



# **WP1 Report: Taking stock as a basis for the effect of the precautionary principle since 2000**

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# Table of Content

## Abstract

<b>Executive Summary</b>	<b>1</b>
<b>1. Introduction</b>	<b>6</b>
<b>1.1. About the RECIPES project</b>	<b>6</b>
<b>1.2. Objectives of this report</b>	<b>6</b>
<b>1.3. Methodology</b>	<b>7</b>
<b>1.4. Structure</b>	<b>7</b>
<b>2. Clarification of concepts: precaution, the precautionary principle, innovation, and the innovation principle</b>	<b>9</b>
<b>2.1. Precaution and the precautionary principle</b>	<b>9</b>
2.1.1 Modern technology and the need for precaution	9
2.1.2 History of the precautionary principle	10
2.1.3 Versions of the precautionary principle	14
<b>2.2. Controversies surrounding the precautionary principle</b>	<b>15</b>
<b>2.3. Legal status of the precautionary principle</b>	<b>18</b>
<b>2.4. Risk, uncertainty and the precautionary principle</b>	<b>20</b>
<b>2.5. Normative and ethical underpinnings of the precautionary principle</b>	<b>21</b>
2.5.1 Ethics and precaution	21
2.5.2 General normative underpinnings of the precautionary principle	22
<b>2.6. Innovation and the innovation principle</b>	<b>25</b>
2.6.1 Definition of innovation	25
2.6.2 Innovation and the precautionary principle	28
2.6.3 The innovation principle	29
2.6.4. The innovation principle in EU Member States	34
<b>2.7. Responsible (Research and) Innovation</b>	<b>35</b>
<b>2.8. Risk Governance Frameworks</b>	<b>36</b>
<b>2.9. Concluding remarks</b>	<b>37</b>
<b>3. Stakeholders of the precautionary principle</b>	<b>40</b>
<b>3.1. Outline of the stakeholder landscape</b>	<b>40</b>

3.1.1. Stakeholders who formalize the precautionary principle in laws, regulations and measures	40
3.1.2. Stakeholders involved in formal precautionary principle procedures	42
3.1.3. Stakeholders directly affected by its implementation	43
3.1.4. Stakeholders indirectly affected by its implementation	44
<b>3.2. Stakeholder involvement in the RECIPES project</b>	<b>45</b>
<b>4. The precautionary principle in International Law</b>	<b>48</b>
<b>4.1. Introduction</b>	<b>48</b>
<b>4.2. The precautionary principle in the international legal framework</b>	<b>48</b>
4.2.1. The precautionary principle in international treaties	48
4.2.2. ITLOS and ICJ Case Law	49
<b>4.3. The precautionary principle in WTO law</b>	<b>51</b>
4.3.1. The precautionary principle in WTO law	51
4.3.2. WTO Case law	53
<b>4.4. The precautionary principle in new generation regional trade agreements, as CETA</b>	<b>55</b>
<b>4.5. Perspectives on Innovation at International Level</b>	<b>56</b>
<b>5. The precautionary principle in European Union Law</b>	<b>58</b>
<b>5.1. Introduction</b>	<b>58</b>
<b>5.2. Codification and development of the precautionary principle</b>	<b>58</b>
5.2.1 Codification of the precautionary principle by the Maastricht Treaty	58
5.2.2 Beyond Environmental Protection	60
5.2.3 The Commission's Communication on the precautionary principle of 2000	60
5.2.4 Reflections on the 2000 Communication in the academic literature	64
<b>5.3. Implementation of the precautionary principle in legal acts by the European institutions from 2000 to 2019</b>	<b>65</b>
5.3.1 Facts and figures	65
5.3.2 Implementation of the precautionary principle in legal acts	71
5.3.3 Strength of the implementation of the precautionary principle	77
5.3.4 Impact of the 2000 Communication	77
<b>5.4. Application of the precautionary principle by the European Courts in Court rulings from 2000 to 2019</b>	<b>78</b>
5.4.1 Facts and figures	78
5.4.2 Definitions of the precautionary principle	79
5.4.3 Limited review of the precautionary principle in Court rulings	80

5.4.4 Factors that play a role in judicial review of the Precautionary Principle	82
5.4.5 Inconsistencies in the case law	88
5.4.6 Application of the 2000 Communication by the Court	88
<b>5.5. The application of the precautionary principle by the European Ombudsman</b>	<b>89</b>
<b>5.6. Constitutionalisation of the precautionary principle in France: what can be learned?</b>	<b>90</b>
<b>5.7. Conclusions</b>	<b>93</b>
<b>6. The precautionary principle in selected countries</b>	<b>97</b>
<b>6.1. Implementation and application of the precautionary principle in Denmark</b>	<b>97</b>
6.1.1. The implementation and status of the precautionary principle in Denmark	97
6.1.2. Case law	105
6.1.3. Precautionary principle mechanisms incorporated in Danish policy making	108
<b>6.2. Implementation and application of the precautionary principle in Italy</b>	<b>109</b>
6.2.1. The implementation and status of the precautionary principle in Italy	109
6.2.2. Case law	115
6.2.3. Precautionary principle mechanisms incorporated in Italian policy making	118
<b>6.3. Implementation and application of the precautionary principle in Bulgaria</b>	<b>122</b>
6.3.1. The implementation and status of the precautionary principle in Bulgaria	122
6.3.2. Case law	123
6.3.3. Precautionary principle mechanisms incorporated in Bulgarian policy making	124
<b>6.4. Implementation and application of the precautionary principle in the Netherlands</b>	<b>127</b>
6.4.1. The implementation and status of the precautionary principle in the Netherlands	127
6.4.2. Case law	136
<b>6.5. Implementation and application of the precautionary principle in Norway</b>	<b>137</b>
6.5.1. The implementation and status of the precautionary principle in Norway	137
6.5.2. Case law	142
6.5.3. Application of the precautionary principle in practice	143
<b>6.6. Comparison and conclusion</b>	<b>148</b>

<b>7</b>	<b>Conclusions and Reflections</b>	<b>150</b>
7.1	Overview of main findings	150
7.2	Conceptual Core of the precautionary principle	154
7.3	Reflections	157
<b>8</b>	<b>Literature</b>	<b>161</b>
8.1.	International legal framework	161
8.2.	EU Legal Framework	161
8.3	European Union case Law	162
8.4	Other judicial sources	164
8.5	EU Publications	164
8.6	Scientific literature	165
8.7	Non-scientific literature	183
<b>9</b>	<b>Annexes</b>	<b>186</b>
9.1	Application of the precautionary principle in practice: in-depth analysis of eight seminal EU Court Judgments	186
9.2	Legal analysis: lists	191

## List of tables

Table 1 – Weak versus strong interpretation of the precautionary principle ..... 14  
Table 2 - Policy fields containing references to the precautionary principle ..... 68

## List of figures

Figure 1 - Overview of legal acts containing the term 'precautionary principle' from 2000 to 2019 (according to instrument) ..... 66  
Figure 2 - Overview of legal acts containing the term 'precautionary principle' from 2000 to 2019 (according author ) ..... 66  
Figure 3 - Judgments containing the expression 'precautionary principle' between 2000 and 2019 ..... 78  
Figure 4 - Milestone cases in the EU Courts' application of the precautionary principle.. 79  
Figure 5 - Factors taken into account in judicial review of acts involving the precautionary principle ..... 83

## List of abbreviations

<b>ABs</b>	Appellate Bodies
<b>AIA</b>	Integrated Environmental Authorization
<b>BE</b>	Business Europe
<b>BEUC</b>	The European Consumer Organisation
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>BSE</b>	Bovine Spongiform Encephalopathy
<b>CA</b>	Consortium Agreement
<b>CAST</b>	Council for Agricultural Science and Technology
<b>CBA</b>	Cost Benefit Analysis
<b>CC</b>	Consortium Committee
<b>CEO</b>	Corporate Observatory Europe
<b>CETA</b>	Comprehensive and Economic Trade Agreement
<b>CFCs</b>	Chlorofluorocarbon
<b>CJEU</b>	Court of Justice of the European Union
<b>DG</b>	Directorate General
<b>DOA</b>	Description of Action
<b>EC</b>	European Communities
<b>ECHA</b>	European Chemicals Agency
<b>EEA</b>	European Economic Area
<b>EESC</b>	European Economic and Social Committee
<b>EFSA</b>	European Food Safety Authority
<b>EFTA</b>	European Free Trade Association
<b>EHRM</b>	European Court of Human Rights
<b>EIA</b>	Environmental Impact Assessment
<b>EPSC</b>	European Political Strategy Centre
<b>ERF</b>	European Risk Forum
<b>ERT</b>	European Roundtable of Industrialists
<b>ESA</b>	European Surveillance Authority
<b>ETUC</b>	European Trade Union Confederation
<b>EU</b>	European Union
<b>GA</b>	Grant Agreement
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>GM/Os</b>	Genetically Modified/Organisms
<b>ICJ</b>	International Court of Justice
<b>IDs</b>	Innovation Deals
<b>IPPC</b>	Integrated Pollution Prevention and Control

<b>IRGC</b>	International Risk Governance Council
<b>ITLOS</b>	International Tribunal for the Law of the Sea
<b>MAFF</b>	Ministry of Agriculture, Food and Forestry
<b>MTBE</b>	Methyl tert-butyl ether
<b>NENT</b>	National Committee for Research Ethics in Science and Technology
<b>NGO</b>	Non-Governmental Organisation
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OSPAR</b>	Convention for The Protection of The Marine Environment Of The North-East Atlantic
<b>PACE</b>	Parliamentary Assembly of the Council of Europe
<b>PCBs</b>	Polychlorinated biphenyl
<b>PCG</b>	Project Coordination Group
<b>PFOA</b>	Perfluorooctanoic acid
<b>PO</b>	Project Officer
<b>PP</b>	Precautionary Principle
<b>R&amp;D</b>	Research and Development
<b>REACH</b>	Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>RRI</b>	Responsible Research and Innovation
<b>SIA</b>	Strategic Impact Assessments
<b>SPS</b>	Sanitary and Phytosanitary
<b>STS</b>	Science and Technology Studies
<b>TAR</b>	Regional Administrative Court
<b>TBT</b>	Technical Barriers to Trade
<b>TEU</b>	Treaty on European Union
<b>TFEU</b>	Treaty on the Function of the European Union
<b>UN</b>	United Nations
<b>UNESCO</b>	United Nations Educational, Scientific and Cultural Organization
<b>UNFCCC</b>	United Nations Framework Convention on Climate Change
<b>VCG</b>	Guide Concentration Value
<b>WHO</b>	World Health Organisation
<b>WP</b>	Work Package
<b>WRR</b>	Wetenschappelijke Raad voor het Regeringsbeleid
<b>WTO</b>	World Trade Organisation

## Abstract

*This document fulfils RECIPES delivery 1.1, taking stock as a basis for the effect of the precautionary principle since 2000. The aim of this deliverable was to create a knowledge basis by providing an overview of the literature, legal acts and case law on the use of the precautionary principle since 2000 and to clarify our understanding of the key concepts precaution, precautionary principle, innovation and innovation principle. As such, this report provides input for the next steps in the RECIPES research.*

For this report, the RECIPES Consortium carried out a literature review in order to obtain a common understanding of the key concepts used in this research - precaution, precautionary principle, innovation and innovation principle - by examining relevant literature on the relationship between risk, uncertainty, precaution and the precautionary principle, innovation and the innovation principle. In addition, the RECIPES Consortium examined the implementation and application of the precautionary principle at international level, in EU law, in four Member States and in one EEA country, viz. Denmark, Italy, Bulgaria, The Netherlands and Norway. These Member States were chosen because of the geographical spreading so as to enable RECIPES to gain a better understanding of the roles of diverse legal, cultural and regulatory environments.

This literature review was performed of publicly available scientific articles, other scientific and non-scientific reports or documentation, legislation and case law, published since 2000, up to October 2019.

## Executive Summary

The objective of this report is to create a knowledge basis *by providing an overview of the literature, legal acts and case law* on the effect and the application of the precautionary principle since 2000 and to clarify our understanding of the key concepts precaution, precautionary principle, innovation and innovation principle.

Chapter 2 of this report is therefore dedicated to an examination of the concepts precaution, precautionary principle, innovation and innovation principle.

