



RECIPES

Precaution • Innovation • Science

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

POLICY BRIEF



Precaution and innovation:
Stakeholder perspectives on the future application
of the precautionary principle

Policy Brief, October 2021

Eliciting stakeholder perspectives

This policy brief provides an overview of different perspectives on the future application of the precautionary principle. These perspectives were collected in a year-long stakeholder engagement process in the RECIPES project. In this engagement process, we 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 desirable goals. In what we called a "needs assessment process", we collected and grouped these stakeholder needs, and then further processed them for drafting the RECIPES guidance on the future application of the precautionary principle in EU innovation policy and risk governance.

In the needs assessment, we identified the participants as relevant knowledge-holders and stakeholders for European policies and governance with regard to precaution and innovation. They included (see table below): policymakers and policy advisors; industry and small and medium-sized enterprises [SME]; non-governmental organizations [NGO] and civil-society organizations [CSO]; and academia.

Stakeholder Category	Attendants	
	Spring	Autumn
Policymakers	0	1
Policy advisors	1	3
Industry	4	8
SME	0	1
NGO	4	5
CSO	1	2
Academia (University)	6	7
Academia (Non-University)	1	3

Diversity of stakeholders attending the engagement processes during late spring and over the autumn of 2020

During the multi-stakeholder needs assessment, the RECIPES team identified **three overarching themes** related to the future application of the precautionary principle, as well as prevalent disagreements among the participating stakeholders within these themes. The reader of this policy brief can thus expect to learn about (1) the needs of a selected, but relevant group of stakeholders pertaining to the precautionary principle and its relation to innovation; (2) the proceedings in RECIPES that have emerged on the basis of findings from the needs assessment; and (3) some insights into the expressed demands, agreements and conflicts that appear in the discussion on the precautionary principle and innovation.

In a nutshell

- The participating stakeholders tended to agree that the precautionary principle is an important EU legal principle, and that the EC's 2000 Communication on the Precautionary Principle constitutes a valuable basis for the principle's application.
- They also tended to agree that precaution and innovation could and should go hand in hand.
- Some stakeholders from the chemical, pharmaceutical, and biotech industry sectors pointed out that the precautionary principle holds the potential to seriously inhibit innovation if applied improperly or excessively.
- In line with the above, these industry stakeholders stressed the need for supplementary guidance on how to comply with the normative considerations when applying

the precautionary principle. Better Regulation was highlighted as a valuable source of guidance¹.

- Several stakeholders from NGOs, CSOs, academia, and policymakers warned that too detailed and rigid guidance for applying the precautionary principle may inadvertently inhibit precautionary action when it is most needed.
- Some stakeholders from the chemical industry sector highlighted the innovation principle as a potential tool to complement the precautionary principle. Other stakeholders from the pharmaceutical and biotech industry called for the strengthening of the Better Regulation agenda in regard to precautionary measures to ensure balanced policy decisions.
- Some stakeholders from NGOs and academia maintained that innovation already has a sufficiently strong legal protection and promotion in the EU and beyond.
- The bulk of the needs that stakeholders expressed regarding the future application of the precautionary principle addressed one or more of these three themes: organization of expertise, participation, and scope of application².

¹ For an introduction to the EU approach to Better Regulation, please visit: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

² The themes are thoroughly explored in: <https://recipes-project.eu/results/recipes-co-creative-process-and-needs-assessment-results>

Identified themes in the needs assessment:

- Needs pertaining to the **organization of expertise** revolve mainly around the contestability of knowledge-related standards for the application of the precautionary principle in risk regulation.
- Needs pertaining to **participation** are concerned with clarity issues in terms of when to involve stakeholders, whom to involve, and how to do so, when applying the precautionary principle in risk regulation, and in the development of innovations such as new technologies.
- Needs pertaining to the **scope of application** deal with the issue of when, where, and how the precautionary principle is to be applied, considering its relationship with other principles.

Assessing stakeholder needs: Is there room for improvement in applying the precautionary principle?

The needs assessment constitutes the main stakeholder engagement process of RECIPES, in which the needs of a diversity of affected and interested stakeholders were collected. The procedure stretched over a year of digital (mainly workshop-based) interactions in which initial presumptions based on insights gained through previous research in RECIPES were discussed with the stakeholders. This previous research included a stock-taking report, assessing the application of the precautionary principle since 2000³, and nine case studies on the relationship between the precautionary principle

³ The report can be viewed here: <https://recipes-project.eu/results/taking-stock-precautionary-principle-2000>

and innovation in different policy areas⁴. Concluding an iterative course of stakeholder-supported discussions and refinement regarding these insights, the needs assessment comprised a set of facilitated workshops. The aim of the workshops was to identify what specific needs exist from the stakeholders' point of view in order to ensure an appropriate application of the precautionary principle in the future.



