



Taking stock as a basis for the effect of the precautionary principle since 2000

During the first half-year of the RECIPES project we performed a stock-taking exercise of publicly available scientific articles, other scientific and non-scientific reports or documentation, legislation and case law, published since 2000. The results of this stocktaking exercise were presented in a report.

The objective of the report was to create a knowledge basis on the effect and the application of the precautionary principle since 2000 and to clarify the relationship between precaution and innovation.

The report presents an overview of the discussions and reflections on the precautionary principle in the literature and its application in law and practice since 2000, on innovation and on the 'innovation principle'. As such, it provides input for the next steps in the RECIPES research.

This synthesis report presents the main findings from the full report.

Framing the Precautionary Principle

The precautionary principle allows decision-makers to act despite scientific uncertainty. Since the 1970s the precautionary principle has steadily advanced as a general – although contested- principle in

international law and in the whole domain of risk governance. There is, however, no universal definition of the precautionary principle.

The principle achieved global recognition in 1992 when it was included in Principle 15 of the Rio Declaration resulting from the UN Conference on Environment and Development. The provision reads as follows:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their abilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Also in 1992, the European Union stipulated through the Maastricht Treaty on the European Union in Art. 130r (now Art. 191 TFEU) that the European Union's environmental policy 'shall be based on the precautionary principle', yet without providing a definition of the precautionary principle. In 2000, the European Commission adopted a Communication on the Precautionary Principle to guide the use of the precautionary principle in the EU, however again without providing a definition of the precautionary principle.

Nowadays, versions of the precautionary principle have been adopted in more than 50 international agreements.

The application of the precautionary principle does not require a predetermined action. Rather, the action required from the application of the precautionary principle depends on the formulation (weak versus strong) of the precautionary principle in the specific legal act.

The precautionary principle is essentially an appeal to prudence addressed to policy

makers who must take decisions about products or activities that could be seriously harmful to public health and the environment. For that reason, the precautionary principle does not require a predetermined action or does not offer a predetermined solution. Rather, the precautionary principle can be seen 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 the harm.

The strength of the precautionary principle is argued to lie precisely in its open-endedness and flexibility, which creates a possibility and an incentive for better regulation.

The precautionary principle has been praised as a ground-breaking way to protect the environment and public health. At the same time, the precautionary principle has also been criticised as vague, incoherent, unscientific, arbitrary and the like.

The Precautionary Principle and Innovation

Some also worry that the precautionary principle may inhibit innovation. No single definition exists of 'innovation'. Elements that generally reoccur in definitions of innovation are: an active and intentional enterprise of bringing about (positive) functional change.

There also seems to be ambiguity about 'what' can be considered innovation. The term is used to describe processes that use new knowledge and technologies, as well as processes to generate new products and the new or improved products themselves. It also appeared that in general innovation is perceived as positive, however, the content and/or outcome of innovation is in principle neutral.

The precautionary principle expresses a need for caution with regard to the introduction of novelty in the world. The discourse surrounding innovation instead

adheres to the conviction that the introduction of novelty constitutes progress.

The tension between precaution and innovation might be a consequence of the fact that innovation often focusses on particular, short-term goals from an individual (company/innovator) perspective, while the precautionary principle refers to long term, universal, public or general values/phenomena. The precautionary principle is thought to guard against the (unintended) consequences that may also affect 'the rest' of society or 'the world' in the long run, even those that cannot represent themselves, such as nature and future generations.

However, in principle, innovation is not considered to be incompatible with upholding the precautionary principle.

The 'innovation principle'

The term 'innovation principle' was first proposed by the European Risk Forum (ERF) in 2013.

In advance of the October 2013 European Council on innovation, the ERF, in a letter addressed to the then three Presidents of the EU institutions and signed by 12 CEO's, proposed the formal adoption of an 'innovation principle' which would imply that

"whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed".

This 'innovation principle' does not have a legal status and is not a general principle of EU law. Rather, it is a policy that defines an objective.

The tension between the precautionary principle and an innovation principle reflects a tension between EU's objectives: the EU aims to foster jobs and growth with scientific advancement, and to ensure a high level of environmental protection and sustainable development (see Art. 3 (3)

TFEU. The main question is how to reconcile science, innovation and precaution.

The Precautionary Principle and the 'Innovation Principle'

The literature review revealed that some authors try to relate an innovation principle to the precautionary principle. Von Gleich and Petschow (2017) have derived three interpretations from current debates around the introduction of the 'innovation principle'.

