

RECIPES

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REconciling **sC**ience,
Innovation and **P**recaution
through the **E**ngagement
of **S**takeholders

POLICY BRIEF

Precaution for responsible innovation:

Guidance on the application
of the precautionary principle in the EU

Policy Brief, April 2022

RECIPES guidance: Executive summary

This policy brief is the executive summary of the RECIPES guidance on the application of the precautionary principle in the European Union (EU). This guidance advises on how to responsibly deal with uncertain risks¹ in the development and implementation of technology in the EU. It helps EU risk regulation and innovation policy to use the precautionary principle for responsible technological innovation.

Target groups of this guidance are primarily EU policymakers, EU agencies², and EU policy support organizations and bodies³ that are concerned with risk regulation or the governance of science, technology and innovation. The guidance offers them ideas about how to further improve addressing uncertain risks in EU risk regulation and innovation policy.

The guidance also addresses researchers and innovators and various societal actors who can contribute to a society-wide innovation system. The guidance shows these target groups that their contributions are needed for applying the precautionary principle for responsible technological innovation.



Key messages

- 🌀 **The precautionary principle works best in a dual role: as a safeguard and a compass.** As a legal principle and safeguard, it can justify early policy or regulatory action to manage uncertain risks. As such, it ensures that the rights of current and future EU citizens are protected. As a compass and policy principle in research and innovation, the precautionary principle can trigger upstream debates and research about the potential impacts of emerging technologies and related innovation pathways, and can lead to adjustments in innovation development and stimulate responsible innovation. By playing this dual 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.
- 🌀 Precaution is often defined as a risk management principle applied after scientific assessment takes place. However, there is good reason to **invoke the precautionary principle in risk assessment (as well as in problem scoping)**. Such an approach **safeguards against understating uncertainty** and opting by default for the application of a more narrowly focused quantitative risk assessment that is inadequate for dealing with states of knowledge characterized by strong uncertainties and/or ignorance.

¹ 'Uncertain risks' are understood in the RECIPES guidance as threats for which it is not possible to confidently quantify the magnitude of a defined and agreed upon range of outcomes or the probabilities of these outcomes.

² For instance, the European Environmental Agency (EEA) or the European Food Safety Authority (EFSA).

³ 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).

The overall process of risk governance should be precautionary in the sense that it is consistently sensitive to uncertainties and knowledge gaps, as well as to potentially serious harm.

⚙️ **Early and recurrent risk research and anticipatory and foresight processes in risk and innovation governance (precautionary principle as a compass) are a cornerstone in responsible innovation.**

Responsible innovation 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 a responsible innovation perspective, the precautionary principle is essential to help ensure responsive, adaptive and integrated management of the innovation process.

⚙️ **Participation of relevant stakeholders and knowledge-holders is another cornerstone of responsible innovation.**

A transdisciplinary approach is required in which not only scientific experts from multiple disciplines but also other knowledge-holders (e.g. professionals, workers, consumers 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. Moreover, participatory processes can uncover and help address conflicts of knowledge, values and interests in connection with dealing with uncertain risks.

Why is it strategically relevant to address the relationship between precaution and innovation?

The precautionary principle is an important instrument for EU law and policy. The precautionary principle allows policymakers to adopt decisions to counter potential serious harm, despite a situation of scientific uncertainty.

The precautionary principle is a general principle of EU law, laid down in the EU Treaty and case law. This implies that there are principally no defined boundaries with regards to the question as to which risks or what technologies the precautionary principle can be applied. It should be noted, though, that in each application of the principle, the scope of application is informed by the relevant laws.

The precautionary principle is an open and flexible principle. It is not – and cannot be – used as a rigid decision-making instrument. The principle urges policymakers to carefully reflect on the situation and the uncertainties around it, but does not offer predetermined solutions. This also implies that policymakers have more discretion compared to situations of standard risk management. The best course of action in the case of an uncertain risk depends strongly 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 policymakers.

They are expected to maneuver 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.



What can you expect from the guidance?

The guidance connects the precautionary principle with a new concept of governing research and innovation

There have been fierce debates among EU-level stakeholders about the relationship between precaution and innovation in the wake of the emerging notion of an 'innovation principle' at the European level.⁴ In this debate, it is important to clarify the application of the precautionary principle, in particular with respect to its influence on innovation.

