WP2 Conceptual framework for comparative multiple case study analysis

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List of abbreviations

CA	Consortium Agreement
CUA	Complexity, Uncertainty and Ambiguity
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. Introduction

This document fulfils RECIPES delivery 2.1, the literature research for the multi-case study analysis, and covers the theoretical component of criteria for multi-case study analysis. Those criteria are presented in delivery 2.2 as the comparative multiple-case design, which is the methodological framework developed in task 2.2. Thus deliveries 2.1 and 2.2 are tightly linked, and should be taken together as the overall case study framework for WP2. The comparative multiple-case design contains the practical methodological framework required by each partner to execute the case study analysis for task 2.3. Delivery 2.3 explains the case study selection process which was undertaken to arrive at the eight cases studies to be carried out in WP2.

1.1 Context

This report is part of the EU funded project entitled REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders (RECIPES).

The precautionary principle guides decision-makers faced with high risks, scientific uncertainty and public concerns. As a general principle of EU law, it allows decision-makers to act despite scientific uncertainty.

The precautionary principle is also criticised for hindering technological innovation, therefore some stakeholders have developed an innovation principle, which requires taking into account the potential impacts of precautionary action on innovation.

The RECIPES project aims to reconcile science, innovation and precaution by developing new tools and guidelines, based on co-creation with stakeholders, to ensure that the precautionary principle is applied while still encouraging innovation.

The RECIPES project comprises three research phases.

In the framing phase of the project, the RECIPES Consortium will examine the effect and the application of the precautionary principle since 2000 by combining legal analysis, desk research and a narrative literature review, complemented with a media analysis of the public discourse around the principles of precaution and innovation, to understand the different stakeholder perspectives.

In the analytical phase of the project, an innovative conceptual framework for comparative multiple case study analysis will be developed, in order to perform case-study analyses. This will be combined with scenario building.

In the developmental phase of the project, scenario workshops will be combined with a multi-criterion assessment framework to develop and assess the usefulness of the to-be-proposed new tools.

The underlying report is the first part of the analytical phase of the project. It is the conceptual component of the case study framework.

1.2 WP2 and this report

The overall aim of WP2 is to understand and explain the differences in the application or potential application of the precautionary principle in 8 different case topics, in a way that reflects the particular context of the case study topic. 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 report which presents the stock taking of the precautionary principle since

2000. In addition, WP2 feeds into WP3, the development of new tools and approaches to the PP in a co-creation approach, as well as ensuing communications in other work packages.

The complete list of WP2's project deliverables and milestones can be seen below:

Deliverables

D 2.1: Literature research on multi-case study analysis
D 2.2: Development of criteria for multi- case study analysis
D 2.3.1: Selection of case studies
D 2.4.1: Intra-case study analysis
D 2.4.2: Inter-case study analysis
D 2.4.3: Identification of issues cutting across multiple case studies
D 2.5.1: Comparison of case study analysis with results of WP1

Milestones

M 2.1: Formulation of hypotheses on role and interaction of PP/ IP
M 2.2: Methodological framework for comparative multi-case study analysis
M 2.4: Emerging themes and conclusions of individual and cross-case analysis
M 2.5: Developing scenarios of application PP and IP to emerging technologies

This document fulfils delivery 2.1: Literature research on multi-case study analysis, and covers the theoretical concepts behind the criteria for multi-case study analysis. Those criteria are presented in delivery 2.2 as the comparative multiple-case design, which is the methodological framework developed in task 2.2. Thus deliveries 2.1 and 2.2 are tightly linked, and should be taken together as the overall case study framework for WP2. The comparative multiple-case design contains the practical methodological framework required by each partner to execute the case study analysis for task 2.3. Delivery 2.3 explains the case study selection process which was undertaken to arrive at the eight cases studies to be carried out in WP2.

WP2 tasks 1-4 encompass the entire case study analysis component of WP2. Task 2.5 concerns the synthesis of the WP2 case study analysis with WP1, and development of scenarios for the future of the precautionary principle and innovation in the EU. Task 2.5 is thus the key linkage between WP2 (and aspects of WP1), and WP3 and the ensuing RECIPES project deliverables. The scenarios developed for task 2.5 will be validated in stakeholder workshops, and will themselves help inform the development of new tools for policy makers in further RECIPES work packages.

1.3 Objectives

This objective of this report is to underpin D2.2, the methodological framework document. Taken together, both documents will guide both the primary research of the individual cases (task 2.3) and the cross-case comparison and comparison across cases (task 2.4).

This report is divided into 3 larger parts.

1. An introduction to the conceptual framework for WP2 and the research questions to be answered.

2. A literature review of the case study methodology: This i) Provides a rationale for the decision to use a case study methodology in the RECIPES project; ii) Provides a solid set of best practices on which to base the case study analysis framework.

3. A discussion of the key analytical concepts which will underpin the methodological framework.

1.4 Approach

The structure of this report is as follows:

Chapter 2 provides an introduction to the case study research component of the RECIPES project. We also introduce a set of research questions to be explored throughout WP2.

Chapter 3 introduces the case study research methodology. We cover some of the background literature on the case study research method, and introduce appropriate definitions and points of consideration.

Chapter 4 provides an introduction to the key theoretical concepts for WP2. We discuss complexity, uncertainty and ambiguity, and their applicability to the case study topics.

Chapter 5 discusses risk governance as a possible useful framework for organizing the case study methodology. We discuss the IRGC and Safe Foods frameworks.

Chapter 6 provides a preliminary synthesis of the findings of WP1 with an eye to how this has fed into the actual case study methodology. We look at the core components of the precautionary principle to be considered in the case study research task, as well as the tension between innovation and the PP.

Chapter 7 concludes by linking the planned outcomes of this overall case study endeavour to further RECIPES work packages.

2. Introduction

The 8 case study topics that will be analyzed in WP2 include a wide range of high profile and pressing issues at the EU and global level: gene-editing techniques, GMOs, endocrine disrupters, neonicotinoid insecticides, nanotechnologies, glyphosate, financial risks, and artificial intelligence. In order to understand how these topics interact with the precautionary principle and innovation, we will undertake an in-depth analysis of the specific case topic context, including scientific, risk and legal opinions, and social and cultural factors. Each individual case is characterized by different legislative, regulatory, and legal histories with regards to the precautionary principle – some have an extensive record of legal and regulatory decisions, others have little to none. They are also nested within different regulatory frameworks, industry structures, socio-cultural contexts, and even regional and region-political strategic considerations. These unique, idiosyncratic aspects of each case make them ideal for investigation using a case study methodology, which is particularly useful in providing an in-depth appreciation of an issue or event.

Furthermore, the comparative nature of WP2 aims to gain insights into existing gaps of understanding surrounding the application of the precautionary principle across the EU. Hence, the RECIPES consortium emphasizes the need to analyze all of the RECIPES case-studies according to a common conceptual and methodological framework, in order to increase the comparability across cases and thus the quality of the individual and cross-case analysis. This will also help give transparency regarding the methodology used in the work package.

The framework addresses several key aspects of the RECIPES project's larger conceptual approach to the precautionary principle, specifically the consideration of innovation, and the framing of precaution within a risk perspective which considers the risk properties of complexity, uncertainty and ambiguity.

Complexity, uncertainty and ambiguity present epistemological challenges which limit our ability to understand, analyse and communicate about risk and innovation. Part of the task of the research teams is to analyze where and how this occurs in the specific case study. The theoretical and conceptual ideas outlined in this framework should provide a backbone from which to consider these issues in the case study research process.

As reported in the RECIPES WP1 report, consideration of innovation means going beyond the "narrow" investigation of the dichotomy between potential false applications of the PP or incorrect rejections of the PP. Rather, it requires consideration of the dynamic, uncertain pathways in which technological development takes place, and the role of regulation in shaping those pathways. As will be discussed in the section on innovation, there is a potentially mutually reinforcing relationship between regulation and the precautionary principle, and technological development. A case study approach is ideally suited to address this distinction. Here again complexity, uncertainty and ambiguity play important roles.

Furthermore, WP2 is conceptualized as a way to provide a better understanding of the practical application of the PP in the EU and national legal contexts. Existing research, including the results of WP1 of the RECIPES project, has shown that the conditions under which the precautionary principle has been applied appear to be poorly defined, with ambiguities in determining what level of uncertainty and significance of hazard justify invoking the PP, and inconsistent definitions of the PP across cases. The rest of this report lays out a framework for carrying out investigation into those areas.

2.1 The research questions & the methodology

Before digging deeper into the case study methodology and key theoretical concepts, this section will introduce the main research questions as well as case specific questions.

Each case study topic consists of different technological risks, at different stage of development and deployment, and with completely different legal and legislative frameworks. As a result we have developed a flexible methodological framework which will allow the research teams to learn as much as possible about the case topic using the appropriate and relevant sources. At the same time, the framework is set up to allow the overall case study endeavour to maintain methodological clarity and rigour, so that the intra-case and inter-case analysis in task 2.4 can deliver meaningful results.

The uniqueness of the individual cases has important implications for the content of the methodological investigation, which will be covered in the section of this report on key concepts, as well as in the methodology report itself.

