RECIPES

Precaution • Innovation • Science

Guidance on the application of the precautionary principle in the EU

The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665

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With thanks to:

The RECIPES consortium for review and feedback

Manuscript completed in December, 2021

Document title	Guidance on the application of the precautionary principle in the EU
Work Package	WP3
Document Type	Deliverable
Date	30 December 2021
Document Status	Final version

Acknowledgments & Disclaimer

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824665.

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The RECIPES team is very grateful to those whose contributions have informed the development of this guidance document. We owe a considerable debt of gratitude to the participants in RECIPES citizen meetings, the interview partners of the RECIPES case studies, the participants in the multi-step stakeholder consultation process on the future application of the precautionary principle, and the members of RECIPES advisory panel. We acknowledge with great appreciation that these individuals took their time to commit themselves to our work and provided us with valuable input, feedback, and ideas.

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1 General introduction

This guidance document provides orientation and inspiration on how precaution can be used in risk regulation and innovation policy of the European Union (EU) to deal responsibly with uncertain risks in the development and use of technology and thus support the current EU research and innovation strategy.

It is motivated by current debates about the relationship between precaution and innovation and related calls for a critical review of the application of the precautionary principle and the exploration of possibilities for improvement in the principle's application, in particular with respect to its influence on innovation.

The guidance is aimed at EU policy makers, European agencies[i], and EU support organizations and bodies[ii]. These target groups can stimulate and resource an improved use of the precautionary principle in EU risk regulation and innovation policy.

1.1 The precautionary principle and responsible innovation

In the past decade, the EU has fostered an innovation ecosystem in which technologies (and other innovations) are not thought of as ends in themselves, but are brought in line with fundamental values and principles upon which the European Union is built. The current research and innovation strategy of the European Commission (2021 - 2024) identifies research and innovation as a key driver in achieving European Commission goals that are geared towards a sustainable and prosperous future for people and planet, based on solidarity and respect for shared European values.

Among other things, the Commission's research and innovation strategy identifies the following tasks for research and innovation. Research and innovation shall help restore ecosystems and give space to nature so that Europe can become the first climate-neutral continent. They shall help improve people's health at all ages, tackle emerging threats and improve crisis preparedness so that citizens are protected and European values defended. They shall further help develop innovations, policies and institutions to support democratic processes and enhance trust in democratic institutions, so that more resilient democracies are built across the EU[1].

The present document sets precaution out as a crucial element for this value-based approach towards innovation that emphasises non-economic values in particular. The guidance document presents the precautionary principle and precautionary thinking as tools that can guide technological development and also established technologies, if required, into directions that help achieve European values incorporated in normative anchor points such as a high level of protection of human health and environment, quality of life, or sustainable development. Further, the precautionary principle and precautionary thinking are presented as tools that should be used in a participatory manner that supports democratic processes in EU innovation and technology governance.

The notion of 'responsible research and innovation' (RRI) was launched by the European Commission and has been strongly promoted as an innovative governance concept in its former research and innovation programme Horizon 2020 (2014-2020). RRI is committed to a responsible vision of innovation as laid down in the European Commission's current

[i] For instance, the European Environmental Agency (EEA) or the European Food Safety Authority (EFSA).

[ii] For instance, the Science Advice for Policy by European Academies (SAPEA), the European Political Strategy Centre (EPSC), or the European Parliament's Panel for the Future of Science and Technology (STOA).

research and innovation strategy. RRI addresses the observation that innovation – as a goal in itself – does not always lead to results that are beneficial to society as a whole or else may be accompanied by negative side effects.

Science and technology scholars, such as Stilgoe et al.[2], have identified anticipation, reflexivity, inclusion and responsiveness as important characteristics of Responsible Innovation (RI). These four elements can be described as follows:

- *Anticipation*: "Anticipation involves systematic thinking aimed at increasing resilience, while revealing new opportunities for innovation and the shaping of agendas for socially-robust risk research"[3].
- *Reflexivity*: "Reflexivity, at the level of institutional practice, means holding a mirror up to one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held"[4].
- *Inclusion:* Inclusion could mean taking the time to involve different stakeholders as to lay bare the different impacts of a new technology on different communities.
- *Responsiveness:* "Responsible innovation requires a capacity to change shape or direction in response to stakeholder and public values and changing circumstances"[5].

Importantly, this guidance document considers that the precautionary principle connects to these four dimensions. Hence the exercise of precaution as going beyond formal inclusion of the precautionary principle in EU policies or regulations for the authorization of products or processes (which we refer to as the 'application of the precautionary principle as a safeguard'). There are other ways to use precaution in shaping our common technological future such as foresight processes, anticipatory risk research and monitoring. Policy makers can use funding and incentive schemes for research, development and innovation that are accompanied by a strengthened emphasis on such precaution-related mechanisms (we refer to this type of exercising precaution as 'using precautionary principle as a compass' in innovation policy and development).

The use of the precautionary principle as a safeguard is an approach for policy and regulation to respond to improved anticipation of uncertain, however, potentially serious risks. In this way it links especially with the dimensions of responsiveness and reflexivity of the concept of RI.

The use of the precautionary principle as a compass is an approach that helps innovation systems to deliver improved anticipation. This interpretation of the precautionary principle links especially to the dimensions of anticipation and inclusion of the concept of RI.

The knowledge generated through the use of precautionary principle as a compass (e.g., via technology assessment, foresight processes or risk research) can help promote a timely and more broadly informed application of the precautionary principle in EU risk policy and regulation. Exercise of the precautionary principle as a compass has value, also independent of the precautionary principle formally included in policies or regulations. It can stimulate and shape 'responsible innovation', e.g. clean production, development of inherently safe chemicals as alternatives for currently used chemicals of concern, technologies supporting new ways of living that are more protecting for humans and the environment alike.

The two ways of exercising precaution can serve as important mechanisms for building capacity for anticipation and responsiveness in technology governance. They should be organized in a manner that allows to achieve also high levels of reflexivity and inclusion.

The current document provides guidance regarding the proposed two-way use of precaution by

- outlining the founding features of the idea of precaution and the application of the precautionary principle with a special focus on the relationship between precaution and innovation.
- pointing out possible ways forward in the two-way use of the precautionary principle to enhance European society's capacity to anticipate, identify and manage scientifically uncertain but plausible and potentially serious risks in technological innovation.
- pointing to existing tools and guidelines that can contribute to enhancing this capacity: by helping to build a strong basis of expertise for assessing and communicating uncertainties and for related decision-making, and by helping to include relevant input (knowledge, values, concerns) of societal actors in dealing with uncertain risks through participatory processes.

1.2 Sources of the guidance

The guidance that this document offers is based on the results of research carried out in the context of the EU-funded project entitled "REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders" (RECIPES). RECIPES supports the idea that there is no inherent contradiction between precaution and innovation, and that a prudent use of precaution can help steering innovation into societally beneficial directions.

The main sources for the guidance are the insights that were achieved through the following empirical activities. First, RECIPES carried out an extensive review of how the precautionary principle has been applied in practice at international level, EU-level and in five European countries since the year of 2000[6]. Second, RECIPES conducted nine case studies and an inter-case study analysis informed by the results of the stock-taking report and aimed at understanding and explaining the potential differences in the application of the precautionary principle depending on the topic and the context[7]. Third, RECIPES carried out a year-long stakeholder engagement process. In this process, the research team asked a range of stakeholders to identify specific needs that in their view would need to be addressed in order to assure that the application of the precautionary principle encourages innovation and promotes that precaution is a driving force in shaping and guiding innovation towards societally beneficial goals. This 'needs assessment process' was informed by the results from the stock-taking report and the case studies[8].

1.3 Structure of the guidance

The guidance document is organized in three parts. Each of them deals with one of the thematic areas that the project has identified as central to further developments in the application of the precautionary principle through the RECIPES research activities described above. The three themes are: *i)* scope of application, *ii)* organization of expertise, and *iii)* participation.

Each part offers an executive summary that highlights the major points regarding the specific theme and describes conclusions and advice from this part. The literature references are also listed separately for each part. Accordingly, the three parts can also be read as guidance documents on their own.

1.3.1 Scope of application

This part provides guidance with regard to when precautionary principle is relevant and in what ways it can be applied towards uncertain risks, in particular in relation to new technologies. It provides the basic understanding of the role of the precautionary principle which also informs the other two parts of the guidance. In particular, it points out how the

application of the precautionary principle as a legally given safeguard can be complemented by use of the precautionary principle as a policy approach and compass for directing innovation towards societally beneficial goals. It specifies that the precautionary principle used as a safeguard is an instrument that lets policy makers intervene when there are reasonable concerns that an uncertain risk will do severe damage. It offers considerations and principles that should be taken into account, underlining that standard instructions on the application of the precautionary principle are ill-advised given the advantages of a flexible use of the principle. Further, this part provides an overview of different ways through which the precautionary principle, used as a policy approach and compass, can be inserted in innovation processes.

1.3.2 Organization of expertise

This part of the guidance delves deeper into knowledge-related aspects. It highlights that well-organized and timely collection and generation of 'actionable knowledge' – on the nature of the uncertainties, the seriousness of potential adverse effects, and possible alternatives to the risk (technology, product) under scrutiny – are key for dealing informed and prudently with uncertain risks and for applying the precautionary principle prudently. The guidance sets out possible ways to broaden and strengthen the knowledge base in dealing with uncertain risks. One key advice is that policy makers and scientific expert advisors take care that the widest possible range of potentially usable knowledges are included in problem scoping and the assessment of uncertain and potentially serious risks. The pluralisation of the knowledge that is considered in regulatory risk assessment is a tool to reduce the risk of blind spots that may result from taking into account exclusively 'routine' regulatory science. The guidance points out that invoking the precautionary principle also in risk assessment (as well as problem scoping) is a safeguard against understating uncertainty and opting by default for the application of a more narrow-focused quantitative risk assessment that is not suited to deal with states of knowledge characterized by strong uncertainties and/or ignorance. Learning within and across regulatory domains, and promoting early risk research and anticipatory and foresight processes (use of precaution as a compass) are other possible ways to strengthen the knowledge base for dealing with uncertain risks that the guidance identifies. It points to a range of existing tools and guidelines which can be useful in building a broad actionable knowledge base and in assuring the quality of the knowledge.

1.3.3 Participation

This part of the guidance deals specifically with the topic of participation and specifies the value of participatory approaches in relation to precaution. It explains why participation should be inserted throughout the innovation cycle and provides considerations on how to strengthen participation in the different phases of the innovation cycle in order to inform both application of the precautionary principle as a safeguard and use of precaution as a compass. It points out in particular that participatory processes can spark dialogue that helps to identify conflicting claims of knowledge and values which is important for decision-making on precaution. More specifically, the guidance sets out what needs to be considered to reduce the likelihood of common shortcomings in designing and performing participation processes. It gives advice on how to select appropriate methods for participatory processes and to deal with questions of transparency, facilitation, and power asymmetries of participation processes. It points to a number of existing tools and guidelines which can help in dealing with related issues.

Guidance on the scope of application of the precautionary principle

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With thanks to:

The RECIPES consortium for review and feedback

Executive summary

- **The precautionary principle is an important instrument for EU law and policy**. The precautionary principle traditionally ensures that policy makers may adopt decisions in situations of scientific uncertainty.
- **The precautionary principle is a general principle of EU law, laid down in EU legislation and case law.** This implies that there are in principle no defined boundaries with regards to the question to which risks or what technologies it can be applied.
- **The precautionary principle is an open and flexible principle.** It is not and - cannot be – used as a rigid decision instrument. The principle urges policy makers to carefully reflect on the situation and the uncertainties around it but does not offer predetermined solutions. This also implies that it leaves more room for the discretionary power of policy makers than during situations of standard risk management. What the best course of action is in the case of an uncertain risk, depends highly on the context of the situation. This emphasis on prudence – and the subsequent open-endedness and flexibility – forms arguably the core strength of the principle.
- **The use of the precautionary principle however also poses challenges to policy makers.** They are expected to manoeuvre levels of uncertainty to find the right course of action in a specific situation. Meanwhile, different stakeholders might address them with varying demands and considerations. Some stakeholders fear that the precautionary principle is applied haphazardly, thereby discouraging innovation. Others are afraid that the scope of the precautionary principle will be too limited, resulting in serious harm to public health and the environment.
- **This guidance proposes a two-way use of the precautionary principle**. On the one hand, **the precautionary principle acts as a legal safeguard**, through its formal inclusion in EU policies or regulations for the authorization of products or processes. The use of the precautionary principle as a safeguard is an approach for policy and regulation to respond to improved anticipation of uncertain, however, potentially serious risks. In this way it links especially with the dimensions of responsiveness and reflexivity of the concept of Responsible Innovation.
- On the other hand, **the precautionary principle can also be used proactively as a compass** that helps policy makers guide innovation towards more societally acceptable directions. Introducing precaution into the processes of innovation will result in technologies that are better suited to the demands and values of society.
- **For the application of the precautionary principle the following elements are to be considered**: scientific uncertainty (related for instance to a lack of knowledge or a situation of ambiguity), the seriousness of the risk (a particular threshold of possible harm must be present, but EU institutions enjoy a wide discretion in the determination of the acceptable level of risk), the level of scientific analysis (a scientific examination must have been done) and the characteristics of the risks or the anticipated risks.
- **As a safeguard, the precautionary principle works as an appeal to prudence**: when there are reasonable grounds of concern and the possible damage that it could do or when an existing risk proves more harmful than first understood, the precautionary principle permits policy makers and legislators to intervene despite scientific uncertainty. It is based on the acknowledgment of the limits of science in always providing full certainty; even in this case policy makers should still be able to act, ensuring the appropriate level of protection. As such, the precautionary principle functions as a guiding principle which provides helpful criteria for

determining the best course of action in confronting situations of potential risk and scientific uncertainty on the probability of harm.

- **Precautionary action requires scientifically underpinned grounds for concern, not certainty, nor an exhaustive risk assessment**. Uncontested scientific proof of risk cannot be available in cases of uncertain risks. The EU Court of Justice re-confirmed in 2021 that *"an exhaustive risk assessment cannot be required in a situation where the precautionary principle is applied, which equates to a situation in which there is scientific uncertainty."*

- **The use of cost-benefit analysis is of limited value in cases that require the precautionary principle.** Not only the risks assessment of new products and technologies can be plagued by inconclusive evidence and uncertainties, the proclaimed benefits are often also poorly known. One cannot weigh fundamentally unknown costs against fundamentally unknown benefits without making highly speculative assumptions. If risks can be reliably quantified it is the *principle of prevention* that is applicable instead, and regulators can set an acceptable risk level and implement the risk reduction measures needed to keep the risk below the maximum acceptable level.

- **The choice who or what gets the benefit of the doubt is a policy issue and should be made explicitly.** The decision on whether precautionary action is justified in a given case needs to take into account the 'knowledge condition' (e.g. reasonable grounds for concern) and consider what is at stake, and subsequently choose which interest(s) is/are given the benefit of the doubt: environmental protection, public health, corporate interests, intergenerational justice or national economy, to name a few. Such risk management decisions need to be informed by transparent deliberation over the outcomes of the risk assessment (what is known, is unknown, can be known, cannot be known) and in consideration of wider social and economic factors, legal requirements such as a chosen level of environmental or human health protection, and policy imperatives such as Sustainable Development Goals.

- **The five phases of the application of the precautionary principle are** (1) a priory-risk reduction through anticipation, (2) early warnings, (3) assessing the situation, (4) deciding on the appropriate measures and (5) monitoring the situation. Using the precautionary principle as a compass, by anticipating possible negative side effects of new technologies, allows that harm can be avoided before it materializes. The precautionary principle as a safeguard is relevant as soon as there are reasonable grounds for concern, as well as it can benefit risk assessment processes, pointing to scientific uncertainty and knowledge gaps. Moreover, evaluation should be made as to which measures are appropriate to implement, considering what can and should be done, as well as who can and should act. Finally, there should be ways to monitor the situation once the measures have been taken.

- **The knowledge generated through the use of precautionary principle as a compass (e.g., via technology assessment, foresight processes or risk research) can help promote a timely and more broadly informed application of the precautionary principle in EU risk policy and regulation**. Exercise of the precautionary principle as a compass has value, also independent of the precautionary principle formally included in policies or regulations. It can stimulate 'responsible innovation', e.g. technologies supporting new ways of living that are more protecting for humans and the environment alike.

- **The precautionary principle can be used as a compass for policy makers and legislators to guide innovation towards more societally desirable directions**: it can be understood as an ethical responsibility, that can guide policy makers and legislators into innovation pathways that protect the society from possible harm. Introducing precaution in the process of innovation can lead to technologies that are

better suited to the demands and values of society, in line with Responsible Innovation. Using the precautionary principle in innovation implies a broadening of innovation in two ways: making space for the societal and environmental aspects of the technology besides only the technical, scientific and economic ones, and anticipating how the technology will function in society.

- **The use of the precautionary principle as a compass is an approach that helps innovation systems to deliver improved anticipation**. This interpretation of the precautionary principle links especially to the dimensions of anticipation and inclusion of the concept of RI.

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1 Introduction

This guidance informs EU policy makers, scientific advisers and legislators about the scope of application of the precautionary principle. It is based on the research from the Horizon2020 project RECIPES and part of a series of three guidances. The other two guidances focus on 'Organization and production of expertise' and 'Participation'.

1.1 The need for this guidance

The precautionary principle is an important instrument for EU law and policy. However, it is sometimes not clear when the principle is relevant and in what ways it can be applied. It is a persistent myth that the Europe suffers from excessive precaution. RECIPES' case studies, along with previous case studies on the application of the precautionary principle in Europe and elsewhere, demonstrate that precautionary interventions tend to be too late and to fall short of adequately reducing occurrence of harm to human health and the environment. This guidance proceeds from this observation and seeks to identify barriers to precautionary action and to suggest some ways of overcoming them.

Emerging developments in science and industry only strengthen the urgency for more guidance about the scope of application of the precautionary principle. New technologies provide ever more possibilities to alter the world in more detailed, bigger and lasting ways. Aspects of our surroundings that were thought to be unchangeable, have increasingly become modifiable. Through nanotechnology some of the smallest physical building blocks can be influenced. Biotechnology provides new ways to recreate and transform life. Developments in information sciences, neuroscience and behavioural sciences make even human thought, conduct and reasoning subject to possible technological control. And the discipline of geo-engineering promises interventions that can affect the Earth as a whole. Moreover, while in the past human action could only affect the people nearby and within the short-term, new technological developments often give the ability to harm not only existing individuals but also future generations and humanity as a whole[9].

New technologies offer all kinds of possibilities to solve important societal issues. Medical technology for instance has done a lot to reduce human suffering and improve well-being. The increased power by means of technology however also demands responsibility, as power exercised thoughtlessly often turns out to be destructive, power in the hands of a few tends to serve the goals of the few and power that remains unchecked often turns out to be corrupted. The past shows us that scientific and technological progress is not necessarily accompanied by human or environmental progress. In the context of the increasing transgression of planetary boundaries, in many cases because of (unsustainable) technologies, the need for government to take responsibility grows urgent.

This guidance subsequently answers to an urgent need for more guidance on when and in what ways the precautionary principle can be applied towards new technologies. This will hopefully ensure a swifter and more effective use of the principle within EU innovation policy.

1.2 Outline of guidance

This document consists of three parts. The first part is about when the precautionary principle is relevant. This can help policy makers and legislators recognize when this principle, and, for instance, not the prevention principle, is relevant. This part is useful for all policy makers and legislators that deal with the precautionary principle in the context of technologies that are accompanied by uncertain risks, but also useful for other stakeholders e.g., producers who apply for market authorisations.

The second part specifically describes how the precautionary principle is to be used as a safeguard; as an instrument that lets policy makers and legislators intervene when there are reasonable concerns that an uncertain risk will do severe damage. It contains considerations and principles that should be taken into account. This part is useful for policy makers and legislators that (possibly) have to intervene in situations of uncertain risks.

The third part is specifically concerned with the use of the precautionary principle as a compass. It gives an overview of the different ways through which the precautionary principle should be applied. Applying the precautionary principle as a compass has a potential to shape and (re)direct innovation pathways in such a way that the new technologies and products are designed to be inherently safe, compatible with a circular economy and cleanly produced.

2 When to apply the precautionary principle

2.1 The precautionary principle in short

The precautionary principle guides policy makers faced with uncertain risks and public concerns of a technology. The principle is based on the acknowledgement of the limits of science in providing conclusive evidence, i.e., the impossibility of full certainty.

The principle essentially becomes relevant when standard risk management procedures do not suffice because of a situation of uncertainty about the risk. When a risk poses a threat to human health or the environment, but the risk is difficult to assess scientifically, policy makers should still be able to act.

The precautionary principle was first developed in the early 1970s, as a legal principle in domestic law in Germany (the so-called 'Vorsorgeprinzip'), Switzerland and Sweden[10]. This 'Vorsorgeprinzip' was introduced as part of a policy for taking care of nature and the environment at a time when limitations of scientific understanding over environmental change became apparent[11]. In the early 1980s, references to precaution, the precautionary principle or to a precautionary approach found their way into the international setting[12] and the principle was codified for the first time in 1992 in Principle 15 of the non-binding Rio Declaration on Environment and Development[13]. In that same year, the precautionary principle was introduced in what is now called the Treaty of the Functioning of the European Union, in Article 191.

Today, a universally accepted definition of 'the' precautionary principle does not exist and we observe that different versions and interpretations of the precautionary principle are used at international, European and national level.

2.2 The place of the precautionary principle within the EU

Within the EU, the precautionary principle is considered to be a general principle of EU law, laid down in EU Treaty, legislation and case law. This implies that there are no defined boundaries with regard to what uncertain risks or technologies it can be applied.

Principles of EU Law are legal principles that – in contrast to a rule or a policy – are open-ended in character, not applied in an all-or-nothing approach,[iii] and do not dictate a particular outcome. Principles can, in contrast to policies or approaches, also be legally binding and form the basis of specifically formulated rules. For instance, the precautionary principle explicitly underpins EU's Regulation of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The rules in this Regulation, stipulating a registration and authorisation procedure, have in part been established on the basis of the fact that the EU recognizes the precautionary principle as a guiding standard.[iv]

Considering the invocation of the precautionary principle, it is important to distinguish between applying the precautionary principle in the context of EU regulation and existing

[iii] This means that a rule in general always applies when particular clearly defined criteria are met. Principles on the other hand are only invoked after due consideration for which sufficient or necessary criteria are less easily definable.

[iv] "To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention" (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ L 396, 30.12.2006*, recital 69).

national laws (for instance, in the context of REACH), and the political decision to invoke the precautionary principle for a particular subject matter before any regulation or law is available[14].

In the first case, the action required from the application of the precautionary principle depends on the formulation of the principle in the specific legal act. For example, EU food safety legislation has expressly defined the precautionary principle for application in that sector. EU secondary environmental legislation however provides no equivalent definition, though as we have noted above, the Treaty on the Functioning of the European Union (TFEU) directly refers to the precautionary principle as a basis for EU environmental policy. This has left the precautionary principle open to interpretation within each individual environmental policy area.