A first interpretation is to consider the innovation principle to 'only' complement the precautionary principle or 'One More Principle to be Considered'. According to this view, regulatory assessment processes should try to reconcile the two principles and achieve a more balanced use of the precautionary principle. It remains unclear, however, what exactly should be balanced with the precautionary principle and how this balancing could be carried out.

A second interpretation labelled as 'Systematic Assessment of Potential Threats and Benefits', sees the innovation principle also as complementing the precautionary principle but is aimed at systematically balancing precautionary measures with societal benefits of innovations. It suggests an ambitious and science-based appraisal process corresponding with the agendas of better regulation and responsible research and innovation (RRI).

A third interpretation asserts that the introduction of the innovation principle should limit the application of the precautionary principle or 'Downgrading the Precautionary Principle'. The precautionary principle is challenged on the ground that it stifles innovation and hence jeopardizes EU competitiveness, jobs, and growth.

For the RECIPES research it is premature at this stage to take a position with respect to these interpretations.

Nevertheless, these are very useful insights that should guide the case studies that will be carried out in Work Package 2.

The case-studies will explicitly consider the effect of the precautionary principle on innovation in the particular field, whether and how precaution and innovation have been considered, and study how the application of the precautionary principle could be improved, in order to stimulate socially desired innovation.

Implementation of the precautionary principle at various policy levels

Besides an overview of the discussions and reflections on the precautionary principle, innovation and the 'innovation principle', we also examined the practical application of the precautionary principle at international, EU and Member State level.

Implementation at international level

The literature research revealed that, despite occurrences in more than 50 international treaties, the definition and legal status of the precautionary principle at international level remain unclear.

The restrictive approaches of the ITLOS, ICJ and WTO show that the precautionary principle still faces many obstacles to being recognized as a genuine principle of international law.

However, this is not surprising, since wide divergences between states persist in relation to precautionary action, the way it has to be implemented and the goals it should seek to achieve. In that regard, clashes occurred in particular within the framework of the WTO between the European Union ('EU'), a fierce defender of precaution, and the United States and Canada, proponents of a science-based approach.

Implementation at EU level

We studied the application of the precautionary principle at EU level in EU law and practice since 2000, the year of the adoption of the Commission's Communication on the Precautionary principle.

In this Communication, the Commission described the situations in which the precautionary principle should be applied:

"In those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environmental, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community"

We moreover examined in how far the guidelines that were developed by the European Commission in its Communication have been applied in the legal practice.

We therefore performed a review of the literature and an empirical study looking at all legal acts that used or referred to the term precautionary principle. This bird's-eye perspective gave us an idea whether and how the precautionary principle was used over the years.

Our 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. Whilst this is a relatively modest figure for a period of 19 years, it should be acknowledged that before that period, express reference to the precautionary principle hardly appeared in legal acts and that today there exists still a lot of acts that apply the precautionary principle without mentioning though the precautionary principle. This means that in practice there are likely to be many more situations where the precautionary principle is being applied.

Furthermore, it appears 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.

It must be acknowledged that the bird's-eye perspective is an important starting point but is not able to precisely grasp the actual application of the precautionary principle in EU legal acts. To this end, the case studies that will be carried out in Work Package 2, will investigate in detail the application of the precautionary principle in various policy areas.

Moreover, although our analysis does not reveal an increase in number over the years, but shows an evenly spread number of acts over the years, we may very well consider the number of 135 legal acts, of which today 94 acts still in force, to be more elevated when seeing this in the context before the Communication was adopted in 2000.

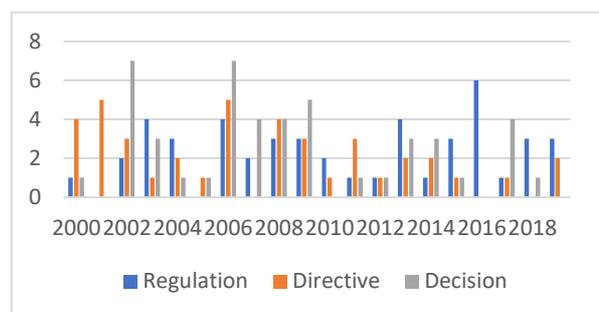


Figure 1: Number of legal acts expressly mentioning the precautionary principle

We also found that where the precautionary principle is used as a guiding principle it is often poorly explained.

This corresponds to the views expressed in the academic literature. Moreover, there are few acts which provide a definition of the precautionary principle.