2.2 Research Questions

Overall research goal for the WP2 multi-case study task

In this section, we first introduce research goals overall case study component of WP2, then rephrase the research questions which apply specifically to the individual case studies.

The overall research question/goal of the RECIPES multiple case study research project (Task 2.1 – 2.4) is:

Understand the complexities and controversies around the actual and possible application of the precautionary principle. This includes consideration of when the PP has not been invoked, but aspects of the conceptual core of the PP, and in particular scientific uncertainty, is present to invoke the PP.

Additional research questions include:

What is the relationship between precaution and innovation across the cases?

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)?

If the PP has not been invoked in the case study, have the uncertainty conditions nonetheless been present for its possible usage?

A corollary to the above primary research question to be answered at the task 2.4 stage is:

How do the overall complexities and controversies around the actual and possible applications of the precautionary principle differ across the cases?

Specific case study research goals

Stake (2006) makes a crucial comment about the shift in focus that takes place between understanding the individual case – "what helps me understand *this* case", to the cross-case analysis of the group of cases – "what helps me understand this *set* of cases (and perhaps *all* PP cases)"?

In light of the broader research questions and the aforementioned diversity of case study topics in terms of legal case history, the individual case study level (task 2.3) research questions/goals are:

*Understand the complexities and controversies around the actual and possible application of the precautionary principle for the **specific case study topic**. Where the PP has not been explicitly invoked, 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?

Moreover a broad set of secondary research questions will be considered at both the case and cross-case comparison level:

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

How do the risk properties of complexity, uncertainty and ambiguity add to this understanding, and how have they been understood by stakeholders (legal, policy makers, and the risk community)?

How does each given case challenge the innovation/PP juxtaposition?

Key Takeaways for the WP2 case study methodology

The goal of WP2 is to perform 8 case studies and a cross-case comparison in order to develop scenarios on the future application of the PP-IP (task 2.5). This will feed into the design of new tools and guidelines for the precautionary principle in respect of reconciling precaution and innovation (WP3).

The goal of the overall cross-case comparison is to understand the complexities and controversies around the potential application of the precautionary principle in practice across the eight case studies.

The goal of individual case studies is to understand the complexities and controversies around the possible application of the precautionary principle for the ***specific case study topic.*** If the PP has not been invoked in the case study, the researcher will analyse if uncertainty conditions nonetheless been present for its possible usage?

WP2 will investigate whether innovation considerations were taken into account in the individual case studies.

3. Case study research: Insights from the literature

3.1 Context

This section builds on selected literature on the case study research method.

While the case study research method is among the most popular methods in social science, it still lacks a perceived scientific legitimacy in some academic circles, and is often described as lacking a rigorous and accepted set of methods, rationales and protocols (Yin 2018). A common critique of the case study method is that it lacks documentation and standards regarding methodology. Thus, while the case study method is among the most widely used methods for understanding contemporary phenomenon – both formally, and certainly informally in how we learn things and develop new theories and research hypotheses – it still lacks both credibility and a substantial body of literature explaining how to carry out case studies and defend the research form as a legitimate form of inquiry (Yin 2018).

Nonetheless, there is a small but growing body of literature addressing the case study research method, including a number of textbooks, as well as journal articles directed at the methodology itself, and a variety of examples of case study analysis from which to draw on. In this report, we will draw selectively on sources in the field to inform the conceptual and methodological frameworks. In order to meet the challenge of developing a novel framework for the WP2 research task, we need to both incorporate some of the case study research foundational theory and examples from various contexts, while keeping in mind the specific goals and limitations of the RECIPES project.

It is important to acknowledge from the onset that the unique combination of factors to be investigated is truly a unique research endeavor: **using a multiple case study method to compare socio-technological innovations across different social, regulatory, and legal contexts.**

3.2 The case study research method: a background

Various sources in the literature define case study research differently. In the following section, we will delve into the discussion and try to arrive at what is useful for the RECIPES project. In order to add some clarity to the discussion it is useful to think of the entire case-study endeavor as resting on a foundational trilogy (Yin 2018):

- *Case study research as a mode of inquiry.*
- *The case study as the research being carried out.*
- *The case as the unit being studied.*

Leaving aside the multiple case comparison aspect of the RECIPES project for now, each of the 8 case studies being undertaken in the RECIPES project would be an example of a case study research endeavor. The case study is the research performed in carrying out the research – *doing a case study*. Lastly, the case refers to the unit under investigation – the topic, geographic area and temporal duration to be investigated.

Not all of what is referred to as a case study would fall within the domain of case study research as a formal methodology. These rather fall under the category of non-research case studies, which appear in newspapers, magazines, videos, and blogs, teaching or practice case studies. This includes training material such as the well-known Harvard Business Case method, which is popular in business, law and even medical training. A

final type of non-research case studies are those included as part of administrative archives (Yin, 2018).

3.2.1 Case study research

Yin postulates a 2-fold definition of case study research, consisting of its scope and features:

Scope: Case study research is an empirical method that investigates a contemporary phenomenon in-depth, in real-world context. This is *especially* relevant when the boundaries between the phenomenon and the context are unclear.

Features: Case study research deals with a technically distinctive situation with more variables of interest than data points:

- *where prior theoretical propositions will be helpful in guiding the development, design, data collection and analysis of the data*
- *and where multiple sources of evidence are present, with the need to triangulate the data (Yin, 2018)*

Another less stringent rewording here makes the connection between the individual case study and the general set of cases: "A case study may be understood as the intensive study of a single case where the purpose of that study is – at least in part – to shed light on a larger class of cases (a population). Case study research may incorporate several cases, that is, multiple case studies" (Gerring 2007).

3.2.2 The Case: Unit of inquiry

The case can be defined as the specific, spatially and temporally delimited phenomenon observed at a single point in time or over a period of time. Both Stake (2006) and Merriam (1998) view case studies as appropriate for the study of bounded systems, programs, units or objects, as opposed to events and processes. In particular, Merriam views case studies as exhibiting several key attributes: they focus on a particular situation, event or phenomenon, they yield a detailed description of the case, and they help increase the readers understanding of the case (Yazan 2015). Eisenhardt (1989) also emphasizes the single unit nature of case study research, with her broad definition, "the case study is a research strategy which focuses on understanding the dynamics present within single settings."

These definitions are applicable to the RECIPES WP2 cases. Each of the 8 WP2 cases form a single unit at the intersection of the case topic within bounded geographic (either EU or selected national areas) and time frame. While a timeframe of 2000-2018 was used for some areas of WP1's research, the case study researchers should include any relevant aspects of the case study up to the present, and it is perfectly acceptable to bring in information and context from before 2000. Nonetheless, all else equal, preference should be given to looking at more recent rulings, governance decisions and stakeholder activity where research time and effort constraints exist.

According to this description, evidence or legal cases which do not fall within the topic or geographic area would not be included in the case itself, but rather might be used as an external reference point. An example might be looking at the regulatory decision for a given threat in the US; while the decision provides relevant context for looking at comparable EU cases, it wouldn't fall within the case study boundary.

3.2.3 The Multiple Case Study Method

While some academic fields treat single and multiple case study methods as almost separate methods (political science and anthropology), most fields and scholars do not treat them as different methods (Yin 2018). Nonetheless, there is basic agreeance that

distinct differences exist when carrying out individual case study analysis compared with multi-case study analysis (Stake 2006). We cover this further in the below section on case study analysis, which provides valuable insights for both designing the case study protocol, and for the later analysis stage (task 2.4).

In comparison with 'larger n' research methods such as statistical analysis, or large n cross-case analysis of many legal cases, multiple case study comparisons still encompass a relatively small number of cases. This means that the particular characteristics of the cases and their relationship to one another can be incorporated into the cross-case comparison component by a single group of researchers in a way that larger numbers of cases simply could not (Yin, 2018). This is one of the strengths of multiple case study research; the comparison researcher can become familiar enough with the details of each case to make highly context-specific comparisons in a way that is simply unfeasible with more cases or data points.

Transferability

RECIPES WP2 is first and foremost a multiple case study analysis task.

As such, the underlying purpose in carrying out the individual case research is to increase our understanding of the individual cases, with the end goal of to transfer in-depth **knowledge about the specific cases to our understanding of how the precautionary principle is used in the EU setting.** This was emphasized in section 2.2 on the research questions of the various levels of analysis.

This is perhaps the fundamental underlying rationale for case study research in the RECIPES project: the belief that an individual precautionary principle case can yield insights which are relevant to other PP cases, or topics where the conditions for the PP are present, but the PP has not been invoked. Whereas large N statistical or cross-case work 'wash out' case specific causal mechanisms, case study research can better identify salient mechanisms which nonetheless may be relevant to the whole population (Yin 2018). However, as we will discuss in the case selection section, this does not imply direct parallels or similarities between the various case studies. Insights gained from a case may add to our understanding of why a totally different outcome occurs in a different case, or any number of multi-dimensional differences and similarities in outcome. This leads to nuanced, contingent results rather than one-size-fits-all prescriptions.