First, the concepts precaution and the precautionary principle have been examined. The history and the various interpretations of the precautionary principle - ranging from weak to strong formulations - have been examined as well as the controversies surrounding the precautionary principle. We have discussed that the precautionary principle is a legal principle, but that a universally accepted definition of 'the' precautionary principle does not exist. Different versions and interpretations of the precautionary principle are used at international, European and even national level.

Yet, irrespective of how the precautionary principle is interpreted in different instances, we can say that the precautionary principle in general concerns 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 offer a predetermined solution. Rather, the precautionary principle is 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. Some therefore argue that the strength of the precautionary principle precisely lies in its open-endedness and flexibility, which creates a possibility and an incentive for better regulation.

We also have observed that practice and literature operate several constituent elements of the precautionary principle. Literature has identified a 'conceptual core'<sup>1</sup> of the principle, based on various definitions and understandings of the principle, that forms the main components of the precautionary principle.

*RECIPES takes scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and burden of proof to form the main components of the precautionary principle.*

In addition, we have examined the concept of innovation, its relation to the precautionary principle and the emergence of the 'innovation principle'.

Also for innovation, no single definition exists. In general, it is used to refer to a technological improvement. It is a term which specific significance largely seems to depend on the context of its use. It is important to note that 'innovation' is in the eye of the beholder. Something is called an innovation by someone because the person in question 'assumes' that it will be an improvement. RECIPES critically looks at the specific way innovation is used in a particular instances, and what assumptions play a role in the use of the term.

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1 Cameron, J., 'The Precautionary Principle in International Law', in 'O Riordan, T., Cameron, J., Jordan, A., (eds.) Reinterpreting the Precautionary Principle, London: Cameron May 2001, p. 116.

Therefore, RECIPES does not consider innovation as a goal in itself as this hides the factual uncertainties and different opinions that exist with regard to the desirability of a particular new technology. The tension between possible positive and negative effects that new technologies can bring is central in the project. RECIPES examines how the precautionary principle can be applied to new technologies whilst not needlessly missing out on the possible (societal) benefits of such technologies.

*RECIPES will use the term innovation in the sense of responsible innovation. With responsible innovation we mean "taking care of the future through collective stewardship of science and innovation in the present".<sup>2</sup> Defined as such, innovation can be technological inventions and also other kinds of changes such as organizational innovations. This working definition reflects the fact that products of technological development can bring forth a wide range of (societal) benefits; as medical technology and health, electric cars and the environment or digital technologies and the free flow of information.*

Industry proposed in 2013 the so-called innovation principle. It was designed by the European Risk Forum (ERF) in 2013. The ERF defined the innovation principle as:

*"whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed".<sup>3</sup>*

More recently we signal that the European Commission's DG RTD has operated a different definition of the innovation principle, viz.:

*"EU policy and legislation should be developed, implemented and assessed in view of encouraging innovations that help realise the EU's environmental, social and economic objectives, and to anticipate and harness future technological advances"<sup>4</sup>.*

We have concluded that this innovation principle is not a legal principle.

Furthermore, we have observed that authors have connected Responsible Research and Innovation (RRI) with the precautionary principle. RRI could be considered as constituting a process, a practice of the highest integrity and quality, a reflective & critical research culture, and a force pushing for an internal reform of science to better align science, technology and innovation with the values, goals and aspirations of society. RRI can be seen to focus on orienting science and technology along a morally and socially 'right' route.

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<sup>2</sup> Stilgoe, J., Owen, R., Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy* 42, 1568-1580, here p. 1570.

<sup>3</sup> European Risk Forum, 'The Innovation Principle, Stimulating Economic Recovery', Open letter to Barroso, Van Rompuy and Schultz, 24 October 2013. Retrieved from [https://corporateeurope.org/sites/default/files/corporation\\_letter\\_on\\_innovation\\_principle.pdf](https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf), last accessed 5 May 2019, p. 2.

<sup>4</sup> [https://ec.europa.eu/info/news/innovation-principle-makes-eu-laws-smarter-and-future-oriented-experts-say-2019-nov-25\\_en](https://ec.europa.eu/info/news/innovation-principle-makes-eu-laws-smarter-and-future-oriented-experts-say-2019-nov-25_en).

Finally, the chapter embeds the concepts of precaution, precautionary principle, innovation and innovation principle in two appropriate risk governance frameworks that relate to risk and/or safety governance: International Risk Governance Council (IRGC) Risk Governance Framework and the Safe Foods project' General Safe Foods framework. It herewith aims to connect RECIPES to the larger risk governance landscape in which enactment of the precautionary principle may take place.

Chapter 3 presents the RECIPES stakeholder landscape. The precautionary principle in practice gives direction to what is right and fair in situations of scientific uncertainty, and how interests should be weighed up. However, the principle does not establish *which* measures are linked to *which* situations of scientific uncertainty. The question of how and when the principle should be implemented is a delicate balancing act to be made by decision-makers under uncertain circumstances. Within this balancing exercise, we distinguish four stakeholder groups. Firstly, there are parties who formalize the precautionary principle in laws, rules and measures. Secondly, there are parties who implement the precautionary measures. Thirdly, there are parties who are directly affected by the way in which the precautionary principle is applied. Fourthly, there are parties indirectly affected. On the basis of these four categories, we first describe the stakeholder landscape and their relation to the precautionary principle. Subsequently, we shortly describe different stakeholder groups and their desired involvement in the RECIPES project.

Chapter 4 studies the implementation of the precautionary principle at international level. The restrictive approaches of the ITLOS, ICJ and WTO show that the precautionary principle still faces many obstacles to being recognized as a general principle of international law.

Chapter 5 provides insights in the implementation and use of the precautionary principle at the EU level since 2000, the year of the adoption of the Commission's Communication on the Precautionary principle. Through the Maastricht Treaty, the precautionary principle has acquired a constitutional status. Hence, as of Maastricht, the precautionary principle found its way into the EU environmental measures, without however a concrete understanding of its meaning. The breakout of the so-called mad cow or BSE crisis in 1996, which put into question the EU system of regulation on food safety, was pivotal in understanding the reach and meaning of the precautionary principle beyond the field of environmental protection.

A literature review combined with an empirical study looking at all legal acts that used or referred to the term precautionary principle provides for a bird's-eye perspective as to 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 still exists a lot of acts that apply the precautionary principle without expressly mentioning it. This means that in practice there are likely to be many more situations where the precautionary principle is being applied. To this end, 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.

The precautionary principle is recognised as a general principle of EU law. However, there is no single definition of the precautionary principle in the EU legal acts. 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.

Our analysis also showed that the European Courts have codified the definitions and requirements for application of the principle over time into standard formulations which

are used repeatedly. Nonetheless, the Court is at times inconsistent in applying the principle and visibly struggles with the application of the precautionary principle in specific cases. Furthermore, the Court's review of the application of the precautionary principle is limited and leaves ample room for the Commission to exercise its discretionary powers. 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 that the Courts leave the EU legislator and the Commission much discretion to do so. However, the Court's review looks at manifest errors and often lacks consistency. Importantly, the Court has largely ignored reviewing the temporary nature of a precautionary measure. This leads to the conclusion that although the EU courts have followed the 2000 Communication in general, some judgments seem to overlook the dynamics of science. In this way, the requirement set forth in 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.<sup>5</sup>

Our analysis also 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.

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 need for a general uniform definition of the precautionary principle, 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. At the same time, it needs to be examined how the requirement of carrying out an impact assessment prior to adopting a precautionary measure should be implemented -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 and how the precautionary principle could fit within a broader risk analysis framework.

To explore ideas in this direction this study also looked into the effects the constitutionalisation of the precautionary principle had in France, being the only European country that has constitutionalized the precautionary principle. Our study reveals that here not a lot has changed. The French doctrine is critical of the effects of the constitutionalisation of the precautionary principle in French law, noting in particular its incorrect application.<sup>6</sup> The question as to whether the EU could learn from the constitutionalisation of the precautionary principle in France has therefore been answered in the negative. What could be of interest is the suggestion of authors to set up a specialised scientific body to draw orientation for the implementation of the risk assessment and provisional and proportionate measures to be adopted and to improve the monitoring of temporary character of precautionary measures.

Chapter 6 looks into 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 these countries the precautionary principle is not incorporated in the constitution. The precautionary principle also mostly does not occur directly in the national

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<sup>5</sup> See also Rogers M.D., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, p. 481.

<sup>6</sup> *Inter alia*, Ibid. Capitani, A. (2005). Ibid. Godard, O. (2009). Ibid. Boutonnet, M. (2014). Ibid. Deguergue, M. (2006).

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. Furthermore, in the countries that we examined, no reference to an 'innovation principle' could be found.

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 be influenced by the political stance of the government and the politicisation of the topic. Thereby it 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.

Chapter 7 concludes and provides reflections to feed into the next phase of the RECIPES project.

# 1. Introduction

## 1.1. About the RECIPES project

This report is part of the EU funded project entitled **RE**conciling **s**cience, **I**nnovation and **P**recaution through the **E**ngagement of **S**takeholders (RECIPES).

The RECIPES project aims to reconcile and/or align science, innovation and precaution by developing new tools and guidelines, based on co-creation with stakeholders, to ensure that the precautionary principle is applied while still encouraging innovation.

The RECIPES project comprises three research phases.

First, in the framing phase of the project, the RECIPES Consortium will examine the concept of precaution and the precautionary principle as well as the effect and the application of the precautionary principle at international, EU and national level since 2000. This stock-taking exercise also comprises an analysis of the background and the meaning of the concepts innovation and the 'innovation principle'.

The underlying report is the result of this research. This report is complemented with a media analysis of the public discourse around the principles of precaution and innovation, and citizens meetings to understand the different stakeholder perspectives<sup>7</sup>.

Second, in the analytical phase of the project, a conceptual framework for comparative multiple case study analysis will be developed. This framework will serve to carry out nine case-studies whereby the application of the precautionary principle to different innovations will be studied in-depth.

Finally, in the developmental phase of the project, scenario workshops and a policy-makers workshop will be organised to develop and assess the usefulness of proposed existing or new tools and guidelines, aimed to help policymakers to apply the precautionary principle whilst taking into account innovation.

## 1.2. Objectives of this report

The objective of this report is to create a knowledge basis on the use of the precautionary principle since 2000 and to clarify our understanding of precaution, precautionary principle, innovation and innovation principle so as to provide input for the second phase of the project. This knowledge basis will be generated by:

- An examination of the precautionary principle, precaution, innovation and innovation principle, legal status and the relationship between risk, uncertainty, precaution and innovation;
- An analysis of recent and on-going controversies, competing interests and concerns of the different stakeholders;
- An examination of the implementation of the precautionary principle at international level since 2000;
- An examination of the implementation and application of the precautionary principle by the EU institutions and the European Court of Justice, since the publication of the Commission's Communication in 2000, to understand the use of the precautionary principle in various fields;

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<sup>7</sup> The media analysis and the citizens meetings will be presented in separate reports.

- An examination of the implementation and application of the precautionary principle in four Member States and one EEA country.

This report therefore does not offer a normative or theoretical framework but instead presents an *overview* of literature and models in relation to precaution, the precautionary principle, innovation and the innovation principle. The study undertaken presents a stocktaking exercise as regards the literature, law and case law on the precautionary principle. It thus considers how the precautionary principle has been implemented in laws and dealt with by courts at international, EU and national level. It will offer our understanding of the key concepts of precaution, precautionary principle, innovation and innovation principle. Based on the findings of this report, the second phase of this project will develop in WP 2 a conceptual framework on the basis of which case studies will be carried out and future scenarios will be built.

### 1.3. Methodology

This report takes stock of the literature on precaution, the precautionary principle, innovation and the innovation principle as well as legal acts, case law, soft law and main policy documents, from 2000 to October 2019. For the purpose of this study and to limit the scope of the study, other documents such as codes of conduct and risk assessment practices will not be examined.

Hence this report carries out desk research, a review of academic and non-academic (grey) literature, and an empirical analysis of the application of the precautionary principle at the international and EU level and in five countries: Denmark, Italy, Bulgaria, The Netherlands and Norway.

### 1.4. Structure

The structure of this report is as follows:

Chapter 2 presents our understanding of the key concepts of precaution, precautionary principle, innovation and innovation principle by examining relevant literature on the relationship between risk, uncertainty, precaution and the precautionary principle, innovation and the innovation principle.