Its flexibility and open-endedness are arguably one of the strengths of the precautionary principle[15]. This also means that there is no clear rule for when and how the principle should be applied. This has to be dealt with on a case-by-case basis. However, based on previous applications of the principle, legal literature and the outcomes of the RECIPES project, several general guidelines become visible for when the precautionary principle is relevant.

2.3 Guidelines for when the precautionary principle is relevant

Precautionary action means adopting risk management measures that reduce the probability - or remove the possibility - that the harm can occur, and/or reduce the magnitude of the harm, would it occur[v]. The precautionary principle has been criticised by some for being 'vague' about which knowledge condition (scientific uncertainty about possible harm) triggers its consideration. It is, however, evident that the term scientific uncertainty cannot be defined and fixed with any degree of generality. What grounds for concern can trigger risk management measures in a specific case of uncertain risk? This is a key variable of the different understandings and definitions of the precautionary principle[16]. In practice, precautionary interventions can be applied when the possibility of occurrence of harm is considered 'plausible', or when there are 'reasonable grounds for concern' regarding the potential harm of a substance, technology, process or intervention.

The following reflections and clarifications can help when dealing with the key question above.

The basic triggers for the application of the precautionary principle are the seriousness of the harm and the scientific uncertainty around it[17]. The potential consequences of a risk is what matters more than the probability of occurrence. It is not the level of probability that triggers application of the precautionary principle but the existence of tenable and scientifically underpinned grounds for concern. In other words, the precautionary principle is not about hypothetical risks, neither about well-known risks where the probability of harm can be reliably quantified. The latter class of risks is the domain of the principle of prevention and regulators can set an acceptable risk level and implement the preventative risk reduction measures needed to keep the risk below an agreed maximum acceptable level. In the case of risks that require the precautionary principle, the 'need for some kind of plausibility 'proof' of a threat of harm must therefore not run to demanding conclusive evidence of this threat of harm to justify precautionary action. In a recent judgment of the EU Court of Justice on the precautionary principle, the Court indeed endorsed that *"an exhaustive risk assessment cannot be required in a situation where the precautionary principle is applied, which equates to a situation in which there is scientific uncertainty"* [18]

[v] It is important to note that precautionary action does not automatically imply the implementation of bans (provisional or otherwise). There is a wide variety of regulatory measures that could be applied (See Renn O., and Dreyer, M. (2009). *Food Safety Governance*, Springer, pp. 80-81).

We will now further elaborate on four elements that are useful to consider when one thinks of applying the precautionary principle:

- Scientific uncertainty (2.3.1)
- The seriousness of the risk (2.3.2)
- The level of scientific analysis that has been done (2.3.3)
- The character of the technology or the anticipated risks (2.3.4)

2.3.1 Scientific uncertainty

The first element to consider is that of scientific uncertainty. When a technology is accompanied by 'uncertain' risks, the knowledge required for standard assessment procedures is still lacking. The establishment of scientific certainty about a risk is important because this presupposes the possibility for the ability to manage a risk. There is no way to prepare or act in the face of harmful effects of something if one does not now (enough) what for instance the probability or the nature of the effects will be.

Scientific uncertainty may mean different things in different situations, as different situations demand different types and amount of knowledge (see also RECIPES Guidance on The Organization and Production of Expertise). Furthermore, sometimes more knowledge will expose even more uncertainties[19].

Scientific uncertainty remains as long as there is no certainty. The search for evidence never stops and evolves in the light of scientific and technological progress. One should not forget that the absence of evidence of risk is not the evidence of the absence of risk. Scientific uncertainty can be related to:

- A lack of data or inadequate models of risk assessment.
- Being the result of a form of indeterminacy, when not all the factors influencing the causal chains are known.
- When there is ambiguity or contradicting data/opinions.
- Because certain risks are still unknown, which often is labelled as 'unknown unknowns', boiling down to border with ignorance.

During most risk assessments a large and diverse body evidence has to be assessed. Often the quality of just 'one' piece of evidence does not suffice to attain scientific certainty about the risks in question. For instance: though there may be evidence that a new material is less toxic than previously assumed, if there remains significant unclarity about the possibilities of bioaccumulation, scientific uncertainty about the situation as a whole is still relevant. It is therefore important to not reduce the risk assessment to single pieces of evidence, but to look at the situation as a whole (see: Guidance on organisation of expertise).

Box 1: Causes for scientific uncertainty

Scientific uncertainty can have multiple causes[20]:

- There simply might not have been enough time to gather sufficient empirical evidence or develop theories to adequately assess the nature, seriousness or the probability of the risks. For instance, with regard to some new nanotechnology applications the precise effects on human health are still unclear.
- No research has yet been undertaken to study the effects of a technology. Scientific certainty may even have been wilfully obstructed because of private interests, as has been the case of the risks of the chemical DDT.
- Certainty about risks are 'inherently' impossible difficult to assess adequately. The use of gene drives for instance might for instance have effects on ecosystems worldwide. The interconnectedness of such ecosystems with other ecosystems and social-systems, such as agricultural systems, makes the risks of this technology inherently difficult to estimate.
- No clarity or consensus exists yet about the acceptability of a risk. The application of biotechnology to humans for instance brings up ethical discussions. A careful public debate is required before a standard risk assessment procedure can be established.
- There is an absence of applicable risk management or risk governance procedures. When the nature and the probability of a risk are known, but it is not known how to deal with it, there still exists fundamental uncertainty since the effects would be irreversible and uncontrollable.

2.3.2 Seriousness of the risk

A second element to consider is the seriousness of the risk. The precautionary principle is not applied to just any type of uncertain risk. A particular threshold of possible harm must be at issue. It is however difficult and even ill-advised to qualify rigid thresholds completely beforehand. In some cases there can emerge new insights with regards to what types of harm are acceptable and new forms of harm or new exposure pathways can be discovered when knowledge about risks advances. Moreover, the acceptability of the harm can also be related to the extent that it is, for instance, deemed unnecessary or easily preventable.

As described in section 1.2, the precautionary principle is only mentioned in the Treaty on the Functioning of the European Union in relation to the protection of the environment. In practice the scope is broader[21] and the principle can be invoked in every situation where there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the level of protection chosen for the EU[22]. EU institutions do moreover enjoy a broad discretion, in relation to the determination of the level of risk deemed unacceptable for society[23].

This broad discretion should however not lead to a situation where 'all-risks' are to be avoided at all costs. Moreover, it can be important to contrast the risks concerned with the situation of 'doing nothing'. For instance: uncertain risks related to the development of a vaccine might be justifiable in the case of a growing pandemic. (Though it should be noted that, for instance, a lack of regulatory approval is also accompanied by risks related to distrust of the public). In any case it is important to explicate on what grounds and considerations a risk is deemed sufficiently serious in a specific case. In this way companies also know what to expect when developing an innovation.

2.3.3 Some form of scientific analysis

Thirdly, the precautionary principle is not intended to apply to hypothetical effects or imaginary risks, and it should be based on a scientific examination of the issue[24].All legal formulations of the precautionary principle include a knowledge condition, i.e. the tenability of the grounds for concern that justify application. The UNESCO 2005 report stated for instance that the judgement of plausibility of the grounds for concern should be grounded in scientific analysis, it cannot be a fantasy or wild speculation[25]. The European Commission's 2000 Communication on the precautionary principle states 'reasonable grounds for concern' as a prerequisite for the adoption of 'provisional risk management measures'[26]. This leaves room for interpretation, and European stakeholders have expressed somewhat opposing interpretations in the current debate about the role of precaution in innovation.

It is indeed difficult to qualify this further, as this is highly dependent on the context of the situation. Notably, in the case of early warnings science scientists have often not yet been able to do an analysis. The precautionary principle may trigger the need for such an analysis. In other words, it may very well make sense to acknowledge the precautionary principle and scientific uncertainty in the risk assessment phase, not limiting the principle to risk management. The guidance on social organisation of expertise discusses this insight and its implications in more detail.

It should also be stressed that the 'seriousness' of the expected damage should be taken into account in this case. When the expected damage is deemed enormous, the need for a detailed and extensive scientific analysis should be less strict.

2.3.4 The characteristics of the risks and risk anticipation

The fourth element to consider is the characteristics of the risks or the anticipated risks. Though it can depend on the context of the situation whether the precautionary principle is relevant, previous cases in which the principle was applied have some similarities:

- Novelty
  First of all, the precautionary principle is often applied to technologies that are relatively new and which are subsequently often accompanied by unknown effects. This was for instance the case with biotechnology and the first generations of nuclear power plants. This is not surprising since technological applications that are merely slight adjustments of existing technologies are less often characterized by uncertainties. To the extent that they are similar to older technologies, the way to measure their (possible) harm has already been examined as well as the best measures to take against their harms.

- Knowledge
  The precautionary principle can be used also in cases of technologies that are not new, but present a new state of knowledge that requires reconsideration of possible risks. For instance, glyphosate was at the beginning considered relatively safe to use and was marketed since the 1970s, but subsequently new information and studies questioned its safety; because of the potential impacts on the health and the environment, the precautionary principle hence applies.

- Systems
  The precautionary principle is also often used in the context of technologies that pose systemic risks. Their negative effect is often not merely demarcated by a specific incidence, but tends to affect a whole system or even multiple (interlinked) systems. In many cases these are ecosystems, in some cases these are systems that are (indirectly) affected by the disruption of public health. Characteristic in this regard is the fact that such risks often can spread or 'spill over'. This makes them less easy to contain and control. An example of this are neonics (neonicotinoids).

The use of this class of neuro-active insecticides has been identified as one of several key factors that have been contributing to the observed sharp world-wide declines in pollinator diversity and abundance over the past decades.

- Dependencies
  Another reoccurring aspect is that the technologies in question specifically disrupt systems on which humans are dependent. Their disruption often poses risks in relation to things that humans need to survive in the long run. A prime example of this are the different services that ecosystems provide, like food, purification of air and water, and flood regulation. This can however also relate to social systems. Some people for instance argue that the precautionary principle should be applied in the context of the use of AI in healthcare to the extent that people are considerably dependent on the sustainability of the healthcare system.

- Vulnerability
  Another aspect that is often at play in the context of the precautionary principle is that of vulnerability. Precaution is especially relevant in relation to systems that do not have the ability to recover or 'defend' themselves. This may both apply to, for instance, natural systems, and overlooked social groups. These are not only vulnerable in the sense that they are less able to physically protect themselves, but also in the sense they often have less means to let their interests be known. Vulnerability in this sense logically requires a cautionary approach.

- Irreversibility
  The precautionary principle is often applied in the context of irreversible effects. The irreversibility of effects intrinsically poses difficulties for control as it prevents going back to the known and secure situation. Irreversibility is especially an issue in relation to the rights of future generations. Instigating irreversible negative consequences, for instance through introducing polluting and non-circular technologies, by definition diminishes the freedom of future generations. Irreversible negative effects are especially problematic in the context of finite resources. For instance, making use of the limited stock of oil worldwide for airplane-fuel not only leads to irreversible global warming effects, the same oil can subsequently possibly not be used again as a source to kickstart or transition more new sustainable technologies and industries.

We will now turn to the question how the precautionary principle can be used as a safeguard.

3 The precautionary principle as a safeguard

The precautionary principle traditionally serves as a legally given safeguard that gives policy makers the necessary space to intervene when there are reasonable concerns that an uncertain risk will do severe damage. The principle allows them to act prudently despite scientific uncertainty in the case of reasonable concerns, for instance through (temporarily) banning a technology. To ensure the chosen level of protection in the EU policy makers are even obliged to make use of this safeguard.

The principle however does not offer predetermined solutions. It is essentially an appeal to prudence. Policy makers should always carefully think for themselves about which precautionary measures are appropriate in a particular situation. Nevertheless, the following checklist presents some considerations and principles that are often relevant in the context of the application of the precautionary principle. Please note that these considerations may, at times, be at odds with each other and need to be weighed and selected carefully when applied.'

We distinguish five phases in the application of the precautionary principle:

1. A priori risk reduction through anticipation of possible risks before market introduction
2. Early warnings become strong enough to reach the policy agenda
3. Assessing the situation
4. Deciding on the appropriate measures
5. Monitoring the situation

We will discuss the considerations and principles in relation to the precautionary principle in order of these five phases.

Box 2: General preconditions for precautionary governance

It is important to note that the precautionary principle can only serve its function when a variety of other institutional requirements are met. Precautionary action can only be taken to the extent that relevant knowledge about new uncertain risks reaches the relevant authorities (see also: guidance 'Organization and production of expertise'). To guarantee this, there needs to exist a certain degree of transparency, openness and trust inside the research and development community, and for instance room for whistle-blowers and criticism.

Researchers need to be able to communicate freely about (possible) new risks, and authorities have to be able to examine such warnings independent of political or private interests. Furthermore, there needs to be a certain degree of accountability with regard to communicating such risks when necessary. This also requires clarity about such responsibilities and the burden of proof. Industry actors for instance have to know what is expected from them with regard to reporting and examining on early warnings.

Of primary importance in this regard is also the research culture. When researchers and innovators are driven by a 'move fast and break things'-approach and (financially) incentivized to bring a new product as fast on the market as possible, they are less inclined to take into account precaution and signal early warnings. Research programmes which for instance have sustainability as an aim of their programme, as is the case with the missions of the new Horizon Programme, may have a more intrinsic incentive for being precautious.

3.1 A priori risk reduction before market introduction

If the precautionary principle only comes into play *after* the market introduction of new products and technologies and after early warning signals of unanticipated impacts have become strong enough to reach the policy agenda, harm is done that could have been avoided. In the literature on the precautionary principle, this is referred to as *culpable ignorance*). When precautionary thinking and systematic anticipation of possible negative side effects would steer and shape the innovation trajectory when new technologies are still on the drawing table, harm can be avoided before it materializes. As such, the use of the precautionary principle as a compass marks a shift from *a posteriori* control (after early warnings have reached the policy agenda) to the level of *a priori* risk management (inherently safe/clean technologies). It also means that lock-in on particular technologies should be avoided. To that end, Europe should strive for nurturing a diverse plurality of competing technologies that can perform the same function (e.g. energy supply, transport, food packaging, telecommunication, or infectious disease control). Such alternatives should be developed in parallel such that if one technology, product or substance turns out to bring unforeseen harm, a safer alternative can rapidly replace it. Investment in sufficient redundancy and diversification of technologies is essential for achieving a resilient society that can rapidly respond and adapt when early warnings of unacceptable side effects of innovations emerge.

3.2 Early warnings

As soon as reasonable grounds for concern are expressed, the precautionary principle will become relevant. Already in the case of such early warnings there ideally should already be responsibility with regard to examining them. There can be a duty for decision-makers to investigate.

3.3 Assessing the situation

When there are indications that there are reasonable grounds for concern, it becomes necessary to assess the situation into more detail. This is the moment when there is a need for a risk assessment, even though risk may not be ascertained. To the extent that the situation allows, a scientific analysis is done and as much evidence is collected as possible. The EC Communication[27] established the precautionary principle as a principle relevant for risk regulation, specifically risk management. However, the precautionary principle may benefit risk assessment processes as well, pointing to scientific uncertainty and knowledge gaps (see also Guidance on the organisation of knowledge and expertise).

The precautionary principle requires to take into account the following considerations, also in risk assessment:

- Inclusiveness: include all actors that may be relevant for getting a full picture of the threat (see: Guidance on participation and Guidance on expertise).
- Independence: be aware of the different interests of the parties that deliver information. If a party has a substantial interest in the assessment of the situation, it can be better to let an independent party do it.
- Carefulness: Different types of risks and different technologies require different standards and methods of risks assessment. (see: Guidance on organisation of knowledge and expertise).

When the risks can be reliably characterized and quantified, the principle of prevention should be invoked. The principle of prevention is referred to in the Treaty of the Functioning of the EU that states that policy on the environment in the Union shall (also) be based on the principle that preventive action should be taken[28].

3.3.1 Choose who/what gets the benefit of the doubt

The decision on whether precautionary action is justified in a given case needs to take into account the 'knowledge condition' (e.g. reasonable grounds for concern) and subsequently choose which interest(s) is/are given the benefit of the doubt: environmental protection, public health, corporate interests, intergenerational justice or national economy, to name a few. Ultimately such decisions are taken on normative and political grounds and are therefore primarily risk management decisions. The decision needs to be informed by transparent deliberation over the outcomes of the risk assessment (what is known, is unknown, can be known, cannot be known) and in consideration of wider social and economic factors (e.g. proclaimed benefits of which there also can be inconclusive evidence and uncertainties – societal needs, quality of life factors, etc.), legal requirements such as a chosen level of environmental or human health protection, and policy imperatives such as Sustainable Development Goals. How to address wider social considerations may already be defined in problem scoping and as part of the risk assessment policy. Examples are the question of what weight should be placed on present versus future risks, or to risks to especially vulnerable groups versus risks to the general public. In order to strive to lower the general risk level and avoid precautionary action itself having serious adverse consequences, the decision on what kind of precautionary action is required needs to consider risk offsetting, the pros and cons of different precautionary measures and the availability of alternatives for the regulated product or technology.

3.4 Deciding the measures that are appropriate

Once the relevance of the precautionary principle and the need to take action has been established, one has to assess which measures are the most appropriate to take. At least the following considerations are relevant:

What can be done? First of all, once the situation asks for precautionary measures it is useful to make an overview of the actions that are possible. At the least the following measures can in principle be taken:

- Prohibit the technology: a first option is to completely ban the technology in question. Such a ban can however also be specified in terms of time and conditions. For example, banned until the safety of the product has been assessed with certainty. In the case of a moratorium, an indication should be given about the evidence that is necessary to lift a ban. It is however sometimes difficult to ever acquire certainty in the case of biological systems due to their complexity. For instance, the use of Bisphenol A has been limited in the EU to protect health and environment because of its hazardous properties; it has been banned in infant feeding bottles since 2011 and in plastic bottles and packaging containing food for infants and children under 3 years old since 2018 with Regulation 2018/213[29].
- Limited admission of the technology: Another option would be to allow for limited admission of the technology in question. For instance, in terms of:
- *Product:* Some neonics have for instance been banned for certain applications, while others have not (yet).
- *Area:* some risks can be clearly limited to their application in a particular area. In some cases, like wind turbines, there are for instance reasonable concerns for the disruptive effects of noise pollution for the natural behaviour of animals, and thereby of their disruptive consequences. These risks do not apply when such technologies are not placed near a nature reserve.
- *Users:* Some uncertain risks are, especially in the case of health-risks, limited to specific groups of people. Prohibition of a product could in that sense be limited to, for instance, children, the elderly or the more vulnerable.
- *Usage:* finally, some uncertain risks are clearly related to their specific usage. In the case of PFAS-chemicals a distinction is sometimes made by jurists between non-essential use (not essential for the functioning of society), substitutable use (essential but substitutable by safer chemicals) and essential use (and no suitable alternative exists)[30].
- Adjustment of the technology: Another option is the demand that the manufacturer of the technology adjusts it in such a way that the uncertain risks are resolved. Examples of this are kill switches in biotechnology or removing the chemical that is causing the risks from a substance.
- Extra safety measures: In the case of nanotechnology, the precautionary principle for instance led to specific legislation in consumer product areas. Food consisting of engineered nanomaterials should according to the EU Novel Foods Regulation[31] for instance be assessed using the most up-to-date test methods to assess their safety and specific methods applicable to them may be needed[32].
- Scientific Development: The application of the precautionary principle (also) leads to more research into the risks. As long as there is scientific uncertainty, research is conducted until scientific uncertainty disappears and scientific certainty is established.

- Reversal of the burden of proof: The European Commission is of the opinion that with prior approval mechanisms, the burden of proof is placed on the manufacturer. Whilst in absence of such mechanisms, this should not be the general rule; but may be ad hoc the case[33].

What should be done? After it has been established what the options are, the question is what should be done. Relevant considerations to take into account are the following:

- The relevant legal framework: depending on the risk and technology in question, different (regional) laws may be applicable.
- The policy framework: On top of the legislation, policies might have been developed that can guide the decision.
- The experience from earlier examples and solutions: it might be wise to look at similar cases to assess which measures are appropriate and effective, being mindful that uncertain risks (and their potential solutions) are difficult to compare.

Moreover, the following **principles and considerations** can play a role in deciding on what should be done[34]:

- Legality: measures may not transgress existing laws.
- Non-discrimination is a general principle of EU law providing that similar situations must not be treated differently unless there are objective reasons for doing so. For instance, the adoption of restrictive measures justified by the precautionary principle for the protection of public health cannot create discriminatory treatment between companies[35]. Non-discrimination can also be triggered by the inconsistency of measures adopted under the precautionary principle. For example, when EU countries adopt differentiated measures for the protection of human health, they might discriminate between national and non-national EU citizens[36].
- Consistency*:* the measures should, if possible, ideally be consistent with measures already taken. This ensures a sufficient level of legal certainty. It should however be noted that inconsistencies in the application of the precautionary principle are deemed to arrive due to the specificity of different situations. Changes in the legal norms and the knowledge about a new technology can offer new insights into the measures that are necessary. One should thus be very reserved inferring general rules of consistency based on earlier measures.
- Subsidiarity*:* The EU attaches importance to the principle of subsidiarity. This means that decisions are retained by Member States if the intervention of the European Union is not necessary. However, when a product is in development across the whole EU it might be advised to impose EU wide measures. This depends on the extent that the EU has competence over the domain in question.
- Checks and balances: When it comes to the types of risks that the precautionary principle is concerned with, it is important that there exists a clear division of responsibility, accountability and oversight in relation to the measures taken. When the independence and quality of assessments by industry is doubted, it is better to make an independent, disinterested actor responsible for this.
- Impact assessment: When the precautionary principle is invoked, an impact assessment should be applied to set out the necessary elements for the exercise of the principle. It is important to note that uncertain situations are difficult to assess through the means of e.g., a cost benefit analysis, and thus the impact assessments should be carried out with modesty. This is because one cannot weigh fundamentally unknown costs against fundamentally unknown benefits without making highly speculative assumptions[37].

- According to the EU Court, impact assessments need to be carried out to ascertain that a given measure is necessary and appropriate for the pursuit of a legitimate aim[38]. The EU Court also argues that the formal requirements of such an impact assessment are moderate[39]. It would not be sensible to argue that all precautionary interventions must prove that the benefits of a precautionary intervention outweigh the costs, as this is often impossible to sufficiently make clear in the case of scientific uncertainty.
- The EU courts have defined the principle of proportionality as requiring that measures are appropriate, suitable and should not go beyond what is necessary to achieve the objectives pursued[40]. Notably, this can be difficult to assess in the case of uncertain risks[41].
- When health is at stake, the European Court of Justice allowed competent authorities wide discretionary power to decide, on the basis of the 'scientific risk assessment', 'which measures appear to it to be appropriate and necessary to prevent the risk from materialising'[42]. The EU Court also stated that 'a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management'[43].
- The Commission defines this as 'comparing the overall cost to the EU of action and lack of action, in both the short and long term. Also emphasized is that this is not simply an economic cost-benefit analysis and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. An examination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible[44]. Other points that are useful to take into account during the cost-benefit analysis are:
- The fact that many benefits of innovations are in themselves also accompanied by significant uncertainty.
- That there may be alternative technologies or innovation pathways that provide the same benefits, but do not carry (the same) risks.
- Be aware that some measures can lead to regrettable substitution. For instance, while phthalates are strictly regulated and even banned for some products, a complete ban of phthalates could result in industry using other chemicals that are less known and perhaps even more harmful.