At the same time, WP2's prioritization of the results of the cross-case comparison touches on an intrinsic tension in multiple-case study research. Often, research teams place emphasis on the comparison component of multiple case study analysis, at the expense of the individual case study work (Stake 2006). Furthermore, the structure of WP2 and indeed the RECIPES project as a whole does indeed place strong emphasis on the cross-case comparison, and it's influence on the PP scenarios (task 2.5) for transferring the WP2 knowledge onto the rest of the project. Thus, several aspects of the project have been put in place to ensure the unique vitality (Stake 2006) of each case will be preserved and communicated: 1) The results of each case study will be communicated in a standalone report, which should ensure the individual research partner's analysis of the case topic is available for dissemination; 2) All case study partners will take part in task 2.5, giving them the opportunity to channel their case study specific insights into the synthesis and scenarios; 3) Multiple case study partners will have a formal role in task 2.4's cross-case comparison itself.

3.2.4 Further points of consideration

Qualitative vs Quantitative

Case study research is often grouped together with non-quantitative approaches, such as ethnographic, anecdotal, participant-observation, process-tracing, and other methods. Some degree of debate surrounds whether or not quantitative data as well as qualitative data should be considered in case study research. While Stake and Merriam suggest only qualitative data should be used Yazan (2015), Hartley (2004) and Yin (2018) argue that case studies should not actually be viewed as a method, but rather a research strategy, which can and should combine qualitative and quantitative methods as is appropriate. In that view, the researcher is encouraged to combine multiple methods in order to capture the complexity of the phenomenon. From this perspective, a definition of case study comes not from method, but from theoretical orientation (Hartley, 2004).

Yin (2018) also advocates the use of both types of data, to allow for multiple sources of converging evidence. Yin coined the term triangulation to describe seeking out multiple different pieces of evidence to confirm a given finding, trend or theory.

The bottom line is that debate over qualitative versus quantitative data has some theoretical merit, but does not take priority over the primary goal of maximizing the quality of the enquiry. The RECIPES case studies will rely on both types of evidence in the form of desk research (qualitative and quantitative), which will be supplemented by key expert interviews (qualitative).

Multiple investigators

Various sources point to the advantage of employing multiple researchers in a given case study: enhanced creativity, complementary viewpoints, different perspectives, and providing confirmation or refutation of findings. In the RECIPES project, all 8 case study teams consist of more than one researcher, often from various backgrounds and experience levels. In addition, the entire WP2 case study endeavor is somewhat unique in the literature, as it is structured as different individual case study teams performing each case study and a separate team leading the cross-case analysis component. This is supported by Stake (2005), who suggests that a separate team perform the cross-case comparison. This method has a number of advantages, such as avoiding single-case partner burnout, and providing space for the comparison research team to consider the project's theoretical constructs more explicitly than the individual case research groups.

With regards to the individual case studies, we further strengthen this multiple investigator process in at least 2 ways: 1) An internal peer review process by which case study partners will review the output of other case study partners; 2) A review and engagement with each case study by the IASS team as the leaders of WP2. In both cases, this will bring in valuable experience from researchers who are highly familiar with the theoretical constructs, via an interactive back and forth process.

Finally, it is worth considering an interesting aspect of the RECIPES project, that the comparison with extant literature, concepts and theories will take place within the context of the larger work done by consortium partners (WP1). This represents a kind of decentralized or networked case study 'research team', which actually consists of almost all RECIPES research partners in some way. To our knowledge, such an endeavor is not documented in the literature, but has likely been carried out in some form in other multi-partner research projects involving case studies, such as other Horizon 2020 projects.

Key Takeaways for the WP2 case study methodology

The goal of the individual case studies is to better understand the case topic in its context.

The case unit boundary consists of the case topic, the geographic area, and time period 2000-present (with some allotment for looking to relevant earlier time periods).

The goal of the cross-case comparison is to make transferable connections between

the cases which increase our broader overall understanding of the application of the PP-Innovation-IP in the EU.

3.3 Case study methodology

Having introduced the theoretical rationale for using case studies and discussed various aspects of terminology, evidence, and the role of multi-case work, we now relate the case study method more directly to the RECIPES project, and in particular the WP2 methodological framework. We will do this through a combination of introducing the particular concept and exploring how this relates directly to the RECIPES project.

3.3.1 The role of theory

An obvious and important consideration in any research design, especially in more novel cases such as the RECIPES project, is the degree to which the case study methodology should ask researchers to bring theory and preliminary conclusions to the process. In other words, to what extent are the preliminary phases of the research design and execution informed by a strong theoretical background, as opposed to being open to allowing theory to emerge at a later phase?

Drawing on existing theoretical constructs can be very useful for identifying emerging trends and patterns as they are discovered throughout the case study research process. Furthermore, given the well-defined output and research intention of the RECIPES project, it makes sense to approach the case study methodology design with our theoretical backgrounds, rather than searching for emerging constructs which may be required in less well understood case study research areas. However, we acknowledge the need to remain open to discovering new theories and patterns during the research process, which may necessitate reworking some of the methodology during the case study research period.

However, while early identification of a research question, theoretical constructs and even tentative hypotheses about their relations is helpful in guiding the research, various sources emphasize the need to re-work and refine theory throughout the cases study process (Eisenhardt 1989, Yin 2018).

At the same time, and perhaps counter-intuitively, a strong recommendation coming out of the literature is for researchers to try to approach the mechanisms with which the case operates without a preset idea of how the variables will interact. **In essence, the case study approach we are developing asks the researchers to bring forth their own knowledge and experience, engage with a set of existing theoretical constructs in the research, and nonetheless remain as open-minded as possible to possible interrelations between those variables, and potentially new constructs and theories which may develop!**

3.3.2 Designing the framework

The very first issue of concern is laying out the process by which case study methodology should be developed and implemented. In the literature the different recommendations for how to do depend on the degree of theory that is viewed as appropriate for informing the methodology design. For instance, Eisenhardt (1989) lays out relatively theory-free strategy for developing a methodology: 1) Define the research question and prior constructs; 2) Select the cases; 3) Craft the data collection methods; 4) Enter the field and collect the data (combining collection and analysis); 5) Analyze the data within case

and across case; 6) Hypothesize relationships; 7) Enfold into the literature; 8) Reach closure.

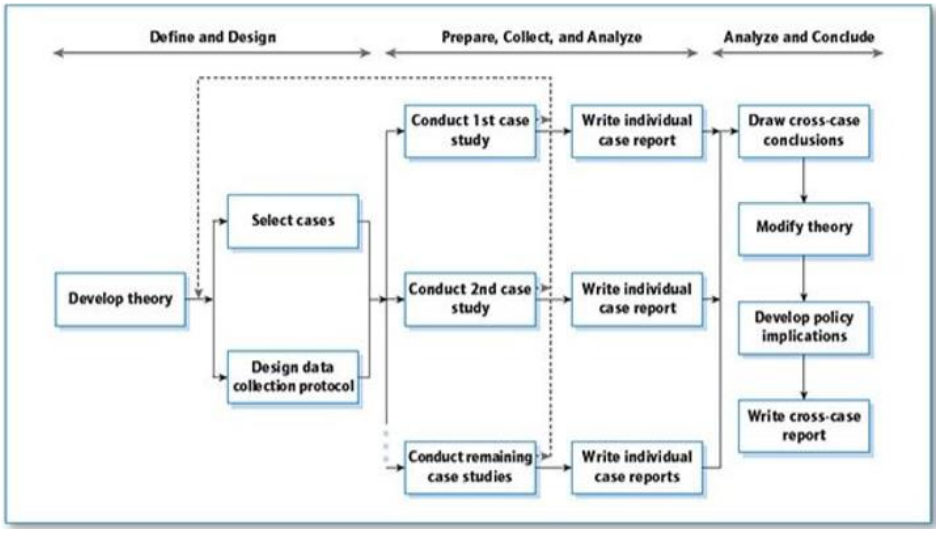
Note that after defining the research question, which is of course somewhat theory-led, much of the research process takes place before relationships are hypothesized and compared with the literature. While this is useful for exploration or theory development, this process sacrifices the incisive analysis and data-collection that can take place with the help of a theoretical lens.

Thus, since the RECIPES project is informed by a vast body of research on the precautionary principle, and the individual expertise on the individual case topics, we adopt for a more theory-led design framework. Below we describe the basic outline as described by Yin:

1) Build a research design, consisting of some preliminary theory:
    a. Choosing research questions
    b. Choosing propositions (theoretical constructs) to be employed
    c. Define units of analysis & select cases
    d. Establish the logic for linking data to propositions
    e. Setting the criteria for interpreting the findings
2) Collect evidence
3) Analyze the evidence
4) Report on the findings

The below figure demonstrates the essential logic of a multi-case study research design (Yin 2018).

Figure 1: Depicting the multiple case study research process



Source: Yin 2018

Note the iterative process by which each case study feeds back into the initial theory development; this is process is largely the guiding principle by which the WP2 methodology is built. However, we note the caveat that in the RECIPES project the 8 cases will be carried out simultaneously, meaning that all individual case reports will feed into the cross-case conclusions and theory refinement at once. However, the methodology will allow for interim discussion about adding changes to the case study protocol as is seen fit.

Key Takeaways for the WP2 case study methodology

The development of the WP2 case study methodology has been led by theory, and researchers should bring their own additional theoretical and practical knowledge to their case research.