Chapter 3 describes the stakeholder landscape. The precautionary principle gives direction to what is right and fair in situations of scientific uncertainty, and how interests should be weighed up. Decisions can have far-reaching consequences for the stakeholders involved. In Chapter 3, we therefore describe the stakeholder landscape and their relation to the precautionary principle.

Chapter 4 proceeds to examining the development of the precautionary principle in international law in international treaties, in the ITLOS and ICJ Case law before moving on to the WTO and to its case law. The chapter also provides a brief analysis of the precautionary principle in new generation regional trade agreements through the short analysis of the CETA agreement with respect to the precautionary principle.

Chapter 5 outlines the development of the precautionary principle, from the codification of the principle in the Maastricht Treaty in 1992, to the Commission's Communication in 2000. The Chapter continues by analysing an overview of legal acts by European Institutions since 2000. It highlights how and when the principle is used, and what factors explain the

principles application and furthermore the impact of the Communication. Equally, it analyses the application of precautionary principle by European Courts since the Communication. A review is subsequently provided of the cases in which the precautionary principle is invoked, as well as a detailed discussion on the factors that play a role in judicial reviews of the principle. This is followed by an analysis of the application of the 2000 Communication by the court. It also examines what effects the constitutionalisation of the precautionary principle had in France, as the only European country in which this occurred, so as to seek insights for the EU to possibly further develop the precautionary principle.

Chapter 6 provides an analysis of the implementation of the precautionary principle in four selected Member States and one EEA country; Denmark, Italy, Bulgaria, the Netherlands, and Norway. For each country, the implementation and status of the precautionary principle is examined. This includes an overview of the legal status and applications of the principle and explores how it is used in policies, strategies and administrative practices. The Chapter also analyses case law of each country which focuses on the application of the precautionary principle. It concludes with a discussion as to the precautionary principle mechanisms incorporated in the policy making of each country.

Chapter 7 provides an overview of the main findings and gives various observations for the next analytical phase in the project.

## 2. Clarification of concepts: precaution, the precautionary principle, innovation, and the innovation principle

In order to develop new tools and guidelines for the precautionary principle, it is important to have a common understanding of the main concepts used in this research. This chapter will therefore present our understanding of the key concepts precaution, precautionary principle, innovation and innovation principle by examining relevant literature on the relationship between risk, uncertainty, precaution and the precautionary principle, innovation and the innovation principle. Section 2.1 will clarify the concepts of precaution and the precautionary principle. Section 2.1.1 defines and stresses the need for precaution. Section 2.1.2 sketches the history of the precautionary principle, followed by a discussion of different versions of the precautionary principle (section 2.1.3). The precautionary principle has been critiqued in recent times, section 2.2 therefore presents the controversies surrounding the precautionary principle. Section 2.3 subsequently turns to the legal status of the precautionary principle. Section 2.4 examines the relationship between risk, uncertainty and the precautionary principle. Section 2.5 continues with the precautionary principle's normative and ethical underpinnings. Section 2.5.1. relates ethics and precaution, where 2.5.2 sketches the general normative underpinnings of the precautionary principle. Section 2.6 is about innovation and the innovation principle. Section 2.6.1 provides a definition of the concept 'innovation'. Section 2.6.2 continues to explore the relationship between innovation and the precautionary principle, and section 2.6.3 addresses the 'innovation principle' as proposed by the European Risk Forum in 2013 and its perceptions in society. Section 2.6.4. briefly investigates the use of an innovation principle at EU Member State level. Section 2.7 connects the RECIPES research with Responsible Research and Innovation (RRI) and section 2.8 presents risk governance frameworks on which the RECIPES research can build. Section 2.9 finally summarises and presents some concluding remarks.

### 2.1. Precaution and the precautionary principle

#### 2.1.1 Modern technology and the need for precaution

As UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology states: 'Human life is, has always been, and will always be full of risks. The urge to deal with the risks we face is a basic condition of our existence.'<sup>8</sup> This ethos can be found in a wide variety of aphorisms that predate the precautionary principle, like 'better safe than sorry', and 'look before you leap'. Precaution denotes, in a general sense, prudence. It constitutes an appeal for anticipation and foresight prior to an action, to avoid or diminish undesirable and unforeseen impacts<sup>9</sup>.

Caution towards technology can be inspired by it being new, which implies that not only are its possible positive and negative effects unknown, one also does not yet know how to deal with unforeseen effects if they occur. Another source for caution towards technology is distrust towards the maker or user of the technology. New technology equals new capabilities and to this extent it provides power to the maker and/or user.

The felt need for precaution towards technological development has, in some regards, become more urgent since the twentieth century, for multiple reasons:

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8 World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), The Precautionary Principle, p. 7.

9 UNESCO COMEST (2005) The Precautionary Principle. UNESCO, Paris.

- The rate and pace of technological development has, compared to previous era's, increased significantly in the modern age.<sup>10</sup>
- Technology has become more powerful.<sup>11</sup> The impact of some modern technologies is irreversible, long lasting and spread over a large area due to global chains. The increased 'power' of technology in the 20th century has resulted in a need for policy makers to not only take into account direct consequences, but consequences for the future of the planet and future generations and has consequently led to an increased need for bioethics and the (legal) responsibility for measures to be adopted.
- Modern technology is often developed on an industrial scale. Technological applications that turned out to be harmful are sometimes produced on a large scale.
- The power that is imbued in those who possess the ability to design and make use of technology has become more centralized in the modern age.<sup>12</sup> The access to different kinds of technology 'in general' seems to have improved (for instance: access to smartphones). However, especially in the case of high end and military technology and the design of bigger technological infrastructures or complex chemicals, access is less equally distributed. As technological progress has become more capital intensive, the design and use of newest technologies tends to become more restricted.
- The complexity of technology has in many regards increased which makes it more difficult to anticipate on its effects. Developments in biotechnology for instance raise difficult questions with regard to what it means to be human and how far we should intervene in our humanity.
- Foresight also seems to be more difficult in the sense that society itself has become more complex. Adequately estimating and managing the effects of a particular technology on a society may need to take into account a wide variety of variables concerning law, economics, existing technological infrastructures and societal expectations.<sup>13</sup>
- Modern society is characterized by foresight and reflexivity. This is partially due to the fact that modernization itself brings forth new (manufactured) risks, like pollution, newly discovered illnesses and crime.<sup>14</sup>

### 2.1.2 History of the precautionary principle

The early stages of national and international environmental policies can be characterized by a curative approach to environmental damage caused by human activities, in the form of the Polluter Pays Principle. This Polluter Pays Principle turned out to be practicable only if accompanied by a preventive policy aiming at limiting damage to what could be repaired or compensated for. A 'prevention is better than cure' model marks the second stage of environmental protection policies. This stage was characterized by the idea that science can reliably assess and quantify risks, and the Prevention Principle could be used to avoid or diminish further damage. The emergence of increasingly unpredictable, uncertain, and unquantifiable but possibly catastrophic risks such as those associated with Genetically Modified Organisms, climate change etc., has confronted societies with the need to develop a third, anticipatory model to protect humans and the environment against uncertain risks of human action: the precautionary principle. The emergence of the precautionary principle

10 [https://en.wikipedia.org/wiki/Accelerating\\_change](https://en.wikipedia.org/wiki/Accelerating_change).

11 Hans Jonas, *The Imperative of Responsibility*, 1984.

12 Sheila Jasanoff, *States of Knowledge*, 2004.

13 Bijker, W., Law, J. (1992). *Shaping Technology, Building Society: Studies in Sociotechnical Change*. Cambridge, MA: MIT Press.

14 Ulrich Beck, *Risk Society, Towards a New Modernity*, 1992.

has thus marked an important shift from post-damage control (civil liability as a curative tool) to the level of a pre-damage control (anticipatory measures) of risks.<sup>15</sup>

Since the 1970s the precautionary principle has steadily advanced at the international level and in the whole domain of risk governance.<sup>16</sup> The development of precautionary approaches or methods and precautionary policies also precede the precautionary principle as it is known today. Some scholars argue that part of the Hippocratic Oath – ‘As to disease, make a habit of two things – to help, or at least, to do no harm’ – as an early example of the precautionary approach.<sup>17</sup> The removal of the handle of a water pump by the Doctor John Snow in 1854 in order to stop a cholera epidemic is for example mentioned by Harremoës *et al.* as an early precautionary measure.<sup>18</sup> Snow did not know the precise cause of the epidemic, but took the measure anyway. It is safe to say that the principle of ‘better safe than sorry’ was already part of many practices and codes of conduct – in Engineering, Chemistry, Medicine and other high-risk domains – in modern societies, before it was formalized under the name of the precautionary principle. We will shortly describe some of the causes that have been given for this advancement to give insight into the context and rationality behind the principle.

First of all, much progress was made during the twentieth century with regard to developments in science and technology. Modern technology offered new opportunities and enlarged the capacities of societies to understand, predict and control nature. These new opportunities and capabilities sparked discussions about the possible risks of these technologies and the right way to govern them. In his influential book *The Imperative of Responsibility* of 1979 philosopher Hans Jonas summarized these doubts with the statement that our power to act due to modern technology exceeds our power to foresee, evaluate and judge.<sup>19</sup>

New knowledge about ways to master nature was moreover accompanied by knowledge of nature. So, for instance, while the scientific discipline of biology made it possible to adjust the DNA of plants, the same discipline also showed the impact that this could have on ecosystems and how human life depends on such ecosystems. Paradoxically, scientific progress moreover also uncovered, besides possibilities of increased control over the world, also the uncertainties to do so ‘the right way’. Examples of such limitations were insights into the complexity, instability and interconnectedness of ecological and socioeconomic systems, the inherent limits of reason and language and the cultural dependence of normative statements.

Criticism on science and technology and the discovery of new uncertainties found its way in new disciplines and movements, like STS (Science and Technology Studies), technology assessment, risk assessment, bioethics, post structuralism, philosophy of science etc. The emergence of the precautionary principle in this sense seems to be related to a general shift in attitude of modern societies towards uncertainties.<sup>20</sup>

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15 De Sadeleer, N. (2002) *Environmental Principles*, Oxford University Press, 433 pp.

16 Zander, J. *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010.

17 Hayes, A. W., ‘The precautionary principle’, *Archives of Industrial Hygiene and Toxicology* 56(2), 2005, pp. 161-6.

18 Harremoës, P. et al., *Late lessons from early warnings: the precautionary principle 1896-2000*, European Environment Agency, Copenhagen, 2001.

19 Hans Jonas, *The Imperative of Responsibility. In Search for an Ethics for the Technological Age*, 1979 (German), University of Chicago Press 1984 (English).

20 See also: Ulrich Beck. *Risk Society, Towards a New Modernity*. London: Sage Publications.

Recently, the principle is also mentioned in the domain of human health,<sup>21</sup> human rights<sup>22</sup> and in relation to technologies of the NBIC convergence.<sup>23</sup> At the same time, due to the growing importance of innovation, the precautionary principle is increasingly criticized (see below on controversies surrounding the precautionary principle).

Hence, although precautionary thoughts are 'as old as the concept of government itself',<sup>24</sup> it was only in the 1970s that it was first developed as a legal principle in domestic law in the early 1970s, notably in Germany (the so-called '*Vorsorgeprinzip*'), Switzerland and Sweden.<sup>25</sup> This '*Vorsorgeprinzip*' was introduced as part of a policy for taking care of nature and the environment at a time when limitations of scientific understanding over environmental change became apparent.<sup>26</sup> Martuzzi reminds us that the German *Vorsorgeprinzip* is primarily a 'foresight' principle, a more positive concept than the word 'precaution'. Understanding the precautionary principle as a foresight principle emphasises a proactive, anticipatory, imaginative attitude according to which preventing or bypassing exposures and possible adverse effects is preferable to mitigating them or analysing whether they are worth the benefits.<sup>27</sup>

In the same period, in the United States, two federal statutes, the Clean Air Act and the Endangered Species Act, were qualified as precautionary instruments by, respectively, the federal Court of Appeals and the US Supreme Court.<sup>28</sup>

By the end of the 1970s, raising awareness of the vulnerability of the environment, the impossibility for scientists to accurately identify all threats to it and the importance of considering the availability of products and processes that would prove less harmful to it, led to the adoption of international instruments embracing a precautionary approach, usually without any mention of the word 'precaution' as such.<sup>29</sup> The first of them was Principle 14 of the 1982 World Charter for Nature<sup>30</sup>, followed by, for example, the 1982 UN Convention on the Law of the Sea, the 1985 Vienna Convention for the Protection of the Ozone Layer<sup>31</sup> and the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal.<sup>32</sup> All those multilateral environmental agreements ('MEAs') were sectorial, either of a binding (e.g. 1982 UNCLOS) or non-binding nature (e.g. 1982 World Charter).

