

RECIPES
Precaution • Innovation • Science

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

POLICY BRIEF

Precaution and innovation:
Exploring collaboratively a significant relationship

In a nutshell

- The emergence of an innovation principle at the European level has triggered discussions around precaution and innovation.
- The relevance of the precautionary principle is clear at all levels (international, EU, national).
- The relevance of the precautionary principle cuts across policy fields.
- The precautionary principle is applied as a general normative guide.
- The fact that the precautionary principle is not formalised in a uniform way in international and national jurisdictions is viewed differently (flexible use vs. lack of legal certainty).
- EU law, case law and the 2000 European Commission Communication give little guidance for applying the precautionary principle.
- In contrast to the precautionary principle, an innovation principle does not exist in EU legislation and currently cannot be found in any of the Member States' legal orders.
- There are current efforts and initiatives to give an innovation principle a role in the context of law.
- Requests for the introduction of an innovation principle are often linked with demands for a different application of the precautionary principle. It is especially these requests that have been heavily opposed by other actors.
- With the launch of an innovation principle the question of how to encourage innovation while minimising hazards to people and the environment has become topical.

The precautionary principle: a topical issue

The precautionary principle first emerged during the 1970s in German law. Since then it has been increasingly incorporated by states and international institutions in various international instruments and conventions, by the European Union (EU) in the Maastricht Treaty, and by several EU Member States in their national legislation.

While the precautionary principle has a role in law and policy at all levels (international, EU, national), it is not undisputed. The principle has been endorsed as a powerful framework for improving decision-making for the environment, human health and consumer safety. At the same time, it has been criticised as vague, incoherent, unscientific, arbitrary and the like. In recent years, the debate on the precautionary principle has moved to a new level of intensity, mainly at the European level. The main reason for this is the launch of the so-called innovation principle.

The debate involving policy and academic circles and different groups of stakeholders brings up questions like:

- Is there a need for an innovation principle and if so, what would be the nature of this need?
- Is there a need for an application of the precautionary principle that explicitly relates to innovation and if so, what would be the nature of this need?
- Is there a need for having the precautionary principle and an innovation principle working together in practice, and if so, what would be the nature of this need?
- Can there potentially be a tension between an innovation principle and the precautionary principle and if so, what would be the concrete nature of such a tension?

The RECIPES project investigates the relation between the precautionary principle and innovation. To establish the baseline for its research, RECIPES has taken stock of the application of the precautionary principle at the international, European and national level and described the emergence of an innovation principle.

Taking Stock: Use of the precautionary principle since 2000

RECIPES has 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. In this year, the European Commission issued its Communication on the Precautionary Principle. The Communication sets out some constituent elements of the precautionary principle without including detailed guidance as to how to implement the principle. As with other general notions contained in EU legislation the Communication sees decision-makers and ultimately the courts as responsible to elaborate the application details.

RECIPES examined the body of literature on the precautionary principle and of legal acts, case law, soft law and main policy documents, leaving out other documents such as codes of conduct and risk assessment practices. The results of the stock-taking study help to understand the scope and ways of application of the principle on different policy levels.

The precautionary principle, a general normative guide

The RECIPES study demonstrates the clear relevance that the precautionary principle has at international, EU and national level. Various interpretations of the principle are applied at these levels. They differ, amongst others, in the ways they draw on the several normative underpinnings and ethical considerations that the precautionary principle (although not explicitly) incorporates. Still, the various versions of the precautionary principle share a common basic idea: We should not take full

scientific certainty as necessary to protect us from potentially dangerous effects from a new product or technology. To put it in simplistic terms: When in doubt, be cautious.

The fact that the precautionary principle is not formalised in a uniform way in international and national jurisdictions is viewed differently. Some see it as a necessary condition for a flexible use of the principle, which is responsive to multiple judicial and regulatory traditions and allows application to a broad range of policy fields and regulatory sectors. Others have suggested that there is a lack of a generally accepted firm definition of 'the' precautionary principle and a specified methodology. This would undermine legal certainty and produce inconsistent decisions.



Implementation at EU level

The precautionary principle in legal acts

In order to understand how the precautionary principle is used in practice by the EU institutions in legal acts, RECIPES investigated in how many legal acts the principle is used or referred to. The analysis revealed a limited number of acts (135 acts with 94 acts still in force) that expressly refer to the term 'precautionary principle' from the years 2000 to 2019. This appears as a relatively modest figure for a period of 19 years. It should be acknowledged, however, that before that period, express reference to the precautionary principle hardly appeared in legal acts and that today there are still a lot of acts that apply the precautionary principle without explicitly mentioning it. The analysis suggests further that the precautionary principle is used in a variety of policy areas, albeit still with a focus on environmental, consumer protection and internal market policies.

RECIPES has delved into those legal acts that were still in force in July 2019. Only few of these 94 acts attempt to provide a definition of the precautionary principle. A majority of the acts refer to the principle only in the recitals, which explain the rationale(s) of the act (63%), or in the annexes (8%). Only in 27 acts (29% of the cases) the precautionary principle is mentioned in the provisions of the respective act. As regards these cases, the provision of concrete guidance as to how the principle is to be applied to the particular situation covered by the legal act is the exception rather than the rule.