The WP1 report and this WP2 report provide theoretical background that individual case researchers and the cross-case comparison team will draw on.

3.3.3 Case selection

This section briefly explains the case study selection process. More details on the specifics of the case study selection process can be found in D2.3, where an introduction to each case study is also provided.

The sampling logic associated with case studies is another clear characteristic that differentiates it from other research methods, particularly statistical analysis. Case selection is the process by which the case is selected from the population. A variety of methods exist for selecting the unit to be studied across the scientific disciplines. Traditionally *sampling* refers a random selection from the population, as is common in survey methods, with the intention of assessing the relative frequency of occurrence of a phenomenon.

Usually in multiple case study research theoretical sampling is employed, with each case selected carefully. The most common method is to employ *replication logic*, where cases are select according to their appropriate fit with one another (Yin 2018). Theoretical replication describes intentionally choose cases that replicate, counter, add to, or challenge the preliminary theoretical types and framework (Meyer, 5). Case selection is directed at pursuing informational richness, rather than representativeness. In other words, cases are not selected for their similarity with one another, but rather their potential to add to our overall understanding. The RECIPES case studies were selected by replication logic.

Shortly, the 8 cases which have been selected are:

1. New gene-editing techniques (i.e. CRISPR-Cas9)
2. Genetically Modified Organisms (GMO's)
3. Endocrine disruptors
4. Neonicotinoid insecticides
5. Nanotechnologies
6. Glyphosate
7. Financial risks and urban waste planning
8. Artificial Intelligence in Health Care

3.3.4 The methodology/protocol

Please note the key document for the case study researcher or research teams is the actual methodological framework (D2.2). *In any and all cases, the methodology framework document is the should be referred to regarding which specific areas need to be investigated and reported on for the case study research task 2.3.*

Given the above sections on theory and theoretical constructs in the case study work, some component of the case study design was already decided by the RECIPES project.

The theoretical constructs we are drawing on our covered in chapters 4, 5, and 6 of this report. Combined with the comments on data collection and analysis described in this section, they have informed the methodological framework presented in 2.2.

As specified in the RECIPES proposal, and reinforced by the literature, the majority of the research in the WP2 will consist of desk research. However, expert interviews will also be used by research teams to supplement the analysis. We will not provide guidelines on how the research teams should carry this out. The case study research teams should refer to this report and the WP1 report in order to familiarize themselves with the theoretical concepts underpinning the methodology.

3.3.5 Going outside of methodological framework

The WP2 case study task will take place over a 6 month period, with each case study partner working in parallel. Thus, even more so than in single case study research or in consecutive multiple case studies carried out by a single research team, the issue of going outside of the methodological framework is of utmost importance. **Some deviation from the methodology is permitted, and is well-rationalized within the literature.** Nonetheless, we encourage 2-way discussion between the research team and the IASS to encourage transparency and inform the other research partners of potential new avenues to explore.

The literature on the case study method is adamant that a reasonable effort should be made to adhere to the framework, while stressing the legitimacy of altering or adding data collection methods throughout the course of the case study (Yin 2018, Eisenhardt 1989). This may appear at surface to be inconsistent, but it is important to remember that the underlying purpose of the case study method is to arrive at the deepest understanding of the given case possible, so if other opportunities arise within the process of collecting and analysing data, researchers are encouraged to pursue them if they add to the overall understanding of the case. Regardless of the pre-planning of the case study methodology, it should remain an open-ended process without predefined research design templates.

Given the particular nature of the RECIPES case study task, whereby different partners carry out case studies at the same time, it will be challenging to coordinate and update the methodology to remain relatively uniform. Each case study will exhibit specific attributes that simply could not have been known before, and it is the duty of the research team to try to deepen their understanding of their topic. Given the central role of the IASS team in coordinating the case study task, deviations from the methodology should be communicated so that the other teams can be informed of potential new areas to investigate.

Furthermore, we must reiterate that the small N nature of the case study endeavour is exactly the reason that idiosyncratic changes to the methodology are acceptable. The very task of the multiple case study comparison component of WP2 is to fully understand and compare the individual cases *in their specific context.* Thus with 'only' 8 cases to compare, the idea is that the partners working on the comparison task can account for the unique context of each case when making the in-depth comparison.

Key Takeaways for the WP2 case study methodology

The key document for the case study researcher or research teams is the actual methodological framework (D2.2)

The methodology is a flexible and living process. Going outside of the methodology is permitted in order to better understand the case topic. Open communication between the IASS and the partners can best facilitate this.

3.4 Analysis

3.4.1 Analyzing the data

This section discusses the literature on analyzing case study evidence and applies it to the RECIPES WP2 cases. As discussed in section 3.3, the literature is divided on whether or not analysis of case study evidence should take place at the same time as data collection or if analysis should only take place after the data is collected (Eisenhardt 1989). Evidence collection followed by analysis is most appropriate in both ethnographic field work and cases where theory is largely absent (including 'theory-building' cases) whereby researchers 'go into the field' and collect information largely through interviews. These interviews are then typical analyzed at a later stage in a systematic way to try and draw out patterns and themes.

On the other hand, a strategy of simultaneous research and analysis is most appropriate where theory is already present, hypotheses are being tested rather than discovered, and desk research predominates (Yin 2018). Given the nature of WP2's case study research, we will perform a combined analysis and data collection method. **This is particularly useful in letting researcher perform iterative waves of research across the case methodology, and periodically reevaluate where to focus the most attention in order to best understand the case topic** – something that cannot be known with certainty beforehand and must be determined on a case by case basis as the research is carried out.

As a second point, the cross-case comparison component of task 2.4 more closely follows the strategy of analysis *after* data collection, if each individual case study is taken to represent input data to the analysis. The individual case studies employ more data and evidence collection than the cross-case comparison component, which employs no evidence collection and rather engages exclusively in analyzing the patterns across cases. Nonetheless, the individual case study inputs are not 'raw data' to be analyzed, but themselves pieces of theory led, high-quality analyzed work, which furthermore themselves will have anticipate many of the cross-case comparison thematic areas.

3.4.2 Performing the cross-case comparison

The cross case comparison component of a multiple case study research endeavor is somewhat less explored in the literature than single case study research due to the smaller proportion of comparative case study work. As described in the above section and in the introduction, The RECIPES project presents several challenges:

1. Comparing cases carried out by different research teams.
2. Comparing cases which exist across a breadth of socio-technological risk/innovation pathways.

At the same time, several potential advantages are present:

1. As discussed above, the cases will be carried out in the context of pre-defined theoretical constructs, including the tension between innovation and precaution, and the risk properties of complexity, uncertainty and ambiguity.
2. In the RECIPES project, a two stage analysis will combine primary researcher work with the synthesis provided by the IASS team, to help remove any research bias inherent in any single case.
3. Furthermore, employing an internal peer-review provides an informal pair-wise comparison between cases. Thus one strategy which may be employed is to use the internal peer-review not just to ensure quality, but also to provide a rigorous second assessment of the case, which can then be used by the cross-case comparison researchers.

At this point it is rather difficult to suggest how the cross-case comparison analysis will really take place – as strategies for doing so will develop iteratively over the course of the WP2. Openness in terms of evaluation strategy is in keeping with the literature (Yin 2018).

3.4.3 Evaluation strategies: Single and cross-case

A number of evaluation and synthesis strategies are put forth in the literature for how to best evaluate case study evidence. As stressed above, these strategies depend on the nature of the evidence/data, the existing theory on the case phenomenon, and overall research goals.

One strategy is to consider **plausible rival explanations.** That is, what would be the implications of starting with a different set of research questions, including the key risk characteristics (complexity, uncertainty, ambiguity)? One might consider here what other methods beside the case study investigation would look like and reveal (i.e. what has WP1 suggested versus what have the case studies suggested?) What other research questions could have been addressed and/or theoretical constructs could be posed? What other data collection methods would be feasible and what results mighty they reveal? How has the choice of cases impacted the analysis?

Currently there is no formal standard for investigating 'rival' explanations, but systematically explaining how rival explanations have been examined provides a good bar. Especially in the cross-case comparison component, the team will incorporate rival explanation analysis in to the overall analysis.

At the cross-case level typical suggestions include: 1) Select categories or dimensions of comparison across the cases to allow for comparison; 2) Compare pairs or cases with one another in a pair-wise manner first; 3) Have multiple researchers performing the comparison component to review different aspects of each case. For instance one researcher compares qualitative data, another quantitative, and so on (Eisenhardt, 1989). All of these strategies will organically emerge in either the cross-case or single-case study through partner feedback.

In closing, the following tentative points address the above challenges:

- *Theory is built into the methodology from the onset*
- *Individual case study partners carry out an analysis, which is validated and synthesized by IASS, and potentially fed back against the case study partners*
- *A pair-wise peer review process will ensure quality, and help feed the comparison*
- *The framework development itself was iterated against WP2 partners multiple times*

- *The cross-case analysis involves significant input from multiple single-case research teams, ensuring transferability of single case learnings*
- *The entire process remains open to adjustment as the process unfolds, which is in keeping with the case study literature*

Key Takeaways for the WP2 case study methodology

Data collection and analysis should be combined in iterative waves of research across the case methodology, with and periodic re-evaluations of where to focus the most attention in order to best understand the case topic.