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

22 Tătar EHRM 27 januari 2009, ECLI:CE:ECHR:2009:0127JUD006702101 (Tătar/Roemenië).

23 For instance: Chris Phoenix and Mike Treder, *Applying the Precautionary Principle to Nanotechnology*, 2004 and European Parliamentary Research Service, *Artificial Intelligence ante portas*, Legal & ethical reflections, 2019.

24 Fisher, E. 'Precaution, Precaution Everywhere: Developing a Common Understanding of the Precautionary Principle in the European Community', in *Maastricht Journal of European and Comparative Law* 9, 2002, p. 10.

25 Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018, p. 175; Grimeaud, D., 'The precautionary principle in international environmental and trade law' in Faure M. and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 56.

26 Weimer, M., *Risk regulation in the internal market – lessons from agricultural biotechnology*, Oxford University Press 2019, p. 34.

27 M. Martuzzi (2007) The precautionary principle: in action for public health. *Occupational and Environmental Medicine* 64 (9) 569-570. <http://dx.doi.org/10.1136/oem.2006.030601>

28 Federal Court of Appeals, *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Circ. 1976); US Supreme Court, *TVA v. Hill*, 437 U.S. 153 (1978).

29 See McIntyre and Mosedale, 1997, as cited in Trouwborst, A., *Evolution and Status of the Precautionary Principle in International Law*, Kluwer Law International, The Hague, 2002, p. 18.

30 United Nations General Assembly Resolution 37/7 on a World Charter for Nature, 28 October 1982, 37 UNGAOR (1982).

31 Although, in that specific case of the 1985 Vienna Convention, the word 'precaution' was inserted in the preamble by an amendment adopted in 1990, see Trouwborst, A., *Evolution and Status of the Precautionary Principle In International Law*, Kluwer Law International, The Hague, 2002, p. 27.

32 Trouwborst, A., *Evolution and Status of the Precautionary Principle in International Law*, Kluwer Law International, The Hague, 2002, p. 21 to 23.

In the course of the following decade, the principle went under a double transformation. First, it evolved from an implicit approach to, if not a fully fleshed-out principle yet, an explicit and more broadly recognized course of action: it was the London Declaration, adopted at the end of the Second Conference on the Protection of the North Sea in 1987, which included the 'first forthright formulation of the precautionary principle'.<sup>33</sup> Second, in the beginning of the 1990s, precaution was finally recognized as an approach, which, instead of being used on a sector-by-sector basis, ought to apply to the field of the environment as a whole.<sup>34</sup>

The principle achieved final and global recognition in 1992 when it was included in Principle 15 of the Rio Declaration resulting from the UN Conference on Environment and Development.<sup>35</sup> The provision reads as follow:

*"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."*

The definition conceives the precautionary principle as a duty of states not to use scientific uncertainty in order to not adopt precautionary measures that could prevent environmental degradation. It reflects several elements that had previously been inserted in other international instruments, but it also innovates when it specifies that states should apply precautionary measures according to their abilities.<sup>36</sup> Principle 15 of the Rio Declaration now is the most conclusive definition of the principle at the international level and is widely accepted in the world community, despite the non-binding character of the Rio Declaration.<sup>37</sup>

Also, in 1992, the Maastricht Treaty on the European Union inserted into in Art. 130r (now Art. 191 TFEU) the provision that the European Union's environmental policy 'shall be based on the precautionary principle' – without further elaborating what this implied.<sup>38</sup> In 2000, the European Commission adopted a Communication on the Precautionary Principle to guide the use of the precautionary principle in the EU, however without providing a definition of the precautionary principle.<sup>39</sup>

Another well-known definition of the precautionary principle has been formulated in the Wingspread Statement. In 1998, at the Wingspread Conference on the Precautionary Principle<sup>40</sup>, the precautionary principle was defined as follows:

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33 Trouwborst, A., *Evolution and Status of the Precautionary Principle In International Law*, Kluwer Law International, The Hague, 2002, p. 24.

34 Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018 p. 176.

35 Zander, J. *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 36.

36 Zander, J. *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 36 and 37.

37 Zander, J. *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 36 and p 72.

38 Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018 p. 176.

39 European Commission (2000) Communication (COM (2000) 1 final on the precautionary principle. We will discuss this communication in detail in Chapter 5.

40 Conference at Wingspread, Wisconsin, of 23-25 June 1998, Wingspread Statement on the Precautionary Principle.

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

Nowadays, versions of the precautionary principle have been adopted in more than 50 international agreements<sup>41</sup>, including for example also the OSPAR Convention for the protection of the marine environment of the North-East Atlantic and the UN Framework Convention on Climate Change.<sup>42</sup> No uniform definition however exists.

### 2.1.3 Versions of the precautionary principle

There is abundant academic literature that tries to interpret the different versions of the precautionary principle. Three different ways of interpreting the different definitions of the precautionary principle can be distinguished: a weak, moderate or strong formulation of the precautionary principle. The weaker formulations tend to be more general and non-committing, whereas the strong formulations refer to strict and more rigid applications of the precautionary principle.<sup>43</sup>

The views of the different scholars on a weak versus strong interpretation of the precautionary principle has been summarised in the table below.

**Table 1 – Weak versus strong interpretation of the precautionary principle**

Weak version of the precautionary principle	Moderate version of the precautionary principle	Strong version of the precautionary principle
Uncertainty does not justify inaction. <sup>44</sup>	Uncertainty justifies action	Uncertainty requires shifting the burden and standard of proof.
Use of precautionary principle if threat of <i>serious</i> or <i>irreversible</i> damage, the occurrence of which is <i>likely</i> or <i>probable</i> . <sup>45</sup>	Use of the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be	Use of precautionary principle if presence of <i>any threats</i> to the environment or health. It suffices that the risk of these threats appears as <i>possible</i> and that there is some

41 Trouwborst, A., *Evolution and Status of the Precautionary Principle in International Law*, Kluwer Law International, The Hague, 2002, p. 63.

42 Stirling, A., *Precaution in the governance of technology*, Working Paper Series, Science Policy Research Unit. University of Sussex, 2016, p. 3.

43 See Weimar, M., *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology*, 2019, p. 36; Stewart, R., 'Environmental Regulatory Decision Making under Uncertainty' in Timothy Swanson (ed), *An Introduction to the Law and Economics of Environmental Policy: Issues in Institutional Design*, Vol. 20 Research in Law and Economics, Emerald Group Publishing, 2002, p. 76; Sunstein, Cass R., *Beyond the Precautionary Principle*, U Chicago Law & Economics, Olin Working Paper No. 149; U of Chicago, Public Law Working Paper No. 38, January 2003. Available at SSRN: <https://ssrn.com/abstract=307098> or <http://dx.doi.org/10.2139/ssrn.307098>.

44 Wiener J.B., and Rogers, 2002, p. 320-321 evaluate whether the precautionary principle allows for action, and define the three categories. See also Garnett, K. and Parsons D.J., *Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law*, Risk Analysis, Vol. 37, No. 3, 2017, p. 503-504 and Haritz, M., *An Inconvenient Deliberation. The Precautionary Principle's Contribution to the Uncertainties surrounding Climate Change Liability*, Wolter Kluwer, 2011, p. 128.

45 Rio Declaration, Art. 15.

Weak version of the precautionary principle	Moderate version of the precautionary principle	Strong version of the precautionary principle
	determined with sufficient certainty. <sup>46</sup>	scientific plausibility that the risk exists. <sup>47</sup>
Examples: Rio Declaration, Art. 15; UNFCCC, Art. 3.	Examples: EU Communication of 2000, The Swedish Environmental Code.	Example: Wingspread Statement.

Sandin refers to a weak version as an *argumentative version*. This interpretation of the principle focusses on arguments that might be valid in order to take decisions under uncertainty. The stricter formulation of the principle is labelled by Sandin as a *prescriptive version*, which prescribes a certain form of action in case of uncertainty.<sup>48</sup>

Besides these three interpretations 'weak-moderate-strong' of the precautionary principle, a procedural interpretation of the precautionary principle must be added. Indeed, the weak versus strong interpretations of the precautionary principle focus on the content of the precautionary principle. However, to render the precautionary principle operational as a legal principle, a procedural interpretation is necessary. Hence, the procedural interpretation is not as a substitute for the interpretation of the precautionary principle on a weak versus strong spectrum, rather it has to be seen as a complementary interpretation that focuses on procedural aspects.<sup>49</sup>

As the precautionary principle does not dictate a specific outcome, the procedural rules aiming at reducing uncertainty become indeed particularly relevant.<sup>50</sup> Scott considers that the most important procedural aspects of the precautionary principle are the duty of re-examination, proportionality and a cost-benefit consideration.<sup>51</sup>

## 2.2. Controversies surrounding the precautionary principle

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.<sup>52</sup>

Its application has been debated at EU level, at international level, in WTO disputes as for example on beef hormones and biotech, and in the context of trade agreements as the CETA, the trade agreement between the EU and Canada.<sup>53</sup>

46 European Commission, Communication of the Precautionary Principle, 2000, COM (2000) 1 final  
 47 See Holder, J., and Lee, M., *Environmental Protection, Law and Policy*, Cambridge University Press 2007, p. 21.

48 Sandin, P., 'A Paradox out of context: Harris and Holm on the Precautionary Principle', *Cambridge Quarterly of Healthcare Ethics* 14 (2), 2006, p. 177.

49 Haritz, M., *An Inconvenient Deliberation. The Precautionary Principle's Contribution to the Uncertainties surrounding Climate Change Liability*, Wolter Kluwer, 2011, p. 129.

50 Haritz, M., *An Inconvenient Deliberation. The Precautionary Principle's Contribution to the Uncertainties surrounding Climate Change Liability*, Wolter Kluwer, 2011, p. 129.

51 Scott, J., 'The precautionary principle before the European Courts', in Macrory, R. (ed.), *Principles of European Environmental Law*, Europa Law Publishing, Groningen, 2004, p. 66.

52 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 32.

53 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 32.

The precautionary principle has also led to heated debates in the academic literature. This paragraph will present the controversies around the precautionary principle, as presented in the academic literature.<sup>54</sup>

Proponents of the precautionary principle argue that the principle provides a framework for improving the quality and reliability of decisions over technology, science, ecological and human health and leads to improved regulation. It requests to pause and to review before plunging into innovation adventures that might prove disastrous.<sup>55</sup> As such, and referring back to the normative underpinnings of the precautionary principle, it provides a basis for public discussion and deliberation over what kind of society and moral accountability we collectively would choose to adopt.<sup>56</sup>

Proponents of the precautionary principle also hold that precaution precisely may enjoin innovatory paths in order to stop exposing us to a certain harm.<sup>57</sup> An example where an innovation was enjoined by precaution might be the removal of lead in gasoline.<sup>58</sup> Proponents also argue that the basic idea of precaution does not need to be at odds with cost-benefit analysis and risk-risk trade off analysis. Indeed, more moderate versions of the precautionary principle do evaluate costs and benefits, as for example the Rio declaration as well as the European Commission communication of 2000.<sup>59</sup>

The 2013 Report on Late lessons from early warnings produced by the European Environment Agency, reveals that the misuse or neglect of the precautionary principle can actually lead to an increase in cost, based on various case studies.<sup>60</sup> D. Gee argues that in the face of uncertainty, ignorance and complexity, and wider public engagement, societies could pay attention to the lessons of past experience and use the precautionary principle, to anticipate and minimise many future hazards, whilst stimulating innovation.<sup>61</sup> As the case studies of the 2013 Report on Late lessons from early warnings have shown, the timely use of the precautionary principle can often stimulate rather than hamper innovation, in part by promoting a diversity of technologies and activities, which can also help to increase the resilience of societies and ecosystems to future surprises.