There is a need to further discuss and clarify how the precautionary principle can help implement a transformation-oriented and value-driven approach to innovation as envisioned by the current research and innovation strategy of the European Commission (2020-2024). This strategy identifies research and innovation as key drivers in achieving the European Commission's goals that are geared towards a sustainable and prosperous future for people and the planet, based on solidarity and respect for shared European values. We need a better understanding of how the precautionary principle can help guide established technologies and technological development towards a high level of protection of human health, the environment and social rights (such as the right to safe and healthy work) in the implementation of the desired transformation towards sustainability. **Considering the precautionary principle as a safeguard and compass can make an important contribution to developing this understanding.**

The RECIPES project has demonstrated the clear **relevance that the precautionary principle has at the international, EU and national levels.**⁵ It was in the 1970s that precautionary thinking was first developed as a legal principle in domestic law, notably in Germany (the so-called 'Vorsorgeprinzip'), Switzerland and Sweden. Since then, it has been increasingly incorporated by states and international institutions in various international instruments and conventions, by the EU in the Maastricht Treaty, and by several EU Member States in their national legislation. At the EU level, the precautionary principle is not only a key principle for EU environmental policy, but is also included in all policy areas under the integration principle. While the focus of the application still lies on the 'traditional' policy areas of environmental, consumer and health protection, the principle has also gained relevance in other policy fields.

Various interpretations of the principle are applied at the international, EU and national levels. They differ, among other things, in the ways they draw on the several normative underpinnings and ethical considerations that the precautionary principle incorporates (although not explicitly). Still, the various versions of the precautionary principle share a **common basic idea**: We should not require full evidence of harm to protect us from potentially dangerous effects from, for example, a product, service, or technology. To put it in simple terms: **When in doubt, be cautious.**

The RECIPES guidance **links the precautionary principle to the more recent notion of 'responsible innovation' and highlights the precautionary principle as an important enabler** to the implementation of this new approach to the governance of research and innovation.

⁴ The RECIPES policy brief dealing with the innovation principle can be viewed here: https://recipes-project.eu/sites/default/files/2020-03/PolicyBrief_Recipes_Online20200320_01.pdf.

⁵ The RECIPES stock-taking report on the application of the precautionary principle can be viewed here: <https://recipes-project.eu/results/taking-stock-precautionary-principle-2000>.

"Responsible Research and Innovation" was introduced as a crosscutting issue under the EU Framework Programme for Research and Innovation "Horizon 2020" (2014-2020), and became an operational objective of the strategic plan for the next and current EU Framework Programme, "Horizon Europe" (2021-2027). In EU Member States, there are also research funding initiatives that operate under responsible innovation taken by national research councils such as, for example, the UK Engineering and Physical Sciences Research Council (EPSRC), and the Dutch and the Norwegian Research Council. The concept also resonated internationally, notably in the United States.

Scholars have provided a variety of perspectives of what needs to be addressed by responsible innovations. The editors of an International Handbook on Responsible Innovation however see a shared notion:

"Responsible innovation advocates will argue that the innovation process is neither steerless nor inherently good. Instead of being steerless, innovation can be managed and a growing body of research constitutes a testimony on how we can manage innovation and shape technologies in accordance with societal values and expectations as well as (re-direct) them towards normative targets such as sustainability goals."

Responsible Innovation: A new concept for the governance of research and innovation.
Source of quote: von Schomberg, R., & Hankins, J. (2019). Introduction to the International Handbook on Responsible Innovation. In: von Schomberg, R., & Hankins, J. (eds.), International Handbook on Responsible Innovation. A Global Resource, Edward Elgar, 1-11, here p. 1.

A key prerequisite for responsible innovation is a form of governance that will drive innovation towards societally desirable outcomes, using inclusive innovation processes in which all relevant actors commit themselves to these outcomes. The European Green Deal and the EU Framework Programme Horizon Europe, with its mission-oriented approach and the thematic clusters centered around the United Nations' Sustainability Development Goals, can be seen as incorporating this idea.

Another key prerequisite for responsible innovation is a form of governance that will improve dealing with **unintended consequences of innovation in the process of research and innovation**. This requires mechanisms for anticipating and responding to possible harm associated with innovation and applies to innovations that promise to deliver a collectively defined societal purpose (e.g. climate protection technologies can also have unintended and undesired effects that need to be addressed), as well as to innovations in general. The concept of responsible innovation addresses the observation that market innovations do not automatically lead to results that are beneficial to society as a whole or may be accompanied by negative side effects.