The cross case analysis will employ a number of strategies including pair-wise peer review, iterating the analysis against case study researchers, and remaining open to the best way to compare and contrast the cases.

Plausible rival expectations should be considered at the individual and especially cross-case analysis stage.

3.5 Case Study Literature: Conclusions for RECIPES WP2

A small but growing body of literature has dealt with the case study research method. We have tried to selectively analyze and present aspects of that literature that are relevant for the specific nature of the RECIPES WP2 case study work package; largely encompassing tasks 2.1 – 2.4. In order to meet the challenge of developing a novel framework for the WP2 research task, we need to both incorporate some of the case study research foundational theory and examples from various contexts, while keeping in mind the specific goals and limitations of the RECIPES project.

Specific aspects of WP2 that require attention include:

- *Relatively different case study topics and overall case contexts (including legal records).*
- *Multiple case studies carried out simultaneously by different research teams.*
- *The IASS as a separate team leading the analysis and especially cross-case analysis of the cases.*
- *A large theoretical background going into the case study research: complexity, uncertainty, ambiguity, innovation, and the precautionary principle and innovation principle.*
- *Furthermore, the actual input of WP1: taking stock of the PP in the EU, a desk research review, and stakeholder and citizen engagement, media analysis.*

Developing the methodology in order to best handle these specific attributes of this case study task has been facilitated by the literature review. Theoretical and practical solutions to some of the challenges have been addressed throughout this process. This has had important implications for the content of the methodological investigation, which will be covered in the sections of this report on key concepts, and in the methodology report (D2.2).

4. Key theoretical concepts: Complexity, Uncertainty, Ambiguity

In this section we now move on to the core theoretical concepts which underpin the WP2 case study task. The ideas described in this and ensuing sections should inform the case study researchers in performing their case study research.

WP2 seeks to link the precautionary principle and innovation considerations to the key risk properties of complexity, uncertainty and ambiguity (CUA). CUA present epistemological challenges which limit our understanding and ability to communicate effectively about risk and innovation. The theoretical and conceptual ideas outlined in this framework should provide a backbone from which to consider these issues in the case study research process.

4.1 Complexity

4.1.1 Key theory

Like many contested and widely used terms, defining the term complexity is not a straightforward task. Complexity can also refer to a field of study, to a particular type of a system, or simply provide a description of an event or phenomenon. Complex systems exhibit nontrivial emergent and self-organizing behavior (Mitchell 2011). In such systems, simple entities organize themselves without central control, and depending on the system, can sometimes learn and adapt. They are typically characterized by various non-linear relationships, and as a whole it is difficult to determine cause and effect in the interaction of parts of the system.

Self-organizing or emergent behavior

Complex system behavior results from individual components interacting without central control. These components may be said to be following "simple rules" as in paradigmatic examples like insect swarms and flocking, but emergent order also presents itself in complex economic and financial systems, where actors and systems follow complex and dynamic "rules". Most importantly, centralized, top down control is not required for the system to exhibit organized behavior. This has a 2-way implication for thinking about and analyzing complex systems: 1) Interacting parts can result in the emergence of highly organized, seemingly directed order which could not have been predicted; 2) Analysing the system as a whole does not allow us to understand fully how the individual parts work, and analysing the parts in isolation will not reveal how the system functions.

Non-linear relationships

Complex systems tend to exhibit a variety of non-linear relations, partly due to the complex, intertwining relation between parts of the system. These include:

- *Feedback loops like compounding, economies of scale, network effects*
- *Oscillations or cycles*
- *Tipping points*
- *Phase transitions from one regime to another*

These various non-linear relationships may be conceptually important for understanding the case study topics. Non-linear relationships can both persuasively rationalize the need

for precautionary principle in certain cases, and help explain how technological progress takes place.

In addition to these 2 attributes of complexity which can apply across social, physical and even information systems, we add the key element of human interaction, reflexivity. Reflexivity describes how human agents perceive, anticipate and alter the systems in which they are participating within the specific social, cultural and technological constraints being faced. Reflexivity implies that by perceiving and acting in the system, individuals alter that very system in a type of dynamic feedback loop between the course of events and agent perceptions of those events (Soros 2009).

In WP2, case study researchers will consider the larger social, environmental, ethical and cultural aspects of the case study topics in addition to the technical risks. Reflexivity magnifies the complexity by introducing human anticipation, which further renders the system unpredictable. This includes the interplay of human agency within the context of regulation, innovation, legal decisions, changing societal values, and vested interests which results in higher-level complexity than the technological system alone.

4.1.2 Complexity and the case studies

In this section, we discuss some additional attributes of complex systems which, in addition to emergent effects, non-linearity, and human interaction, are relevant for the case study research task.

Path dependence

Path dependence means that a system's trajectory is at least in part determined by the past. This seems obvious, but is often ignored in both models and overall descriptions of phenomenon. Both external shocks and endogenous dynamics may permanently and irreparably change the system's trajectory. This can result in possible widely diverging outcomes emanating from arbitrarily small differences in initial conditions. Two similar systems exhibiting similar behavior over a period of time may suddenly diverge because of unobserved path dependent effects. For the case studies, this is important: 1) with regard to introduction technology in slightly different societal contexts; 2) As a rationale for the PP which may prevent irreparable harm; 3) By the same token, in the context of how innovation takes place.

Tipping points and state changes

Tipping points and state changes describe potentially permanent changes to systems. The complete wipeout of a species or bio-habitat is an example of such a state change. Given the possibility for permanent changes to the system, this implies that we should exhibit particular caution in introducing changes to systems of high human or environmental value. For the case studies, this is important as a rationale for the PP which may prevent irreparable harm from taking place in the first place.

Towards a definition of Complexity: Difficulty identifying and quantifying causal effects

Complexity implies that human intuition cannot be relied upon to understand cause and effect (IRGC 2018). According to the IRRC framework, complexity can be defined as follows: **complexity refers to the difficulty of identifying and quantifying causal links between a multitude of potential candidates and specific adverse effects** (Renn, Klinke, van Asselt 2011).

This definition is useful, because does not insist on any particular 'complexity aspects' that we have covered in this section being present. It also highlights the challenges social scientists face in undertaking scientific investigation, and it brings us to the resulting scientific uncertainty which is so crucial in precautionary principle decisions, which we will explore in the next section.

Conclusion

In the socio-technological cases being considered in task 2.3, it is important to extend the complexity lens to include not just the complexity of the biological or environmental system in question (including here human health outcomes) but to also directly consider the effect on stakeholders, policy makers and legal actors as part of the complexity of the system itself.

In the context of the RECIPES project two final considerations are of note: 1) Emphasizing the subjective sense of complexity (a system is for us humans difficult to understand, predict and control) as opposed to more technical definitions of complex systems; 2) Emphasizing potential positive aspects of the 'threat or risk' at question, within the complex innovation pathway which takes place. Within the context of the RECIPES project's emphasis on the tension between innovation and precaution, it is important to drive home the unpredictable yet potentially positive societal effects of the technologies under investigation.

Key Takeaways for the WP2 case study methodology

Complexity has a number of causes and characteristics, but we take the broad definition: Complexity refers to the difficulty of identifying and quantifying causal links between a multitude of potential candidates and specific adverse effects.

Complexity includes the interplay of human agency within the context of regulation, innovation, legal decisions, changing societal values, and vested interests, which results in higher-level complexity than the technological system alone.

Complexity also presents itself and in the complex innovation pathways which are relevant to the case studies.

4.2 Uncertainty

4.2.1 Key theory

Uncertainty is one of the key ideas required for analysing the overall social, cultural and political circumstances considered in the case studies. Uncertainty also plays a critical role in the implementation of precautionary principle itself, as scientific uncertainty was pointed to by WP1 as *the* key component of the precautionary principle in the Conceptual Core of the PP identified in the RECIPES WP1 report. It is important to make the distinction between uncertainty more broadly in the social sciences, risk governance and even complexity studies sphere, and scientific uncertainty as it features directly in legal and regulatory applications of the PP. As such, this section will discuss a number of relevant concepts: risk, uncertainty, and scientific uncertainty. We start with the juxtaposition between risk and uncertainty.

Stirling (2008) describes the conventional science-based understanding of risk as the combination of what may happen – the hazards, possibilities, outcomes – with the likelihood that it might happen. This conventional view implies that the outcomes and likelihoods of those outcomes are known, and thus that level of risk can be calculated by combining the probability and severity of the threat. Standard risk analysis takes risk to be a set of known probability distributions across known outcomes, such as in cases where actuaries, regulators or scientists feel comfortable assigning actual likelihoods to the outcome. With the concept of risk, we obviously do not know what is going to happen in a future even, but we do have a relatively good idea of what can happen and with what likelihoods. A very good example of this class of risks is those for which insurance

companies offer coverage: risks which have a large amount of data from which to generate probabilities of occurrence, and relatively small amounts of damage which can be paid out by the insurance provider.

How can we thus describe uncertainty, especially in light of the above description of risk?

Drawing on a variety of sources from across the risk analysis field, we offer the following description. **Uncertainty describes our lack of knowledge about the outcomes or likelihoods, or both, of an event or process.** We hold that this broad definition actually encapsulates the scientific uncertainty description found in WP1.