Keeping options open and following multiple paths means that a particular option can be terminated if it turns out to pose high risks and avoids situations of technological monopolies such as those experienced, for example, in the cases of asbestos, CFCs and PCBs. As such, technological monopolies would instead hamper innovation.<sup>62</sup>

Over the years, however, various criticisms to the precautionary principle have been expressed. The precautionary principle came under attack academically especially from

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54 See e.g. Sunstein, C., *Laws Of Fear, Beyond the Precautionary Principle*, Cambridge University Press. See also Majone, G., 'The precautionary principle and its policy implications', *Journal of Common Market Studies* 40 (1), p. 89-109 or Lofstedt, R., 'The precautionary principle in the EU: Why a formal review is long overdue'. *Risk Management*, 2014; 16(3):137-163.

55 Read, R., and O'Riordan, T., 'The Precautionary Principle Under Fire', *Environment: Science and Policy for Sustainable Development*, 59, 2017.

56 Read, R., and O'Riordan, T., 'The Precautionary Principle Under Fire', *Environment: Science and Policy for Sustainable Development*, 59, 2017.

57 Read, R. and O'Riordan, T., 'The Precautionary Principle Under Fire' *Environment: Science and Policy for Sustainable Development* 59, 2017.

58 Read, R., and O'Riordan, T., 'The Precautionary Principle Under Fire', *Environment: Science and Policy for Sustainable Development* 59, 2017.

59 Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018 , p. 181.

60 Gee, D., 'More or less precaution', in *Late lessons from early warnings II: Science, precaution, innovation*, European Environment Agency, EEA report no 1/2013, p. 643.

61 Gee, D., 'More or less precaution', in *Late lessons from early warnings II: Science, precaution, innovation*, European Environment Agency, EEA report no 1/2013, p. 643.

62 European Environment Agency, *Late lessons from early warnings II: Science, precaution, innovation*, EEA report no 1/2013, p. 673.

2005 onwards, when Cass Sunstein portrayed the precautionary principle incoherent, lacking any orientation in his 'laws of fear'.<sup>63</sup>

Sunstein argues that governments often are not faced with one risk at the time. The world is multi-risk. Or, as Sunstein argues, risks exist on all sides of social situations, and precautionary steps may create dangers of their own.<sup>64</sup> Governments taking precautionary measures must select which risks make top priority and must confront their potential to affect multiple risks at the same time. Precautionary measures to prevent one risk may induce side-effects or the so-called risk-risk trade-offs, such as increases in other countervailing risks. Governments invoking the precautionary principle tend to target only one salient risk at the time. Yet, sound policy-making needs to assess the full portfolio of policy impacts, including additional impacts in other fields. Otherwise it could be that the precautionary measures themselves increase certain risks.<sup>65</sup> Therefore, Sunstein argues that in a world of risks on all sides, the precautionary principle points nowhere.<sup>66</sup> Graham and Wiener argue that the solution is to take a broader, more holistic approach that confronts the multi-risk reality and assesses the full portfolio of multiple impacts.<sup>67</sup> The question hence is not which risk we should address, but which risks should we address more than others.

Sunstein furthermore indicates that the idea of precaution seems to work only because diverse cultures focus on very different risks, with social influences and peer pressures accentuating some fears and reducing others. Several effects as cascades, an availability heuristic (under the availability heuristic, people tend to heavily weigh their judgments of certain practices or risks toward more recent information, making new opinions biased toward that latest news, but this does not necessarily correspond with reality), loss aversion, and group polarisation are highly relevant here and may affect proper decision-making.<sup>68</sup> Inevitably, this will result in significant regulatory differences among states. These regulatory differences raise interesting questions about why different societies focus on different risks. Sometimes, these differences will also result in trade disputes (see below). However, these differences can also present an opportunity to learn.<sup>69</sup>

Critics of the precautionary principle also argue that precautionary measures may be costly, and they worry that precautionary measures to restrict new technologies may inhibit innovation. Unsurprisingly, the application of the precautionary principle has been strongly opposed by vested interests who perceive short term economic costs from its use.<sup>70</sup> From an academic point of view, various law and economics scholars for example view that the precautionary principle has led to risk-aversion in the European Union, which might stifle innovation.<sup>71</sup> Moreover there is also intellectual resistance from scientists who fail to acknowledge that scientific ignorance and uncertainty, are very much attached to

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63 Sunstein, C., *Laws Of Fear, Beyond the Precautionary Principle*, Cambridge University Press, 2009.

64 Sunstein, C., *Laws Of Fear, Beyond the Precautionary Principle*, Cambridge University Press, 2009.

65 Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018 p. 180.

66 Sunstein, C., *Laws Of Fear, Beyond the Precautionary Principle*, Cambridge University Press, 2009.

67 Graham, J.D. and Wiener, J. (eds.), *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment*, Cambridge, Harvard University Press, 1995 and Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018, p. 181.

68 Sunstein, C., *Laws Of Fear, Beyond the Precautionary Principle*, Cambridge University Press 2009.

69 Wiener, J.B., 'Precautionary Principle', in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018, p. 177

70 As reported by Gee, D., 'More or less precaution', in *Late lessons from early warnings II: Science, precaution, innovation*, European Environment Agency, EEA report no 1/2013, p. 643.

71 See for instance <https://laweconcenter.org/wp-content/uploads/2018/11/Portuese-Pillot-The-Case-for-an-Innovation-Principle-A-Comparative-Law-and-Economics-Analysis-2018-1.pdf>.

conventional scientific paradigms, and who wait for a very high proof of evidence before accepting causal links between exposure to stressors and harm.<sup>72</sup>

Similar criticisms as to the precautionary principle in general have been raised with respect to the Commission's Communication on the Precautionary Principle of 2000. It has been claimed for example the Communication does not address the problematic issue of risk-risk trade-offs, nor does it provide a means to assess which risks should be prioritised over other risks when using the precautionary principle. Furthermore, Majone argues that although the Commission favours cost-benefit analysis, it is not clear what is to be taken into account in this analysis.<sup>73</sup>

Stoll argues that the work of Sunstein and others paved the way for a regulatory reform movement initiated in the US. In the EU, this thinking was reflected in the better regulation agenda.<sup>74</sup> Not all scholars are happy with this regulatory reform. Rupert Dean and Tim O'Riordan hold that "in the 'pro-grow' atmosphere of contemporary politics, the precautionary principle has been aggressively targeted by those who seem determined to prevent anything preventing the free rein of the 'free market'".<sup>75</sup>

Yet, interestingly, there are both many critics and proponents of the precautionary principle that call for a revision of the principle. For instance, in an effort to reconcile the debate between critics and proponents of the principle, Wiener calls for making precautionary measures less permanent so that, in order to learn in the face of uncertainty, precaution becomes more provisional and adaptive over time. Provisionality, he argues, offers a bridge from precaution to learning and adaptive policy revision.<sup>76</sup>

## 2.3. Legal status of the precautionary principle

The multiple definitions and interpretations of the precautionary principle inevitably lead to the question as to what legal status the precautionary principle has.<sup>77</sup> Before answering this question it is first important to address the difference between rule, principle and policy or approach.

Ronald Dworkin holds that the law can be divided into three categories: rules, principles and policy. A rule is to apply similarly in all circumstances and in an all-or-nothing approach (e.g. it is a legal rule that a will is invalid unless signed by three witnesses). Principles, on

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72 Gee, D., 'More or less precaution', in *Late lessons from early warnings II: Science, precaution, innovation*, European Environment Agency, EEA report no 1/2013, p. 643.

73 Lofstedt, R., 'The precautionary principle in the EU: why a formal review is long overdue', *Risk Management*, 16, 2014, p. 144 and Majone, G., 'The precautionary principle and its policy implications', *Journal of Common Market Studies* 40 (1), p. 89-109. See also Graham, J.D. and Hsia, S. (2002) 'Europe's precautionary principle: promise and pitfalls', *Journal of Risk Research* 5(4), pp. 371-90.

74 Stoll, P.-T., 'Of Fear and Prudence: Precaution through Better Regulation and Innovation', in Squitani/Darpö/ Lavrysen/Stoll (Eds), *Managing Facts and Feelings in Environmental Governance*, Edward Elgar, 2019, in print. See also Sunstein, C., *Laws Of Fear, Beyond the Precautionary Principle*, Cambridge University Press, 2009 and European Commission, European Political Strategy Centre (EPSC), 'Towards an Innovation Principle Endorsed by Better Regulation', EPSC Strategic Notes Issue 14, 30 June 2016.

75 Read R., and O'Riordan, T., 'The Precautionary Principle Under Fire', *Environment: Science and Policy for Sustainable Development*, 59, 2017.

76 Wiener, J.B., 'Precautionary Principle', in Faure, M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018.

77 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 36 and 37. See also Sirinskiene A., 'The Status of Precautionary Principle: Moving Towards a Rule of Customary Law', *Jurisprudence* 2009, 4(118), p. 351.

the other hand, are open-ended in character, do not apply in an all-or-nothing approach, and do not dictate a particular result. Principles have a high moral content and aim to give direction in particular with respect to justice and fairness. A policy or an approach, finally, is again vaguer, and states a more general goal to be reached.<sup>78</sup> Policies differ from principles in that they set a standard to be reached, for example an improvement of an economic, political or social feature of a society.<sup>79</sup>

Principles, in contrast to policies or approaches, can be legally binding. Principles form the basis of specifically formulated rules. Dworkin describes it as: 'Principles are propositions that describe rights; policies are propositions that describe goals'.<sup>80</sup>

However, not every provision that is called a principle also implies that it is a principle in legal terms, meaning to be legally binding. In order to be qualified as a principle in legal terms the following prerequisites have to be satisfied: an ideal is the underlying origin of the principle (of any principle) *and* there is continuing reference to the principle, in legal documents or by the court.<sup>81</sup>

In practice, the precautionary principle has been used to denote everything from a generally environmental 'approach' to specific and binding decision-making rules.<sup>82</sup> Furthermore, it appears that the discussion about the precautionary principle being a principle or just a policy approach is more an Anglo-Saxon debate.<sup>83</sup> Within the EU setting, however, it is clear that the precautionary principle is considered to be a general principle of EU law, laid down in EU legislation and case law and recognised by the EU institutions and thus has legal value (see Chapter 5).

Irrespective of how the precautionary principle is interpreted, 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 offer a predetermined solution. Rather, the precautionary principle is 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. Some therefore argue that the strength of the precautionary principle precisely lies in its open-endedness and flexibility, which creates a possibility and an incentive for better regulation.<sup>84</sup>

We may observe that practice and literature operate several constituent elements of the precautionary principle. Literature has therefore identified a 'conceptual core'<sup>85</sup> of the principle, based on various definitions and understandings of the principle, that forms the main components of the precautionary principle.

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78 Dworkin, R., *A Matter of Principle*, Harvard University Press, 1985, p. 43-45 and Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 30.

79 Ibid, p. 43.

80 Dworkin, R., *Taking Rights Seriously* (1st ed. 1977), Duckworth, 1996, 90.

81 Verschuuren, J., 'Principles of Environmental Law: The Ideal of Sustainable Development and the Role of Principles of International, European, and National Environmental Law', *Umweltrechtliche Studien*, Nr. 30, Nomos Verlag, Baden Baden, 2003, p. 35.

82 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 26-32.

83 Sirinskiene A., 'The Status of Precautionary Principle: Moving Towards a Rule of Customary Law', *Jurisprudence* 2009, 4(118), p. 349-364, p. 351.

84 See UNESCO COMEST, *The Precautionary Principle*, 2005, 52pp, <https://unesdoc.unesco.org/ark:/48223/pf0000139578>.

85 Cameron, J., 'The Precautionary Principle in International Law', in 'O Riordan, T., Cameron, J., Jordan, A., (eds.) *Reinterpreting the Precautionary Principle*, London: Cameron May 2001, p. 116.