Science and technology scholars have argued that there is a need to promote **anticipation, reflexivity, inclusion and responsiveness** in the governance of science, technology and innovation. More anticipatory, reflexive, inclusive and responsive forms of governing make it easier to raise, discuss and respond to questions about both the intended and unintended impacts of science, technology and innovation. They facilitate directing or re-directing innovation, and the science and research intended to lead to it, towards societally beneficial ends such as sustainability goals or maintaining high levels of protection of human and environmental health.

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."

Reflexivity:

"At the level of institutional practice, reflexivity 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."

Inclusion:

"The waning of the authority of expert, top-down policy-making has been associated with a rise in the inclusion of new voices in the governance of science and innovation as part of a search for legitimacy [...]." 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". "There are various mechanisms that might allow innovation to respond to improved anticipation, reflexivity and inclusion. In some cases, **application of the precautionary principle**, a moratorium or a code of conduct may be appropriate. Existing approaches to technology assessment and foresight may be widened to engender improved responsiveness [...]" (emphasis added)



The guidance highlights how the precautionary principle as safeguard and compass can be used for responsible technological innovation

The RECIPES guidance shows that the **precautionary principle can serve as an important tool** to make innovation governance more anticipatory, more reflexive, more inclusive and deliberative, and generally more responsive in the EU. Specifically, it highlights how the precautionary principle can be used for **responsible technological innovation in the EU**. In the past, scientific and technological progress have not necessarily been 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 governments to take responsibility grows significantly. The guidance subsequently answers to an urgent need for more instruction on when and in what ways the precautionary principle can be applied to new or established technologies.⁶

The document identifies **two ways** in which the precautionary principle can operate for responsible technological innovation in the EU: **safe-**

Four integrated dimensions of responsible innovation.
Source of quotes: Stilgoe, J., Owen, R., Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy*, 42(9), 1568-1580.
<https://doi.org/10.1016/j.respol.2013.05.008>.

⁶ The focus of the guidance includes new and existing technologies as well as cross-cutting technologies such as nanotechnology and specific technologies such as weed control products. The RECIPES case study on the latter illustrates the importance of the precautionary principle in addressing systemic challenges such as biodiversity loss.

guard and compass. The safeguard function builds on the precautionary principle as a **legal principle**, and the compass function on the precautionary principle as a **policy principle**.

The RECIPES guidance provides orientation and inspiration regarding the proposed two-way use of the precautionary principle 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 the EU's capacity to anticipate, identify and manage scientifically uncertain, but 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.

RECIPES guidance: Two-way-use of the precautionary principle for responsible innovation

RECIPES research has identified scope of application, organization of expertise, and participation as three **key themes for the application of the precautionary principle**. The idea of considering the precautionary principle as a safeguard and compass is introduced in the part of the RECIPES guidance that deals with the scope of application of the precautionary principle. It is taken up in the other two parts of the guidance, i. e. the one concerned with the organization of expertise for the application of

the precautionary principle, and the one dealing with participation processes in support of the application of the precautionary principle.

Themes addressed in the RECIPES guidance



Scope of application:

relates to issues such as when and how the precautionary principle is to be applied, considering its relationship with innovation; it introduces a two-way use of the precautionary principle, as safeguard and compass, and points to six phases in the application of the precautionary principle.



Organization of expertise:

revolves around the question of how to organize and timely collect and co-create actionable knowledge required for applying the precautionary principle.



Participation:

concerns conceptual and methodological issues in terms of when to involve stakeholders, whom to involve, and how to do so, when applying the precautionary principle.

The bulk of the points of the stakeholders, who participated in the RECIPES consultation process on how to improve the application of the precautionary principle in the EU, was related to one or more of these three themes. The themes played, to varying degrees, a role in the RECIPES case studies, and the relevant literature recognizes them as important topics in the interpretation and application of the precautionary principle (below you will find more information about the main sources of information of the RECIPES guidance).

SCOPE OF APPLICATION of the precautionary principle

The RECIPES guidance proposes to use the precautionary principle in two ways, as safeguard and compass.