It can therefore be said that there is no single definition of the precautionary principle at the EU level. The EU general food safety law is quite exceptional as it has expressly defined the precautionary principle for application in that sector. EU environmental legislation however provides no equivalent definition, though the TFEU directly refers to the precautionary principle as a basis for EU environmental policy. This has left the precautionary principle open to interpretation within the individual environmental policy area.

This is advantageous as it leaves ample room for flexibility and *ad hoc* solutions for context-specific problems to be tackled. In this manner, it is quite understandable that there is no general definition of the precautionary principle at EU level. This has led to different approaches and interpretations of the precautionary principle. This is why both the literature and the Commission instead of giving a firm definition prefer to speak of the 'constituent parts' of the precautionary principle.

This makes that procedures for the application of the principle, such as the ways in which risk assessments are performed, the transparency in dealing with uncertainties, and how different strengths of evidence for action are evaluated and chosen, become highly relevant.

Besides studying if and how the precautionary principle has been referred to and/or defined in legal acts, we also studied how the European Courts have dealt with the precautionary principle in their case law. We performed a literature review, a review of seminal Court cases and a quantitative analysis.

References to the precautionary principle in case law of the Court of Justice and the General Court between 2000 and 2019 are generally considerably more detailed than references in legal acts. In total, the search on Eur-Lex for the expression 'precautionary principle' yielded 147 results. This includes judgments by both the General Court and the Court of Justice in procedures under articles 260, 263, 267 and 340 TFEU. The subject areas covered in these judgments according to the codes used by Eur-Lex are similar to the findings in legislation. The codes environment (70 times), approximation of laws (53 times), agriculture and fisheries (41) as well as health (21) were used most often.

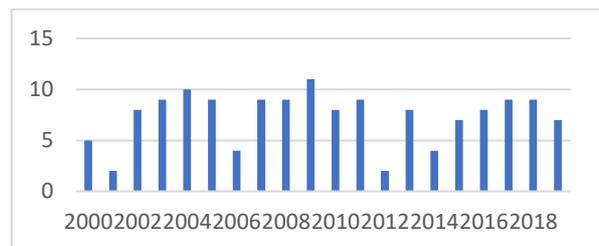


Figure 2: Judgments containing the expression 'precautionary principle' between 2000-2019

From our analysis of these judgments it appeared that whilst only few legal acts operate definitions of the principle, the Court has developed definitions and requirements for application of the principle over time into standard formulations which it uses repeatedly. In particular, the Court's definition of the precautionary principle in the BSE case of 1996 has been repeated as a standard formulation in many other cases:

"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of these risks become fully apparent"

Case C180/96, UK vs. Commission, para. 99

However, the Court is at times inconsistent in applying the principle and visibly struggles with the application of the precautionary principle in specific cases.

This is understandable as it not easy to give clear definitions in relation to different knowledge conditions and risk thresholds.

Our analysis of the EU Courts' case law moreover confirms on a broader scale what the literature suggested for individual cases: the Court's review of the application of the precautionary principle is limited to a small number of potential factors and often lacks consistency.

Importantly the Court has largely ignored to review the temporary nature of a

precautionary measure. Although the EU Courts have followed the Communication in general, some judgments seem to overlook the dynamic of science. In this way, the requirement set forth in the General Food Law and the Communication that precautionary measures should be provisional measures pending a reduction in the scientific uncertainty, is still to be seriously addressed by the EU Courts.

On the one hand, the codification and definition by the Courts makes it easier for applicants to identify the potential factors when asking for a review of a decision. On the other hand, this limits the Court's focus on formal points and leaves little room for substantive argumentation. To be sure, decisions under the precautionary principle often involve the delicate tasks to strike a balance between risk assessments on the one hand and societal risk tolerance on the other. In addition to reasons of separation of powers and rule of law, it is therefore quite understandable and legitimate that the Courts leave the EU legislator and the Commission much discretion to do so.

Noteworthy is furthermore the Ombudsman's view of the precautionary principle as a principle of good administration. This may link up with the acceptance of a lack of a general legal definition of the precautionary principle in EU law and that one should more look into having similar and predictable procedures for the application of the precautionary principle.

In sum, our analysis reveals that the criteria for precautionary action, as described in the Communication are not consequently followed by the EU policy makers or the European Courts. The inconsistencies in the application of the precautionary principle may point to the need to rethink how to apply the precautionary principle. Whilst flexibility is needed, more guidance as regards to the application of the precautionary principle is also considered to be desirable in the literature.