Who can act? In principle, the precautionary principle is directed at public authorities. Moreover, it depends on the measures that need to be taken, but in general this comes down to an interaction between public authorities who issue for example that a ban, regulatory agencies that adjust their admission procedures or a public research institute that is assigned to further examine a particular risk and also particular companies that are required to adjust their technological development or are made responsible to deliver the burden of proof for the safety of the technology.

3.5 Monitoring the situation

Once the appropriate measures have been taken, there should ideally be a way through which the need and effect of the measures are monitored.

- Measures should ideally be subject to review, in the light of new scientific data. According to the European Commission this means that 'measures based on the precautionary principle should be maintained so long as scientific information is incomplete or inconclusive, and the risk is still considered too high to be imposed on society, in view of chosen level of protection. Measures should be periodically reviewed in the light of scientific progress, and amended as necessary'[45].

- This also means that the measures should assign responsibility for producing the scientific evidence. It should be made clear what the conditions for sufficient scientific evidence are, and which parties or methods are capable and/or reliable in providing it in the future.

4 The precautionary principle as a compass

The precautionary principle can also be used proactively as a compass that helps policy makers guide innovation towards more societally acceptable directions. Introducing precaution into the processes of innovation will result in technologies that are better suited to the demands and values of society.

This section gives an introduction in the different ways through which the precautionary principle can shape and (re)direct innovation processes towards inherently safe, clean and sustainable production, consumption and technologies. This makes it possible to pro-actively anticipate on the uncertain risks of emerging technologies and adjust these technologies by making them more safe before they enter the market. This is especially useful for policy makers concerned with R&D-programmes of which there are reasonable grounds that the end product could do serious harm when it is implemented or implemented on a wide scale.

4.1 The precautionary principle and responsible innovation

Applying the precautionary principle in shaping and (re)directing innovation processes, basically implies a broadening of the scope of the precautionary principle. This approach connects to four dimensions that Stilgoe et al.[46] connect to Responsible Innovation:

- Anticipation: "Anticipation involves systematic thinking aimed at increasing resilience, while revealing new opportunities for innovation and the shaping of agendas for socially-robust risk research"[47].
- Reflexivity: "Reflexivity, at the level of institutional practice, means holding a mirror up to one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held"[48].
- Inclusion: Inclusion could mean taking the time to involve different stakeholders as to lay bare the different impacts of a new technology on different communities.
- Responsiveness: "Responsible innovation requires a capacity to change shape or direction in response to stakeholder and public values and changing circumstances"[49].

4.2 Examples of good practices

Examples of good practices[50] that adhere to this are:

- Involving societal stakeholders in the design of the technology
- Safety-by-design: this means the prevention of risks through strengthening safety as design factor in research and innovation of materials, products and processes.
- Constructive Technology Assessment: this means involving different stakeholders in the assessment of the future risks of a new technology
- Financially incentivise low-risk innovation pathways
- Supporting technologies and supply chains that are modifiable, adjustable, repairable and circular as to increase responsiveness. This decreases the chance that design choices in technology are irreversible.

5 Conclusion

This guidance informed EU policy makers, scientific advisers and legislators about the **scope of application** of the precautionary principle.

In particular, this guidance proposed a **two-way use of the precautionary principle**.

On the one hand, the precautionary principle acts as a **legal safeguard**, through its formal inclusion in EU policies or regulations for the authorization of products or processes. The use of the precautionary principle as a safeguard is an approach for policy makers to respond to improved anticipation of uncertain, however, potentially serious risks. In this way it links especially with the dimensions of responsiveness and reflexivity of the concept of RRI and RI.

On the other hand, the precautionary principle can also be used proactively as a **compass** that helps policy makers guide innovation towards more societally acceptable directions. Introducing precaution into the processes of innovation will result in technologies that are better suited to the demands and values of society.

This guidance moreover offered considerations and principles that should be taken into account, underlining that standard instructions on the application of the precautionary principle are ill-advised given the advantages of a flexible use of the principle.

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Guidance on the organisation and production of expertise for precaution in risk regulation and innovation policy

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With thanks to:

The RECIPES consortium for review and feedback

Joy Burrough-Boenisch for linguistic and stylistic improvements

Executive summary

- **The precautionary principle works best in a double role: safeguard and compass.** As a legal principle and safeguard, it can justify early policy or regulatory action to manage uncertain risks. As a compass in research and innovation, the precautionary principle triggers upstream debates about, and research on, the potential impacts of emerging technologies and related innovation pathways. Through this double role, the precautionary principle enhances the EU's capacity to anticipate, identify and proactively manage scientifically uncertain but plausible and potentially serious risks and contributes to (re)directing science and technology to societally beneficial ends.
- **Risk assessment, technology assessment and innovation policies and funding need to be well-informed by the precautionary principle** such that situations that require consideration of the precautionary principle can be detected more adequately and more timely and such that new technologies become less likely to bring new risks. Well-organised and timely collection and generation of ***actionable knowledge*** is key for dealing prudently with uncertain risks. Actionable knowledge for the precautionary principle is knowledge on the severity and nature of potential adverse effects, the nature of the uncertainties on the risks and on the proclaimed benefits, explicit articulation of knowledge gaps or risks and benefits, and knowledge on possible alternatives to the risky technology, or product under scrutiny.
- **Pluralization of expert knowledge in scientific assessment** is essential to assure that science advice for policy (risk management and innovation governance) is in line with best available evidence and considers all relevant scientific issues and knowledges. It should be ensured that as much relevant knowledge and experience as possible is brought to bear on decision-making about uncertain risks. This requires a transdisciplinary approach where not only scientific experts from multiple disciplines but also other knowledge-holders (e.g., workers, consumers, beekeepers or local people) are asked to contribute their specific knowledge regarding the likely consequences of the particular technology under scrutiny that may carry uncertain risks.
- **The EU needs develop good practice and build capacity regarding how actionable knowledge for precaution can best be fruitfully pluralised**. Identifying and mobilising relevant knowledge-holders and working within a diversity of ways of knowing in the co-creation of actionable knowledge for informing the application of the precautionary principle can be challenging. To pursue pluralisation while attending to power requires preventing corporate capture or misinformation campaigners slipping into spaces of co-creation.
- **Explicit and transparent problem scoping in risk assessment** is essential to ensure that the right questions are addressed, relevant aspects and dimensions of the issue are not overlooked, and problem boundaries in the assessment of the uncertain risks are set wide enough to include the concerns of those affected by the risks and the risk regulation.
- **Policy makers should require that risk assessment includes systematic and transparent appraisal of scientific uncertainties, knowledge gaps and ignorance**. An informed application of the precautionary principle requires that assessment authorities identify and characterise the concrete nature of the limitedness or even absence of scientific knowledge (known unknowns and data gaps) in a given case and communicate the uncertainties and conclusions about the plausibility of possible adverse effects to non-specialists too, such as policy makers and risk managers.

- **There is room to reform the regulatory system to become agile enough to learn continuously and be permeable enough that externally produced knowledge can influence and modify routinised assessment processes**. It should consider a wide range of potentially relevant aspects of risks, including non-standardized so-called "endpoints" of the risk assessment. Risks that in retrospect required precautionary action were persistently overlooked as a result of blind spots in the risk assessment protocols and guidance documents used by European Agencies. Knowledge about risks that do not fit in these protocols (mostly academic scientific studies published in the peer-reviewed literature) is often downplayed, marginalised or ignored. Too often, it is necessary that coalitions of concerned scientists and societal actors step in and 'break the script' of routinised assessment and management processes in order to recognise key uncertainties and the potential for serious harm to human and environmental health.
- **Limited learning and information sharing across regulatory domains weakens the system's overall capacity to identify, understand and manage plausible threats.** Ongoing reforms towards a holistic approach to chemical authorisation and regulation at the EU level ('one chemical, one assessment') could lead to improved outcomes. Steps must be taken to ensure that efforts to streamline research and assessment methodologies across agencies and issue areas do not create new blind spots.
- **Regrettable substitution tends to arise from a lack of foresight and non-contextual, substance-centric thinking.** The potential for incremental learning through repeated assessments of similar substances may be a strength and not a weakness.
- **Early risk research and anticipatory and foresight processes in risk and innovation governance** is a cornerstone in responsible (RI). RI obliges researchers to remain sensitive to the plausible social and ecological impacts in on-going research and development processes, and in the development of emergent and potentially future-shaping technologies. From an RI perspective, the precautionary principle is essential to help ensure responsive, adaptive and integrated management of the innovation process.
- **The search for less harmful and ecologically more sustainable alternatives needs to inform the broader array of public and private research and innovation infrastructures** (e.g., research and education funding). The EU should target its substantial legal and financial capacity towards the definition of more ecologically sustainable and, more generally speaking, societally beneficial innovation pathways. Both the use of the precautionary principle as a safeguard and as a compass can contribute to technologies, innovation, and lifestyles that do less harm to humans and the environment. It is important that knowledge collection and generation of the two ways of using the precautionary principle are well interlinked and the results from both processes acknowledged as forming a body of actionable knowledge.

List of boxes

1 Introduction

The purpose of this document is to provide guidance on how to broaden and strengthen the knowledge on which the application of the precautionary principle is based. As shown in part I on Scope of Application of the RECIPES guidance the guidance relates to:

- the application of the precautionary principle as a legal principle and safeguard, justifying early policy or regulatory action, and
- the use of the precautionary principle as a policy approach and compass in research and innovation, triggering upstream debates about and research on emerging technologies (or existing technologies considered safe until demonstrated otherwise) and related innovation pathways.

Both ways of using the precautionary principle are important to enhance European society's capacity to anticipate, identify and manage scientifically uncertain but plausible and potentially serious risks and thereby contribute to directing (or redirecting) science and technology to societally beneficial ends.

1.1 The need for this guidance

The precautionary principle enables decision makers to deal prudently with uncertain risks and act to proactively protect human health and the environment when there are scientifically underpinned grounds for concern that these are at stake. That the precautionary principle is about dealing with uncertain risks[vi] does not mean that risk-related knowledge is of little relevance in the principle's application. To the contrary, well-organised and timely collection and generation of knowledge – on the nature of the uncertainties, the severity of potential adverse effects, and possible alternatives to the risk under scrutiny – are key for dealing prudently with uncertain risks.

In the wake of the emerging notion of an 'innovation principle' at the European level[51], there have been fierce debates among EU-level stakeholders about the quality of the knowledge basis of using the precautionary principle in EU risk regulation. In these debates, grave doubts have been expressed about using regulatory science. Large parts of the chemical, pharmaceutical and biotech industry sectors have called for safeguards against regulatory science that, according to them, bows to political pressure, which leads to politicised risk assessments, over-precaution, and stifling of innovation. An opposite view has been expressed by various civil society organisations that have called for safeguards against corporate capture of regulatory science that leads to industry-friendly risk assessments, under-precaution, and missed opportunities of stimulating, directing or re-directing innovation towards societally beneficial outcomes. These controversies show that the knowledge basis on which the precautionary principle is applied (or not applied) in EU risk regulation, often referred to as 'regulatory science', is a political issue. In the scientific literature, regulatory science has been scrutinised critically in relation to the application of the precautionary principle. One of the conclusions from this critical reflection is that precautionary measures are frequently taken too late and often in a restrictive and piecemeal fashion[vii]. Another is that management of uncertain threats may result in

vi We use the term 'risk' to encompass two types of risk: threats for which it is possible to confidently quantify the magnitude of a defined and agreed range of outcomes and also the probabilities of these outcomes (simply 'risk' or 'routine risk'), and threats for which this is not possible ('uncertain risks').

vii The Late Lessons from Early Warning reports from the European Environment Agency together analyse 34 case studies where long delays between early warnings and regulatory action led to huge error costs. Haunting examples are the case of asbestos, lead in petrol, and mad cow disease (EEA, 2001; EEA, 2013).

regrettable substitution (**see Box 6**). To overcome these issues, it is necessary to recognise that the precautionary principle has important implications for the organisation of risk assessment processes. As will be made clear, it requires a risk assessment practice that is geared towards the identification of scientifically uncertain but plausible threats to protected values. Against this background, this document provides orientation and inspiration regarding the following questions:

- How could the production of 'actionable knowledge' be organised in ways that improve the timely identification of scientifically uncertain but plausible and potentially serious risks and improve their management?
- How could the credibility and transparency of the processes of producing regulatory knowledge for decisions on whether to apply the precautionary principle be improved?

In this document, **actionable knowledge** for the precautionary principle is knowledge on the severity and nature of potential adverse effects, the nature of the uncertainties on the risks and on the proclaimed benefits, explicit articulation of knowledge gaps regarding risks and benefits, and knowledge on possible alternatives to the risky technology, or product under scrutiny. Actionable knowledge includes regulatory knowledge[viii] but is not limited to knowledge relevant for risk assessment or risk management. Moreover, it includes knowledge that may help proactively shape technology and innovation pathways towards a high level of human health and environmental protection.

1.2 Outline of the guidance

The next chapter (Chapter 2) deals with the implications of the precautionary principle for **risk assessment processes** in Europe. The chapter highlights four features of any risk governance regime that are fundamental to ensuring that timely and precautionary actions can be taken. Society needs to be assured that the right questions are being asked, that the right knowledge-holders are involved in answering these to the best of their ability, and that the processes are geared to achieving the systematic identification and appraisal of scientific and other uncertainties and their potential consequences. Moreover, key uncertainties must be communicated in a way that makes it possible to hold policymakers accountable for failures to address plausible threats to human health and the environment. These questions are matters of scoping, knowledge pluralisation, uncertainty appraisal and uncertainty communication[ix].

Chapter 3 then provides some suggestions for **ways forward** to strengthen and broaden the knowledge base for using the precautionary principle in EU risk regulation and for exercising precaution in technology development and innovation policy. Amongst other things, it shows that the use of the precautionary principle as a compass, via risk research or foresight processes for example, ideally at an early stage of technology development, can inform the application of the precautionary principle in an upcoming or existing regulatory arena. It highlights that the value of the use of the precautionary principle as a compass is not exhausted in informing the application of the precautionary principle. Rather, it is another way – beyond formally including the precautionary principle in EU policies or regulations – to shape our common technological future. It can help capture early warnings and help European societies towards more sustainable innovation trajectories.

viii Regulatory knowledge may include diverse forms or bits of knowledge relevant to risk assessment and to informing decisions on whether to adopt precautionary measures in a regulatory arena.

ix Matters of knowledge pluralisation and uncertainty communication are also explored in the guidance on participation.

2 Fundamental issues relating to the knowledge for precaution

In order for assessment processes to enable societies to take precautionary action against plausible harm, society needs to be assured that these processes are capable and intended to identify risks that are plausible, even though scientifically uncertain. If the precautionary principle is a tool for risk management only, then its usefulness would be sorely weakened if the guidelines and protocols used by European agencies to generate knowledge that informs managerial decisions do not adequately address sources of uncertainty. That would substantially compromise Europe's capacity to detect and act upon early warnings of threats that are yet to be completely understood. As demonstrated by RECIPES's case studies, and previous work on the application of the precautionary principle in Europe and elsewhere[52], assessment regimes often fail to account for uncertainties, ignorance and knowledge gaps. Indeed, they tend to emphasise the features of given problems that are most amenable to standardisation, protocolisation and control[53].

It seems that parts of the European risk governance regime are currently premised on an ignorance of known sources of uncertainty about potentially serious and deleterious impacts on protected values. Hence, the impact assessments produced by the regime cannot in themselves give impetus to precautionary interventions because they do not mention plausible threats, to insect biodiversity, for example. Even though uncertainties (especially unquantifiable ones) are often excluded from the scope of assessment processes, precautionary interventions cannot be precluded. Risk assessment procedures will often fail to account for all relevant aspects of the issue at hand, which increases the probability that routine risk assessment fails to detect situations that require consideration of the precautionary principle. For this reason, the broader risk governance regime needs to be open to knowledge claims from the outside (see Chapter 3 for details).

The shortcomings of applying the precautionary principle highlighted in case studies in the scientific literature and stakeholders' publicly expressed doubts about the trustworthiness and legitimacy of regulatory science show the importance of subjecting the science and knowledge underlying the application of the precautionary principle to transparent quality assurance. Transparency has been awarded the status of a cornerstone in the EU's concept of good governance[x]. By transparency of quality assurance, we mean that those responsible for applying the precautionary principle in EU risk regulation (the use of the precautionary principle as a safeguard) specify in publicly available documentation the provisions taken to assure the credibility and social robustness of the science and knowledge basis used in risk governance.

In the following sections, we highlight four features of any risk governance regime that are fundamental to ensuring that precautionary actions can be taken if there is no external interference. Society needs to be assured that (1) the right questions are being asked, that (2) the right knowledge-holders are involved in answering these to the best of their ability, (3) that the processes are intended to systematically identify and appraise scientific and other uncertainties and their implications, and that (4) these are communicated in a way that makes it possible to hold policymakers accountable for failures to address threats to human health and the environment. These questions are matters of scoping (Section 2.1),

[x] The European Commission's 2001 White Paper on European Governance prescribes with regard to the principle of openness, that EC institutions 'should work in a more open manner' and 'actively communicate about what the EU does and the decisions it takes'. The white paper stresses that openness and transparency are particularly important 'whenever the Union is required to apply the precautionary principle and play its role in **risk assessment and risk management'** (European Commission, 2001).

knowledge pluralisation (Section 2.2) and uncertainty appraisal and uncertainty communication (Section 2.3).

2.1 Problem scoping to avoid addressing the wrong problem

Which uncertain risks and aspects of an uncertain risk are considered relevant to include in a risk assessment and which knowledge gaps or blind spots result from the choices made, depends on the scoping of the risk problem. During problem scoping, the risk to be scrutinised is broadly framed and defined, and the range and types of (plausible) effects, the knowledge needed about them, and the experts who will supply this knowledge are identified. Scoping delimits the system used to investigate the risk in the assessment, as well as the procedures necessary for this examination. Explicit problem scoping requires well-informed judgements (**see Box 1**)

Box 1: Judgements relating to risk assessment policy[54]

- The kinds of impact deemed to be within the scope o f the assessment, and those that are outside it;
- The kinds of evidence that should be included and those that should be discounted;
- How to interpret the available evidence;
- How to respond to uncertainties, and;
- How much of different kinds of evidence would be necessary or sufficient to sustain different types of judgement (e.g. that precautionary action is needed)

In practice, it is untenable to make a distinction between a purely scientific upstream risk assessment phase followed by a downstream risk management phase. Scientific and socio-political factors are intertwined throughout the assessment and management of risk. Scoping of a risk problem is often an implicit and informal process in European risk governance and regulatory practice, and it is difficult to ascertain whether it is part of risk assessment, risk management, or both. There are good reasons for scoping to be an **explicit process and a risk governance step in its own right that includes both risk assessors and risk managers**. One reason is that this can help ensure that scientific expert advisors address the right questions, i.e., those that are relevant to the overall goals of policymaking and the needs of risk management and that resonate with the concerns of those affected by the risks and the risk regulation.

Problem scoping organised as an explicit and interactive process can also help ensure that expert scientific advisors address the right questions in the right manner. Policymakers and scientific experts, and, depending on the case, also relevant stakeholders (see part III on Participation of the RECIPES guidance) should engage in dialogue with the purpose of defining the risks and scientific uncertainties that need to be addressed in assessment. This can include, for instance, a participatory bottom-up process to elicit from stakeholders' rival hypotheses on the causal relations underlying a risk and rival risk assessments.[55]

With regard to problem scoping, EU policy makers and agencies can demonstrate quality assurance in the science and knowledge basis of the application of the precautionary principle by documenting the procedures and outcome of explicit problem-scoping processes. This can include, for instance, documentation[xi] that:

[xi] Transparent documentation of problem scoping can also help prevent unjustified accusations of a 'politicisation' of risk assessments.

- Problem scoping allows for interaction and deliberation between risk assessors and risk managers, and, if relevant, also stakeholders.
- Problem scoping is not reduced to defining questions for assessing measurable risk but is sensitive to uncertainties and ignorance that need to be treated differently from risks that can be confidently quantified in the assessment process.
- Review mechanisms for problem scoping are have been used where appropriate, e.g., in response to new scientific findings or stakeholder debates. A typical question to be posed during review is whether a current problem definition (for instance, expressed as a health risk) is so narrow that salient features of the problem have been left out (such as uncertain environmental impact) or, alternatively, that the definition is too broad (for instance, expressed as a general health risk) after specific aspects of a given problem have been solved (providing evidence, for instance, that there is health risk only for especially vulnerable individuals).

2.2 Pluralisation of expert knowledge in assessment

European-level guidelines on procedures for assuring the quality of scientific advice for policy makers and society highlight that the group of scientific expert advisors as a whole need to have 'the full range of expertise required for the topic'[56]. The same applies to risk-related expert advice provided by regulatory agencies such as the European Food Safety Authority (EFSA) or the European Chemicals Agency (ECHA). Including the 'full range of expertise' can assure that scientific reports 'are in line with best available evidence and consider all relevant scientific issues and knowledge'[57]. A plurality of disciplinary perspectives can moreover 'act as a check-and-balance procedure to test disciplinary presumptions and norms that may themselves introduce unintended bias'[58].

When informing decisions on risks and innovation it is critically important that systematic and experiential knowledge is included in the diversity and plurality of expertise applied in the assessment. In addition to scientists, the persons who may be asked to contribute their specific knowledge on the likely consequences of the particular technology under scrutiny that may carry uncertain risks may include relevant stakeholders (e.g., workers, consumers, beekeepers or local residents)[59] (see part III on Participation of the RECIPES guidance). It is of particular importance to include a plurality of perspectives and forms of expertise in the scoping process to reduce the likelihood, that important aspects of the issue are overlooked. Case study analyses have highlighted blind spots of routine regulatory science regarding risks[60]. This calls more generally for the inclusion of a wider range of relevant knowledges and expertise (see Section 3.2).

With regard to involvement of expert knowledge, EU agencies can provide evidence of quality assurance in the science and knowledge basis by documenting the diversity of expertise included in the assessment process and any deliberate attempts to manage conflicts of interest. Here it is important to document that:

- A plurality of scientific disciplines and a diversity of scientific views (including minority views and non-routine regulatory science) have been involved in the risk assessment.
- In cases of strong uncertainty regarding risks and proclaimed benefits, the assessment also includes stakeholders and their experiential and practical knowledge.
- A conflict-of-interests policy has been applied, designed to ensure that when conflicts of interest arise, they are disclosed, acknowledged and managed[61].

