the innovation/products face? Is there value ambiguity across society about the benefits the innovations bring?*

To what extent were the benefits of the innovation were taken into account in applications of the PP?

4.3 Innovation Principle

Length: 1-2 pages

This section looks at if the innovation principle has been invoked in the case study topic.

Note, the innovation principle was not widely accepted and largely did not exist in the time period of 2000-2018. As such, it would be misleading to retroactively assemble practices, regulation and approaches in which the benefit of innovation is emphasized, as being part of the IP.

Has the innovation principle itself formally been invoked with regards to the case study topic?

If so:

- *Which stakeholders were involved in invoking the IP? Were there explicit communications or events linking the IP with the case study topic?*
- *How is it being positioned if so: outline the timeline and the debates surrounding discussion of the IP in regards to your topic?*
- *How are the PP-IP being juxtaposed? Has the presence of the IP had an effect on the regulatory setting, and PP particularly, with regards to your topic?*

If not:

- *Consider how the IP might be positioned in coming years, in the context of the case study topic?*
- *Try to investigate if there are plans or actions to invoke the IP in your case topic (expert interviews may play a role here). Is there evidence that the IP may be employed with regards to the case study topic?*

Besides the IP, what other policies, programs are involved in the development of the case study topic (i.e. patents regimes, government innovation policies, EU innovation bodies, WTO)? (Note: this question might be integrated in the above innovation pathways section if appropriate).

Notes/considerations for this section

This section should go in depth into the benefits of the technology / case study topic.

It should substantially engage with the concepts of innovation, innovation principle and innovation pathways.

The PP-Innovation-IP juxtaposition should be explored.

5 Synthesis

Length: 2-3 pages

Lessons learned: an analytical synthesis of the above research

- 1) *Make overall conclusions about:*
 - i. *The appropriateness of the PP*
 - ii. *The overall tension between PP/ IP*
 - iii. *the role of CUA in understanding your case*

- 2) *A set of recommendations to the cross-case comparison team:*
 - a. *Highlighting where you see your case topic standing out, against the above criteria, in juxtaposition with WP1's findings*
- 3) *Does this case challenge the innovation/PP juxtaposition put forth in WP1 and the conceptual paper (from task 2.1)?*

6 Conclusion

Provide a short conclusion.

7 References

Provide all references that have been used in the case study topic.