*RECIPES takes scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and burden of proof to form the main components of the precautionary principle.*

## 2.4. Risk, uncertainty and the precautionary principle

Today's globalised world is characterised by increased interconnectedness and fast-paced technological change. In addition to opportunities, this also has the potential to increase vulnerabilities and to create new risks with impacts on a large scale, and over a long time span.<sup>86</sup>

These new, or emerging risks, are generally characterised by a high degree of scientific uncertainty regarding the probability of occurrence and the amount of potential loss or harm.<sup>87</sup>

Scientific uncertainty relates to the limitedness or even absence of scientific knowledge that makes it difficult to assess the exact probability and possible outcomes regarding unwanted effects of for instance new technologies or the application of new chemical substances. Scientific uncertainty can stem from more than a lack of data or inadequate models of risk assessment. Scientific uncertainty might also exist in the form of indeterminacy, when not all the factors influencing the causal chains are known. Equally, scientific uncertainty might arise when there is ambiguity or contradicting data. Ambiguity refers to the plurality of scientifically justifiable viewpoints on the meaning and implications of scientific evidence.<sup>88</sup> Ambiguity cannot be reduced to probabilities or error-bars and cannot be governed by approaches that require quantification. Finally, it is possible that certain risks are still unknown, which often is labelled as 'unknown unknowns'<sup>89</sup>, boiling down to situations of ignorance.<sup>90</sup>

Traditional governance mechanisms fall short when dealing with ununitable scientific uncertainty. Hence, there is a lack of appropriate governance mechanisms to efficiently deal with these new, 'uncertain risks'; to resolve trade-offs between diverse, sometimes conflicting, needs and interests; or to deal with potential risks from new technologies in the context of global trade.<sup>91</sup> Especially the increased 'power' of technology in the 20<sup>th</sup> century has resulted in a need for policy makers to not only take into account direct consequences, but consequences for the future of the planet and future generations and has consequently led to an increased need for (legal) responsibility for measures to be adopted.<sup>92</sup> This makes anticipation an essential aspect of precautionary risk governance.

The precautionary principle provides a rational approach to the substantially and ethically justified management of uncertain risks to public health, society or environment in face of

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86 <https://irgc.org/risk-governance/what-is-risk-governance/>.

87 Despite the increasing popularity of the term, there is no single accepted definition of emerging risk. Possible definitions include: a newly created risk; newly identified risk; increasing risk or a risk becoming widely known or established. See Flage, R. and Aven, T., 'Emerging risk – Conceptual definition and a relation to black swan type of events'. *Reliability Engineering & System Safety*, 144, 2015, p. 61-67.

88 SAPEA (2019) Making sense of science for policy under conditions of complexity and uncertainty. Science Advice for Policy by European Academies Berlin: <https://doi.org/10.26356/MASOS>

89 Donald Rumsfeld, U.S. Secretary of Defense, Defense Department Briefing, February 2002.

90 Wynne, B. (1992). Uncertainty and environmental learning. Reconceiving science and policy in the preventive paradigm. *Global Environmental Change*, 2(2), 111-127. doi: 10.1016/0959-3780(92)90017-2

91 <https://irgc.org/risk-governance/what-is-risk-governance/>.

92 See Hans Jonas; an intellectual founder of the precautionary principle.

uncertainty. It is based on anticipation and minimisation and aims to use the best of our knowledge of complex processes to make wiser decisions amid uncertainty. The Precautionary Principle is to supplement, but not necessarily replace, other management strategies that fall short of being able to handle large-scale scientific uncertainty, ambiguity and ignorance.

In cases where the desired level of protection is defined, and the risk of harm can be quantified in a reliable way, traditional risk management tools based on the prevention principle can be used.<sup>93</sup> Yet, where an activity or substance poses a plausible threat of harm but there is insufficient scientific evidence, or a lack of agreement as to the nature or scale of the likely adverse effects, the precautionary principle can help decision-makers to take decisions.<sup>94</sup>

Fisher thus observes that: 'The precautionary principle, by explicitly recognizing the implications of scientific uncertainty for collective decision-making, ensures that decision-makers cannot hide behind a façade of 'facts' where no definitive factual basis exists. Such a façade not only bears little relation to reality but also results in inefficiency and a false form of accountability. As such, the principle is a guide to good decision-making and one consistent with the practice of science'.<sup>95</sup>

## 2.5. Normative and ethical underpinnings of the precautionary principle

The precautionary principle incorporates – although not explicitly – several normative underpinnings and ethical considerations.<sup>96,97</sup>

### 2.5.1 Ethics and precaution

While the precautionary principle is usually portrayed as a societal management and decision principle under uncertainty, the precautionary principle does have a more intuitive framing in the ordinary lives of people as well. There it is based on some general principles which cut across the dominant ethical theories advanced in scholarly works. Ethics in a very general sense can be understood as embedding deontic operators (like permissible, impermissible, and obligatory), applied to decision choices under an umbrella of different ultimate pro-social values and attitudes<sup>98</sup>. Differentiating between individual and social values covers the difference between individual and collective action. The precautionary principle adds the dimension of uncertainty to the decision situation while retaining the element of value-choices which signifies ethical relevance.

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93 European Commission, Science for Environment Policy, Future Brief: The precautionary principle, decision-making under uncertainty, September 2017, issue 18, p. 5.

94 European Commission, Science for Environment Policy, Future Brief: The precautionary principle, decision-making under uncertainty, September 2017, issue 18, p. 5.

95 Fisher E., 'Precaution, Precaution Everywhere: Developing a 'Common Understanding' of the Precautionary Principle in the European Community', *Maastricht Journal of European and Comparative Law*, 2002, 9, p. 7.

96 See The National Research Ethical Committee for Natural Science and Technology (NENT), *The precautionary principle: between research and politics*. Second edition, Oslo, 1997.

97 See UNESCO COMEST, *The Precautionary Principle*, 2005, 52pp, <https://unesdoc.unesco.org/ark:/48223/pf0000139578>.

98 Kaiser, M., Millar, K., Thorstensen, E., & Tomkins, S. (2007). Developing the ethical matrix as a decision support framework: GM fish as a case study. *Journal of Agricultural and Environmental Ethics*, 20(1), 65-80.

Ethical theories can be sorted under different categories, as e.g. consequentialist, deontological and virtue ethics<sup>99</sup>. Cross-cutting between these theories is the domain of objects with inherent moral value. In this respect, one typically differentiates between anthropocentrism, biocentrism and eco-centrism. However, what may be an inherent value in one such approach (e.g. animal welfare and dignity) may be an instrumental value in the other. Thus, protecting a moral object from possible harm can often be accommodated in different theoretical approaches<sup>100</sup>.

The claim that precaution has a broad and intuitive ethical underpinning can be demonstrated by reference to typical examples. For instance: Individual life insurances are normally based on the wish of an individual that close family members might be provided for in case of the individual's early death; Parents may subject their children to vaccination against their will in order to protect them from possible diseases; Industrial leaders may invest in developing alternative technologies in light of market uncertainties in order to shield a company from surprise market events; A home owner may cut down an old tree in the garden which stands close to the neighbouring house in fear that the tree may fall on the house during the next autumn storm. – In these examples, an individual decides to act in a way that imply some costs now but may protect or diminish the possible future harm, while the probability of this harm is impossible to estimate, but the moral object such protected is ascribed a significant value, and the acting individual recognizes a relationship to that object which implies a certain responsibility.

It would not be adequate to explain this category of behaviour by just one kind of ethical attitude or theory. However, such precautionary action is typically governed by just a few widely shared moral principles. Respect for the dignity of a moral person or moral object beyond mere self-interest is involved, together with the recognition that one's own action now may protect that moral object from possible harm later. Safety and security of moral objects is typically a primary concern for people. Furthermore, a trade-off between competing values is normally involved, if only between likely present versus mere possible future realizations of a value. Perceptions of (co-)responsibility play a crucial role, as these often make the difference between choosing anticipatory preventive action versus letting things happen, or leaving the precautionary responsibility to others.

These precautionary actions in the ordinary life of people are typically not guided or justified by precaution as an explicitly recognized principle for action, but they are based on an immediate and intuitive grasp of moral responsibility even when reliable predictions of the possible future harm are not available. They are in many cases also culturally embedded in the forming of social identities in society, like being a good parent or being a good business leader. It is the step from un-reflected heuristic and intuitive moral guidance to explicit anchoring in normative principles, recognized in law and social institutions, which marks the transition to a societal instrument to manage uncertain decision situations.

## 2.5.2 General normative underpinnings of the precautionary principle

Here is a closer look on the explicit normative principles which have a direct bearing on the justification and practice of the precautionary principle. We shall mention six such

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99 See e.g. Reiss, M. J. (2002). Introduction to ethics and bioethics. *Bioethics for scientists*, 1-17.

100 See e.g. Bernet Kempers, E. *Animal Dignity and the Law: Potential, Problems and Possible Implications*. Liverpool Law Rev 41, 173–199 (2020).  
<https://doi.org/10.1007/s10991-020-09244-1>

See also: Johansson-Stenman, O. (2018). Animal welfare and social decisions: Is it time to take Bentham seriously?. *Ecological Economics*, 145, 90-103.  
<https://www.sciencedirect.com/science/article/pii/S0921800917304639>

normative principles with which the precautionary principle is directly linked, and which together are unique a justification of the precautionary principle.

First, the precautionary principle can be used in order hold a person (or a firm or a State) accountable for harm they have caused even if they did not know that damage would follow their action. This is because people have a moral responsibility to make an effort to find out whether their actions might lead to harm. The concept of culpable ignorance stems from philosopher Ian Hacking's work on risk research.<sup>101</sup> According to Hacking, the concept meets three functions:

Firstly, ignorance is considered culpable when an action is taken that is or could have been disastrous, even if, due to chance, no actual damage follows the action. What is culpable is not that one was ignorant, but that one did not make sufficient efforts to reduce or account for that ignorance.

Secondly, the concept may function as an incentive to further investigation and reflection. If ignorance about possible consequences is great, one may delay action until more knowledge is available or opt to move forward with caution.

Thirdly, the concept can be used as a reason for not acting in a certain way. A person may think that it is impossible to be more informed about possible harmful consequences of the action, and that it would be irresponsible to start the planned action on such a poor basis of information. This may be the case even if great benefits are forgone, that is the negative consequences of not acting are significant. This reflects an asymmetry between action and omission, which will be further explored below. A key issue with culpable ignorance concerns the knowledge that one seeks, or with which one is satisfied. In a situation of ignorance and uncertainty no reliable knowledge about future outcomes is available. Yet, ignorance is culpable only if one does not seek out and utilize other relevant information and knowledge, such as general knowledge about the type of situation that one may encounter.

Second, in ethics, actions and omissions are not treated on a par. In traditional ethics, one normally maintains that when facing quite risky decisions with the possibility of bad outcomes, one should refrain from doing anything, even if one's omission to act might cause greater harm. This position is directly coupled to one's moral responsibility: one is seen as more responsible for what one actually does than for what one fails to do.<sup>102</sup> In medical ethics this moral attitude is common: the difference between causing a death and allowing a person to die is considered significant.<sup>103,104</sup> The moral difference between actions and omissions is also often reflected in criminal law: the failure to carry out an obligation is usually a lesser crime and never a greater crime than committing actions that violate prohibitions, even if the consequence of the inaction and the action is the same.<sup>105</sup>

Third, responsibilities are shared. Industrial or technological accidents have seldom only one source of human failure; more typically they are the result of a chain of interrelated actions and systemic technological design.<sup>106</sup> In a moral context a person can only be made responsible for a certain outcome to the extent that their actions contributed to it. A person cannot be held responsible for factors that are beyond their control (or knowledge) but they do have some co-responsibility for certain outcomes to which they have

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101 Hacking, I., 'Culpable Ignorance of Interference Effects', in: MacLean, D., Nelkin D., and Brown, M.S., *Values at risk*. Savage, Md. Rowman and Littlefield Publishers Inc., 1986.

102 Sartorio, C., 'A New Asymmetry between Actions and Omissions'. *Noûs*, 39(3) 2005, 460-482.

103 Foot, P., *Killing and letting die*, 1984, p. 266.

104 Gillon, R., 'Acts and omissions, killing and letting die', *British medical journal* (Clinical research ed.), 1986, 292.6513, p.126.