2.3 Appraisal of scientific uncertainties

The precautionary principle is generally considered a way 'to address *uncertain risks*' and to 'legitimate[s] decisions and actions in situations characterized by uncertainty'[62]. The precautionary principle is essentially about uncertainty. For some time, there has been growing acknowledgement in EU risk policy of the limitations of available scientific knowledge (data, information, incomplete understanding of causal mechanisms) and of the need to take these into account when deciding on management measures. An informed application of the precautionary principle requires that assessment authorities identify and characterise the concrete nature of the limitedness or even absence of scientific knowledge (known unknowns and data gaps) in a given case and communicate the uncertainties and conclusions about the plausibility of possible adverse effects to non-specialists too, such as policy makers and risk managers.

With regard to scientific uncertainties, EU agencies can provide evidence of quality assurance in the science and knowledge basis by documenting the procedure and outcome of a systematic uncertainty assessment and communication[xii]. It is important to document that:

- All plausible sources and types of uncertainty and ignorance have been taken into account (see part I on Scope of Application of the RECIPES guidance) and different key components of uncertainty have been considered[63].
- The judgement of plausibility of possible adverse effects has been grounded in scientific analysis. Scientific assessment should be continuously updated as new knowledge becomes available and the actions chosen should be subject to periodic reviews in the light of advancing knowledge to promote learning and improve policy[64].
- Risk managers are provided with a traceable account of the evidence and uncertainties regarding adverse effects and the reasoning behind the expert judgements on the plausibility of the possible adverse effects.

[xii] For precautionary risk governance, the reflexive approach to uncertainty taken by the Netherlands Environmental Assessment Agency is widely recognised as best practice (Petersen et al., 2013). The European Food Safety Authority (EFSA) has recently undertaken steps towards formal uncertainty analyses towards requiring uncertainty analyses to be part of risk assessments and endorses such developments (EFSA, 2018). EFSA also provides guidance on communication of uncertainty (EFSA, 2019). This approach is, however, narrower in scope (excludes known and unknown unknowns) and is more suitable for the prevention principle (all uncertainty is quantifiable), whereas the Netherlands approach better matches the precautionary principle (substantial unquantifiable uncertainties and known unknowns).

3 Ways forward to strengthen the knowledge basis for precaution in risk regulation and innovation policy

In order to help develop safe and sustainable technologies and products, consideration should be given to broadening and strengthening the knowledge base used when applying the precautionary principle as a safeguard in regulation and when using it as a compass in technology development and innovation policy. These considerations should be discussed in a structured and transparent manner at EU and national levels at the science–policy–society nexus in order to inform current debates about precaution and innovation.

The question which '**grounds for concern**' can trigger consideration of the precautionary principle (the so-called 'knowledge condition') cannot be generalised and needs to be judged **case by case**. The reason for this is that novel ways of causing harm and surprises that may accompany new products and technologies may not fit a universally applicable closed definition of the knowledge condition that justifies precautionary action. In order to be compatible with the precautionary principle, the assessment of risks must reflect on and systematically consider the knowledge condition of the precautionary principle. The assessment process must aim to identify the plausible possible harm that could be caused to protected values (e.g., human health or the environment). Even if they are barred from advising decision-makers to take precautionary measures, assessors must be able to indicate in clear and understandable language the presence of knowledge conditions that trigger the precautionary principle and should systematically search for this (i.e., applying the precautionary principle requires an anticipatory approach to risk assessment). The assessment procedures used when applying the precautionary principle must be very sensitive to identifying plausible threats, as the price of overlooking them can be very high.

The application of the precautionary principle requires a **scientific risk assessment**, even if, by comparison with a 'standard' quantitative risk assessment, this is incomplete. The results of the scientific assessment should show what is known, what is not known and what can be known about the risk in terms of hazard (inherent properties in the activity or substance that could lead to adverse effects), exposure and magnitude (or seriousness) of potential effects. Analysis of the evidence of hazard, exposure and magnitude needs to be complemented by an analysis of uncertainty. Several possible ways forward for broadening and strengthening the science and knowledge base are highlighted below.

3.1 Extending the scope of risk assessment

Box 2 lists several ways to ensure in assessment that as much pertinent knowledge and experience as possible is brought to bear on decision-making about uncertain risks. Such provisions help ensure that the assessment of uncertain risks is based on the **required depth and forms of knowledge**. Precaution is often defined as a risk management principle applied after scientific assessment takes place[xiii]. However, invoking the precautionary principle in risk assessment too (as well as in problem scoping) safeguards against understating uncertainty and opting by default for the application of a more narrowly focused quantitative risk assessment that is unsuited to dealing with states of knowledge characterised by strong uncertainties and/or ignorance.[xiv] The **overall process**

[xiii] The European Commission's Communication on the Precautionary Principle describes the principle as particularly relevant to risk management; the Communication does not explicitly negate a relevance for risk assessment (European Commission, 2000).

[xiv] In the risk governance literature, it has also been found that from a legal point of view nothing precludes that the risk assessment stage has to be carried out in accordance with the obligations stemming from the precautionary principle (Vos & Wendler, 2009).

of risk governance should be precautionary in the sense that throughout it is sensitive to uncertainties and knowledge gaps and to potentially serious harm.

Box 2: Heuristic device to guide assessment of uncertain risks[65]

- Extend the scope of assessment to include *additive and cumulative exposure and synergistic effects*, if the causal connections are not well understood and cannot be modelled with a high degree of confidence; set priorities on the effects of greatest scientific and political concern.
- Address aspects of possible limitations of standard regulatory science and the need to also draw on knowledge from non-standardized studies and engage with non-standard knowledge holders by gathering evidence of potential effects and uncertainty from *as diverse an array of disciplines (e.g. observational studies, toxicological studies, ecological assessment, modelling and monitoring) and other knowledge holders (e.g. consumers, workers, beekeepers, local residents)* at the outset of assessment, in order to elicit the pertinent prioritisation, conceptualisation and interpretation of the different questions that may arise from the scientific data and the comprehensive exploration of the resulting sensitivities.
- Systematically examine the potential adverse effects of the innovative or established technologies or products presenting the uncertain risk in question at the *earliest stages* in the innovation process, before firm financial and institutional commitments are made.
- Subject to the terms of reference, make a detailed and balanced comparison of contending merits and drawbacks of a series of *alternatives* (functional equivalents) to the technologies or products under scrutiny.
- Focus explicitly on the extent to which the technologies or products under scrutiny display properties of *flexibility*, *adaptability*, *reversibility* and *diversity* – all of which offer different ways of hedging against exposure to any residual ignorance that has not been addressed by the other elements of the assessment.
- Shift the *burden of persuasion*, so that it is those wishing to implement the technology or product in question who must acquire relevant data and sustain an argument of the acceptability of the associated risk, subject to an appropriate level of proof.

3.2 Being open to emerging knowledge and 'non-standard' knowledge in risk assessment and science for policy

As indicated in Section 2.2, the 'actionable knowledge' bases should include the widest possible range of potentially usable knowledges.[66] Actionable knowledge is knowledge that can inform decision-making and action. It requires identification of the circumstances favourable for desirable outcome or for averting an undesirable outcome. In the context of great uncertainty and controversy (whether scientific or socio-political), science cannot be expected to speak with one voice and multiple tenable scientific perspectives need to be included.[67] Below, we outline some different types of 'non-standardised' knowledges relevant for risk assessments and science for innovation policy more broadly.

3.2.1 Why risk assessment must be open to 'non-standard' knowledge

In risk assessments of technologies and innovations, 'regulatory science' is essential[68] [xv]. In practice, however, there is a tendency to prioritise and rely more heavily on evidence from industry-sponsored studies conducted according to standardised and internationally validated test guidelines, than on evidence from scientific studies conducted independently and stringently peer-reviewed before publication in scholarly journals.

However, regulatory science may contain **blind spots**, and has in many cases led to risks being overlooked[69]. The case of the re-evaluation of neonicotinoids in the EU is illustrative of how different bodies of knowledge were taken into account, and how this enabled precautionary measures to be considered (**see Box 3**). It is therefore strongly recommended to consider including a **broader knowledge base** (one that includes knowledge from 'non-standardized' studies and involves non-standard knowledge holders) in risk assessment.[xvi]

Box 3: Pluralisation of knowledge in the regulation of neonicotinoids (plant protection products)[70]

In 2013 and 2018 the EU restricted, respectively further restricted the use of a group of 3 neonicotinoids together. The banning of a group of active substances from the same chemical family is highly exceptional in pesticide regulation. Previously, pesticides whose unacceptable impacts were only discovered after they had come onto the market had been phased out one by one. Sublethal effects of pesticides were the key to understanding how neonicotinoids impact pollinators. Knowledge about sublethal effects is not routinely produced because European agencies knowledge is generated by using strict protocols that follow a reductionist approach. These protocols reduce the complex reality of risks to acute risks and to balancing risks against benefits. They are characterised by substance-centric thinking in which:

- The focus is predominantly on acute toxicity measured in standardised lab experiments.
- Safety knowledge is combined with economic or use knowledge such as the efficacy and practical value as a plant protection tool, which is balanced against the knowledge on the hazards to non-target organisms.
- The regulatory knowledge is substance–centred. This implies that it is unlikely that knowledge about a family of chemicals with similar mode of action and their joint overall impact on the environment and non-target species will be produced when European agencies adhere strictly to their protocols. Historic cases have shown that the only way to expose the risks

[xv] In this document, **regulatory science** refers to forms or bits of knowledge that are pivotal in institutionalised risk assessment (e.g., toxicological risk assessment) because they are defined in statutory standards or guidelines. They are authorised and standardised forms of knowledge (e.g., knowledge from high-dose animal testing) which play a central role in informing the adoption of policy measures (e.g., authorisation of chemicals), and, more specifically, in informing the application or non-application of the precautionary principle in a regulatory arena.

[xvi] In this document, ***non-standard knowledge*** refers to potentially diverse forms or bits of knowledge relevant for risk assessment and for informing the application or non-application of the precautionary principle and the adoption of policy measures in a regulatory arena. Relevant knowledge is diverse and besides standardised forms of systematic knowledge may include **non-standardised forms of systematic knowledge**, practical knowledge and experiential knowledge.

concealed in the blind spots of these protocols is to step in and break the script.

In the neonicotinoid case, alternative regulatory knowledge emerged because academic researchers, beekeepers, NGOs and politicians advocating environmental action formed a coalition that managed to intervene in the regulatory space. This reconfigured the regulatory space to include new actors and many more sources and forms of knowledge.

This pluralisation of the knowledge that is considered in regulatory risk appraisal remedied the blind spots of routine regulatory science for low–dose chronic and sublethal effects, which in turn enabled the ban. Key factors enabling this were that academic researchers did not shy away from contributing their knowledge to the bureaucracies involved, despite this being an uphill struggle. They brought key knowledge from academic research on neonicotinoids directly to expert agencies across Europe such as EFSA and EEA and to national and European policy makers. Second, researchers teamed up with beekeepers who were associated with public interest groups. Journalists stepped up their coverage and specialised NGOs teamed up with academic scientists to make their actions evidence-informed.

Together, this created the momentum that ultimately led to the inclusion of a broader range of scientific evidence. This, in turn, made it possible to recognise the unacceptable harm to pollinators of normal authorised use of neonicotinoids. This externally forced inclusion of a wider range of scientific evidence in the regulatory science enabled the exceptional imposition of a ban on a group of chemicals. This turned upside down the routine, closed functioning of the regulatory space and the production of a standard regulatory science that structurally disregards low-dose and chronic, sublethal effects of pesticides. Unfortunately, the process did not lead to durable changes in the authorisation procedure for pesticides in Europe. It is therefore highly likely that routine regulatory science will continue to have serious blind spots in detecting risks to pollinators posed by existing and new pesticides. It also implies a continued need for academic scientists to be socially responsible and engage in coalitions with other societal actors to help bring excluded knowledge and early warning signals to the attention of the regulators and policy makers.

A further lesson from the ongoing debates on Europe's pesticide regulation and the protection of pollinators is that the precautionary principle can be undermined in practice if it is replaced by a limited set of **overly specific protection goals**. In the domain of plant protection products, the last decade has witnessed a prolonged and contentious process of formulating a precise definition of 'acceptable harm' to pollinators. In their current form, the so-called Specific Protection Goals (SPG) assume that pesticide-induced pollinator losses are acceptable if they are within the bounds of bees' 'natural' background mortality.

The formulation of specific protection goals, it is argued, is necessary for the design and implementation of environmental risk assessments. The problem with the ongoing process of establishing EFSA's new 'Bee Guidance',[71] is that it is not entirely clear what the general protection goal is. When the general goal of avoiding 'unacceptable harm to pollinators' is changed into 'unacceptable harm to honeybees' (a managed pollinator that is not representative for wild pollinators) and this is expressed as an acceptable range of pesticide-induced honeybee mortality, in effect the two protection goals (general and specific) collapse. Does specifying an acceptable range of honeybee losses mean that the precautionary principle can no longer apply to pesticide-induced pollinator losses? It seems

that the bee guidance in this way conflates the precautionary principle with the **principle of prevention**.

At present, the SPG is calibrated using highly incomplete and contested data. If the general goal is to ensure that pesticides – in combination with other stressors – do not contribute to the eradication of wild pollinators, then the SPG – however it ends up being derived – cannot be said to close the door on precautionary action, either nationally or at the EU level.

3.2.2 Including the findings from academic studies in the natural sciences in regulatory science

It is increasingly acknowledged that the advances in sciences reported in peer-reviewed publications need to be better included in regulatory risk assessments. In 'A European Green Deal', the European Commission states that '... the regulatory framework will need to rapidly reflect scientific evidence on the risk posed by endocrine disruptors, hazardous chemicals in products including imports, combination effects of different chemicals and very persistent chemicals'[72]. EU legislation mandates regulatory agencies to take peer-reviewed scientific publications into consideration in risk assessments, and it has become mandatory to include a literature search and review of the available publications in the regulatory process[73]. Guidance documents for risk assessments also recommend a review of all relevant toxicity data in the risk assessment process.[74] [75] Yet, in some cases, risk assessment and management processes are critiqued for neglecting full reviews of academic studies and for not updating guidance documents often enough to reflect advances in the sciences[76]. Therefore, it seems that the contribution of non-guideline studies from peer-reviewed scientific literature to regulatory risk assessments needs to be substantially strengthened.

In the recent decision regarding the EU ban on neonicotinoids based on a post-authorisation review by the EFSA that was largely based on non-guidance academic peer-reviewed studies, the EU Court of Justice has indeed endorsed that knowledge from non-standardized studies not only *may* be used by the EFSA but *must* be used: 'account is to be taken of the best scientific and technical knowledge available'[77], and: 'in the context of the review of the approval of an active substance, the conclusion that the approval criteria laid down in Article 4 of Regulation No 1107/2009 are no longer satisfied may be based on any new knowledge, in so far as it is scientific or technical, regardless of the source or document from which it comes.'[78]

Another challenge seems to be how to interpret evidence produced through peer-reviewed studies and weigh it against guideline-compliant studies. In EFSA's 'Guidance on the use of the weight of evidence approach in scientific assessments'[79], reliability, relevance and consistency are considered the three basic considerations when weighing evidence. In environmental and health risk assessments, it is important that both the **relevance** and the **reliability** of the studies are taken into consideration, which in turn depends on the efficient integration of findings from academic research studies[80]. Risk assessments have, however, been criticised for favouring reliability (reproducibility) over relevance.[81] A reason for this may be that reliability is easier to test in 'guideline-compliant" studies, where guidelines – e.g., the OECD's Good Laboratory Practice (GLP)[xvii] – provide standardised requirements as well as recommendations for design, performance and reporting.

GLP has been criticised because it does not address the quality of the experimental set–up, nor does it address the question of statistical power. Indeed, the initial market authorisation of neonicotinoids in Europe was based on the findings of flawed field studies, because the only criterion for inclusion or exclusion was whether the study had a GLP certificate and not whether the experimental set-up was correct or whether the experiment

xvii The aim of GLP is to ensure the quality of the laboratory practices by specifying standard operational laboratory procedures and extensive requirements for data reporting.

had sufficient statistical power to prove absence of ecologically relevant effects[82]. The assessment of reliability in academic studies is much more complex than what is covered by the OECD guidelines and the GLP, and it is clearly more difficult to assess the reliability of novel research contributions[83]. Whereas academic studies are often reviewed as part of risk assessment studies, guideline compliant studies are routinely – but unduly – assigned greater weight because they are considered reliable by default[84]. However, guideline studies can still be unreliable for reasons other than those covered by the guidelines and/or may score lower on relevance, as they do not always represent the most relevant testing approaches and cannot investigate all relevant adverse effects.

By contrast, academic studies are often found to be more sensitive to **key uncertainties and emergent threats** (e.g., in the identification and evaluation of endocrine–disrupting chemicals).[85] In order to enhance the understanding and assessment of the reliability and relevance of academic studies, several more comprehensive tools and guidelines have been developed for the regulatory assessment of chemicals. **Box 4** shows a selection of such tools.

Box 4: Tools and guidelines for understanding and assessing the reliability and relevance of academic studies for chemicals regulation

SciRAP (Science in Risk Assessment and Policy): Bridging the gap between academic research and chemicals regulation and policy
A web-based reporting and evaluation resource developed to facilitate and increase the use of academic toxicity and ecotoxicity studies in regulatory assessment of chemicals. SciRAP provides criteria for the evaluation of the reliability and relevance of studies used by regulators and risk assessors. The intention is to bridge the gap between academic research and chemicals regulation and policy (compared to NUSAP, see **Box 5**, this tool deals more with internal validity than external validity): http://www.scirap.org/

Qualichem *in vivo*: Improving quality assurance of *in vivo* studies that may or may not be following standardised guidelines
An academic paper has proposed using a tool called 'Qualichem in vivo' that is designed to systematically and transparently assess the quality of in vivo studies used in chemical health risk assessment. It is intended to provide a balanced, common framework for assessing the quality of studies that may or may not be following standardised guidelines: Maxim, L., & Van der Sluijs, J. P. (2014). Qualichem *in vivo*: A tool for assessing the quality of in vivo studies and its application for Bisphenol A. *PLOS one*, 9(1), e87738. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0087738

Qualichem_epi: Improving the management of uncertainty through in-depth mapping of heterogeneity in expert judgement
An academic paper has proposed using a method called 'Qualichem_epi' for in-depth mapping of heterogeneity in expert judgement when evaluating the quality of epidemiological studies used in regulatory chemical risk assessment. The method provides an easily understandable colour-based picture of the majority and minority opinions in a scientific advisory group. Its aim is to improve the management of uncertainty by taking full account of the heterogeneity of scientists' judgements about the quality of epidemiological studies: Maxim, L., & Van der Sluijs, J. (2018). Quality of epidemiological studies: Procedural rules for uncertain science for policy, a case study on bisphenol-A. *Environmental Science & Policy*, 84, 80-87. https://www.sciencedirect.com/science/article/abs/pii/S1462901117313114

3.2.3 Diverse scientific disciplines and knowledges

As we have seen above, the regulatory system routinely privileges some ways of knowing, types of knowledge, and source of knowledge over others. Guideline–compliant research (e.g., industry studies) is often judged to be more actionable and more reliable than academic studies. Natural sciences as such do not have privileged access to decision-making processes; a narrow selection of scientific approaches does. The same process of privileging and silencing is at work in the assessment of broader societal impact too. In assessing the social impact of decision-making, contributions that give rise to seemingly clear-cut, quantitative estimates of the social and economic consequences of given policy choices, legislative actions or regulatory interventions are often privileged[86]. The work of Andy Stirling[87] and others has demonstrated that the inclusion of other perspectives tends to provide more holistic appreciation of the costs and benefits of given courses of action and can contribute to a broader policy menu. Secondly, as noted in the recent SAPEA report on science for policy[88], decision-makers should look **beyond economics** when thinking about the future.

In European science for policy advice, there has been some movement towards an appreciation of a plurality of perspectives when resolving pressing social and ecological issues. Recently, the Group of Chief Scientific Advisors to the European Commission underlined the importance of considering '... all good science from all scientific disciplines and perspectives that could contribute to the issue at hand. This includes natural sciences, engineering, medicine, social sciences and humanities'[89]. There is still much work to be done, not least in the domain of risk assessment and management.

3.2.4 Local and experience-based knowledges (extended peer communities)

Early warnings or observed effects of new technologies are crucial for initiating precautionary measures, and such warnings do not necessarily come from regulatory science or academic science. Rather, they may emerge from citizens and practitioners in the field. Non-experts, including citizens, lay-persons and/or practitioners who are close to emergent problems, may have specific local knowledges that are relevant for risk management, particularly in the identification of unrecognised threats[90]. Examples include the beekeepers who gave early warnings on the effects of neonicotinoids on bees in the early 1990s, which initiated the long process of restricting neonicotinoids in France[91]. Also illustrative is the case of Dichlordiphenyltrichlorethan (DDT), in which birdwatchers' observations and knowledges proved instrumental [92]. Other well-documented cases of official experts being proven wrong by others' knowledge or by folk knowledge that was initially silenced and ignored are the Cumbrian sheep farmers after the Chernobyl nuclear accident[93] and the citizen Lois Gibbs in the Love Canal chemical pollution scandal[94]. Relevant non-expert knowledges can also emerge from research using co-production methods including local knowledges[95] and by using 'extended peer communities'[96].

Local and experience-based knowledges may be particularly relevant in scoping and framing phases. As explained by a Norwegian physicist and philosopher[97] 'extended peer communities imply an extension of the traditional scientific community to include non-experts as well. However, this does not mean that laypeople should invade the research laboratories and carry out research. It does mean, though, that laypeople should take part in discussions of priorities, evaluation of results, and policy debates'. It is recommended that 'extended peer involvement' takes place at different decision-making stages, from informing or supporting decision-making assessment to finally evaluating the results of those assessments[98]. Guidance on participation more generally can be found in the RECIPES guidance on Participation, but **Box 5** outlines some resources concerning interpretation and valuation of the diverse and complex knowledges in participatory settings.

Box 5: Resources for interpreting and valuing different types of knowledge in participatory settings

Maxim, L. (2015). A systematic review of methods of uncertainty analysis and their applications in the assessment of chemical exposures, effects, and risks. *International Journal of Environmental Health Research*, 25(5), 522-550.

Maxim L. and Van der Sluijs, J. (2011). Quality in environmental science for policy: Assessing uncertainty as a component of policy analysis https://www.sciencedirect.com/science/article/abs/pii/S1462901111000128.

Norström, A. V., Cvitanovic, C., Löf, M. F., West, S., Wyborn, C., Balvanera, P., ... and Österblom, H. (2020). Principles for knowledge co-production in sustainability research. *Nature Sustainability*, 3(3), 182-190.

OECD (2020). Addressing societal challenges using transdisciplinary research. *OECD Science, Technology and Industry Policy Papers*, OECD Publishing, Paris, doi:10.1787/0ca0ca45-en.

Renn, O. (2015). Stakeholder and public involvement in risk governance. *International Journal of Disaster Risk Science*, 6(1), 8-20.