Van Asselt (2000) distinguishes between variability uncertainty and epistemic uncertainty. Variability uncertainty arises because of relevant, correct, but 'random' system behaviour. Note that this may or may not be the result of complexity.

Epistemic uncertainty results from the actual researchers performing the study and research process, and the collective state of knowledge. She connects the two by claiming that epistemic uncertainty partly results from variability uncertainty, "as variability complicates analysis."

The WP1 report identifies scientific uncertainty as the key foundation of the precautionary principle: "Scientific uncertainty can stem from more than a lack of data or inadequate models of risk assessment. Scientific uncertainty might also exist in the form of indeterminacy, when not all the factors influencing the causal chains are known. Equally, scientific uncertainty might arise when there is ambiguity or contradicting data. Finally, it is possible that certain risks are still unknown, which often is labelled as 'unknown unknowns', boiling down to situations of ignorance."

Given the above definitions, uncertainty can be said to arise in both in the absence of complexity, as well as from complexity directly or indirectly through "incomplete evidence, divergent values, scientific disagreement, gaps in knowledge or the simple possibility of surprise" (Stirling 2018). Nonetheless, **we highlight the functional uncertainty that emerges from highly complex technologies and societal processes.** We take the position that the level of uncertainty about possible outcomes that scientists, policy makers and legal decision makers must grapple with is of primary importance, and the cause of this uncertainty, while also important, is of secondary importance. This sentiment is echoed in the WP1 report's description of scientific uncertainty.

Lastly, it's important to point out that risk and uncertainty are usually associated with negative outcomes, particularly in the context of risk management. However, uncertainty can also be associated with unknown or unpredictable positive outcomes, specifically in the case of positive technological development pathways. This is especially relevant the case given the path dependent, evolutionary process by which technological development takes place (Sterling, 2008). This is important to consider given the tension between precaution and innovation that we are investigating in the case studies.

Key Takeaways for the WP2 case study methodology

Uncertainty is the key risk property in invoking the PP; as the PP's purpose is to allow decision-makers to act despite scientific uncertainty.

Uncertainty describes our lack of knowledge about the outcomes or likelihoods, or both, of an event or process.

In contrast, risk describes situations where possible outcomes are known, and the likelihoods of those outcomes can be well-described.

Given the subjective complexity faced by decision makers in the case study topics, we

highlight the functional uncertainty that emerges from highly complex technologies and societal processes.

It is important to consider cases where scientific uncertainty *is present,* but nonetheless the PP has not been invoked.

4.3 Ambiguity

4.3.1 Key theory

Ambiguity refers to situation where there are completely different, divergent and sometimes contradicting interpretations of the same technological process, innovation or risk. The presence of ambiguity makes it unclear what the intended outcomes of regulation, precaution or risk governance should be – because different societal actors have difference perceptions and viewpoints about the same threat or risk. Ambiguity refers to the fact both that outcomes are potentially uncertain, and that different groups will value these outcomes differently. In other words, ambiguity refers to differing legitimate viewpoints exist about adverse side effects and whether these risks are acceptable (Renn, Klinke, van Asselt 2011).

We can think of ambiguity as divided into two components: 1) Interpretative ambiguity; 2) Normative ambiguity. Interpretative ambiguity refers to the situation where information, data, analyses and risk governance strategies are interpreted in different ways by different actors. Even identical observations or data may result in varying interpretations. This is a paradigmatic attribute of observing a complex system, in particular when considering the training, culture and scientific community in which a scientific researcher operates. Taking this a step further, layperson risk perception and interpretation will again differ from expert opinion and that of other stakeholders. Likely to a greater degree that of experts, this results from a lack of experience in dealing with probabilities, risk analysis, or the specific socio-technical field under analysis (Renn, Klinke, Schweizer, 2018). As risk problems become more complex and scientific uncertainty increases, the interaction of a pluralism of risk perspectives, value preferences, and differing access to information results in a highly complex, contingent and interrelated array of opinions about a given topic.

This unavoidable interpretive ambiguity which results from scientists and researchers simply carrying out their research then feeds into the second component of ambiguity, normative ambiguity. Normative ambiguity points to the diverging ethical and normative assumptions in society. This includes different concepts of what ethical, quality of life, and other risk-benefit parameters are acceptable (Renn, Klinke, Schweizer, 2018).

This also includes the degree to which one views the state's role in intervening in socio-technical areas. For example, significant debate has surrounded European versus American conceptions of product and technological regulation, and the role of government in the lives of citizens. While there is some degree of truth in the idea of European caution versus American risky advancement, it has been shown that the degree and nature of precaution across the two societies varies on a case by case basis, and over time (Wiener, 2013).

From the perspective thinking about precaution and regulation, ambiguity implies the need to emphasize mutual learning across academic, regulatory and other civil society communities, and the need to co-create joint knowledge in the process. In the EU context of the RECIPES project, this is cross-disciplinary push must of course be opened

across national boundaries and cultural differences. Beyond WP2, WP3's focus on new tools appears to be an obvious place to address aspects ambiguity.

Coming full circle, we can link the subjective aspect of complexity to ambiguity. Complexity reorients science away from the belief that we can describe, predict or control the system. This has immediate practical implications for the RECIPES case studies. Given the presence of emergence, non-linearity, and adaptive systems, the level of abstraction or scale at which the researcher decides to observe and describe the system is already a subjective analytical step (Kovacic 2017).This is shows that both ambiguity and uncertainty are not temporary features which can be eliminated by further research. Rather, the fundamental limits of observing the system from any given perspective and scale suggests that incorporating multiple perspectives is a key to the scientific understanding of the system (Kovacic 2017).

Key Takeaways for the WP2 case study methodology

Ambiguity refers to the fact both that outcomes are potentially uncertain, and that different groups will value these outcomes differently.

Ambiguity is present in how scientists and risk specialists evaluate the same evidence, and in how outcomes as risks are evaluated.

Ambiguity implies the need to engage societal stakeholders in the discussion about the harms and benefits of technological innovations and other risks.

5. Existing risk governance frameworks

So far in the report have described how the case study component fits into the overall RECIPES project, presented a literature review of the case study methodology as it applies to WP2, and presented the key risk properties of complexity, uncertainty and ambiguity. In the following 2 sections, we will draw on WP1's research and findings to lay the final step theoretical step for the case study methodology. We aim to provide a working discussion which is relevant to the case study research teams in task 2.3 and to inform the cross-case comparison to be completed in task 2.4.

In this section, we discuss the risk governance frameworks of the IRGC and the safe food framework, which were briefly discussed in the WP1 report as potential guiding frameworks for WP2. WP1 suggested drawing on risk governance frameworks, and in particular the International Risk Governance Council (IRGC) framework, as components of the case methodology. We have thus introduced elements of the framework into the case study methodology (D2.2). It is important to emphasize that is does not imply that the RECIPES project is adopting the IRGC framework in any way. Rather, we are acknowledging that various risk governance frameworks exist and that we will consider whether and how these frameworks are followed in the case studies.

Risk Governance

Risk Governance can be defined as the "the totality of actors, rules, conventions, processes and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken" (IRGC 2018). Risk governance actually combines 2 distinct fields: 1) Risk analysis including risk assessment, management, and communication; 2) Governance of collectively binding decisions associated with regulation and specific context in which risk analysis take place (Klinke, Renn 2019).

IRGC

The IRGC framework recommends a holistic, multidisciplinary and multi-stakeholder approach to risk. It does so by providing policy makers, regulators, risk managers and other key decision-makers with evidence-based recommendations about risk governance. In contrast to traditional risk analysis, IRGC tries to understand the broader stakeholder, expert, and public context surrounding social and environmental risks. By including the stakeholder input and context of broader legal, political, economic and social contexts, risk governance aims at the "development of an integrated, holistic and structured approach, a framework, by which we can investigate risk issues and the governance processes and structures pertaining to them" (IRGC 2005). The IRGC framework has been applied to several relevant PP case topics: nanotechnology, pollination services, synthetic biology, GM crops, and precision medicine.[1]

The IRGC framework contains a 5 step framework: pre-estimation, interdisciplinary risk estimation, risk characterization, risk evaluation, and risk management.

Safe Foods

In addition, the Safe Food project's Food Safety Governance framework might also be relevant for the RECIPES project. The Food Safety Governance framework arose out of the challenges the EU was confronted with in the wake of various food crises in the late 1990s and 2000s. The Food Safety Governance framework is a design with four governance stages (framing, assessment, evaluation, management, with participation and communication as cross-cutting activities), and an organisation into four assessment

[1] See https://irgc.org/issues/

and management tracks distinguishing between risk-, precaution-, concern- and prevention-based approaches (Dreyer & Renn, 2009).

These frameworks offer inspiration for how the application of the precautionary principle can be conceived as part of a general framework of risk governance which also includes stages (in particular risk evaluation) which appear suitable for linkages with innovation. As we discuss in chapter 7, consideration of the IRGC or other risk frameworks might play an important part in the generation of scenarios (task 2.5) for the future of the PP-IP, and in the new tools to be developed in WP3.