Precautionary principle as a safeguard and legal principle

On the one hand, **the precautionary principle acts as a legal safeguard**, through its formal inclusion in EU policies and regulations for the authorization of products or processes. As a safeguard and legal principle, the precautionary principle can justify early policy or regulatory action in a context of uncertainty to avoid potentially serious harm. It can also justify a policy reform under conditions of uncertainty such as the new EU chemicals strategy, which is part of the European Green Deal and aims to ensure that all new chemicals and materials are inherently safe and sustainable, from production to end of life.

As a safeguard, the precautionary principle works as an appeal to prudence: the precautionary principle permits policymakers and legislators to intervene despite scientific uncertainty when there are reasonable grounds for concern that significant harm may result from a new technology or that an existing technology may be more harmful than initially expected. This 'permission to act' reflects the limits of science in providing full certainty. Even in cases of scientific uncertainty, policymakers should still be able to act to ensure the appropriate level of protection. As such, the precautionary principle functions as a guiding principle that provides helpful criteria for determining the best course of action in confronting situations of potential risk and scientific uncertainty on the probability of harm arising and the extent of the harm.

For the application of the precautionary principle as a safeguard the following elements are to be considered: scientific uncertainty (related, for instance, to a lack of knowledge or a situation of ambiguity), seriousness

of risk (a particular threshold of possible harm must be present, but EU institutions enjoy some discretion in establishing what counts as reasonable grounds for concern), level of scientific analysis (a scientific examination must have taken place), and characteristics of the uncertain risks.

Scientifically underpinned grounds for concern are enough to justify precautionary action in cases of uncertain risks. In such cases, action does neither require scientific certainty, nor an exhaustive risk assessment. Uncontested scientific proof of risk cannot be available in cases of uncertain risks. In 2021, the EU Court of Justice re-confirmed that, with regard to plant protection products, "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."⁷

The use of cost-benefit analysis is of limited value in cases that require the precautionary principle. Not only can the risk assessments of new products and technologies be hindered by inconclusive evidence and uncertainties, but the proclaimed benefits are also often not fully evident beforehand. One cannot weigh fundamentally unknown costs against fundamentally unknown benefits without making highly speculative assumptions. If risks cannot be reliably quantified, the principle of prevention is applicable instead, whereby regulators can set an acceptable risk level and implement the risk



⁷ Case C-499/18 P, Bayer CropScience AG and Bayer AG, v. European Commission, Judgment of 6 May 2021, ECLI:EU:C:2021:367; para 81.

reduction measures needed to keep the risk at an acceptable level.⁸

The choice of who or what receives 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 situation needs to take into account the 'knowledge condition' (e.g. reasonable grounds for concern) and consider what is at stake for whom, and subsequently choose which interest(s) are given the benefit of the doubt: environmental protection, public health, social rights, intergenerational justice, national economy or specific economic interests, to name a few. Such risk management decisions need to be informed by transparent deliberation over and communication of the outcomes of the risk assessment (what is known or 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 the Sustainable Development Goals.

Precautionary principle as a compass

In addition to being a safeguard and legal principle, the precautionary principle should also be applied as a **compass and policy principle** in research and innovation. In this function, the precautionary principle:

- triggers **upstream debates and research about the potential impacts** of emerging technologies and related innovation pathways;
- helps **anticipate potential risks and unintended outcomes**;
- helps **stimulate early adjustments** in innovation development.

This implies the broadening of innovation processes in two ways: making space for the societal and environmental aspects of the technology in addition to the technical, scientific and economic ones, and anticipating how the technology will function in society.

The compass function of the precautionary principle links to the dilemma of control. By the time the environmental, health-related and other social implications of technologies are made manifest (possibly only in multi-decadal timeframes), they may already be widely embedded in societal structures, making a change of direction hardly or no longer possible. The use of the precautionary principle as a compass and policy approach means carrying out activities at an **early stage and on an ongoing basis** in technology development to **anticipate** possible risks. One example activity is the funding of early and ongoing **risk research**. Another example activity is making early and repeated use of **foresight approaches or extended forms of technology assessment** (such as constructive technology assessment) in order to elucidate the possible risks and benefits by projecting different scenarios of innovation development and their effects. Exploring possible risks and benefits for affected groups (e.g. consumers or workers) and for vulnerable groups (e.g. children or elderly people) and groups that cannot speak for themselves (e.g. future generations) requires the inclusion of different expert disciplines (e.g. to deal with both physical and social impacts). Experience-based and practical knowledge is also needed, which is why the exploration should take place with the engagement of stakeholders. The time lags associated with non-linear impacts require the additional inclusion of youth groups as well as addressing the issue of intergenerational equity.