Tengö M. et al. (2017). Weaving knowledge systems in IPBES, CBD and beyond—lessons learned for sustainability. *Current Opinion in Environmental Sustainability*, 26, 17-25.

Van der Sluijs, J. (2017). The NUSAP Approach to Uncertainty Appraisal and Communication. In: Spash, C.L. (ed.), *Routledge Handbook of Ecological Economics: Nature and Society*. Routlegde: London, pp. 301-310. ISBN-13: 978-1138931510.

The EU needs to develop good practice and build capacity regarding how actionable knowledge for precaution can best be fruitfully pluralised. Identifying and mobilising relevant knowledge-holders and working within a diversity of ways of knowing in the co-creation of actionable knowledge for informing the application of the precautionary principle can be challenging. To pursue pluralisation while attending to power requires preventing corporate capture or misinformation campaigners slipping into spaces of co-creation.

3.3 Learning within and across regulatory domains

The European regulatory system is highly fragmented and characterised by limited contact between assessors and managers in neighbouring regulatory domains[99]. For this reason, products, substances and processes that have been recognised as harmful in one regulatory domain may nonetheless be considered tolerable within others[100]. Thus, for instance, neonicotinoids are no longer authorised for use as pesticides owing to their harmful effects on bees and other pollinators. Threatened species are nonetheless exposed to neonicotinoids because they are still authorised for use as biocides and in veterinary medicine[101].

Limited learning and information sharing across regulatory domains weakens the system's overall capacity to identify, understand and manage plausible threats[102]. Ongoing reforms towards a **holistic approach** to chemical authorisation and regulation at the EU level could lead to improved outcomes. Part of the EU's European Green Deal agenda, the proposed 'one chemical, one assessment' (OC-OA) strategy for the assessment of chemicals in Europe has the potential to reduce risk migration from regulated to un(der)regulated jurisdictions and regulatory domains. At present, the available strategy documents highlight the potential efficiency gains involved in streamlining the European assessment processes.[103] The emphasis on efficiency might be politically expedient, but regulators and decision-makers should continue to prioritise the system's overall capacity to identify and assess threats with varying degrees of scientific certainty and severity, and to learn across both individual assessment processes and different regulatory domains. Thus, for instance, steps must be taken to ensure that efforts to streamline research and assessment methodologies across agencies and issue areas do not create **new blind spots**[104]. In short, the reform process should be informed by **enhanced efficacy**, **not efficiency in a narrow sense** (cost savings).

A second, widely recognised regulatory problem is the issue of **regrettable substitution** (**see Box 6**). Regrettable substitution takes place when the imposition of controls on one harmful substance or process is replaced by an equally or even more harmful substance or process. The danger of regrettable substitution is often invoked to warn against the imposition of controls on harmful substances, processes and interventions and to warn against using the precautionary principle more generally. Risky activities, the argument goes, tend to give way to even more risky activities. It seems that regrettable substitution tends to arise from a lack of foresight and non-contextual, substance-centric thinking[105]

(see Sections 3.2 and 3.4). It can also arise from the institutional silencing of pertinent knowledge (e.g., relevant academic studies and other knowledge-holders), and from an inability to draw important lessons from previous assessment processes[106]. The aforementioned OS-OA process aims to move past substance-centric thinking towards the regulation of classes of substances, once again with an emphasis on efficiency (speedier authorisation processes with less repeated work). This could help avert some cases of regrettable substitution, but it can also lead to new vulnerabilities. Because the European regulatory system has a track record of ignoring early warning signs and of stalling in the presence of controversy, the potential for incremental learning through repeated assessments of similar substances may be a strength and not a weakness.[xviii]

Box 6: Regrettable substitution – the bisphenol-A case[107]

A prominent example of **regrettable substitution** – the introduction or adoption of chemicals that may not be safer and potentially worse - is the **bisphenol-A case**:

'The hormone-disrupting chemical bisphenol-A (BPA), has been banned for use in baby bottles and other plastic products. However, this may not have completely removed risks for consumers, because BPA may have been replaced by bisphenol-S (BPS), a similar chemical which may be even more harmful to children's health. … Substitution is occurring because BPS has similar technical properties to BPA. Although there is not full scientific certainty and evaluations are on-going, it is not unreasonable to expect that BPS may exhibit similar ED effects as BPA. In summary, manufacturers of the above-mentioned products may be taking advantage of the lack of information and the lower regulatory pressure on BPS compared to that on BPA, which may result in potentially regrettable substitution of BPA. **This is a clear example of substitution with the least regulated alternative**.'[108]

In order to work, the regulatory system must be **agile** enough to **learn** continuously and be **permeable** enough that externally produced knowledge can influence and modify routinised assessment processes. Too often, it is necessary to 'break the script' of routinised assessment and management processes in order to recognise key uncertainties and the potential for serious harm to human and environmental health. In the domain of chemical regulation, precautionary moments appear to arise on an ad-hoc basis and without fostering changes to institutionally sanctioned assessment and management protocols.[109]

3.4 Promoting early risk research and anticipatory and foresight processes in risk and innovation governance

The European regulatory system has a long history of ignoring or responding belatedly to early warning signs[110]. Failure to take timely action often stems from failure to engage in anticipatory research into early warning signs. As a result, regulators and policymakers have often failed to take timely action on identified, but poorly understood hazards and threats caused by new technologies and products[111]. Moving forward, the European polity should ensure that funding and incentive schemes for research, development and innovation are accompanied by a strengthened emphasis on **anticipatory risk research**

[xviii] The move towards the assessment and authorisation of classes is likely to raise the stakes, and will potentially lead to even more politicised, even more controversial regulatory processes.

and monitoring.[xix] The case of nanotechnologies shows that the European innovation ecosystem has come some way in appreciating not just the potential opportunities of emergent technologies, but also their potential risks (**see Box 7**).[112] Anticipation is a cornerstone in **responsible innovation** (RI)[113]. RI obliges researchers to remain sensitive to the plausible social and ecological impacts in on-going research and development processes, and in the development of emergent and potentially future-shaping technologies. From an RI perspective, precaution is essential to help ensure responsive, adaptive and integrated management of the innovation process.[xx]

Box 7: Early risk research on nanosciences and nanotechnologies

'In the Code of Conduct [for responsible nanosciences and nanotechnologies research], the principle appears in the call for risk assessment before any public funding of research (a strategy currently applied in the 7th Framework Programme for research). Rather than stifling research and innovation, the precautionary principle acts within the Code of Conduct as a focus for action, in that it calls for funding for the development of risk methodologies, the execution of risk research, and the active identification of knowledge gaps.'

Neither precaution nor anticipation can be left to science, research and development; they need to be a widely shared and a **systemic responsibility**. In the regulatory system, anticipation needs to be routinised in formal risk assessments and management processes. Thus, for instance, the decision to ban or restrict the use of a chemical (e.g., bisphenol A or neonicotinoids) should consider which substances are likely to take its place (e.g., bisphenol S or sulfloxaflor) (**see Box 7**). If likely substitutes share properties (e.g., mode of action, potential impact on human health or the environment) that informed the original ban, steps should be initiated to discourage substitution from taking place.[xxi] **Substitution**, in short, should be **informed rather than accidental**[114].

The European regulatory system has a relatively poor track record in identifying and tackling threats in the presence of scientific and political controversy.[115] Moreover, the tendency for bans and use restrictions to give rise to highly similar hazard profiles highlights weaknesses in the European approach to chemicals regulation[116]. It has long been suggested that the European regulatory system needs to move beyond the substance-centric, incremental approach to risk management, and towards a system that more effectively encourages the adoption of **safer alternatives**[117]. Although precautious and anticipatory action is often said to be at odds with innovation, regulatory forbearance on harmful or potentially harmful chemicals does not encourage innovation. To the contrary, regulatory inactivity can lead to damaging technological lock-ins. At present, substance-centric regulatory incrementalism favours equally substance-centric

xix What are the conceivable, possible, plausible and probable threats associated with nascent and emergent technologies? Which social and environmental systems, processes and practices may be threatened or disrupted by them?

xx It should be noted that concerns have been raised about the effectiveness of RI and other forms of decentred governance in disciplining and directing the overall course of science and technology (Åm, 2019). When implementing RI through funding policies, there is a risk that responsibility, ethics and anticipation will be reduced to the ticking of boxes. Many scientists and engineers in emergent technologies simply do not construe of anticipation and responsibility as their department, partly because their contributions to the emergence are frequently so minute and so diffused in large scientific-industrial innovation networks (Åm et al., 2021). Moreover, RRI has limited reach beyond publicly funded research.

xxi This could take the form of a new assessment and risk management procedure, directed at closing predictable gaps in the regulatory landscape.

incremental adaptation over much needed fundamental innovation and change[118]. Current efforts to move towards a more **class-oriented approach** to chemical assessment and management may prove helpful and can be used to spur on research on and the development of safer alternatives, whether chemical or non-chemical.

Importantly, the search for safer alternatives is not only a question of risk assessment and risk management. The search for less harmful alternatives needs to inform the broader array of public and private research and innovation infrastructures (e.g., research and education funding). The European polity should target its substantial legal and financial capacity towards the definition of more ecologically sustainable and societally beneficial innovation pathways. To achieve this, the use of the precautionary principle as a compass is essential. Technology assessment, anticipatory risk research, foresight and scenario processes can be used for **proactively engaging with uncertain risks**. Researching, acknowledging, and communicating about these risks and adjusting the technology or innovation accordingly early on is a way to support the development of new and creative ways of living that do less harm to the health of humans and the environment. In order to be able to make good use of the knowledge generated from anticipatory projects such as foresight processes, **knowledge assessment procedures** should be used or further developed (**see Box 5**). Such procedures should allow assessment of the quality of knowledge that is mobilized and used within the innovation policy process. This is especially important in areas in which scientific risk assessments contradict each other, or in the case of serious knowledge gaps[119].

Both the use of the precautionary principle as a safeguard and as a compass can contribute to technologies, innovation, and lifestyles that do less harm to humans and the environment. It is important that knowledge collection and generation of the two ways of using the precautionary principle are well interlinked and the results from both processes acknowledged as forming a body of actionable knowledge. Knowledge from risk research, for instance, can inform the application of the precautionary principle as a safeguard, while knowledge produced from the assessment of uncertain risks in risk regulation can stimulate or boost risk research and other anticipatory projects such as technology assessment or foresight processes.

3.4.1 Precaution-related knowledge for responsible innovation

Current frameworks of 'responsible innovation' attempt to build capacity for anticipation, reflexivity, inclusion, and responsiveness in the governance of science, technology and innovation[120]. Both the use of the precautionary principle as a safeguard and its use as a compass can serve as important mechanisms in this attempt.

Approaches of responsible innovation (RI) address the issue of a responsible design and governance of research and innovation processes. The idea is to transform the research and innovation systems in such a way that innovation and the science and research intended to lead to it, are more anticipatory, more reflexive, more inclusive and deliberative, and, in total, more responsive[121]. This change should make it easier to raise, discuss and respond to questions about the intended and unintended impacts of science and technology[122]. It should facilitate directing or re-directing science and technology towards societally beneficial outcomes such as sustainability goals or maintaining high levels of protection of human and environmental health. Using the precautionary principle as a safeguard is a mechanism that helps policy and regulation to **respond to improved anticipation**. Use of the precautionary principle as a compass is a mechanism that helps innovation systems to **deliver improved anticipation**. The knowledge generated by using the precautionary principle as a compass (e.g., via technology assessment, foresight processes or risk research) can help promote a timely and more broadly informed application of the precautionary principle in EU risk policy and regulation.

Use of the precautionary principle as a compass has value, even when it occurs independently from the precautionary principle formally included in policies or regulations.

It can help when proactively shaping the future in terms of collectively acting 'in the service of new and creative ways of living that do less harm to the health of humans and nature, and it can sustain the viability of the biosphere'[123]. Use of the precautionary principle as a compass can **stimulate 'responsible innovation'**, e.g., technologies supporting new ways of living that better protect humans and the environment.

In line with the idea of responsible innovation, technological development needs to be seen in the light of achieving widely supported public values. The Treaty on European Union provides such values and some normative anchor points for how to define a 'responsible' innovation in terms of positive outcomes or the right impacts of innovation. These include, for instance, sustainable development, promotion of scientific and technological advance, quality of life and a high level of protection of human health and environment, the principle of equality and the precautionary principle itself. Nonetheless, given complexities, uncertainties, and ambiguities regarding impacts, risks and benefits, what counts as 'responsible' in a concrete case in a pluralistic society is rarely self-evident, often hotly contested and needs to be deliberated by a broad range of societal actors. The precautionary principle is a tool for dealing responsibly with complexities and uncertainties in research and innovation in order to achieve **widely supported public values**[124].

3.5 Implications for scientific practice

It is important to emphasize that the use of the precautionary principle as a safeguard and compass requires some more profound changes in **scientific practice**. Action points in this regard are listed in **Box 8**. UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) has highlighted them in its 2005 report on the precautionary principle.

Box 8: The precautionary principle and implication for scientific practice[125]

- Enhance the role of **vulnerability science** by systematically searching for surprises and ways to constrain them, e.g., by learning from examples of surprises and non-linear system behaviour from the past or constructing plausible scenarios by which unlikely undesirable future events might be realised.
- Enhance the role of **systematic monitoring** of observable effects on occupational, public or ecosystem health and the role of **empirical research** into outstanding questions or anomalies in our understanding of particular hazards
- Be more **realistic about the role and potential of science in the assessment of complex risk**. Scientific and technical evidence and analysis remain essential. However – under a precautionary approach – scientific analysis is seen as a necessary but not exclusive basis for effective policy choices.
- **For sustainable development and to develop precautionary measures, build knowledge partnerships with other knowledge holders**. To meet the challenges of quality control in the assessment of complex risks, the science for policy in the face of uncertainty requires new transdisciplinary contacts and integration (internal extension of the peer community) and also new contacts with policy makers, NGOs, industry, media and the public (external extension of the peer community).
- **Ensure whistle-blowers are protected**. Vested interests and the high stakes involved in new technologies can lead to tendencies to hide uncertainties and evidence that may indicate risks because public knowledge of these risks might hamper the further competitive development of that technology. The ethics and the legal framework of whistle-blowing need more careful attention than is currently the case.

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Guidance for participatory approaches supporting the application of the precautionary principle

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With thanks to:

David Gee

René von Schomberg

Roger Strand

The RECIPES consortium for review and feedback

Executive summary

- **EU policymakers and advisory bodies can use the precautionary principle both as a safeguard and as a compass** to guide responsible innovation and thus cope with the most pressing current and future societal problems. Participatory processes need to reflect whether the precautionary principle is applied as a safeguard or as a compass.
- **Participatory processes should be implemented, aiming for the meta-criteria of fairness and competence to foster good governance and adaptive policy-learning**. In this way, an inclusive and adaptive risk governance framework supports policymakers and advisory bodies in enhancing institutional and societal risk governance towards sustainable development.
- **Conflicts of values, knowledge, and interests need to be managed better** because they contribute to inconsistent application of the precautionary principle. Results from the RECIPES project indicates that the inconsistent application of the precautionary principle results from unresolved conflicts between European stakeholders concerning values, knowledge, and interests.
- **Participatory processes can uncover and help resolve conflicts of knowledge and values and thus improve the application of the precautionary principle.** Empirical and theoretical argumentation justifies strengthened deliberative practices to further establish the science-society-policy interface and improve understanding and acceptance between stakeholders despite their varying claims of knowledge and values.
- **Fair and competent participatory processes are vital for the European Union to uphold their commitment to good risk governance.** While ongoing European deliberative activities such as the Conference on the Future of Europe or the Competence Center on Participatory and Deliberative Democracy are excellent starting points, participatory practices need to be improved further to enable policy- and decisionmakers to cope with the multiplicity of risks and uncertainties associated with the most pressing societal problems and to learn to navigate in a multi-risk world aiming for more resilient and sustainable societies.
- **Inclusive and reflexive participatory processes are essential for good governance.** Deliberative processes are useful for uncovering the plurality of public interests and enabling engagement with a wider diversity of relevant knowledge holders. Risks associated with high levels of complexity and social ambiguity require inclusive risk assessment processes and decision-making processes that consider public concerns and interests.
- **Participatory processes should meet the meta-criteria of fairness and competence.** Because participatory processes can and should take many shapes and forms, it may be difficult to assess their quality. Scholars recommend to apply the meta-criteria of fairness and competence to ensure good governance.
- **Choosing the right methodology for participatory processes relies on sound expertise with regards to deliberative methods and analysis of situational factors.** Tools like ActionCatalogue should be applied as a database of methodologies for deliberative practices. Decisionmakers must be aware of the given stage of the assessed innovation, risk governance arrangements, situational and institutional factors, the objective of stakeholder engagement, transparency of the participatory process as well as power asymmetries amongst stakeholders for choosing an appropriate method.

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Annexes

1 Introduction

This document aims to provide guidance on why and how to support the application of the precautionary principle through participatory approaches. It is aimed primarily at European Union (EU) policymakers and public authorities in the fields of risk and innovation governance.[xxii] It also addresses EU-level and European scientific institutions that are concerned with this issue.[xxiii] The contents of this document may, however, be of great interest and value to non-governmental organisations, civil society organisations, industry and businesses and other stakeholders that are participating in current debates concerning precaution and innovation.

The guidance is based on the research from the Horizon2020 project RECIPES[xxiv] and is part of a three-part series. For questions on when to apply the precautionary principle, and what to keep in mind when doing so, please refer to the document on *scope of application*. For questions specifically related to the sources of expertise and their role in the policy cycle of the precautionary principle, please refer to the document on *organization of expertise*. The three documents are connected and build on top of each other. It is therefore recommended that all three documents are read by the intended target group.

The precautionary principle is an anticipatory instrument that the EU uses to ensure that new technologies are introduced and applied in ways that do not violate fundamental EU rights, values, and principles. The EC Communication on the precautionary principle[126], presents the principle primarily as such a **safeguard** that may protect human health and the environment. In addition to this, however, the precautionary principle is applicable beyond regulatory science and the assessment and management of risks. It can be used proactively as a general policy approach and **compass** that helps decision makers to develop and promote an integrated policy for addressing grand challenges such as conserving biodiversity[127], managing climate risks[128] and responsibly developing new technologies such as synthetic biology or nanotechnology[129], especially when such challenges or technologies are associated with high levels of complexity, uncertainty, and societal controversy.[xxv]

In the European Union, the precautionary principle provides an important instrument for the management and proactive regulation of uncertain and serious threats. However, precautionary measures are frequently taken too late, and often in a restrictive and piecemeal fashion. In other instances, the management of uncertain threats may result in *societal conflict, public controversies, regulatory loopholes, and regrettable substitution*. In view of these shortcomings, it is necessary to understand the application of the precautionary principle as a continuing *learning process*. Several case study analyses[130] suggest that it is important to deal with the following question in such a learning process:

> *How could participatory processes be organised in ways that improve the management and regulation of uncertain risks, as well as reduce the likelihood of shortcomings such as those mentioned above?*

[xxii] Examples are the various Directorates-General (DGs) e.g. CLIMA, ENER, ENV, CINEA and the respective executive agencies and service departments e.g. IDEA.

[xxiii] Examples include the Group of Chief Scientific Advisors and Science Advice for Policy by European Academies (in short: SAPEA) (both part of the European Commission's Scientific Advice Mechanism, in short: SAM) and the European Federation of Academies of Sciences and Humanities (in short: ALLEA).

[xxiv] See appendix I for more information.

[xxv] The document on *scope of application* explores and further justifies the use of precaution-based policymaking as a compass that guides innovation.

The project mandate hinges on the Responsible Innovation (RI) approach, which is geared towards building effective cooperation between science and society by ensuring that innovation is always accompanied by social awareness and responsibility[131]. A constituting element of the RECIPES project is thus co-creation based on the inclusion of stakeholders for the advancement of precautionary policymaking. Through participatory workshops conducted in RECIPES, relevant stakeholders have indicated a need that concretizes the above question and the aim of this document:

"Clarity on procedures and practice of participation in decision-making e.g., in agenda setting, policy development, and innovation processes as a whole"[132] is desired. In short, stakeholder needs, academia, and empirical examples in the EU form the foundation that shapes the aim of this document.

Thus, this document aims to demonstrate why and how the application of the precautionary principle should be informed by robust knowledge and promote risk governance that is informed and contextualised by participatory processes. In the second chapter, RECIPES research and normative arguments are explored to argue that strengthened participation is essential when applying the precautionary principle. The third chapter shifts from exploring the *why* to showing *how* participatory processes may be used to improve and strengthen the application of the precautionary principle both in the role of a safeguard and that of a compass (see guidance on scope of application). The strengthened application of the precautionary principle through participation, is argued to be a useful guide for responsible innovation by helping to cope with the most pressing current and future societal problems. For such improvements to take place, meta-criteria such as fairness and competence should be upheld in participatory policymaking, thus fostering good governance and adaptive policy-learning. In short, the last chapter tangibly shows how participatory processes may be used to move toward comprehensive, inclusive, and adaptive risk governance that enhance institutional and societal risk handling[133].

Box 1: Precaution, participation, and innovation

The EU Commission acknowledges the strong link between precaution, innovation and participation as it asks for the implementation of participation in governance processes e.g. by referring to Responsible Research and Innovation (RRI) and declares "participation" one of the principles of good governance[134].

The European commitment to participatory processes in risk governance is heavily supported and called for by researchers, pointing to an evident potential contribution to improved risk governance[135]. In fact, most empirical meta-studies on the link between public participation and risk governance point to strengthened decision-making as a result of deliberation, concluding that future risk governance should be inclusive and participatory[136].

The IRGC risk governance framework illustrates such a future for risk governance practices, in which participatory processes as well as risk communication are attributed an important function. Depending on the characteristics of the risk issue and the given stage of risk governance, appropriate participatory methods may be determined[137]. This guidance integrates these notions to provide suggestions for a deliberative future risk governance.

Like the stages of risk governance, this guidance stresses the role of innovation in relation to precaution and participation. The concept of responsible innovation (RI) is a tenet of the reasoning behind this guidance. Von Schomberg[138] establishes how RI "marks the paradigm shift from a justification in purely macro-economic terms towards a justification of the purpose and direction of innovation in terms of broadly shared public values". In the last chapter of this guidance, the innovation cycle is exemplified, showing how deliberative methods can express public values.

The guidance document thus adds itself to a range of arguments that identify and call for the strong link between precaution, participation, and innovation.

2 Rationale of participatory processes in applications of the precautionary principle

In this chapter, the rationale behind participatory processes in the application of the precautionary principle is explored and the strengthening of deliberative practices is justified. The chapter approaches the rationale from two angles: (1) Lessons learned from RECIPES research and (2) theoretical and democratic arguments for strengthened participation.

2.1 Two major lessons derived from RECIPES research

The RECIPES project has facilitated a range of case studies from which common emerging themes have been identified[xxvi]. From these themes, it is suggested that conflicts around the precautionary principle often stem from controversies between claims of knowledge and claims of values. This indicates that issues regarding the precautionary principle may be relieved through greater participatory deliberations on the normative assumptions of knowledge and values.