The rethinking of the practical application of the precautionary principle could contain a

more clear definition of various terms and an explanation of how the precautionary principle could fit within a broader risk analysis framework.

Our analysis reveals that the following issues would need more research as to whether more guidance (for example in a communication by the Commission) is needed: the requirement of carrying out an impact assessment prior to adopting a precautionary measure -the lack of which, as the Court has ruled in its case law, is a breach of the precautionary principle-, the recognition of the precautionary principle as a principle of good administration, as well as the temporary nature and the situation when new scientific evidence becomes available. This is in particular important for striking the delicate balance between concerns on health, safety and environmental protection and economic interests.

Implementation at national level

We also examined the implementation of the precautionary principle in four Member States (Denmark, Italy, Bulgaria and the Netherlands) and one EEA Country (Norway). These countries were chosen because of their geographical spreading and to gain a better understanding of the roles of diverse legal, institutional, cultural, and regulatory environments.

In the countries that we examined, the precautionary principle was not incorporated in the constitution. The precautionary principle also mostly did not occur directly in the national laws and it is not a well-defined legal concept in the national legislation. This corresponds with the findings at the international and European level.

The precautionary principle was applied to a large varieties of topics in the countries under examination. Some topics are reoccurring, as neonicotinoids and GMO's. However, there are also country-specific topics. Whether a weak versus moderate or strong policy approach was taken, seemed to depend on the political stance of the government and the politization of the

topic. Thereby confirmed the examination of the implementation and use of the precautionary principle in selected countries to a large extent the research in the previous chapters of the full report.

Reflections and next steps

Need for a conceptual framework

The report aimed to give an overview of the discussions on the precautionary principle in the literature and its application in law and practice since 2000, the year of the adoption of the Commission's Communication on the Precautionary principle.

As such, this report does not have the ambition to offer a conceptual framework. It is clear though that the RECIPES project will benefit from conceptual guidance. To this end, we have looked into existing frameworks on risk and/or safety governance for the purpose of the analytical phase of the project, that will be carried out in Work Package 2.

Existing frameworks on risk and safety governance

In order to develop a conceptual framework, it is important to look into various existing frameworks that relate to risk and/or safety governance so as to connect RECIPES to the larger risk governance landscape in which enactment of the precautionary principle may take place. It should be emphasised, that the RECIPES project will not adopt one framework or model on the basis of which the research design of the case studies in Work Package 2 will be developed, so as to allow the case study research to empirically look at what happened in the various policy areas. Such findings might agree with existing frameworks, but could also advance new elements.

Environment, health and consumer protection

From our analysis, it appears that the precautionary principle is evoked in many contexts and potentially also out of context.

Initially, the precautionary principle aimed to enable decision makers to act in situations of uncertain risk in the domain of the environment and by extension that of health and consumer protection.

Although the research shows that the precautionary principle is still mainly used in these traditional sectors, the principle was also applied in other domains.

In the analytical phase of WP 2, the RECIPES Consortium will examine the applicability of the precautionary principle in financial risks and urban planning and artificial intelligence. A first challenge will therefore be to examine whether and how the precautionary principle applies to emerging risks outside the environmental and health domains.

Review of the 2000 Communication

Whereas the 2000 Communication does not provide a definition, the European Commission and the European Courts have tried to further define the precautionary principle and the conditions for its use. Our study revealed various inconsistencies in the Courts' rulings; whilst the legal acts hardly elaborate on the precautionary principle.

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

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

This issue will therefore be taken up in the course of the RECIPES project.

Impact assessment

We have discussed that the impact assessment is an important element in the decision-making process at the EU level. Our analysis reveals that the case law of the Courts highlights the importance of carrying out an impact assessment.

Impact assessments are carried out when proposals for legislative acts or implementing and delegated acts or financial programmes, recommendations for the negotiations of international agreements are being drafted and when these proposals are expected to have significant economic, social or environmental impacts. To this end, the EU institutions must write an impact assessment report with a description of the environmental, social and economic impacts, including impacts on small and medium enterprises and competitiveness, and an explicit statement if any of these are not considered significant; who will be affected by the initiative and how; the consultation strategy and the results obtained from it.

Precaution and innovation

This study has undertaken a stocktaking exercise as regards the literature, law and case law on the precautionary principle. Therefore, it cannot provide firm

conclusions on the relationship between the precautionary principle, innovation and the innovation principle at this stage of the project.

The case-studies will now further take up the challenge to examine if and how precaution and innovation can be combined.

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Full report: all RECIPES Partners

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