It is part of the dilemma of control that anticipation may not provide scientific evidence for adjustments in the innovation process because the technology is not yet sufficiently developed and widespread. Anticipation can, however, **help to understand the relevant uncertainties and possible ways of exploring alternative innovation pathways**. Anticipation activities are already taking place in EU innovation governance, but could be applied more widely and systematically.

The knowledge generated by using the precautionary principle as a compass and policy

⁸ However, what is acceptable at one point in time may not be at a later point, so that reviews of risk management are required.



principle can stimulate responsible innovation. Responsible innovation can consist of technologies that support new ways of living that better protect humans and the environment alike. It can also consist of nurturing more diverse innovation approaches (including social innovation) that help to better prepare for identified uncertainties, e.g. regarding how a technology will work in different cultural, social and ecological settings. The knowledge generated by using the precautionary principle as a compass can also help **promote a timely and more broadly informed application of the precautionary principle** in EU risk policy and regulation.

Phases of applying the precautionary principle

The six phases of the application of the precautionary principle can be summarized as follows: (1) ensuring value-based innovation processes, (2) *a priori* risk reduction through anticipation, (3) early warnings, (4) assessing the situation, (5) deciding on the appropriate measures and (6) monitoring the situation. The first two phases concern the use of the precautionary principle as a compass. The first step involves the choices as to what kind of innovation is going to be made, considering what innovations are needed for the pursuit of values that drive EU policy such as a high level of protection of human health and environment, quality of life, and sustainable development. By anticipating possible negative side effects of alternative technological or socio-technical innovation

pathways, the precautionary principle can help steer technology and innovation development into societally beneficial directions. The precautionary principle as a safeguard is relevant as soon as there are reasonable grounds for concern about a specific technology. The principle also benefits risk assessment processes by pointing to scientific uncertainty and knowledge gaps. Moreover, an 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, the situation should be monitored once the measures have been taken.

ORGANIZATION OF EXPERTISE for the two-way-use of the precautionary principle

Risk assessment, technology assessment as well as innovation policies and funding need to be well-informed by the precautionary principle to ensure that situations that require consideration of the precautionary principle can be detected more adequately and timely, and to ensure that new technologies become less likely to bring new risks. Well-organized and timely collection and generation of *actionable knowledge*⁹ is key for dealing prudently with uncertain risks. Actionable knowledge for applying the precautionary principle is knowledge of the severity and nature of potential adverse effects, the nature of the uncertainties on the risks and the proclaimed benefits, explicit articulation of knowledge gaps regarding risks and benefits, and knowledge of possible alternatives to the risky technology or product under scrutiny.

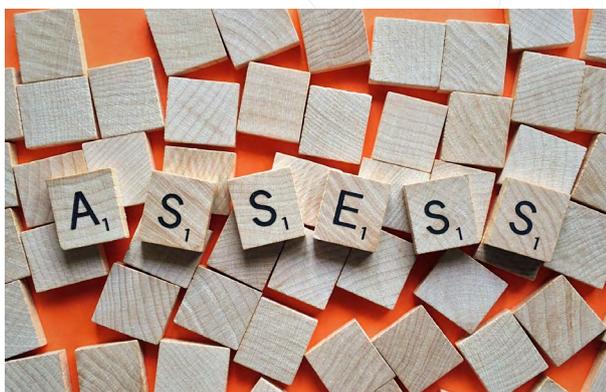
The pluralization of expert knowledge in scientific assessment is essential to ensure that scientific advice for policy (risk management and innovation governance) is in line with the best available evidence and considers all relevant scientific issues and knowledge. It should be ensured that as much relevant knowledge

⁹ On the science of actionable knowledge as an emerging area of inquiry that "aims to understand and catalyze transitions in scientific knowledge making and use" see: Arnott, J.C., Mach, K.J., & Wong-Parodi, G. (eds.) (2020). Advancing the science of actionable knowledge for sustainability. *Current Opinion in Environmental Sustainability*, 42 (Special Issue), A1-A6, 1-82.

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. professionals, workers, consumers and local people) are asked to contribute their specific knowledge regarding the likely consequences of the particular technology under scrutiny.