RRI & Gender

Science, Technology and Society Studies have clearly shown that there is a fundamental gender dimension in research practice and technology development. Social dynamics spanning the R&I sectors are also deeply influenced by gender relations. The RECIPES Project will adopt a co-creative approach which draws on the tradition of participatory technology assessment (pTA) and is closely aligned with the principles of Responsible Research and Innovation (RRI) including gender among its key areas.

We view the risk governance frameworks as an ideal place to address various aspects of Responsible Research and Innovation (RRI). In particular, part of our assessment of the usefulness of risk governance frameworks overall is in assessing how they can address RRI considerations. In addition to risk governance, consideration of another key aspect of RRI, gender, has been incorporated into the case study methodology where analysis of differences in PP-innovation-IP has been included. Gender perspectives will be considered in the analysis (Task 2.3) and in the interpretation of cases (Task 2.4). The specific topics dealt in the most part of the selected cases studies require a careful consideration of sex and gender variables (e.g. endocrine disruptors, financial risks urban waste planning), considering how differently women and men are affected by risks even very diverse by nature. The importance of taking into account a gender and diversity perspective in all the phases of the project is also guaranteed by the presence of gender experts within the consortium (K&I).

Key Takeaways for the WP2 case study methodology

The IRGC framework is one risk governance framework which may be a useful framework for the WP2 case study methodology, and the scenarios and new tools (WP2).

Our inclusion of the IRGC framework in the methodology might add to the analysis and does not imply that the RECIPES project is adopting the IRGC framework.

6. Synthesis with WP1

This section explores aspects of several concepts that pointed to by the WP1 report as important considerations for the case study methodology. This included a discussion of the core components of the PP, as well as innovation and the innovation principle.[2]

6.1 PP Interpretations & Core component

The WP1 report showed that since 2000, the precautionary principle has been used in a variety of policy areas, albeit with a focus on environmental, consumer protection and internal market policies. This holds for both the EU level as for the Member States. The analysis moreover showed that, in EU law-making, that the principle is used in different areas, sometimes even as guiding principle for Member States or the Commission, but hardly ever defined or explained with regards to the particular situation covered by the legal act in question. The report pointed out that on the one hand this leaves ample room for flexibility and ad hoc solutions. On the other however, this may also create room for problems as the EC Communication appears not to be applied consistently.

Core Components

WP1 identified several key components of the legal definition or interpretation of the PP which deserve particular attention: scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and the burden of proof. While it is important to remember that these core components were derived from an analysis of the legal principle, as opposed to a more broad conception of precautionary thinking, they also form key areas of investigation for the case study methodology.

The threshold of damage refers to the level of damage to health or the environment that should be reached before any precautionary measure has to be adopted by the EU authorities or Member States. With regards to the requirement for some form of scientific analysis, the European Commission Communication refers to 'reasonable grounds'. The consideration of cost-effective measures refers to the obligation of the regulator of an activity to opt for the 'least economically cumbersome' precautionary measures. Lastly, scientific uncertainty was discussed at length in section 4 of this report. In order to make the core components functional for the case study task, we posit the following logical ordering of these core components:

Primary importance: Assuming some form of **scientific analysis** has taken place which reveals **scientific uncertainty** AND the **threshold of damage** is met, the PP should or may be invoked.

Secondary importance: **Cost effective/proportionality**, and **reversibility of the measure** are secondary considerations for which specific measures should be employed when invoking the PP, ONCE the PP has been decided on.

The **reversal of burden of proof** is an attribute which depends on how scientific uncertainty must be demonstrated in the case topic specific context (i.e. according to applicable national/EU rules and treaties specific to individual technologies).

[2] In all cases, readers are encouraged to refer to the lengthy and informative precautionary principle discussion found in the WP1 report for more detail.

Key Takeaways for the WP2 case study methodology

WP1 identified several key components of the legal definition or interpretation of the PP which deserve particular attention: scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and the burden of proof.

6.2 Innovation & the innovation principle

Technological innovation has been one of the driving factors in improving human well-being over the past centuries. New developments in medicine and health care, communication, agriculture, and production and transport systems have delivered quality of life improvements across the globe, and continue to do so. At the same time, regulation of new technology plays an important role in protecting humans and the environment from various harms which result from technological processes.

We stress that consideration of how innovation takes place requires consideration of both the dynamic, uncertain pathways of technological development, and the potential harms caused by new innovations, all within the context of the role of regulation in this dynamic process. This means going beyond the "narrow" investigation of the trade-off between precaution and innovation. While industry pressure plays a significant role in seeking to erode legitimate precautionary measures, there is a potentially mutually reinforcing relationship between regulation and the precautionary principle, and technological development.

Drawing on the WP1 report, the term innovation is used to describe processes that use new knowledge and technologies, as well as processes to generate new products and the new or improved products themselves. However, while it seems that that the majority, if not all of the technologies to be considered in the PP – IP debate are of the new product nature, it is difficult to really differentiate between the production process and final product of most of the case study topics. For example, when considering emerging risks in AI or Crispr gene editing, it is possible to reformulate the debate along a "processes and use of knowledge" innovation discussion as opposed to a purely product innovation discussion.

In addition to new products and processes, the literature points to social innovation, which tends to have a more normative or even political dimension. While technological innovation might only refer to a transformation or creation of a technological instrument with all the indirect political consequences this might have, social innovation directly refers to the organization of a group. Social innovation implies an overturning of the existing practices of a group with a more social objective in mind. To date however, such considerations are well outside of the remit or the PP, or any form of technological regulation. The case study topics may nonetheless touch on such ethical or societal considerations.

Finally, we point to the somewhat less usual case, whereby a new product or technology is specifically developed to circumvent regulations *whereby the PP was invoked*. For example, the financial products case study will look at how potentially risky financial products are being developed to finance costly infrastructure investments required to meet or maintain water quality thresholds, which are required under EU precautionary principle measures. Here, innovations (financial products) are being development with

differing repercussions. This is to say that there is not always a clear linear narrative in which a new technology challenges the PP, but the other way around: the PP sets up the environment under which particular innovations become necessary. These then can create knock-on effects that affect the original risk (water quality) or create new risks elsewhere (e.g. flood exposure, market dynamics, etc.). The complexity, uncertainty and ambiguity dimensions cover these dynamics quite well, and in particular analysing non-linear effects could be useful.

6.2.1 Innovation Principle

The innovation principle says that "whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed" (ERF 2015). Furthermore, according to the European Political Strategy Centre (EPSC), the European Commission's in-house think tank, the innovation principle should provide guidance in choosing and designing regulatory tools that foster innovation, rather than hamper it (EPSC 2016). It goes without saying that technological progress led by innovation is crucial to improving our standard of living, productivity, and even lowering our negative environmental impact through improved, cleaner processes (EPSC 2016).

When considering the innovation principle, we should separate it somewhat from the general concept of innovation. As documented in the WP1 report, the innovation principle and its increased rising importance at the EU policy making level is largely the result of a concerted effort by industry funded researchers and policy groups. In legal terms it is not a principle. However, innovation in itself is a valuable concept and policy to pursue and to take into account when adopting (precautionary) measures.

6.2.2 Critique of IP

At the same time, the innovation principle can be critiqued by pointing out that innovation is only a means to achieve other purposes and not an end in itself (ETUC, 2016). We view that whilst recognizing that the innovation principle is not a legal principle innovation should be considered whilst considering whether to adopt precautionary measures.

However, without downplaying the high importance of innovation, we point out that various aspects of the complexity and uncertainty discussion shed doubt on the symmetry of innovation and precaution. If there is uncertainty about the outcome of a technological innovation with potential serious harm to human health or the environment as a consequence, even if the possible expected harms and/or benefits are theoretically symmetrically distributed the possibility of causing irreversible negative harm to the system must prioritized above potential gains. This is often referred to as the *ruin problem* or *gambler's ruin problem* (Taleb 2014). In one direction the system can be totally destroyed by a possible negative outcome, while in the other direction it may provide linear or even exponential benefits. In such situation, the inherent logic behind the precautionary principle becomes very clear – the risk or irrevocable damage prevails over any benefits.

Finally, there is some evidence that the false negatives are far more common than false positives in applying the precautionary principle, which represents a possible empirical asymmetry to go along with the 'technical' asymmetry associated with the ruin problem (Gee, 2013).

Sketching potential PP-IP futures

As developed in WP1, drawing on Von Gleich and Petschow (2017) we point to the lack of proposals for how to operationalize the IP, and note three possible proposals brought

forth for how the PP-IP may interact in the future. These possibilities may inform the later stage WP2 synthesis and scenario tasks.

1) Complementary (passive): the IP as 'another' principle to be considered along with the PP. According to this view, regulatory assessment processes should try to reconcile the two principles and achieve a more balanced use of the precautionary principle. It remains unclear, however, what exactly should be balanced with the precautionary principle and how this balancing could be carried out.

2) Complementary (active): More systematically trying to 'balance' precautionary measures with 'innovation' measures. This view sees the innovation principle also as complementing the precautionary principle but is aimed at systematically balancing precautionary measures with societal benefits of innovations. It suggests an ambitious and science-based appraisal process corresponding with the agendas of better regulation and responsible research and innovation (RRI).