The needs assessment provided two main outcomes for RECIPES. First, it provided insights into the diversity of perspectives of the participating stakeholders on the precautionary principle and its relation to innovation. Second, the perspectives of the stakeholders on needs regarding the future application of the principle were identified, providing an important input into the development of the RECIPES guidance.

While there seemed to be agreement among all participating stakeholders that the precautionary principle is an important EU legal principle and that precaution and innovation should go hand in hand, there were also varying and partly contrasting views on how to align precaution and innovation in the future. For example, it became clear that some stakeholders saw a potential adverse effect of the precautionary principle on innovation. In their view, there is a need for better guidance on how to assure a more systematic and consistent application of the precautionary principle especially in regard to giving due respect to other relevant principles such as the proportionality principle or the so-called innovation principle, in order to avoid such effects.

Several other stakeholders warned against establishing excessively rigid guidance or regulation in regard to applying the precautionary principle. In this contrasting view, a high degree of rigidity hindered prudent dealing with threats associated with deep scientific uncertainty. Furthermore, in the view of these stakeholders, there was no need for additional tools to promote innovation (such as the innovation principle) because innovation already had a lot of strong legal protection and promotion in the EU.

Three major themes for improving the application of the precautionary principle

Three themes proved to be particularly prominent throughout the needs assessment process. These themes (see text box above) give direction for developing the RECIPES guidance. Below we explain the themes by highlighting some of their key aspects.



Organisation of expertise

In regard to the theme "organisation of expertise" the questions discussed in the workshops included for example: How can scientific quality and scientific integrity in regulatory processes underlying the invocation and application of the precautionary principle be assured? How can transparency on criteria for selecting scientific advisors and scientific results in these processes be improved?

One stakeholder from the chemical, pharmaceutical, and biotech industry sectors stressed, for instance, that there was a failure to clarify the scientific grounds for invoking the precautionary principle and to define and enforce standards for scientific integrity and best available science in (precaution-based) risk management decisions. In this view, there was a need to strengthen the governance of scientific

advice and technology assessment in EU regulatory science. In the context of this part of the discussion, participants across the different stakeholder groups agreed on the importance of rules and policies for conflicts of interests in EU agencies generally, and specifically in regard to applying the precautionary principle.

Stakeholders agreed also with the general idea of strengthening scientific integrity and quality but expressed varying views on how to achieve this. Stakeholders from the chemical, pharmaceutical, and biotech industry sectors maintained that in current EU practice there was undue emphasis on who produces science, rather than on the excellence of the quality of the evidence itself. In contrast, some stakeholders from CSOs/NGOs and academia emphasised that scientific quality required that expert groups were as diverse as possible to ensure that expertise is sourced from different scientific backgrounds. In this view, it was stressed that 'reasonable grounds for concern' as a basis to invoke the precautionary principle were different from a detailed, quantitative risk assessment.

Another issue relating to scientific quality and integrity was the role of the precautionary principle in the different stages of the risk regulation process. There was a view from academia that the precautionary principle has a legitimate role to play in both risk assessment and risk management. A precaution-based assessment could, for example, include a balanced comparison of alternatives to the innovative product or process in question in order to gather information on the relative benefits and risks of various functional equivalents. In a contrasting view expressed by stakeholders from the chemical, pharmaceutical, and biotech industry sectors, the precautionary principle should be applied only during risk management. In this view, the precautionary principle has unduly permeated the risk assessment stage in EU regulatory practice, for instance by informing scientific assessments through mechanisms such as 'cherry picking' data or studies or unjustified use of worst-case exposures. In this perspective, the application of the precautionary prin-

ciple in risk assessment threatens to undermine the evidence-based approach to policy making and increase administrative discretion and the politicisation of decision-making on risk.



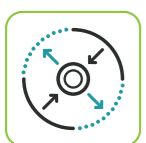
Participation

The theme "participation" was discussed dealing with questions such as: What could be methods for more systematic, qualified, and fair involvement of all relevant stakeholders in processes underlying the invocation and application of the precautionary principle? What would be societally credible hosts and fora for public and stakeholder deliberation and participation, for instance in regard to discussions about proportionality, non-discrimination, and consistency of precautionary measures in a given risk case?

Some stakeholders from NGOs and CSOs found that there is a basic need for innovative forums for society-science discussions about the role of the precautionary principle in regard to innovation and, more specifically, a responsible approach to innovation. If public engagement concerning the precautionary principle was to be fostered, it required new settings where scientists can exchange ideas with societal actors about the future use of the principle. A prominent discussion point, also raised by stakeholders from NGOs and CSOs, was power asymmetries in stakeholder engagement in regard to precaution and innovation that needed to be analysed and addressed.