The EU needs to develop good practices and build capacity regarding how actionable knowledge for precaution can be fruitfully pluralized. It is important to explicitly identify and mobilize relevant knowledge-holders regarding the issue at hand. It further requires that risk assessors work with a greater diversity of ways of knowing than is the case today. Good practices need to be developed for weaving a wider range of knowledge, such as experience-based or practical knowledge, into risk assessments. Participatory and deliberative governance approaches play a crucial role here (see next Section). To pursue the pluralization of knowledge while attending to power requires preventing corporate capture or misinformation campaigners from slipping into spaces of knowledge 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.



Policymakers should require that risk assessment includes a systematic and transparent appraisal of scientific uncertainties, knowledge gaps and ignorance. An informed application of the precautionary principle requires risk assessment authorities to identify and characterize 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 policymakers and risk managers.

There is room to reform the regulatory system to become more flexible to act on early warnings and more open to including externally produced knowledge (various forms of knowledge produced outside of academia or governmental agencies) in routinized assessment processes and guidelines. It should consider a wide range of potentially relevant aspects of risks, including non-standardized so-called 'endpoints' of the risk assessment. There are reported past cases where uncertain risks that should have required precautionary action were overlooked due to blind spots in the risk assessment protocols and guidance documents used by EU agencies. Knowledge about risks that does not fit in these protocols (mostly academic scientific studies published in the peer-reviewed literature) was downplayed, marginalized or ignored. Too often, it is necessary that coalitions of concerned scientists and societal actors step in and 'break the script' of routinized assessment and management processes in order to recognize key uncertainties and the potential for serious harm to human and environmental health.

Limited learning and information sharing across regulatory domains weaken the system's overall capacity to identify, understand and manage plausible threats. Ongoing reforms towards a holistic approach to chemical authorization 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 rather than a weakness.

The search for less harmful and more ecologically 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 and are respectful of social rights. 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 are acknowledged as forming a body of actionable knowledge.

PARTICIPATORY PROCESSES to support the two-way-use of the precautionary principle

Inclusive and reflexive participatory processes are essential to promote good governance and adaptive policy-making in the application of the precautionary principle as a safeguard and compass. Under conditions of high levels of uncertainty, a key question is: How can one judge the severity of a (future) situation and the appropriateness of precautionary measures, when the potential harm and its likelihood are unknown or highly uncertain? In this situation, it requires the participation of a diversity of knowledge-holders and stakeholders in the task of finding a balance between doing too little or doing too much with regard to the protection of human health, social rights (such as the right to safe and healthy



work), and the environment. When a given uncertain risk is also subject to strongly divergent socio-cultural attitudes, political perspectives, or economic interests (high level of social ambiguity and potential for social conflict and mobilization), a broad societal discussion may be required.

Inclusive-deliberative processes can uncover the plurality of relevant knowledge, views and concerns of stakeholders including citizens that need to inform the application of the precautionary principle. They can help address conflicts of knowledge, values and interests that may be associated with the question of how to deal with the uncertain risks of a given technology.

Participatory processes need to rely on sound expertise with regard to deliberative methods and analysis of situational factors. Tools such as the ActionCatalogue¹⁰ should be consulted as a database of methodologies for deliberative practices. The ActionCatalogue is an online decision-support tool that enables researchers, policymakers and others conducting transdisciplinary research to find appropriate participatory methods and formats for their specific needs. Funders and organizers of participatory processes should have sound knowledge about e.g. the level of maturity concerning an innovation, the prevailing risk governance arrangements, the overall objective of stakeholder engagement in those arrangements, and power asymmetries amongst stakeholders as well as other actors involved in the risk governance process when choosing

¹⁰ The action catalogue, developed by the EU-funded Engage2020 project, can be viewed here: <http://actioncatalogue.eu/>.

a specific method or format of participation. Furthermore, they should be aware of the general need for transparency with regard to participatory decision-making processes.

Participatory-deliberative processes, implemented as instruments of good governance and adaptive policy learning in the application of the precautionary principle, should aim for fairness and competence. Inclusive as well as fair and competent participatory processes are vital for the EU to uphold its commitment to good risk governance.