3) Downgrading the PP: in particular attacking the uncertainty condition inherent to the PP. This view asserts that the introduction of the innovation principle should limit the application of the precautionary principle. Here the precautionary principle is challenged on the ground that it stifles innovation and hence jeopardizes EU competitiveness, jobs, and growth

6.2.3 Complex innovation

We advocate moving beyond a simple innovation versus precaution juxtaposition, and rather recognizing that technological development takes place in a complex, evolutionary, path-dependent and uncertain way. In this view, a potentially mutually reinforcing relationship between regulation and technological development exists.

Drawing on WP1, we reiterate that innovation is thus not a linear and uniform process or outcome that just 'happens'. What, how, and by whom the innovation takes place is crucial. From the vague idea until proof of concept until the concrete implementation in society and its consequences for the world, one might argue we need to consider which values have been taken into account. Precaution in relation to innovation in regard to, for instance, the protection of 'human, animal or plant life or health' can also mean introducing them in different steps of the innovation process: in how researchers are trained, who are involved in the processes of Research & Development, which projects get funded, how the development process is organized, how the outcome is distributed and implemented, and how dangerous signals are communicated or monitored after launch.

6.2.4 Hypothesis on the PP-IP relationship

As discussed throughout the section on innovation and the innovation principle, in our view the PP should not be viewed as a hindering factor for innovation, per se. Rather, it can be utilized as a means to spurn socially viable, responsible and sustainable innovation. Furthermore, a lack of regulation and regulatory consistency can impede investment and the development of innovations. Nonetheless, as emphasized in the WP1 report, there is at face value a potential inherent tension between the PP and the IP. The precautionary principle is concerned with uncertain and unknown risks. The precautionary principle thus expresses a need for caution with regard to the introduction of novelty in the world. The discourse surrounding innovation instead adheres to the conviction that the introduction of novelty constitutes progress.

The use of PP is and will always entail both a certain risks of misuse, and the danger that industry or political pressure will prevent its correct usage. Thus it is important to have strong institutions to ensure that PP is not misused e.g. for national trade politics. It is our preliminary view that the PP should always be applied on a case-to-case basis, and is

not a blanket one-size-fits-all tool. Thus the case study research task should aim towards generating findings that are nuanced enough to consider case specificities. This implies a need to regularly involve all relevant stakeholders and the public in a structured technology assessment process. This potential relationship will be further explored in the case studies, and synthesized with WP1 in tasks 2.4 and 2.5.

Key Takeaways for the WP2 case study methodology

Innovation is crucial for human and societal betterment, but must be regulated to try to prevent harm. This leads to a complex interplay between regulation and innovation.

The innovation principle can be critiqued for its claim that precaution and innovation must be held at equal standing. The *ruin problem* provides such a critique.

Overall, PP should not be viewed as a hindering factor for innovation, and the case studies will explore how the PP, innovation and the IP interact at the case topic level.

6.3 Further considerations

Finally, this section ties in several other considerations brought forth in the WP1 report which are relevant for WP2. These will be partially addressed in the case studies, as well as in the cross-case comparison component.

Beyond environment, health and consumer protection

Initially, the precautionary principle aimed to enable decision makers to act in situations of uncertain risk in the domain of the environment and human health. However, it has also been applied by the EC for general, financial and institutional matters, for the area of freedom, security and justice and in the fields of transport, services, regional policy, industrial policy and competition. Thus, a question remains regarding the appropriateness of applying the PP in cases that may not directly harm human health of the environment.

Definition and review of 2000 Communication

Another area of concern referred to in WP1 is the potential need to review 2000 Communication, which does not itself provide a definition. Given the different definitions in the various existing court interpretations of the PP, the case studies may identify the need to refine the definition, or how it is applied.

As referred to above, the commonalities between different definitions reviewed are scientific uncertainty, a hint at the type of risk (to human health), the action to be taken (protective measures/ risk management measures), and an assessment of the available information. There is however no clear indication of what threshold is necessary to trigger the precautionary principle, or what the assessment of the available information should entail. Our study revealed various inconsistencies in the Courts' rulings; whilst the legal acts hardly elaborate on the precautionary principle.

Thus, it might be considered whether there is a need for revisiting the 2000 Communication, a view the literature suggests, to clarify the threshold that needs to be attained before the precautionary principle can be applied, the meaning of 'significant damage', the requirements for the risk assessment and the evaluation of the precautionary measures that will be taken as well as possible inclusiveness of the decision-making process.

Important aspects to consider hereby could be the requirement of carrying out an impact assessment prior to adopting a precautionary measure, the lack of which, as the Court has ruled in its case law, is a breach of the precautionary principle, the recognition of the precautionary principle as a principle of good administration, as well as the temporary nature and the situation when new scientific evidence becomes available. This is in particular important for striking the delicate balance between concerns on health, safety and environmental protection and economic interests.

6.3.1 Media analysis and Citizen Meetings

WP1 also included a media analysis and citizens meetings, as a way to understand how European citizens think about the precautionary principle, innovation, and the innovation principle. Various aspects of the findings from both sub-tasks have been included in the methodology, and will be addressed by the scenarios task (2.5).

The media analysis highlighted how deep dives into cross-cutting issues and data can reveal the mechanics of how the PP is framed by the media, and understood by the public. Furthermore, the analysis revealed a relative lack of 'innovation principle' focused articles, which the need for a deeper dive into how the IP is playing a role in PP considerations. The case study methodology will tackle both of these issues. In terms of content the importance of trade treaties was highlighted, which we have included in the case study methodology.

The citizens meetings found that participants did not see precaution and innovation as being in contradiction with each other and that the precautionary principle was almost universally recognized as an appropriate and effective tool to regulate uncertainties arising from development of technologies.

Citizens emphasized the importance of involving institutions with scientific knowledge and democratic responsibilities, independent from external interests and with high transparency often surfaced during the discussions. Distrust, or at least scepticism towards the neutrality of institutions not complying with the above (especially politicians and companies) were often expressed in relation to technology, power and economic interests. Finally, a general view was that stakeholders and citizens should be widely involved and engaged in the process when applying the precautionary principle. Again, many aspects of this finding are included in the case study methodology.

7 Next steps: Link with Scenarios and WP3

In this final section, we sketch three possible scenarios for linking up the outcome of the case study analysis with the synthesis to create scenarios for WP3.

The following could be discussed at stakeholder scenario-workshops (task 3.1). As discussed in the section on the WP1mcitizens meetings, we point out that the citizens did not see precaution and innovation as being in contradiction with each other. Because of this, all three scenarios aim to strengthen both precaution and innovation.

1. *Focus on innovation*

In this scenario the PP is actively used to encourage innovation. Through rethinking of research-schemes and other kind of tools the PP will initiate development of technologies that are not harmful for health and the environment, and which will be in accordance with RRI principles.

It is important to keep in mind that innovation is not just the development of specific technical products. Innovation is also about the use of technology in society, such as how and for what purpose the technology is used. This may concern the whole structure and societal organization of the usage of the technology in society.

An example of where the PP has stimulated such kind of innovation is the neonicotinoid ban in Italy which triggered an innovative insurance scheme against crop failure known as 'The Mutual Fund (MF) strategy for maize in Italy'. This proved to be a better option for the farmers than prophylactic use of neonicotinoids on maize (Furlan et al. 2018).

2. *Continuation of current practice*

The frame for this scenario will largely build on the present structure for the regulation of the PP and innovation. The scenario will highlight existing examples of successful use of the PP under current regulation and will suggest tools to strengthen the PP. Since 2000 the PP has only had a rather limited distribution, so this scenario will suggest how to expand the use of the PP and to further unfold the principle. Based on the WP1 report 'The effect of the PP since 2000', the scenario will describe possible ways to develop the PP without stifling innovation.

3. *Focus on precaution*

This scenario will propose an extension of the PP concept involving issues put forward by stakeholders and citizens. Referring to the interview meetings this will involve ethical issues, broad involvement in technology assessments by interdisciplinary experts, stakeholders and citizens, inter-departmental coordination, and case by case assessments. Such tools can encourage a more sustainable and socially relevant development.

An example of a possible way to implement such tools is the drafting of Danish legislation in the field of GMO. Here DBT held a so-called consensus conference where randomly selected citizens during three weekends discussed the burning issues with experts and stakeholders. Based on this, citizens agreed on a long list of recommendations to politicians containing their views on all controversial issues regarding (Furlan, 2018).

8 Conclusion

The overall aim of WP2 is to understand and explain the potential differences in the application of the precautionary principle in 8 different case topics, in a way that reflects the particular context of the case and the arguments for invoking the precautionary principle. The multiple case study component of the RECIPES project is one of the key analytical phases of the project.

This report has described how WP2's case study component fits into the overall RECIPES project, presented a literature review on the case study methodology as it applies to WP2, presented the key risk properties of complexity, uncertainty and ambiguity, and formed a linkage with the rest of the RECIPES project by building on concepts from WP1, and suggesting next steps into WP3.

Taken together with the case study methodology itself (D2.2), this lays the foundation for carrying out the case study research task, as well as the cross-case analysis of the 8 case studies and transitioning these findings into the rest of the RECIPES project.

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