2.1.1 Two major lessons

Based on the findings of inter-case study analysis, the present report derives the following two points relevant to the precautionary principle and its link to participation:

1. Inconsistencies in the application of the precautionary principle may be linked to conflicts over claims of knowledge, values, and interests[139]. An implicit challenge in these conflicts occurs when conflicting claims over knowledge and/or values both arise at the same time. Therefore, value conflicts and competing problem framings need to be addressed in decision-making, mainly because the articulation of values and alternative perspectives guide the selection and interpretation of evidence and help to identify decision alternatives. In other words, besides the evidence gained from scientific research, risk and uncertainty assessment, the knowledge and dialogue with stakeholders in participatory processes can contribute to a better understanding and a higher quality of the process of problem scoping at science-policy interfaces.
2. Clarifying values, knowledge, and interest conflicts is essential to improve the interaction of all actors involved. The aim of mitigating value/knowledge claims through deliberation is heavily embedded in frameworks for responsible innovation (RI). As such, RECIPES research calls for a strengthening of the RI approach, which "is critical of the dominant global economic paradigm, highlighting that there are market deficits in delivering innovations on societally desirable goals"[140]. Responsible Innovation marks the "paradigm shift from a justification in purely macro-economic terms towards a justification of the purpose and direction of innovation in terms of broadly shared public values"[141].

In short, RECIPES research first and foremost indicates that the inconsistencies in the application of the precautionary principle are linked to conflicts over claims of knowledge, values, and interests[xxvii]. It follows that such conflicts should be clarified in line with the

[xxvi] Case studies range from GMO through neonicotinoid insecticides to AI and are available via https://www.recipes-project.eu/results/analysis-case-studies

[xxvii] The distinction between knowledge and values is also among the 12 lessons cited in the European Environmental Agency Report *Late lessons from early warnings* (2013, p. 12): Lesson 8 "Ensure use of 'lay' and local knowledge, as well as relevant specialist expertise in the appraisal" and Lesson 9 "Take full account of the assumptions and values of different social groups".

basic principles of RI, accepting that innovation should be given direction (and be regulated) on a basis of broadly shared public values. Identifying such values requires carefully thought-out deliberative processes. Additionally, these conflicts must be explored and addressed through deliberation among a broad range of societal actors, in line with the basic principles of RI.

2.1.2 Linking the lessons learned with a RECIPES needs assessment

If carefully thought-out participatory practices are necessary to minimize inconsistencies in the application of the precautionary principle, the crucial questions to address in this guidance is:

> *At what stage(s) in the cycle of precaution-based policymaking are participatory processes appropriate? How does should the kind of participatory process be determined and carried out?*

These questions were reflected explicitly in RECIPES research, when a range of stakeholders were engaged to discuss the central issues (and their subsequent needs) of the application of the precautionary principle. In this needs assessment of the RECIPES project, stakeholder needs in relation to participation were clustered and named as the following themes: transparency, facilitation, asymmetries, public engagement, and public interest.

The central questions established above naturally link to the themes of facilitation and public engagement, pertaining to when and how relevant stakeholders should be involved, as well as who to select for inclusion. The themes of transparency and asymmetries delve more into the practical facilitation of participatory processes, calling for guidance on specific considerations that are required to reach fair and competent practices. Last, the need for clarity on the public interest links directly to the second main lessons learned from RECIPES research, as participatory processes inherently bear the objective of identifying broadly shared public values.

2.2 Theoretical foundations for strong participatory processes

As established above, RECIPES research clearly calls for a strengthening and improvement of participatory procedures in the application of the precautionary principle. This objective is reflected in academic literature and may be justified through normative, substantive, and instrumental argumentation. This chapter thus strengthens the message of the sub-chapter above, showing why policymakers need to move toward a framework of good governance through a strengthening of participatory methods.

Drawing on previous work by a variety of authors, Bidwell and Schweizer[142] differentiate between three main arguments for participation: (1) normative, (2) substantive and (3) instrumental:

- *Normative* arguments for participation are typically based on philosophical principles of democracy and citizenship. Participation in this sense stems from the democratic ideal that members of the public have a right to influence the decisions that affect them, the things they value and the type of knowledge they consider relevant to include in scientific assessment of the issue at hand. In this line of argument, the normative ideal of citizen engagement and empowerment is the overriding goal.
- Following *substantive* argumentation, the quality of information in a process improves through the addition of a variety of perspectives on both the cognitive and the normative dimensions of a complex issue. Inclusion of knowledge from non-experts (engagement of other knowledge-holders, including citizens) leads to better decisions. From the substantive perspective, the goal of participation is to improve outcomes by bringing a wider range of relevant knowledge into the decision-making

process, whether the knowledge is about local context, technical data, or public values and preferences. As such, strengthening participatory procedures is imperative in the approach toward good governance.

- The *instrumental* arguments emphasise that participation is used to gain more legitimacy of and acceptance for decisions and ease their implementation. Four main forms of instrumental argumentation are that participation serves: a) to gain "legitimacy or support"; b) as a way to confirm a draft decision; c) to educate both experts and the public regarding aspects of the problem where they might be ill-informed about (mutual learning process); or d) to meet legal obligations. In this sense, participation also links to a strengthened science-society-policy interface (**see box 2**), ensuring greater acceptance between these three major stakeholder groups.

Box 2: Science-Society-Policy-Interfaces for the governance of sociotechnical transformations to sustainability

Environmental research responds to an increasing demand by public and private decision makers for actionable knowledge. The growing demand for expertise reflects the extent to which policy has become evidence-informed in fields such as global warming, biodiversity, ozone depletion, air pollution, forest conservation, and sustainability policy in general, all of which are increasingly linked to issues such as food security, development and economic growth. At the same time, environmental research and policy advice also face novel challenges such as meeting the scientific credibility, delivery in time, and societal "usefulness" under scientific uncertainties and contested values and political interests.

These challenges are the starting point for research on science-society-policy-interfaces. It aims to contribute to the analysis of the design of research and assessments as well as their interactions with society. It asks what knowledge about risks, uncertainties and socio-political ambiguities of a particular issue is necessary to help to deal with the challenges?

Research at the Science-Society-Policy Interfaces has contributed to a variety of practical attempts to integrate insights into recent research and stakeholder activities, including recent intergovernmental negotiations on the IPCC reform process, the establishment of the IPBES and the Biodiversity Knowledge network. By combining scientific analysis and practical engagement, this approach tries to generate concepts, criteria and guidelines for the handling of risks under conditions of complexity, uncertainty and ambiguity[143], and by evaluating and exploring design options and procedures in fields such as water, energy and ecosystem services[144,145].

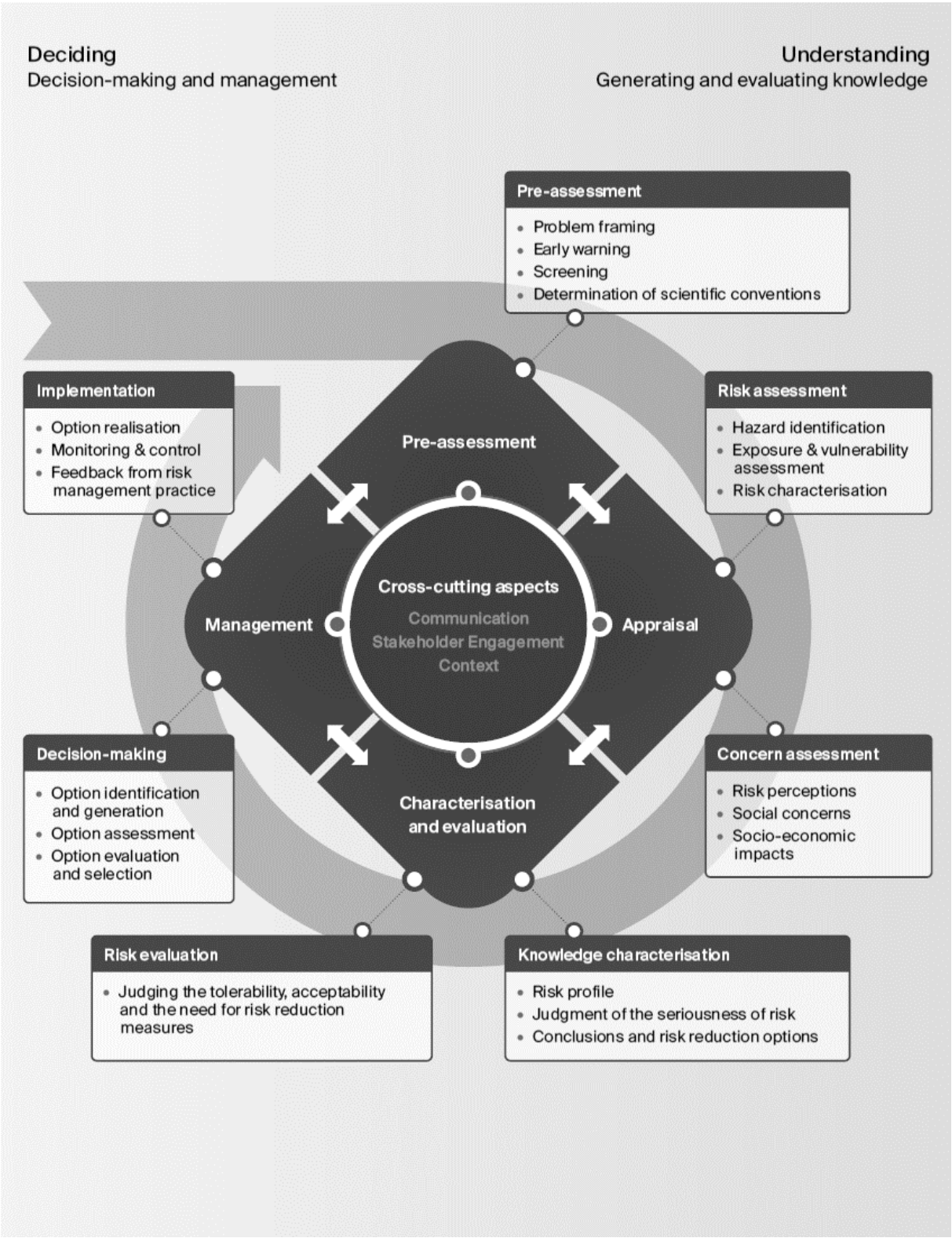
The three points of argumentation illustrate a holistic justification for participatory approaches to precaution-based policymaking. The points made above may be supplemented with a conclusion proposed by the IRGC[146] arguing that effective stakeholder involvement helps risk managers in several ways, by:

1. Providing fair, accurate and appropriate information to ensure that stakeholders are aware of the risks and benefits associated with technologies, products, activities or situations;
2. Assessing stakeholders' opinions and preferences regarding risks, risk technical assessment and risk management decisions, so that this information can be incorporated into the decision-making process;
3. Creating the conditions for informed consent, behaviour change and building public confidence in appropriate risk management decisions; and
4. Contributing to mutual understanding that helps to resolve ambiguities and conflicts about trade-offs and preferences among and between stakeholders, regulators and society.

Among the many examples in the environmental domain, the Aarhus Convention (Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters)[147], establishes that sustainable development can be achieved only through the involvement of all stakeholders and focuses on interactions between the Public and public authorities in a democratic context[148]. Following the argumentation of Bidwell & Schweizer[149], seeing the conclusion by the IRGC, and noting the European commitments such as the Aarhus Convention, participation is essential when facing uncertain and ambiguous risks. Dealing with the questions derived from RECIPES research are thus fully justified as good governance practices rely on clarifying values, knowledge and interest conflicts.

The arguments of this chapter fall in line with the three central principles of governance presented by the IRGC[150]: Communication and inclusion; integration; and reflection. It is useful to explicitly state that risk communication is a vital and ongoing part of effective risk governance. It is a cross-cutting function at the centre of the risk governance framework. It is the continuous process of sharing or exchanging risk-related information, data and knowledge among the diverse groups involved in risk governance, such as scientists, policymakers, regulators, industry, consumers and the general public. Without risk communication, there cannot truly be any successful stakeholder involvement. Effective and early communication is the key to creating long term trust in risk management when knowledge about a risk is complex, uncertain and/or ambiguous. Stakeholder involvement then goes beyond communication by ensuring that stakeholder knowledge, interests, values and worldviews are incorporated and given their due in the governance process. In addition, stakeholders are important agents for disseminating the results of the risk governance process and facilitating outreach throughout. These points are all reflected in the illustration on the next page, highlighting the most important features of good risk and uncertainty governance as developed by the IRGC.

Figure 1: The IRGC risk governance framework[151]



3 Choosing participatory methods and tools

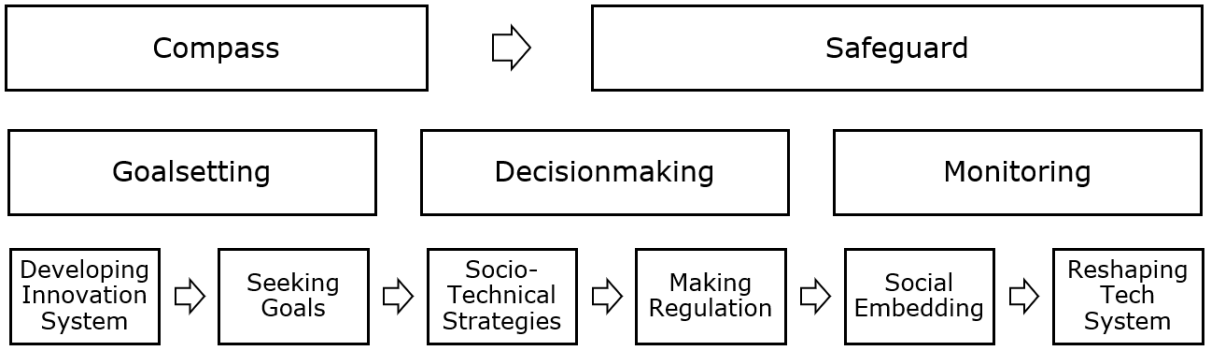
In the second chapter it was argued that the identified inconsistencies in the application of the precautionary principle are to a major extent the result of conflicting views on values and knowledge. Policymakers and regulating agencies need to assess and consider societal values, public interests and knowledge claims for evidence-informed policymaking. Public participation plays a prominent role in this regard. Results from the RECIPES project and academic literature point to participation as being the primary approach to illuminate and process claims of knowledge and claims of values. Chapter two thus already delved into central considerations that are required to improve governance procedures in the EU. In this final chapter, the previously established essential question is addressed: Which form of participation needs to be applied at what stages of precaution-based policymaking? In other words: "What are the challenges when choosing participatory methods? While there is not simple answer to this question, the chapter provides input on the five themes from the RECIPES needs assessment. The immediate need that is addressed in this chapter is that of facilitation. By considering distinct phases of innovation, we help to choose who to include and how to do so. This is further related to the precautionary approach, being either that of a guiding compass, or that of a safeguard. This last chapter thus shifts from the previous chapters' policy level of ideal risk governance and normative argumentation to a rather practical level of methodological considerations.

Strict rules may prove too inflexible in volatile situations. Guidelines for participation in general, and especially participation in risk estimation, need to be problem-oriented and adaptive to changing conditions. Participation cannot be theory-based because the outcome of practices always will be uncertain[152]. Therefore, the guidelines and tools provided in this guidance should not be applied in an arbitrary manner. Rather, they should be considered carefully as to how they may aid in ensuring greater transparency and inclusivity as well as earlier participation. This guidance takes the stakeholder need of *facilitation* and applies it as an entry point to provide concrete guidance of participatory processes at all stages of the innovation cycle. The discussion on facilitation sheds light on the stakeholder need of the *public interest* as well. From there, the topics of *public engagement*, *transparency*, and *power asymmetries* will be nuanced and discussed. These stakeholder needs are addressed in a broader manner and should thus be considered for each participatory process, regardless of the innovation phase that policymakers and regulators may be facing.

3.1 Participation in the innovation cycle

Facilitating participatory approaches to define precautionary decision-making is a difficult task. As this document emphasises, however, participation is extremely important to prioritise if the wicked problems that call for precautionary measure are to be solved. As established in the EU project *PACITA*, "Whenever societal decision making is disconnected from the perspectives of those that feel its consequences in the daily lives, alienation and dissatisfaction enters the relationship between governments and citizens"[153]. While difficult to facilitate, participatory procedures are essential to get right. One major lesson from the *TAMI* project on methodology in technology assessment is that the relationship between method and outcome is complex and requires great consideration. In line with the basic principles of RI, participation in precautionary decision-making should be held to a high standard of inclusion, responsiveness, reflexivity, and anticipation[154]. In this section, participation is examined from three perspectives: (1) Where in the innovation process are you? (2) Is the precautionary approach that of a compass or that of a safeguard? (3) What are the goals of this participatory process? On the basis of & Ladikas[155], Burgess and Chilvers[156], and Arnstein[157] these questions are answered in the following model and section.

Figure 2: Normative typology of the innovation governance cycle and its relation to precaution



The figure above illustrates a normative typology of the distinct phases in innovation (bottom row), the immediate role of policymakers and public authorities in relation to the innovation phase (middle row), and the precautionary approach to the innovation phase (upper row). While the reality of innovation is more fluid[xxviii], the distinction allows us to set up some considerations and criteria for participatory processes in the specific innovation phases. This will improve the integration of knowledge, and at the same time create more fairness for former unheard voices. The result in general should end with more competence in governing processes both in innovation and risk analysis. The following section delves into each of these phases and their implication for precaution-based participatory processes.

1. Developing innovation system

In the early stages of innovation governance, the concept of situation appreciation is especially important. Innovation evolves (and may be governed) within societal, political, and scientific boundaries. It is within the *situation appreciation* biases and motivations can be found. To achieve some sort of anticipation, an innovation system may therefore be developed, which aids our understanding of innovations and their evolution. In other words: What is our society calling for currently? What scientific areas are seen as the frontiers of innovation? What current political proceedings are expected to affect European innovation?

Early stages of the innovation governance cycle are, as the questions above indicate, inherently future oriented. **Participatory methods at this stage should thus reflect the need to acquire contextualized knowledge of current trends and future expectations.** Because no innovations pose any tangible threat at this stage, a precautionary principle should only be used as a compass, steering the development of the innovation system. In practical terms, this would entail anticipatory inclusion of the very entities that the precautionary principle aims to protect: human health and the environment.[xxix] As such, **citizens and environmental spokespeople should be included in these early participatory processes, alongside researchers** who may provide knowledge on the frontiers of science. Due to the future oriented nature of this innovation governance phase, the participatory process should not be given an unlimited mandate; **the stakeholder engagement should be kept around the level of dialogue, consulting, joint scenario building and foresight, and collaboration.** An example of a suitable method for a situation like this could be CIVISTI[158].

[xxviii] Innovation processes are in reality non-linear, reiterative, and considerably more complex than the figure illustrates.

[xxix] The guidance document on scope of application presents and establishes the use of precaution as a compass.

2. Seeking goals

Having mapped the innovation system, the task is to set the innovation goals within that system. In this phase, it should be clear what the societal, political, and scientific boundaries and trajectories are. What follows is the decision on where to go from here.

The phase thus continues to be future oriented yet increases in its ability to affect change. As indicated by the RECIPES needs assessment, the notion of the public interest has proved a complex entity. While participatory processes at all stages of the innovation cycle shed light on the public interest, the specific aim at this stage is to explore this very topic. **Participatory methods at this stage should thus aim for collaborative and broad decisions being made on a basis of anticipation and foresight.** In other words, the aim is again to guide innovation, by exploring and seeking general goals for future technologies. It goes without saying, that this stage also requires a precautionary principle that acts as a compass, as anticipation and foresight lie at the very core of this stage. This again means that stakeholders who are usually not embraced by research and innovation activities should be prioritized at this stage. If basic rights of European citizens are to be protected from potentially harmful technologies it is evident that these citizens should be included (and prioritized) when deciding on directions for future innovation. **Participatory processes at the stage of goal setting should, in short, ensure that the voices of the citizens are heard.** As the aim of this stage is closer to decision-making, the mandate of the participatory process should be rather high, without reaching the level of direct decisions; **the stakeholder engagement should reach levels of collaboration and empowerment.** An example of a suitable method for a situation like this could be consensus conferences[159] or the Conference on the Future or Europe[160].

3. Socio-Technical strategies

Technologies being developed within the defined boundaries and in the aim of collectively set goals will eventually meet the social system. The interaction between a technology and the social system is understood as partly linear, and partly non-linear in the sense that some aspects of the interrelation may be affected and anticipated, while some are harder to identify[161]. Considering the social system in the development of technologies is the primary approach to avoid unforeseen and unwanted side-effects of the socio-technical system. Thus, participatory processes during technology development may improve the eventual implementation of a technology considerably.

This phase relates the social world to a tangible technology. **The aim of the participatory process is therefore to bring together the various actors that define the socio-technical system and take their various perspectives into account**. Consensus should not be the primary goal, as the task is to map the various input to anticipate the potential meeting between technology and social system. As argued throughout this document, participation may help us explore the conflicting views on values and knowledge. At this stage, these conflicts become more influential and should thus be pursued through participatory processes. **The ability to anticipate in this regard requires niche input from knowledge holders (e.g., researchers, policymakers, industry-representatives) who should be included in participatory processes. These should, however, be accompanied by spokespeople of the social system that are holders of other relevant forms of knowledge (e.g., CSOs, (potentially affected) citizens, consumers).** This is a crucial stage for policymakers, regulators, and developers to identify potential early warnings of threats to human health or the environment and/or to identify potential ways to make the innovation more safe, clean, environmentally friendly, healthy, and sustainable. As such, **the participatory mandate is again kept at a medium-low level of consulting, involving, and collaborating.** An example of a suitable method for this phase of the innovation governance cycle could be stakeholder working groups[162].

4. Making regulation

Oftentimes, it is when a technology reaches the marketplace, that the public discussion really starts. Policymakers and regulating agencies may need to assess whether a technology poses a serious threat to the human health or the environment. As argued throughout this document, however, such assessments are often inconsiderate of early warnings, usually posed by laypeople. Assessments are also affected by scientific disputes and the lack of certainty within the academic community.

In this phase, policymakers and regulators are faced with a tangible technology and an uncertain output of the socio-technical system. **Participatory processes at this stage should therefore aim to vocalize the citizen's concerns and ideas on what to do with technologies.** As Árvai argues: "risk is a concept that needs to be *understood* – by lay people and experts alike – not *corrected*"[163]. Having a focus on *risk communication* is therefore very important in this stage to create good and informed risk management decisions. citizens' concerns and ideas are influenced by normative assumptions on knowledge and values, which should all be explored. At this stage, the precautionary principle becomes most relevant as a safeguard, justifying that regulatory decisions are made to protect human health and the environment. To identify whether a technology poses a serious threat, it is then vital to prioritize the entities that may be threatened. **Thus, this stage calls for great inclusion of (potentially affected) citizens.** Involved participants are used to identify threats and aid decision-making at this stage. Thus, **the participatory mandate should be at a rather high level of collaboration and empowerment.** An example of a suitable method for this situation could be citizen's hearings[164].