Public participation has been incorporated into international treaties such as the 1992 Convention on Biological Diversity, regional instruments such as the 1998 Aarhus Convention, as well as in EU environmental legislation. **Participatory-deliberative practices need to be improved further to enable policymakers and decision makers to address the multiplicity of risks and the 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 on complex topics require **buy-in and follow-through of policymakers and regulators.** This demand should be reflected in the **allocation of resources** in project calls, regulation processes, and decision-making. Ensuring fair and competent participation requires that policymakers and regulators are able and expected to prioritize good governance practices and adaptive policy learning. Such prioritization should be facilitated through the allocation of resources as a basic practice of regulation and decision-making.

Main sources of information for the RECIPES guidance

The main sources for the guidance are the insights that were gained through the following

empirical activities of the RECIPES research project:

- An extensive **review of the literature and legal documents and a legal analysis** of how the precautionary principle has been applied in practice at the international level, EU level and in five European countries since the year 2000.¹¹
- Nine **case studies** and an inter-case study analysis aimed at understanding and analyzing the commonalities and differences in the application of the precautionary principle towards innovation in the EU depending on the topic and the context.¹²
- A year-long **stakeholder engagement process** in which participants from the policy sector, industry/business (predominantly from the chemical, pharmaceutical, and biochemical industry), civil society (including organizations concerned with environmental protection, consumer protection, and occupational health and safety), and academia (mostly scholars of science and technology governance) identified needs with regard to the future application of the precautionary principle. The stakeholders were asked what they thought was needed to ensure that the application of the precautionary principle encouraged innovation and, by that, contributed to the achievement of societally beneficial goals.¹³
- A series of **review workshops** in which draft versions of the guidance were discussed amongst the above-mentioned stakeholders as well as other knowledgeable stakeholders (including European and national agencies in the fields of environmental protection, health protection, and occupational health and safety) who had not contributed to the origin of the drafts, i.e. the stock-taking report, the case studies and the needs assessment.

¹¹ The stock-taking report can be viewed here: <https://recipes-project.eu/results/taking-stock-precautionary-principle-2000>.

¹² The case study reports can be viewed here: <https://recipes-project.eu/results/analysis-case-studies>.

¹³ The needs assessment report and the related RECIPES policy brief can be viewed here: <https://recipes-project.eu/results/recipes-co-creative-process-and-needs-assessment-results>.

Main source for this policy brief

Guidance on the application of the precautionary principle in the EU¹⁴, RECIPES publication, April 2022

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Policy Brief

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¹⁴ The full guidance can be viewed here:
<https://recipes-project.eu/results/guidance-future-application-precautionary-principle>.

ANNEX: List of project journal publications to date

Please find further publications on the RECIPES website

- Sabrina Röttger-Wirtz, "Case C-616/17 Blaise and Others: The Precautionary Principle and its role in judicial review – glyphosate and the regulatory framework for pesticides", *Maastricht Journal of European and Comparative Law* (Vol. 27 2020): 529–42. <https://doi.org/10.1177/1023263X20949424>.
- Fritz-Julius Grafe and Harald A. Mieg, "Precaution and innovation in the context of wastewater regulation: An examination of financial innovation under UWWTD disputes in London and Milan", *Sustainability* (Vol. 13 2021): 9130. <https://doi.org/10.3390/su13169130>.
- Jeroen P van der Sluijs, "Insect decline, an emerging global environmental risk", *Sustainability* (Vol. 46 2020): 39-42. <https://doi.org/10.1016/j.cosust.2020.08.012>.
- Jeroen P van der Sluijs, Stéphane Foucart and Jérôme Casas, "Editorial overview: Halting the pollinator crisis requires entomologists to step up and assume their societal responsibilities", *Current Opinion in Insect Science* (Vol. 46 2021): 6-13. <https://doi.org/10.1016/j.cois.2021.08.004>.
- Laura Drivdal and Jeroen P van der Sluijs, "Pollinator conservation requires a stronger and broader application of the precautionary principle", *Current Opinion in Insect Science* (Vol. 46 2021): 95-105. <https://doi.org/10.1016/j.cois.2021.04.005>.

What is RECIPES?



The RECIPES project aims to reconcile innovation and precaution by developing tools and guidelines to ensure the precautionary principle is applied while still encouraging innovation.

The RECIPES project works closely with different stakeholders through interviews, workshops and webinars.

Project title: REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders

Project consortium: 11 partners from 7 European countries

Project duration: 01/2019 – 06/2022

Funded by: EU's Horizon 2020 research and innovation programme



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