How many EU legal acts make reference to the PP (2000-2019)?

Legal acts in total		Legal acts still in force (in July 2019)	
Regulations	47	Regulations	40
Directives	41	Directives	27
Decisions	47	Decisions	27
SUM	135		94

These findings are first indicators of the actual application of the precautionary principle in EU legal acts and policy and will be complemented by insights from case studies being carried out in RECIPES.

Application of the precautionary principle by the EU Court of Justice

The EU Court of Justice has recognised the precautionary principle as a general principle of EU law, that means as superior to written rules (such as laws) and applied by the courts as a source of law. While only few EU legal acts include definitions of the precautionary principle, the Court of Justice has developed standard formulations that it repeatedly uses to define the principle and to name the requirements for its application.

RECIPES' study of the EU Courts' case law shows that the precautionary principle is dealt with in some detail in many cases decided by the EU Court of Justice. It further reveals that the Court has consistently held that health and environmental concerns take precedence over economic concerns; this corresponds with the European Commission's 2000 Communication.

RECIPES' analysis confirms on a broader scale what the literature suggests for individual cases: The Court's review of the application of the precautionary principle is largely limited to procedural issues. Unless there are procedural mistakes or manifest errors of assessment, the Court is reluctant to review decisions by the regulator on the basis of the precautionary principle. Among the cases analysed by RECIPES there was one instance¹ in which an individual applicant invoked the precautionary principle and succeeded. In this case the Court, by reference to the European Commission's 2000 Communication, found that the lack of an impact assessment prior to adopting a precautionary measure was a violation of the precautionary principle.

RECIPES further found that the Court has not in all cases reviewed measures based on the precautionary principle in the light of new scientific data.

¹The reference for this case is: CJEU, T-584/13 BASF Agro BV and Others v European Commission [2018], ECLI:EU:T:2018:279.



Implementation at national level

The application of the precautionary principle in the five RECIPES country cases – Denmark, Italy, Bulgaria, The Netherlands, Norway – resembles the situation at EU-level in some respects. The precautionary principle is

mentioned in a variety of legislative acts and policy documents but not defined in the national legislations. In addition, the country studies show a diverse picture of the application of the principle. There are for example country-specific topics as for instance the application of the precautionary principle to shale gas in Bulgaria or climate change in The Netherlands.

Media coverage at national level

In the first half of 2019, RECIPES performed a media analysis for three newspapers in three countries: the *Süddeutsche Zeitung* in Germany, *Le Monde* in France and *The Guardian* in the UK. The analysis found for all newspapers included that the precautionary principle is understood in many different ways, by different spokespersons and related to different topics and cases. Attempting to consolidate these, the following themes were identified:

- ⦿ The precautionary principle is relevant in relation to nature/biodiversity conservation.
- ⦿ The precautionary principle is relevant in relation to health risks.
- ⦿ The precautionary principle is part of a controversy over what 'good/relevant science' and scientific uncertainty is/implies.
- ⦿ The precautionary principle is one way of regulating industries.
- ⦿ The precautionary principle is a controversial topic in international trade debates and in debates over efficient development.

The relation between precaution and innovation was found to be addressed only in a few articles. In these articles the argument that precaution hinders innovation as well as the argument that precaution steers innovation in a more sustainable direction is mentioned. You can find the synthesis report of this research [here](#).

Implementation at international level

One of the main observations of the RECIPES study regarding the international level is that the status of the precautionary principle as a general principle of international law remains a contested issue. Some consider the principle at international level as a non-binding political guideline, while for others it is an emerging or even established general principle of international environmental law.

The precautionary principle is, according to the World Trade Organization (WTO), highly controversial in the area of international trade. While the WTO has recognised the precautionary principle as relevant under international law and even within the WTO framework, its dispute settlement body has continuously refused to apply it in favour of restrictions to international trade.

Innovation principle: an emerging notion

It is seven years ago, that the notion of an innovation principle in relation to EU policy and regulation first appeared. RECIPES has carried out a review of the emergence and evolution of this notion drawing on scientific literature and policy documents.

Innovation principle in the context of EU policy

The term 'innovation principle' was launched by the European Risk Forum (ERF), an interest group of multinational companies and trade associations in Brussels, in 2013. The ERF proposed the formal adoption of the innovation principle in European risk management and regulatory practice in an open letter to the EU-institutions. Since then, the innovation principle has increasingly been referred to in EU policy papers. In 2016, the innovation principle was for the first time politically endorsed by the Council (Competitiveness Council). In 2017, the European Commission under its open innovation policy introduced the innovation principle as a tool to systematically assess the impact of new EU policy and legislative initiatives on innovation.

Innovation principle in the context of law

In contrast to the precautionary principle, the innovation principle does not exist in EU legislation and currently cannot be found in any of the Member States' legal orders.

The RECIPES study has found that there are current efforts and initiatives to give the innovation principle a role in law. At EU-level, this includes the European Commission's definition of the innovation principle as a tool to help design EU legislation in a way that creates innovation-friendly conditions. Further, the innovation principle will for the first time be included in an EU legal text, if the references to the principle remain in the final versions of a regulation and decision for Horizon Europe (the future EU research and innovation funding program). The draft versions of these documents do refer to the innovation principle.