105 Nagel, T. *Mortal questions*, Cambridge University Press, 2012.

106 Perrow, C. *Normal accidents: Living with high risk technologies*-Updated edition, Princeton university press, 2011.

contributed.<sup>107</sup> Very often, we assume special responsibilities as a consequence of the professional roles we hold. In the context of the precautionary principle, one may claim that, for example, scientists hold a special co-responsibility for assessing and communicating information about the uncertainties involved in a specific decision.<sup>108,109</sup>

Fourth, the needs of present generations should be met provided they do not impair the ability of future generations to meet their needs.<sup>110</sup> This implies an ethical balance between present and future generations.<sup>111</sup> The fact that inter-generational equity has been formulated in an explicit manner quite recently may be seen as the result of the recognition that many recent actions and decisions have far-reaching consequences into the future (e.g. storage of radioactive waste).<sup>112</sup> Another reason to be explicit about intergenerational equity is that cost benefit analysis (CBA) tends to discount future interests and needs in such a manner that they have little value. In discounting it is assumed that in the future, incomes and welfare will have increased substantially. Discounting in Cost Benefit Analysis (CBA) tends to favour activities that have short-term gains and long-term negative effects. Inter-generational equity demands that there are certain limits and restrictions on the extent to which future needs and consequences can be discounted.<sup>113,114</sup> The precautionary principle, being directly related to the principle of sustainable development, incorporates inter-generational equity in the sense that considerations of possible significant long-term and future harm provide enough reason to act now, even though present interests may not be threatened.

Equity also has another dimension: intra-generational equity.<sup>115</sup> The distribution of benefits and risks is not only due to individual behaviour and merit, but also due to systematic socio-economic differences among various groups of people and societies.<sup>116</sup> In this way equity issues arise, most notably between developing countries and the industrialized countries. The precautionary principle is built around the idea that the costs of human-made risks should not be externalized, neither to the local environment nor to the environment of other societies or nations.<sup>117,118</sup>

Fifth, deliberations based on the precautionary principle should explicitly consider the negative impacts that human activities may have on nature, even if these impacts do not

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107 Hacking, I., *Risk and dirt. Risk and morality*, 2003, pp. 22-47.

108 Mitcham, C., and Von Schomberg, R., 'The ethic of scientists and engineers: from occupational role responsibility to public co-responsibility', *Research in philosophy and technology*, 20, 2000, pp. 167-189.

109 Von Schomberg, R. 'Organising collective responsibility on precaution, codes of conduct and understanding public debate', in Fiedeler U. et al. (Eds), *Understanding Nanotechnology*, AKA Verlag Heidelberg, 2010, pp. 61-70.

110 Borowy, I., *Defining sustainable development for our common future: A history of the World Commission on Environment and Development* (Brundtland Commission). 2013. Routledge.

111 Weiss, E.B. *Intergenerational equity: a legal framework for global environmental change*. United Nations University, 1999.

112 Shrader-Frechette, K., *Nuclear power and public policy: The social and ethical problems of fission technology*, Springer Science & Business Media, 2012.

113 Beder, S., 'Costing the earth: equity, sustainable development and environmental economics', *NZJ Env'tl. L.*, 4, 2000, p. 227.

114 Portney, P R., Weyant, J.P., *Discounting and intergenerational equity*. Routledge, 2013.

115 Padilla, E., 'Intergenerational equity and sustainability'. *Ecological Economics*, 2002, 41, pp. 69-83.

116 Beck, U., Lash, S., & Wynne, B., *Risk society: Towards a new modernity* (Vol. 17), Sage, 1992.

117 Söderholm, P., & Sundqvist, T., 'Pricing environmental externalities in the power sector: ethical limits and implications for social choice', *Ecological Economics*, 46(3), 2003, pp. 333-350.

118 Okereke, C., 'Global environmental sustainability: Intragenerational equity and conceptions of justice in multilateral environmental regimes', *Geoforum*, 37 (5), 2006, pp. 725-738.

pose direct risks for humans.<sup>119,120,121,122</sup> This normative underpinning is a consequence of the recognition that respect of the dignity of other moral objects is not restricted to the rational human world alone.

Sixth, precautionary decisions should involve the participation of all those affected. The ethical principle behind this idea is that decisions that affect parties other than the decision-maker should be consented to by these parties in conditions of transparent process and with freely accessible information.<sup>123,124</sup> This condition is linked to the ethical principle of justice and fairness, however this may be specified in diverse ethical theories.

## 2.6. Innovation and the innovation principle

In order to get a clear understanding of the possible tension between precaution and innovation and to create opportunities for aligning the goals of precaution and innovation, it is necessary to better understand what is meant with 'innovation'.

### 2.6.1 Definition of innovation

#### History of the concept of innovation

The historian Benoit Godin notes that the (dominant) meaning of innovation, has shifted considerably over the ages.<sup>125</sup> From the Reformation to the nineteenth century, 'innovation' denoted something strictly forbidden and was mostly used to accuse someone of going against the natural order. In the nineteenth and twentieth century the concept acquired a more positive signification. It moreover became an instrumental part in certain belief systems: a 'structuralizing principle of thought and action'.<sup>126</sup>

Innovation became a catalyst and umbrella term, symptomatic of a general shift in how people looked at 'change' and societal change in particular that occurred gradually after the French Revolution.<sup>127</sup> Instead of looking at continuities in the world, people increasingly became aware of, accepted and promoted changes in every sphere of society, for instance in religion (Reformation), politics (political revolutions), economics (industrial revolution) and science (scientific revolution). Change was increasingly perceived as radical and revolutionary instead of gradual and evolutionary. Instead of being oriented towards preserving the past, innovation was thought of as bringing new possible futures. And

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119 Oughton, D., Forsberg, E.-M., Bay, I., Kaiser, M. & Howard, B., 'An ethical dimension to sustainable restoration and long-term management of contaminated areas', in *Journal of Environmental Radioactivity*, Vol. 74, Issues 1-3, 2004, pp. 171-183.

120 Kaiser, M. & Forsberg, E.-M., 'Consensus conference on environmental values in radiation protection: a report on building consensus among experts', *Science and Engineering Ethics*, vol. 8, (4), 2002, pp. 593-602.

121 Kaiser, M., 'Practical ethics in search of a toolbox: Ethics of science and technology at the crossroads', in Gunning, Jennifer and Søren Holm (ed.), *Ethics, Law and Society* Vol. II, Ashgate Publishing Ltd: Cardiff, 2006, pp. 35-44.

122 Diaconescu, A., 'The Insertion of the Precautionary Principle in the Environment Protection as a Legal Norm in the European Countries', *Law Review*, 2017, p. 7.

123 Gethmann, C.F., Carrier, M., Hanekamp, G., Kaiser, M., Kamp, G., Lingner, S., Quante, M., Thiele, F., *Interdisciplinary Research and Trans-disciplinary Validity Claims*, Springer: Cham, Heidelberg, New York, Dordrecht, London, 2015, DOI 10.1007/978-3-319-11400-2.

124 Kaiser, M., Millar, K., Thorstensen, E., & Tomkins, S., 'Developing the ethical matrix as a decision support framework: GM fish as a case study'. *Journal of Agricultural and Environmental Ethics*, 20(1), 2007, pp. 65-80.

128 Benoit Godin, *Innovation Contested: The Idea of Innovation over the Centuries*, 2015.

126 Benoit Godin, *Innovation Contested: The Idea of Innovation over the Centuries*, 2015, p. 8.

130 Benoit Godin, *Innovation Contested: The Idea of Innovation over the Centuries*, 2015, p. 5-6.

finally, while changes used to be explained by god, nature or necessity, people become more aware of their own history and their capacity to change their future.

It is in this context that the rise of 'innovators' and the emergence of the 'ideology' of innovation can be explained according to Godin. A core thought of this worldview is that individual entrepreneurship and creativity is key for achieving a better future. International organizations and governments began to see innovation in relation to economic problems, job creation, and international competitiveness and launched innovation policies. 'Research & Development' was understood as a source of innovation and innovation as a tool for prosperity. In discourses 'innovation' was increasingly equated with prosperity.<sup>128</sup> Instead of being an instrument to achieve something else, innovation has become a value per se: 'Today, innovation means anything, everything...and nothing. Innovation is an umbrella term, a concept that groups a diversity of things, activities and attitudes that serves, more often than not, the practical (technology and the market).'<sup>129</sup>

### **Innovation today**

Innovation is a central pillar of the European Union. Article 173 TFEU states that 'the Union and the Member States shall ensure that the conditions necessary for the competitiveness of the Community's industry exist. For that purpose, in accordance with a system of open and competitive markets, their action shall be aimed at: [...] fostering better exploitation of the industrial potential of policies of innovation, research and technological development'.

The term innovation has increasingly been used over the last decades and many different definitions and typologies of it seem to co-exist in academic literature. Kanter (2006) defines innovation as ideas that create the future.<sup>130</sup> Elements that consequently generally reoccur in definitions of innovation are: an active and intentional enterprise of bringing about (positive) functional change<sup>131</sup>. In a similar vein, Pfothenhauer and Jasanoff understand innovation as sociotechnical imaginaries. With 'imaginary' they refer to collectively held representations and meanings of widely shared problem articulations and of desirable societal futures achieved through innovation as a means of addressing societal challenges.<sup>132</sup>

Besides these characteristics, however, there seems to be a lot of ambiguity about 'what' can be considered innovation. The term is used both to describe processes that use new knowledge and technologies, as well as processes to generate new products and the new or improved products themselves.<sup>133</sup> The academic literature on innovation can accordingly be divided into a stream that investigates the organizational and social processes that produce innovation, and a stream that approaches innovation as an outcome that manifests itself in, for instance, new products, product features and production methods.<sup>134</sup>

Another ambiguity exists in relation to *the possible object* that is at issue in innovation. The most common usage of the word is in relation to technology, 'technological innovation', but it is also used in relation to new ideas, services, methods, processes or products. The Organisation for Economic Co-operation and Development (OECD) for instance distinguishes four types of innovation<sup>135</sup>: product innovation (a good or service that is new or significantly improved), process innovation (a new or significantly improved production

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128 Economist Joseph Schumpeter is often cited as the 'inventor' of this perspective on innovation.

129 Benoit Godin, *Innovation Contested: The Idea of Innovation over the Centuries*, 2015, p. 8.

130 Kanter, R. M. 2006. Innovation: The Classic Traps. *Harvard Business Review*, 84(11): 72-83.

131 See for instance: Jan Fagerberg and Bart Verspagen, 'Innovation studies—The emerging structure of a new scientific field,' *Research Policy*, 2009.

132 Pfothenhauer, S., Jasanoff, S., 2017. Panacea or diagnosis? Imaginaries of innovation and the 'MIT model' in three political cultures. *Soc. Stud. Sci.* 47, 783–810. doi:10.1177/0306312717706110

134 M.E. Porter, *The competitive Advantage of Nations*, Macmillan, New York, 1990.

134 Phills Jr., Deiglmeier, & Miller, 'Rediscovering Social Innovation,' *Stanford Social Innovation Review*, 2008, 37.

136 <https://www.oecd.org/site/innovationstrategy/defininginnovation.htm>

or delivery method), marketing innovation (a new marketing method involving significant changes in product design or packaging, product placement, product promotion or pricing) and organizational innovation (a new organizational method in business practices, workplace organization or external relations).

A third point of disagreement exists in innovation literature about the nature of the 'positive' dimension. Sometimes the 'positive renewal' of an innovation is primarily framed as relating to a particular use or interest, for instance a faster smartphone. Other times, the significance of the innovation is placed in relation to more general or universal principles. This is especially the case in relation to 'social innovation'. Social innovations can be distinguished from technological innovations in that they are not material but relate to social practices. Not a technical artefact, but 'a way of doing things' is (positively) renewed in social innovation. 'A social innovation is a new combination and/or new configuration of social practices in certain areas of action or social contexts prompted by certain actors or constellations of actors in an intentional targeted manner with the goal of better satisfying or answering needs and problems than is possible on the basis of established practices.'<sup>136</sup>

In this sense, it is important to note that 'innovation' is in the eye of the beholder. Something is often called an innovation by someone because the person in question 'assumes' that it will be an improvement.

It is important to note that such predictions depend on uncertain knowledge and presuppositions of the person in question. The use of the term 'innovation' is often surrounded by a considerable amount of ambiguity and subjectivity. When someone calls something an innovation, it is implicitly assumed to be an improvement from a particular perspective. In a more general sense, the term is used to express the idea that the products of technological development can bring forth (societal) benefits.