5. Social embedding

As established in this document, innovation is confined by the political, societal, and scientific trajectories that define society. Some technologies become deeply embedded in society to reinforce such innovative confinements. A European example of this could be livestock farming, to which the technological approach is locked in several member states. Innovations with the goal of more sustainable and animal friendly systems struggle with implementation as the existing technologies are too institutionalised. In other cases, the debate on technologies may be deeply inflamed and stuck between relevant stakeholders.

At such an innovation phase, participatory approaches may aid the movement from a deadlocked system towards alternative innovation. **The participatory aim is thus to spark dialogue and societal imagination toward new innovation systems.** One thereby has to identify and consider what so called '*images of the future*' are present[165] amongst different societal levels and sectors as well as how action is or could be embedded in these images. The precautionary principle drives this process as a safeguard, as it calls for action due to the threats that a deadlocked innovation system may pose. **Interfering with an entire innovation system requires input from a broad range of actors, and this phase should thus include citizens, experts, stakeholders, and policymakers.** As the aim is focused on dialogue and imagination, **the participatory mandate may be kept at a rather low level of dialogue and involvement.** An example of a suitable method for this innovation governance phase could be scenario workshops[166].

6. Reshaping tech system

At times, innovations are seen to potentially reshape the existing tech system. Potentially, their merge into the socio-technical system has had noticeable impacts and the innovation may be forming a technological trajectory. Technologies are bound by the existing socio-technical system, but may very well go to affect and change the system to something else entirely. A timely response to early signs of a reshaping tech system may help policymakers point out a direction for the future innovation system.

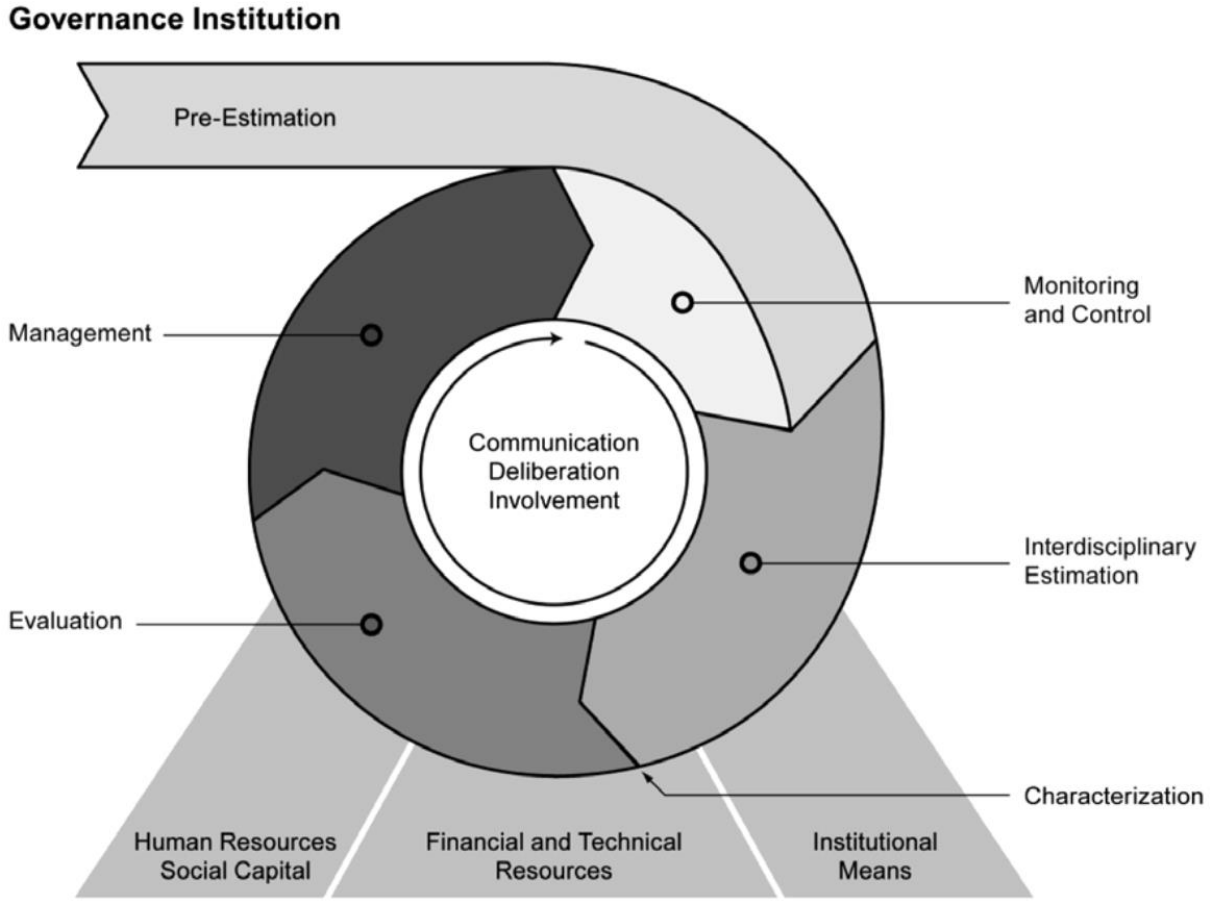
At this late stage of the innovation governance cycle, a tangible technology has created tangible outcomes in the socio-technical system and may show signs of a reshaping of the tech system. **The aim is thus to explore where the technology may take our society and whether it may pose a threat to human health or the environment.** Niche information and political goals are of great value at this stage, meaning that citizens are not the primary target. **Instead, CSO's, researchers, policymakers, and industry representatives should be prioritized.** The mandate for these stakeholder groups and the aim of defining future goals for a tech system should be held rather high. **Participatory processes at this stage could be at the higher levels of empowerment and collaboration.** The 'reshaping' of a tech system can be experienced differently at different levels in society. Having this in mind is also in its place for new possible goal settings. An example of a suitable method for such a situation could be the future search conference[167].

When going through the guidance above, five conclusions become evident:

1. Participation should be play a role in all phases of the innovation cycle to guide innovation and protect the environment and human health from harmful technologies.
2. The precautionary principle (both as a safeguard and a compass) compels us to include stakeholders that have been previously neglected in decision-making processes on innovation.
3. Situational appreciation will help to find appropriate methods for participatory processes.
4. Participatory processes are complex and depend on a great variety of factors. Approaching participation in a routine-like manner may lead to dismissible results at best, misleading results at worst.
5. Participatory methods spark dialogue that help to identify conflicting claims of knowledge and values.

The five points above all fall in line with the risk governance model[168] as illustrated in figure 1. An alternative model of adaptive and integrative risk governance has been developed by Klinke & Renn[169] and may be seen in figure 3 below. Here the IRGC model is used as a basis and further augmented by organizational requirements, thus reflecting the third conclusion above. Thus, the four stages of risk governance are accompanied by a fifth stage of risk-estimation as well as situational considerations, such as institutional capacity, social capital, resources, and more.

Figure 3: Adaptive and integrative risk governance model[170]



The central notion of this guidance is that participatory efforts regarding complex issues characterised by uncertainty need to be strengthened through early inclusion of knowledge claims that traditionally have been undervalued in risk governance. This requires paying attention to organizational capacities in support of knowledge networks that are more inclusive and integrated early in decision-making and innovation. Consequently, the question arises: what counts as *relevant* knowledge.[xxx] Results from the case study comparison as well as the stakeholder needs assessment indicate that the term "relevant knowledge" should be understood in a broader sense, instead of focussing exclusively on scholarly expertise. Concerns of stakeholders and the public need to be taken into account during risk appraisal. Scholars argue that this will lead to more responsive and adaptive risk governance[171].

3.1.1 Main points on participatory methods

- Depending on the developmental stage of technological innovation, participatory processes may reflect a precautionary approach that acts as a compass or a safeguard.
- Participatory processes may prove useful throughout the innovation cycle and are vital to move toward a framework of integrative and adaptive governance of risk and uncertainty.

[xxx] See guidance document on development and organization of expertise.

- Choosing an appropriate participatory method requires an analysis of the situational context. Depending on the risk problem and societal challenges associated with the risk problem a specific available participatory method should be chosen (Renn & Schweizer, 2009; Renn & Schweizer, 2020; Webler, 2020). [172] This approach will enhance acceptability and effectiveness of participation and ensure that the participation process will contribute to problem solving and support decision making[173].

3.2 Fair and competent participatory processes

One early point of this guidance is that participation is no straightforward task. The beginning of this chapter showed how one may approach methodological choices based on contextual awareness and clear goal setting. In 2019, the EC committed to a renewed and strengthened prioritisation of deliberative democracy[174]. A clear example of this aim is the establishment of the Competence Centre on Participatory and Deliberative Democracy. Webler and Tuler[175] and Renn et al.[176] indicate how policymakers and regulators may embody the EC commitment through the participatory meta-criteria of fairness and competence. It is thus the responsibility of regulating bodies and policymakers to ensure that they have the competence and fair approach that is necessary to move toward a framework of good governance and deliberative democracy. The remainder of this chapter supplements the concrete guidance with important considerations and criteria that may increase institutional competence and increase fairness in participatory processes.

Box 3: Database of participatory methods

When aiming to choose an appropriate method for participation, the digital tool Action Catalogue.eu (http://actioncatalogue.eu/) is of great use. Through the Action Catalogue, facilitators are navigated through well-developed research methods focused on stakeholder and citizen's involvement. The tool is not only a database of methods, but also a platform that provokes reflexivity and thoughtfulness.

By guiding the facilitator through different criteria, the Action Catalogue presents the most appropriate participatory methods based on preferred attributes, such as geographical scope, direct participants, objective of public participation, and objective in applying the method.

Requiring the facilitator to consider these criteria might bring them to make more deliberate decisions on the research method and to be aware of the strengths and weaknesses of a given method, especially in terms of the type of participation. As such, the Action Catalogue should not just be seen as a tool that provides a research method based on some input, but also an invitation to be more considerate, self-critical, and deliberate in the development of participatory approaches.

3.2.1 Public engagement

The above guidance of participatory approaches and methodology choice applies a broad notion of stakeholder categories that may be included and/or prioritized at various stages. The RECIPES needs assessment, however, indicated that there is a need for more clarity regarding stakeholder categorization and especially, the concept of public engagement. In this section, more light is shed on some of the nuances that should be considered when assessing the need for participatory processes. In other words: What does one need to consider when involving the public in risk management processes? How may one, more

deeply, consider the various groups that could be involved in participatory processes? How does the specific type of risk affect methodology choice in participation efforts?

Participation is vital to the precautionary principle because uncertainty calls for public deliberations. When the scientific community cannot make clear-cut assessments of emerging technologies, opinions, needs, and rights must be assigned a bigger role. While decision-making should always be informed by scientific research, public engagement is essential when uncertainty persists. Yet public engagement is a tricky notion requiring the following questions to be considered: Who is the public? At what stage of technological development is public engagement required? How do we meet this increased need for including the public at more stages of technological development while mitigating the perceived possible negative effects of some aspects of public engagement?

Inclusion of the public has been an on-going topic throughout the research efforts of RECIPES. The stakeholders' needs assessment consultations made it abundantly clear that a central need for times of uncertainty is earlier and more extensive inclusion of the public. At the same time, public engagement is time-consuming and expensive. Some stakeholders also point to the fact that some questions may not make sense to discuss with the public[177]. Balancing the clear need for greater public engagement with its potential drawbacks is therefore one of the main themes of this guide.

The case study and needs assessment analyses conducted within the RECIPES project also showcase controversial views on the involvement of the public in risk management processes. The GMO-case study, for example, shows a disagreement about the extent to which the general public should be involved during the application of the PP. It examined the national context in Bulgaria and concluded that general public engagement resulted in pressuring the Government and the Parliament, which led to decisions that seemed to be based on political opportunism. At the same time, in the case studies on nanotechnology and the water infrastructure planning in Milan, public engagement has been identified as having a positive effect, leading to more open, transparent and broadly supported decision-making[178]. The main conclusions from the case study analysis on public engagement were that participatory processes and methods in decision-making are valuable, but careful consideration needs to be made regarding the eligibility of the questions to be discussed and evaluated and the ones which should not be included. Overall, deliberative methods should be deployed without distracting potential differences in evidence and reasons for conflicts of interests, values and knowledge. It was also emphasised that there is a need for more integrative risk governance approaches, foresight and stakeholder involvement with regard to risk regulation and innovation policy[179].

To make the most from public engagement processes, the specific role and contribution of each involved stakeholder group, including citizens, should be clarified. The International Risk Governance Council (IRGC)[180] defines stakeholders as "*socially organised groups that are or will be affected by the outcome of the event or the activity from which the risk originates and/or by the risk management options taken to counter the risk*". It distinguishes four types of stakeholders[xxxi], based on the organisational structure of stakeholder groups, their proximity and exposure to the risk issue as well as groups that are not always defined as stakeholders, but could have similar influence and will and should sometimes also be involved. The four stakeholder groups are:

- Directly affected groups: these are socially or politically organised formal groups such as official advocacy groups, governments or industries. These groups are or will be affected by the event or activity from which the risk originates and/or by the

[xxxi] An alternative categorization by the UN Rio Declaration establishes nine major groups through which broad participation should be facilitated (c.f., https://sustainabledevelopment.un.org/aboutmajorgroups.html).

risk management options taken to counter the risk, or they have a strong interest in all of these aspects.

- Directly affected public: is the group that will experience positive or negative impacts from the events or activities from which the risk originates and/or by the risk management options taken to counter the risk. These might be individuals and non-organised groups, community members or certain marginalised populations. Depending on the specific risk, it could be the case that the entire general public is directly affected.
- Observing public: these are groups that may or may not comment on the risk issue or influence public opinion, including scientists, the media, cultural elites and opinion leaders.
- General public are all the individuals who are not directly affected by the risk management activities but are part of the emerging public opinion on the issue.

In addition, it is of key importance that all major sectors of society (the so-called *Major Groups*) are included (**see Box 4**).

Box 4: Nine major groups essential for participation

Since the first United Nations Conference on Environment and Development in 1992 in Rio de Janeiro (Earth Summit), it was recognized that achieving sustainable development would require the active participation of all sectors of society and all types of people. Agenda 21, formalized nine sectors of society as the main channels through which broad participation would be facilitated in UN activities related to sustainable development. These are officially called "Major Groups" and include the following sectors:

- Women
- Children and Youth
- Indigenous Peoples
- Non-Governmental Organizations
- Local Authorities
- Workers and Trade Unions
- Business and Industry
- Scientific and Technological Community
- Farmers

https://sustainabledevelopment.un.org/aboutmajorgroups.html

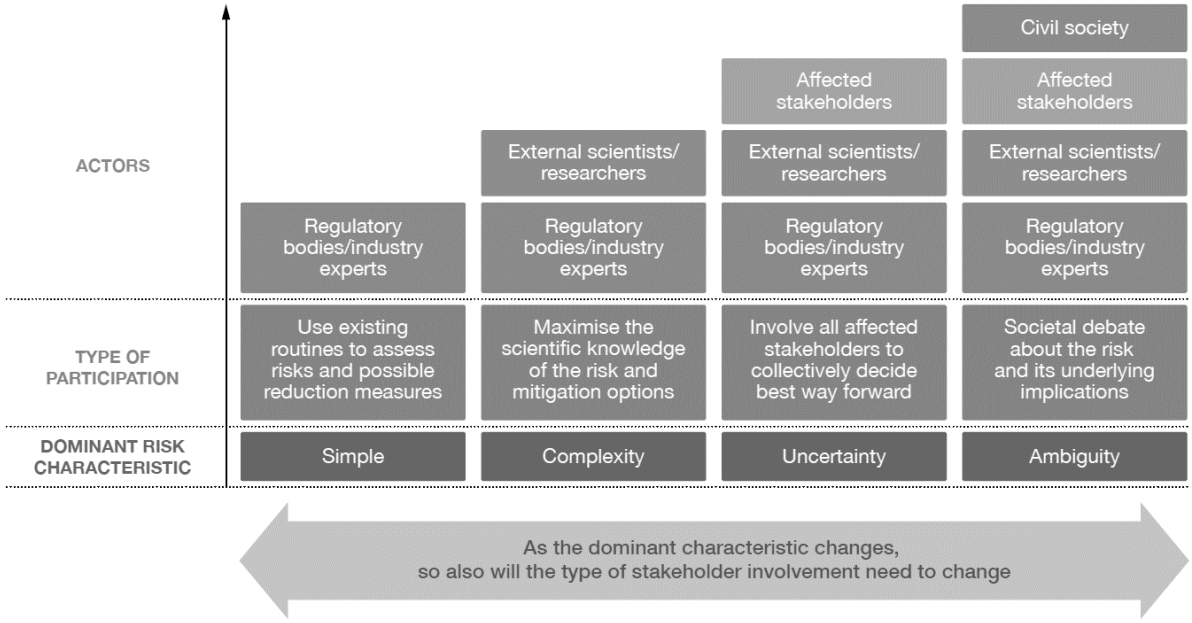
Successful stakeholder involvement could facilitate the risk management process in several ways:

- by providing fair and accurate information that ensures involved actors are acquainted with any potential risks and benefits associated with technologies, products, activities or situations;
- by evaluating stakeholders' opinions and attitudes in terms of risk assessment of technologies and risk management decisions, so that this information can be incorporated into the decision-making process;
- by establishing conditions for informed consent, behaviour change and enhanced public confidence in relevant risk management decisions; and
- by contributing to the process of reaching mutual understanding that could resolve ambiguities, trade-offs and conflicts among the various interested groups such as stakeholders, regulators and society.

To develop methodologies for stakeholder participation, risk managers who are in charge of the process need to carefully examine two crucial aspects prior to selecting a specific engagement method, namely the type of risk under scrutiny and the respective phase of the risk governance process.

IRGC developed a flexible framework (in the form of an 'escalator') for suggesting the appropriate level of stakeholder involvement, depending on the knowledge about the risk (see Figure 4 below). To assess when and how to engage different stakeholders and the general public, IRGC recommends using the dominant characteristic of the risk to decide the appropriate level of stakeholder involvement.

Figure 4: The risk management escalator[181]



Stakeholder involvement, depending on the type of risk

An important factor that needs to be considered to decide when and how to engage stakeholders and/or the general public in any stage of the risk management process is the risk type. Depending on their characteristics, risks can be simple, complex, uncertain or ambiguous[182]. With *simple risks,* the connection between cause and effect is clear. With *complex risks, on the other hand,* it is difficult to identify and quantify the causal relationship between cause and effect as many intervening factors affect it. Examples of complex risks include health consequences of toxic substances and climate change modelling. Such problems require the involvement of experts who can reliably determine a given risk to explain the respective complexity and to clarify dissenting views[183].

A risk is considered *uncertain* when there is a lack of scientific or technical data, which results in undermined confidence in the cause-effect relationship. An example of this type of risk is natural disasters like earthquakes or floods. Uncertain risks require the engagement of policymakers, scientists and directly affected stakeholder groups to decide on appropriate trade-offs between different risk management options[184].

With *ambiguous risks,* the information available is subject to various interpretations, leading to different perspectives regarding the respective risk, including the likelihood of potential adverse effects. Examples of risks with high ambiguity include biological hazards like bacteria and viruses as well as genetic modification in agriculture. When approaching these risks, participation must include not only experts/scientists/researchers and affected stakeholders, but civil society as well. High ambiguity requires the most inclusive stakeholder and public engagement strategy, one which aims to find a consensus regarding the dimensions of ambiguity to address risks and benefits and to balance the existing pros and cons related to the respective issue. Most risks, however, are a mixture of these characteristics. For example, endocrine disruptors are highly complex, uncertain and ambiguous, while nuclear energy is highly complex and ambiguous, but less uncertain[185].

In short: The main aim of a comprehensive knowledge about risks, uncertainties and ambiguities of a particular issue is to enable all actors in society to deal with risks in a socially and sustainable manner. Therefore, it is of important to merge approaches of understanding and deciding about risks phenomena and to enhance the institutional capacities and individual capabilities to anticipate and tackle the societally most pressing problems. Here the precautionary principle and participatory approaches have a crucial role to play in the adaptive and integrative governance of risks and uncertainties[186].

Furthermore, sometimes it is difficult to characterise a risk in terms of its complexity, uncertainty and ambiguity. In these cases, the IRGC advises beginning with a deliberation with the aim of defining and specifying the most suitable path for evaluation and management of the respective risk[187].

Stakeholder involvement, depending on the phase of the risk governance process

According to the risk governance framework developed by IRGC, stakeholder engagement can have different aims and take different forms depending not only on the given risk characteristics, but also on the respective phase of the risk management process[188]. Each risk management process has four distinct phases, including *pre-assessment* (aiming to frame and define the context), *appraisal* (assessing facts and concerns), *characterisation/evaluation* of the respective risk after confirming the result of the risk appraisal and *management*, when a decision is made[189]. The aim of stakeholder engagement during the *pre-assessment* phase is to frame and define the problem to design the upcoming risk governance phases. The objective of stakeholder involvement during the *appraisal* stage is to contribute to the information pool or to raise awareness about the limits of existing knowledge as well as the risks under evaluation. Relevant stakeholders in this phase include technical experts, scientists, affected communities, governments, industries, and local communities[190]. Renn[191] has identified several engagement instruments that are appropriate for application during the appraisal stage, namely expert panels, expert hearings, meta-analysis and Delphi methods.

During the *risk characterisation and evaluation* phase, debate depends on the characteristics of the risk. When the issue in question is highly uncertain, but has low to medium ambiguity, the stakeholders from the pre-assessment stage should be reconvened to evaluate new knowledge and draw conclusions about the respective risk to ensure a balanced view of the positive and negative aspects of the problem under scrutiny. If the risk is considered highly ambiguous, stakeholders that will be affected by the risk management decision have to be included as well. Highly uncertain and ambiguous risks require wider stakeholder and public engagement to find the right balance when assessing the acceptability of a given risk. Suitable tools include round tables, stakeholder meetings, mediation, etc[192].

In the *management* phase, stakeholders are engaged with the aim to identify and evaluate measures for decreasing and managing unacceptable risks. Suitable measures at this stage include citizen advisory committees, citizen panels, citizen juries, consensus conferences, and public meetings[193].

In addition to the risk type and the phase of the risk governance process, the IRGC framework also discusses the broader context, related to the specifics of the political, institutional, social and economic environment. In proper risk-related decision-making, it is crucial to recognise the capabilities of key actors as well as regulatory style. Another important factor to be considered is the risk culture as it has influence on the level of risk tolerance and the trust in the respective risk governance institutions[194].

Objectives of stakeholder engagement

Participation processes may categorise their aim as one of the following three main outcomes of stakeholder engagement:

1. Communication*:* effective risk governance needs to have proper risk communication, which is defined as the process of sharing/exchanging risk-related knowledge and data among actors engaged in risk management, including experts, scientists, policymakers, industry, consumers, regulators and the general public. The objectives of such communication include: i) improved stakeholder literacy regarding the issue at stake (e.g. provision of information about complex technologies and natural hazards); ii) behavioural change (e.g. communication campaigns about hand washing and physical distancing during the COVID-19 pandemic)[195].