At Member State level, Germany has been found an interesting case in this context. In 2016, the Federal Government introduced the "Fourth Act to Amend the Genetic Engineering Act". In the explanatory memorandum for the act, the Federal Government makes the assumption that the release and placing on the market of organisms produced by new breeding techniques will also ensure a high degree of safety based on the precautionary principle and the innovation principle. This is presumably the first case in which reference to an innovation principle is included in a (draft) national legal text. Further, the German Liberal Democratic Party has called for installing the innovation principle in all impact assessments for federal legislation. This call has been subject of a controversial debate in the German Bundestag.



Innovation principle, a controversial issue

Requests for the introduction of an innovation principle are often linked with demands for a different application of the precautionary principle. It is especially these requests that have been heavily opposed by other actors.

Large parts of the chemical, pharmaceutical and biotech industry sectors have promoted the use of the innovation principle to complement (or even oppose to) the precautionary principle. They advocate the innovation principle as a safeguard against over-reliance on the precautionary principle. Over-precaution and risk-adverse policies and legislation would hamper scientific creativity and technological innovation. This has aroused suspicion and mistrust among civil society organizations, members of Green Parties (at EU and national level), and legal and sustainability scholars who have expressed concern that an innovation principle could undermine the precautionary principle and threaten the high level of environmental and health protection in the EU. In the view of many proponents of the precautionary principle, precaution is about stimulating and steering, not blocking innovation. Policy debate about an innovation principle mainly takes place at the European level.

Next steps: A collaborative process

The RECIPES research presented above together with the case study research currently being carried out (winter 2019/2020) prepare the ground for the core tasks of the project. RECIPES will develop scenarios for the future of the precautionary principle taking into account innovation. Informed by the scenarios and related discussions it will create tools and guidelines to the precautionary principle to help policy makers and other stakeholders to ensure the principle is applied while innovation is still encouraged. These tasks will be performed collaboratively with different stakeholders.

RECIPES case studies

RECIPES carries out an analysis of legal and policy initiatives on the precautionary principle and an examination of the application of the principle based on nine case studies:



New gene editing techniques (CRISPR-Cas9)



Genetically modified organisms



Endocrine disruptors



Neonicotinoid insecticides



Nano-technologies



Glyphosate



Finance, risk and urban water infrastructure



The use of artificial intelligence in healthcare



Microplastics in food products and cosmetics



In the first half of 2019, RECIPES has carried out an initial analysis of the types of actors that can be included in the RECIPES case studies, the scenario workshops and the policy dialogues that will deal with the outcomes of the scenario workshops. As a result of this stakeholder mapping RECIPES distinguishes the following stakeholder groups:

- Policy makers in the field of risk assessment, evaluation and management (at EU, national and local level)
- Agencies, authorities and public knowledge organizations in these fields (see above)
- Research / academia
- Industry / businesses
- Funding sources / finances
- Non-governmental organisations, associations and interest groups
- Citizens and civil society organisations
- Future generations and the world (be represented, for instance, by young people)

RECIPES will address several of these actor groups in the next steps of the project.

Citizen Meetings – the first step in the RECIPES co-creation process

In May and June 2019, RECIPES invited citizens in Denmark, Norway, the Netherlands, Italy and Bulgaria to reflect on issues related to precaution and innovation in relation to research and to provide their ideas and opinions. Among the major findings in the five citizen meetings was that participants did not see precaution and innovation as being in contradiction with each other and that the precautionary principle was almost universally recognised as an appropriate and effective tool to regulate uncertainties arising from the development of technologies. A general view was that stakeholders and citizens should be widely involved in the process when applying the precautionary principle. You can find the synthesis report of this research [here](#).

Sources of this policy brief²

Taking stock as a basis for the effect of the precautionary principle since 2000. Maastricht: Maastricht University, [RECIPES report, 2020](#)

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RECIPES approach for stakeholder mapping. The Hague, Rathenau Institute, Unpublished manuscript of RECIPES, 2019.

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² The first three sources can be downloaded from the RECIPES Website.

What is RECIPES?



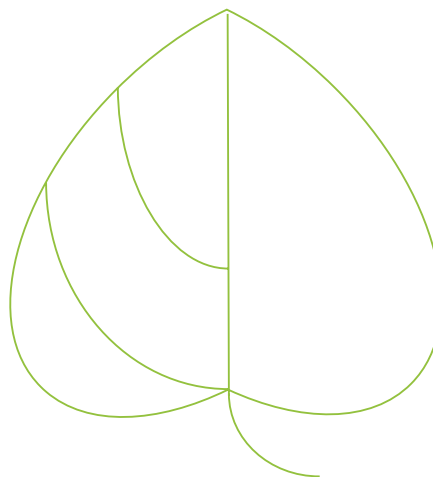
The RECIPES project aims to reconcile innovation and precaution by developing tools and guidelines to ensure the precautionary principle is applied while still encouraging innovation.

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

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

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