Another major discussion point was the challenge to legitimately, effectively and transparently organize the science-policy interface in the processes of invocation and application of the precautionary principle. One more question that was discussed was: Where in the innovation governance process could democratic dialogue and participation help strengthening a precautionary approach to technology development and, more generally, development of innovations? In this discussion, there

was for instance a view held by stakeholders from academia that possible downsides and risks could be detected and addressed earlier in the innovation process, if broad public and stakeholder engagement played a (larger) role already in the research agenda-setting phase. A few stakeholders from SMEs, as well as the chemical sector, stressed the need for education rather than participation. In this view, promotion of scientific literacy and understanding of political processes among students and the wider public could help foster a science-based, informed and objective discourse on new technologies.



Scope of application

The discussion about the theme “scope of application” addressed topics such as: Should the application of the precautionary principle be broadened from human health, safety, and environmental protection to the protection of human rights such as individual privacy and data protection? Protection of these rights were considered by some stakeholders across the different groups as essential in areas such as artificial intelligence and machine learning. Another topic was the role of the precautionary principle in EU technology and innovation policy. In the view of some industry stakeholders, the precautionary principle has developed into an overarching EU policy principle which was considered an unfortunate development. Other stakeholders foremost from CSOs, NGOs and academia, by contrast, supported the idea to use the precautionary principle as a general policy principle to guide research, technology and innovation policy. Application of the precautionary principle to research could mean that funding is allocated to research on environmental, health and safety hazards, to step up scientific research on potentially serious risks, and to explore and compare different innovation pathways using information on the relative benefits and risks of these different pathways.

The EC’s 2000 Communication on the precautionary principle states that precautionary measures need to respect other principles. They should, for instance, be proportional to the seriousness of the potential hazard and the chosen level of protection and take into consideration their positive and negative consequences. Compliance of EU regulatory practice with these other principles (proportionality; non-discrimination; consistency; examination of the benefits and costs of action and lack of action; examination of scientific developments) was another prominent point of discussion. Mainly in the view of industry, these principles have not been respected consistently in the past, and the EC’s 2000 Communication should be updated with supplementary guidance in this regard. Focus was on the need to strengthen the application of the proportionality principle in order to achieve a sound balance between managing risks and supporting innovation⁵. For others, mainly participants from CSOs, NGOs and academia, in establishing a highly restrictive and programmatic set of conditions under which precaution may be applied, the EC’s 2000 Communication may be inadvertently inhibiting precautionary action precisely where it is most needed, i.e. where both, information (for instance on long-term effects) and time are limited, consistency and proportionality are most difficult to evaluate, and the consequences of underestimating the nature and scale of risks are most severe.

In the discussion, one view from industry was that the innovation principle should be used, complementary to the precautionary principle, as a tool to promote innovation. A different view, expressed mainly from academia and NGOs, held that innovation has already sufficiently strong legal protection and promotion in the EU and beyond. There seemed to be general agreement among the stakeholders that precaution and innovation are not in any fundamental conflict and ideally should go hand in hand. At the same time, they seemed to agree that it is a relevant but still largely open question what role the precautionary principle and precaution have in the broader governance of research and innovation.



Next Steps: Drafting of guidance

The results of the needs assessment are a major input into the development of the RECIPES guidance – as are the results of the stocktaking report and the nine case studies which informed the needs assessment process. The guidance will cover the three themes explained above. It will deal amongst others with the following questions:

- How to strengthen and broaden the knowledge base in the application of the precautionary principle so as to enhance European society’s capacity to anticipate, timely identify and manage scientifically uncertain but plausible and serious risks? What types of knowledge and considerations are relevant at what stages of risk governance? How could the application of the precautionary principle in EU risk regulation be informed through innovative processes of knowledge generation and collection, e.g., through learning within and across adjacent regulatory domains?

- How may participatory efforts be organised in ways that improve the assessment and regulation of uncertain threats? How may so-called ‘wicked problems’ be addressed through innovative engagement methods? What considerations are essential for the organisation of participatory efforts to minimize the shortcomings discussed by stakeholders?
- What considerations should policymakers and regulators go through to ensure a good application of the precautionary principle? How may various framings of the precautionary principle affect different stages of the policy cycle? How should one navigate between the precautionary principle and other relevant principles in assessing risks and steering innovation?

A pre-final version of the guidance will be discussed at a policy workshop in early 2022 to further improve its clarity, plausibility and policy relevance⁶.

⁶ You will find more information on the guidance development here: <https://recipes-project.eu/results/guidance-future-application-precautionary-principle>

⁵ Previous RECIPES research has found no evidence for a disproportionate use of precaution with demonstrable effects on innovation. Instead, precaution has been found to hold the potential to stimulate societally desirable innovation.

Main source for this policy brief

Needs Assessment. Hvidovre; The Danish Board of Technology Foundation; RECIPES report, 2021

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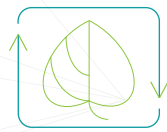
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What is RECIPES?



RECIPES
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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

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