2 Consultation*:* collection of feedback from stakeholders and the general public about their knowledge, attitudes, interests and values in order to include knowledge from other knowledge bearers in the risk assessment and existing concerns in the planning and the risk management process. The objectives are: i) to engage a wide diversity of knowledge bearers and relevant ways of knowing; ii) to focus on public preferences by understanding affected populations' viewpoints (e.g. applied in cases when a decision between similar options has to be made or when scientific arguments cannot resolve conflicts); iii) to ensure informed consent by providing information to stakeholders and the general public about the potential consequences of specific risks and the respective risk management options (e.g. involving citizens in national consultations, related to important future policy changes)[196].

3 Deliberation*:* stakeholders are active participants in the decision-making or risk management process. Objectives include: i) stakeholder self-commitment, which aims to ensure the willingness of stakeholders to take responsibility and to modify their behaviour/attitude to participate in a given risk management measure (e.g. homeowners switching to renewable energy as part of the low-carbon energy transition); ii) co-management/co-regulation directly involves stakeholders in designing regulations, risk management measures and programmes for risk monitoring (e.g. action plans for sustainable development)[197].

In sum, stakeholder and public engagement gives all affected and involved parties the chance to participate in the debate about responsible innovation. Thus, engagement may support mutual trust and enhance competence.

3.2.2 Main points on public engagement

- Methodological approaches to public engagement should be informed by an understanding of characteristics of the potentially affected societal groups.
- A categorisation of risk should inform the methodological choices for participatory processes. Risk problems may be considered simple, complex, uncertain, and or ambiguous.
- Depending on the objective of participatory processes, methodological adjustments may be necessary. General objectives of public engagement are communication, consultation, and deliberation.
- Risk and uncertainty communication is intrinsically linked to engagement processes and should be seen as a constant companion throughout all phases of risk governance.[xxxii]
- Communication on risks and uncertainties require competencies and capacities to communicate within the agencies (internal communication) and external experts, stakeholder groups, and the public (external communication).

[xxxii] See figure 3 for an illustration of risk communication and its role in risk governance.

3.2.3 Transparency

Appropriate and well-facilitated participation carries with it the challenge of transparency. An on-going message throughout the RECIPES project is that invocation and application of the precautionary principle is based on notions of uncertainty and acknowledgement of scientific limitations. For this exact reason, participatory efforts in risk governance should rely on inclusion, diversity, and importantly, *transparency*[198]. Results from the inter-case study comparison and the needs assessment point out this requirement. However, they also indicated that practical achievement of transparency is difficult. When is transparency required? What are the standards for transparency?

This guidance aims to address

- transparency in participatory approaches, pointing to merits and;
- the lack of clarity on how transparency may be achieved; and
- specific approaches to transparency, which are distinct for agenda-setting, policy development, and the innovation process.

The first RECIPES expert consultation that was organised on June 3rd indicated an overall interest in raising transparency standards in participatory procedures. The results of the inter-case study comparison point towards an understanding of transparency as the outcome of timely deliberative processes, in which available information is actively disseminated and discussed[199].

Birkinshaw[200] established the comparable notion that transparency entails not only the timely access to information, but also "conducting affairs in the open, subject to public scrutiny". This means that transparency entails not only dissemination, but also inclusion and consideration of public and expert opinion, e.g. in decision-making and issue-framing. Opposition to such a definition of transparency may likely refer to a potential pandering to irrelevance: High standards for transparency may result in obsessions over details and obscure the actual aims at hand, effectively weakening decision-making and innovative processes[201]. However, efforts to foster transparency are assumed to build trust, strengthen public innovation, and improve democratic engagement[202].

For transparency to become an operationalizable concept in precautionary approaches, this guidance calls for an active demonstration of timely and deliberative efforts to include and inform relevant stakeholders. In practice, this is reflected in planning and reporting, which should also be released for public scrutiny. Decision-makers and innovators alike should document how they plan to achieve transparency, as well as how their actual transparency efforts were eventually carried out. Documentation on these efforts should be available in open access digital repositories.

The requirements could support the application of the precautionary principle by encouraging decision-makers and policymakers, as well as industry developers, to actively demonstrate their efforts of transparency, rather than meeting a range of established minimum requirements[203]. This requires demonstrating early dissemination and engagement efforts that allow potentially affected citizens and other stakeholders to be informed of future developments. It also requires such inclusion processes to be deliberative, including stakeholders, especially affected citizens, in the development process.

In short, transparent participation is more than access to information[204]. It requires transparency in the form of both *forced*- and *intentional* access to information – the latter consisting of an active release of information as well as a passive release in the form of

freedom of information.[xxxiii] It also requires participatory approaches to provide open access to both formal and informal decision-making arenas[205]. An active demonstration of these features would ensure that participatory approaches to precaution are conducted in a transparent manner, ideally resulting in competent, effective, and safe decision-making.

3.2.4 Main points on transparency

- Transparency can be defined as timely and deliberative efforts to include and inform relevant stakeholders to ensure that affairs are conducted in the open or subject to public scrutiny.
- Decisionmakers need to actively demonstrate the above-mentioned meta criteria of competence and fairness for transparent participatory processes.

3.2.5 Power asymmetries

Situations that call for invocation of the precautionary principle are characterised by power asymmetries between affected stakeholders. Be it the developers of a new technology, potential customers, regular citizens, or future generations, stakeholders are affected in different ways when a novel technology or product enters the EU. Similarly, their ability to voice their rights and needs is currently unequal at various levels of decision-making and innovation steering. Who is included in participatory processes? What questions may participants deal with? Whose voices should be strengthened and how may we contextualise various opinions? Asymmetries of power, comparable to the notion of information asymmetries[206], cannot be ignored in participatory processes because such processes do not exist in a power vacuum. Explicitly, the need to explicate asymmetries among "included stakeholders in technology development, as well as risk assessment and risk management"[207] has been established as an issue that must be addressed. What is more, RECIPES identified a need to establish "how to address disagreements on the question of what type, level and to which extent asymmetries exist and which are problematic"[208].

Thus, the guidance on asymmetries aims to illuminate:

- the potential adverse impacts of power asymmetries in participatory approaches to the application of the precautionary principle;
- potential pathways to addressing and explaining power asymmetries among stakeholders in participatory processes; and
- the merits and pathways of early inclusion of stakeholders with a heightened focus on under-represented voices.

The notion of power transparency is crucial to establish whether potential adverse impacts of power asymmetries in participatory processes exist. As rights, needs, and interests of future generations must be fairly and properly represented in participatory processes, technology assessment, risk assessment, and risk management could benefit from a greater contextual understanding of the role that (potential) stakeholders play in participation. Participation in the application of the precautionary principle could mirror this approach by requiring an increasing effort to map and address the needs and rights of underrepresented and underpowered stakeholders, such as future generations and directly affected citizens. In line with the section on transparency in general, these mapping efforts should be disseminated and scrutinised publicly to ensure the accountability of the facilitators. Similarly, power transparency requires a greater effort to map and address the organised interests[209] that may affect participatory processes and subsequent decision-

[xxxiii] Meijer et al (2012) distinguish between forced access to information (leaking and whistle-blowing) and intentional access to information (freedom of information or active release of information).

making. In particular, the opportunities and challenges in including industry representatives require great consideration and care due to the following power asymmetries in participatory processes[210]. The issue of transparency has been usefully addressed by the conceptualisation of *recursive reflexivity*, defined as "…holding a mirror up to one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held"[211]. In this way, recursive reflexivity applied to responsible innovation "can identify and critique dominant knowledge forms concerning innovation, technocracy, and even democracy while enacting the meaningful change it seeks to bring about through its interventions"[212].

Although inequalities and asymmetries cannot be completely removed, participatory processes can be conducted in a more neutral manner by means of guiding towards increased transparency on power asymmetries. Participatory processes may benefit from power transparency in that different framings and presuppositions are contextualised, resulting in a more informed foundation for applying the precautionary principle.

3.2.6 Main point on power asymmetries

- Power asymmetries may be made explicit in participatory processes through an active documentation of existing asymmetries, thus aiming for power transparency.

4 Overview of guidance

The EU funded project RECIPES (REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders), aims to ensure an application of the precautionary principle that encourages innovation and promotes precaution as a driving force in shaping and guiding innovation towards societally desirable goals with foresight and anticipation. This guidance adds to this purpose by showing how and why participatory processes should be prioritised to achieve good governance practices in the EU. The document sets out by justifying participatory processes through normative, substantive, and instrumental argumentation. It goes on to suggest how adaptive and integrative approaches of risk governance can be operationalised, pointing to the metacriteria of fairness and competence. The final chapter illuminates how participatory processes may be facilitated through well informed methodology choices and considerations.

The RECIPES guidance documents have been shaped by a stakeholder needs assessment conducted in the autumn of 2020. Here, it was indicated that three main topics regarding the application of the precautionary principle could be addressed: Participation; Organisation and development of (scientific) expertise; and scope of application of the precautionary principle. This document thus serves one of three approaches to the central aim of RECIPES, in which the future application of the precautionary principle is to be improved. It is highly recommended that the other two guidance documents are visited to understand the full output of the RECIPES project.

While fruitful engagement and participation is a difficult competence to achieve, the EC has shown its commitment to try with activities such as the Conference of the Future of Europe[213] or the Competence Centre on Participatory and Deliberative Democracy[214]. While such actions are necessary to achieve future good governance practices, this document should aid and stimulate the process in which European deliberative approaches are strengthened and integrated in risk governance and decision-making.

For an overview of all main points in the guidance on participation, please see the table below:

Overview of guidance for participatory approaches supporting the application of the precautionary principle

Rationale for strengthened participation	Theoretical considerations underpin the two main lessons learned from RECIPES research that (1) conflicts of interest and knowledge create inconsistency in the application of the precautionary principle, and (2) strengthened, thought-out participatory processes can help uncover and mitigate such conflicts. Aiming for good governance practice, a strengthening of the science-society-policy interface through participatory processes is justified.
Choosing methods	Awareness of situational factors may aid the selection process when determining the most appropriate methods for participatory processes. Consideration of varying frameworks is important to attain situational awareness. The application of the precautionary principle requires consideration from the perspective of the innovation cycle, as well as that from risk governance.
Fairness and competence	While participatory processes may be difficult to assess consistently, the meta-criteria of fairness and competence provide a useful indicator for facilitation choices.
Public engagement	Methodological approaches to public engagement should be informed by the relevant stakeholder group. The public may be considered to be the directly affected group; the directly affected public; the observing public; or the general public. Similar to the relevant stakeholder group, a categorization of risk should inform the methodological choices for participatory processes. Risks may be considered simple, complex, uncertain, or ambiguous. Depending on the objective of participatory processes, methodological adjustments may be necessary. General objectives of public engagement are communication, consultation, and deliberation. Communication on risks and uncertainties require competencies and capacities to communicate within the agencies (internal communication) and external experts, stakeholder groups, and the public (external communication).
Transparency	Transparency can be defined as timely and deliberative efforts to include and inform relevant stakeholders to ensure that affairs are conducted in the open or subject to public scrutiny. Decisionmakers need to actively demonstrate the above-mentioned criteria for transparent participatory processes. Transparent participatory processes are a non-negotiable part of a change toward good governance and fair and competent deliberations.
Power asymmetries	Power asymmetries may be documented in participatory processes through an active documentation of existing asymmetries, thus aiming for power transparency.

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Appendix I: Two main lessons learned from RECIPES research (Full version)

In an early stage of the RECIPES project, nine case studies were conducted to analyse a broad range of sectors in their application of the precautionary principle[xxxiv]. A comparative inter-case analysis followed these case studies to identify common emerging themes. From these themes, it is suggested that conflicts around the precautionary principle often stem from controversies between claims of knowledge and claims of values. This indicates that issues regarding the precautionary principle may be relieved through greater participatory deliberations on the normative assumptions of knowledge and values.

Two major lessons derived from RECIPES research

Based on the findings of inter-case study analysis, the present report derives the following two points relevant to the precautionary principle and its link to participation:

1. Inconsistencies in the application of the precautionary principle may be linked to conflicts over claims of knowledge, values, and interests[215]. The results of the inter-case study comparison and the literature indicate that the compiled knowledge needs to build on robust scientific evidence, and that this needs to be contextualised, e.g., in participatory processes, so that evidence-based knowledge can evolve into evidence-informed collectively binding legitimate decisions. In this sense, as many scholars argue, it is important to note that RRI cannot be promoted in a prescriptive manner, but rather is to be understood as "a contextual process" requiring an ongoing cultural dialogue, one which is iterative in nature[216]. In other words, besides the evidence gained from scientific research, risk and uncertainty assessment, the knowledge and dialogue with stakeholders in participatory processes can contribute to a better understanding at science-policy interfaces. An implicit challenge in these conflicts occurs when conflicting claims over knowledge and or values both arise at the same time. Therefore, value conflicts and competing problem framings need to be addressed in decision-making, mainly because the articulation of values and alternative perspectives guide the selection of evidence and help to identify decision alternatives. This is reflected in the following lessons of the comparison of the case studies analysis with results from a stocktaking report[217].

2. Clarifying values, knowledge, and interest conflicts is essential to improve the interaction of all actors involved. Responsible Research and Innovation (RRI) or Responsible Innovation (RI) are frameworks which aim to start discussions about values, norms and ethical matters which take different forms of evidence and understanding into account. "RI is critical of the dominant global economic paradigm, highlighting that there are market deficits in delivering innovations on societally desirable goals"[218]. Governance here is understood as a concept to "steer the innovation process towards societally beneficial objectives." Following von Schomberg[219], the "question of how to define positive outcomes or 'the right impacts' of innovation can be found in the normative anchor points in basic treaties and constitutions." Therefore, Responsible Innovation marks the "paradigm shift from a justification in purely macro-economic terms towards a justification of the purpose and direction of innovation in terms of broadly shared public values"[220]. So how can RRI criteria be better embedded and aligned with societal needs? The question of what 'ethical acceptability', 'sustainability', or 'social desirability' mean, however, has yet to be satisfactorily put into deliberative practice. One reason for this is that

[xxxiv] Case studies range from GMO through neonicotinoid insecticides to AI and are available via https://www.recipes-project.eu/results/analysis-case-studies

"in a pluralistic society, normative parameters cannot be defined a priori and cannot be established by experts alone but must instead be deliberated by a broad range of societal actors"[221].

In short, the insights of the inter-case study analysis indicate that the reasons for complexities and controversies lie in the conflicts between claims of knowledge and values.[xxxv] Additionally, these conflicts must be explored and addressed through deliberation among a broad range of societal actors.

Dealing with normative issues and assumptions about knowledge, values and interests is crucial because conflicts can arise due to pressure from various sources. The core line of conflicts becomes evident when science becomes involved in policy decisions and when complicating factors such as uncertainty, complexity and ambiguity are brought into the picture. This includes the interplay of human agency within the context of regulation, innovation, legal decision-making, changing societal values, and vested interests, adding yet another level of complexity than the technological system alone. This raises the question of how different knowledge and evidence claims, norms and values can be compared, evaluated and assessed, and how the results feed into scientific policy advice and collectively binding legitimate decision-making.

Aims for participation from the RECIPES inter-case analysis

The findings of the inter-case study analysis indicate that the main reasons for complexities and controversies can be conflicts over claims of knowledge, evidence, and values. This leads to the key question of participation and deliberation: How can different knowledge and evidence claims, norms and values be articulated, evaluated, and assessed to feed into scientific policy advice for collectively binding legitimate decision-making? On a basis of the RECIPES inter-case analysis, these questions can be formulated as three needs that should be addressed:

1. A comprehensive understanding of each other's meaning of framing and stimulating reflection on different (issue-)frames[222].
2. The need for the organisation of knowledge networks, which should be organised so that problems addressed in the Global Sustainable Development Goals (SDGs) gain priority. This is linked with the need for more inclusive and deliberative assessment methods, without delegitimising the role of experts and avoiding 'partisan' risk assessments[223,xxxvi].
3. More integrative risk governance frameworks that connect different types of uncertainties to inform risk assessors on the applicability of the precautionary principle in the case of accumulated uncertainties[224,xxxvii].

In short: The findings mainly point to three dimensions: 1. questions of mutual understanding and (issue-)framing; 2. the procedural integration and assessment of different forms of knowledge and values; and 3. (normative) questions concerning Governance for Sustainable Development within a pluralistic society.

[xxxv] The distinction between knowledge and values is also among the 12 lessons cited in the European Environmental Agency Report *Late lessons from early warnings* (2013, p. 12): Lesson 8 "Ensure use of 'lay' and local knowledge, as well as relevant specialist expertise in the appraisal" and Lesson 9 "Take full account of the assumptions and values of different social groups".

[xxxvi] This need is partly addressed by the document on *organization of expertise*.

[xxxvii] The document on *scope of application* provides considerations for the different types of uncertainty and when the precautionary principle is relevant.

Questions of mutual understanding and issue-framing is a focus point in this document. Voss & Kemp[225] argue that the multi-dimensional and dynamic concept of sustainability has fundamental implications for the governance of modern society. Under the heading of 'reflexive governance for sustainable development', they point out that decision-making for public policies has "to deal with interconnected issues of complexity, uncertainty, path dependence, ambivalence and distributed control". To tackle the most 'wicked' problem of modernity, they point to six key strategies; the third essential strategy is termed "iterative, participatory goals formulation"[226]. In the same vein, one of the dimensions of RRI is reflexivity on R&I values and beliefs, which is inextricably linked to public dialogue[227].

Therefore, clarifying conflicts over knowledge and values is essential to improve the interaction of all actors involved. This is especially relevant and challenging in the realm of governance of systemic risks[228], mainly because the properties of systemic risks require interdisciplinary and cross-sectoral cooperation, a close monitoring system, and the engagement of scientists, regulators, and stakeholders to be effective as well as socially acceptable[229]. One reason for this is that, in a pluralistic society, normative parameters cannot be defined a priori and cannot be established by experts alone, but instead must be deliberated by a broad range of societal actors[230].

To sum up, varying understandings of how values and knowledge should be framed are linked with the inconsistencies identified in the application of the precautionary principle. To reduce inconsistencies, but also to improve the interaction of relevant stakeholders, innovative approaches to participation that follow the principles of RRI should be strengthened. The crucial question to address is:

> *Which form of participation needs to be applied when in the cycle of precaution-based policymaking?*

The question addresses the very core of precaution-based policy making, because if the sustainability transition is the greatest challenge of our time, the European Green Deal[231] is Europe's response to this challenge: "Since it will bring substantial change, active public participation and confidence in the transition is paramount if policies are to work and be accepted. A new pact is needed to bring together citizens in all their diversity, with national, regional, local authorities, civil society and industry working closely with the EU's institutions and consultative bodies". With inclusion at the very heart of RRI values, the need for precautionary policy making points towards "richer deliberation on the substance of decision-making"[232]. In this sense, the challenge to "improve our capacity for analysis and reflection" can be understood as a key challenge and a need for improving the organisational capacities of institutions and consultative bodies[233].

Results and reasoning in the needs assessment

Early research efforts in RECIPES raised the question of which form of participation needs to be applied at what stage of precaution-based policymaking? It did so, because innovative participation is argued to be the strongest response to the inconsistencies that occur based on varying claims of knowledge and values. The RECIPES project followed up on this question through a co-creative assessment of stakeholder needs. During this needs assessment, relevant stakeholders were able to indicate five sub-themes that needed to be addressed by RECIPES research:

The need for Transparency (sub-theme 1) is expressed by all involved stakeholders, because decision-making processes shaped by a precautionary approach require the availability of reasoning to citizens. With regards to the type and extent of transparency, especially transparency in the agenda setting of public research is desired. Varying views on the appropriate method(s) of Facilitation (sub-theme 2) of participatory decision-making processes were expressed. At the core of this sub-theme are questions pertaining to when, who and how relevant stakeholders should be included.

The balancing of different stakeholders is a main question when looking at Asymmetries (sub-theme 3). At the core of this sub-theme is a need for clarity on how to do so, and to which extent asymmetries have a negative influence. A need for the prioritised inclusion of relevant major stakeholder groups for the achievement of sustainable development[234] including the guidance needed regarding the well-being of future generations[235] as well as "earlier and more consistent" stakeholder participation and "transdisciplinary considerations" was expressed[236].

A need for a specification regarding Public engagement (sub-theme 4) is identified. The main controversies revolve around the "[q]uantity and timing of public engagement", which should be as early as possible and applied at "all steps of the practical application of the precautionary principle". Furthermore, the need for more "deliberative formats to aid decision-making [and] build public understanding" is expressed. At the same time, it should be ensured that participating citizens are "knowledgeable on the given subject" to improve the quality of public engagement[237].

The "[n]eed for a clear definition of the Public Interest (sub-theme 5), related to transparency, participation, as well as the separation of economic interest and the production (and evaluation) of science" is voiced. The normative *ambiguity* sparking from different values leads to *uncertainty* and "conflicting views on how to define it [the public interest]"[238].

The RECIPES needs assessment indicated that relevant stakeholders saw a need for improvements and clarity in participatory approaches to the application of the precautionary principle. It confirmed early RECIPES research and provided concrete themes that this document aims to address. It also contextualized the initial issue of how to deal with conflicting claims of knowledge and values. Through the needs assessment, it became clear that the issue was not only about the claims that are made in precaution-based policymaking, but also the people that make them and the participatory constellation they engage in.

4.1 Demand for policymaking that takes precaution and participation into account

In the needs assessment of the RECIPES project, stakeholder needs in relation to participation were clustered and named as the following sub-themes: transparency, facilitation, asymmetries, public engagement, and public interest.

The core of the needs expressed with regards to participation in the five subthemes could be summarised as an overall need for clarity on the deep implications of two main principles of participation and stakeholder involvement: "inclusion and selection". That is, what and whom to include, on the one hand, and what and how to select (closure), on the other[239]. Inclusion and selection are therefore two essential parts of any decision- or policymaking activity. Inclusion is also at the core of the RRI approach: "Inclusion is the conceptual dimension that characterises RRI the most"[240]. The term inclusion draws on notions of adaptive and integrative governance: Inclusion in that sense, reflects "the capacity to learn from previous and similar risk-handling experiences to cope with current risk problems and apply these lessons to cope with future potential risk problems and surprises"[241]. If issues of participation regarding precautionary measures is to be resolved, it is necessary to include knowledge and people based on previous experiences and mistakes, being open and adaptive at the same time. From this it follows that it is important to critically consider: 1. who is included? 2. what is included? and 3. what is the scope and mandate of the process? Bearing in mind the late lessons from early warnings[242], the questions above are, while simple in nature, not yet used sufficiently for self-reflection and critique.

The first two questions are linked to facilitation, mainly questions pertaining to when, who and how relevant stakeholders should be involved. The third issue addresses the need for clarity on how to address asymmetries as well as public interests. A common denominator across all sub-themes can be seen in the expressed need for clarity "pertaining to the constituting elements of the public interest", which points to normative ambiguity sparking from different values and "conflicting views on how to define [the public interest]"[243].

Endnotes

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