There often is uncertainty whether an innovation will deliver its proclaimed benefits. Therefore, RECIPES does not consider innovation as a goal in itself as this hides the factual uncertainties and different opinions that exist with regard to the desirability of a particular new technology.

*RECIPES will use the term innovation in the sense of responsible innovation. With responsible innovation we mean "taking care of the future through collective stewardship of science and innovation in the present".<sup>137</sup> Defined as such, innovation can be technological inventions and also other kinds of changes such as organizational innovations. This working definition reflects the fact that products of technological development can bring forth a wide range of (societal) benefits; as medical technology and health, electric cars and the environment or digital technologies and the free flow of information.*

Technological improvements have contributed to progress in society in a wide variety of ways. Technological progress can be accounted for some of the major variables in history with regard to overall improvement of well-being, the reduction of sickness, poverty and hunger, as well as possibly solving future challenges.<sup>138</sup> However, such assumptions have

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137 Howaldt et al., 'Social innovation: towards a new innovation paradigm', *Mackenzie Management Review*, 2016.

137 Stilgoe, J., Owen, R., Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy* 42, 1568-1580, here p. 1570.

138 Such analysis can be found in: Steve Pinker, *Enlightenment Now: The Case for Reason, Science, Humanism, and Progress*, 2018.

also been criticized.<sup>139</sup> New technologies that initially were thought to bring only benefits for instance brought with them dangerous effects, like Asbestos for instance. Another criticism is that innovation is often used as a 'technological fix'; human problems (like unhappiness, poverty) often have societal causes which can simply be resolved through technology. Innovation is moreover argued by some to combine some of the most important qualities of humans – creativity, intelligence, collaboration, entrepreneurship, perseverance and courage – in the service of finding solutions to problems.

## 2.6.2 Innovation and the precautionary principle

The precautionary principle is concerned with uncertain and unknown risks. The precautionary principle in this regard thus expresses a need for caution with regard to the introduction of new phenomena, like a new technology.

The discourse surrounding innovation instead adheres to the conviction that the introduction of a new technology constitutes progress. Another difference between the two is that innovation discourse generally focusses on particular, short-term goals from an individual (company/innovator) perspective, while the precautionary principle tends to refer to long term, universal, public and/or general values. Innovation is articulated, developed and marketed by a specific group of producers with a specific functionality for a specific audience.

The precautionary principle, in contrast, is thought to guard against the (unintended) consequences that may also affect 'the rest' of society or 'the world' on the long run, even those that cannot represent themselves, such as nature and future generations. A technological innovation is, for instance, developed and introduced by a particular company with particular aims and benefits in mind. The precautionary principle, in contrast, is applied by referring to normative frameworks (like international treaties) that protect the environment (citizens, nature) in which the technology is introduced. This does of course not mean that innovation is by definition incompatible with upholding the precautionary principle.

Innovation is not a linear and uniform process or outcome that just 'happens'. It matters what is innovated, how this is done and who are involved.<sup>140</sup> During a trajectory of an innovation, from vague idea until proof of concept until the concrete implementation in society and its consequences for the world, it matters how public values have been taken into account. Precaution in relation to innovation in regard to, for instance, the protection of 'human, animal or plant life or health' can also mean introducing them in different steps of the innovation process: in how researchers are trained, who are involved in the processes of Research & Development, which projects get funded, how the development process is organized, how the outcome is distributed and implemented, and how dangerous signals are communicated or monitored after launch. If the normative frameworks to which the precautionary principle refers to are made part of the innovation process, implicitly, the precautionary principle could be respected. The design of a new technology could then already be in line with environmental and public health norms before is completed and introduced to consumers.

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139 For example: Michael Huesemann, *Techno-Fix: Why Technology Won't Save Us Or the Environment*, 2011.

140 see for instance: Van de Ven, 2017. Bijker, W. E., T. P. Hughes & T. J. Pinch (red.) (1987). *The Social Construction of Technological Systems*. New Directions in the Sociology and History of Technology. Cambridge: MIT Press. Maclaine Pont, P., R. van Est & J. Deuten (2016). *Met beleid vormgeven aan sociotechnische innovatie*. Den Haag: Rathenau Instituut.

### 2.6.3 The innovation principle

The European Commission attaches a lot of importance to innovation. The 'Innovation Union' flagship initiative is a central part of the EU's Europe 2020 strategy and is seen as means to deliver 'smart growth', defined as 'developing an economy based on knowledge and innovation'.<sup>141</sup> Research and innovation also play a central role in the recent European Green deal.<sup>142</sup> One of the ways in which innovation recently has appeared on the EU policy agenda, is by means of the so-called 'innovation principle'.

The term 'innovation principle' was first proposed by the European Risk Forum (ERF) in 2013. The European Risk Forum presents itself as an expert-led, not-for-profit think tank that supports high-quality risk assessment and risk management decisions by the EU institutions and raises awareness of risk management issues.<sup>143</sup> The ERF is an umbrella organisation and the vast majority of ERF members come from the biotech, pharmaceutical and agri-sectors, as Bayer, BASF, CEFIC or Syngenta AG. All are industries that have struggled with the EU over the licensing of their innovative products and that might have a distrust in the precautionary principle.<sup>144</sup> The group does not (yet) include other innovative industries as digital economy, or artificial intelligence.<sup>145</sup>

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. The ERF defined the innovation principle as follows:

*"whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed".<sup>146</sup>*

The European Political Strategy Centre (EPSC), an in-house think-tank of the European Commission, issued in 2016 a Strategic Note on the Innovation Principle in the context of better regulation which the European Commission lists as one of the documents on which the innovation principle was established.<sup>147</sup> The EPSC stated that "An innovation principle means ensuring that whenever policy is developed, the impact on innovation is fully assessed. The principle should provide guidance to ensure that the choice, design and regulatory tools foster innovation, rather than hamper it".<sup>148</sup>

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141 See [https://ec.europa.eu/info/research-and-innovation/strategy/goals-research-and-innovation-policy/innovation-union\\_nl](https://ec.europa.eu/info/research-and-innovation/strategy/goals-research-and-innovation-policy/innovation-union_nl),

[https://ec.europa.eu/commission/presscorner/detail/en/MEMO\\_10\\_473](https://ec.europa.eu/commission/presscorner/detail/en/MEMO_10_473) and D. Gee, 'More or less precaution', in Late lessons from early warnings II: Science, precaution, innovation, European Environment Agency, EEA report no 1/2013, p. 661.

142 [https://ec.europa.eu/info/research-and-innovation/strategy/european-green-deal\\_en](https://ec.europa.eu/info/research-and-innovation/strategy/european-green-deal_en)

143 <http://www.riskforum.eu>.

144 Garnett, K., Van Calster, G., Reins, L., 'Towards an innovation principle : an industry trump or shortening the odds on environmental protection?', *Innovation and Technology*, 2018, vol. 10, issue 1, p.2.

145 Garnett, K., Van Calster, G., Reins, L., 'Towards an innovation principle : an industry trump or shortening the odds on environmental protection?', *Innovation and Technology*, 2018, vol. 10, issue 1, p.2

146 European Risk Forum, 'The Innovation Principle, Stimulating Economic Recovery', Open letter to Barroso, Van Rompuy and Schultz, 24 October 2013. Retrieved from [https://corporateeurope.org/sites/default/files/corporation\\_letter\\_on\\_innovation\\_principle.pdf](https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf), last accessed 5 May 2019, p. 2.

147 European Political Strategy Centre (2016). Towards an Innovation Principle Endorsed by Better Regulation. EPSC Strategic Notes, Issue 14, 30 June 2016. See: [https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation\\_en](https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation_en).

148 [https://ec.europa.eu/epsc/sites/epsc/files/strategic\\_note\\_issue\\_14.pdf](https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf), last assessed 19 June 2019. See also Garnett, K., Van Calster, G., Reins, L., Towards an innovation principle : an industry

In 2017, the European Commission under its open innovation policy and a Task Force of its Directorate General for Research and Innovation (DG RDT) introduced the innovation principle “with the purpose of systematically assessing the impact of new EU policy and legislative initiatives on innovation”<sup>149</sup> and initiated two Innovation Deals (IDs) aimed to identify and tackle regulatory obstacles to innovation.<sup>150</sup>

In the Commission’s Communication ‘A renewed European Agenda for Research and Innovation - Europe’s chance to shape its future’ of 15 May 2018, the Commission holds that: “to ensure that European policies are developed with innovation in mind, the European Commission already applies the innovation principle when preparing major legislative initiatives. Member States should step up similar efforts”.<sup>151</sup> In the footnote it is further specified that “The innovation principle is an integral part of the EU Better Regulation approach, and ensures that whenever policy and legislation are developed, the impact on innovation is fully assessed”.

Moreover, the following recent development deserve special mention here: the European Commission’s proposal for Horizon Europe, the future EU research and innovation funding programme, make reference to the innovation principle.<sup>152</sup> In case these references are part also of the final versions, the innovation principle is for the first time included in an EU legal text.

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trump or shortening the odds on environmental protection?, *Innovation and Technology*, 2018, vol 10, issue 1, p.3.

149 Commission of the European Communities (CEC) (2017b). Management Plan 2018. DG RTD. Ref. Ares(2017)6345021-22/12/2017. The Management Plan 2018 of DG RDT further states: “As from the adoption of the Commission Work Programme 2018, future initiatives will be screened to identify those where the innovation principle could be implemented” (CEC 2017a, p. 4). At the European Commission’s website the innovation principle is described as a tool “to help achieve EU policy objectives by ensuring that legislation is designed in a way that creates the best possible conditions for innovation to flourish” ([https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation\\_en](https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation_en)).

150 See the Commission’s website at: [https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers\\_en](https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers_en). Two Innovation Deals (IDs) have thus far been initiated with the participation of DG RTD: One on waste water treatment and reuse, and one on utilisation of used propulsion batteries as stationary energy storage (see the website). According to Ashford and Renda, IDs appear to be planned as tools for the clarification of EU legislation (2016, p. 73). They see it as an important feature of the IDs that they “seem to be destined for specific cases in which legislation must be clarified, or interpreted, not amended. They are in this respect, presented as a tool for addressing cases in which legislation is difficult to interpret for new players, but never as a way to change EU or national law” (Ibid., p. 72). Ashford and Renda emphasize that less regulation should not be the objective in innovation deals (Ibid., p. 73).

151 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, A renewed European Agenda for Research and Innovation - Europe’s chance to shape its future. The European Commission’s contribution to the Informal EU Leaders’ meeting on innovation in Sofia on 16 May 2018, Brussels, 15.5.2018 COM(2018) 306 final, p. 9.

152 The draft regulation is available at: [https://eur-lex.europa.eu/resource.html?uri=cellar:b8518ec6-6a2f-11e8-9483-01aa75ed71a1.0001.03/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:b8518ec6-6a2f-11e8-9483-01aa75ed71a1.0001.03/DOC_1&format=PDF); recital 3, p. 16 refers to the innovation principle. The draft decision is available at: [https://eur-lex.europa.eu/resource.html?uri=cellar:7cc790e8-6a33-11e8-9483-01aa75ed71a1.0002.03/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:7cc790e8-6a33-11e8-9483-01aa75ed71a1.0002.03/DOC_1&format=PDF), the annexes at: [https://eur-lex.europa.eu/resource.html?uri=cellar:7cc790e8-6a33-11e8-9483-01aa75ed71a1.0002.03/DOC\\_2&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:7cc790e8-6a33-11e8-9483-01aa75ed71a1.0002.03/DOC_2&format=PDF); reference to the innovation principle is made under

Pillar III, paragraph 2.2. of Annex I. p. 68. The source of this information is a letter of the European Consumer Organisation (BEUC) to the European Parliament of 6 December 2018 calling for deletion of the innovation principle from the Horizon Europe research funding programme; the letter is available at: [https://www.beuc.eu/publications/beuc-x-2018-112\\_precautionary\\_principle\\_under\\_attack\\_please\\_delete\\_so-called\\_innovation\\_principle.pdf](https://www.beuc.eu/publications/beuc-x-2018-112_precautionary_principle_under_attack_please_delete_so-called_innovation_principle.pdf).

Some time has passed now since the proposition of the 'innovation principle' by the ERF. Although the EU Commission initially adopted a similar definition as the ERF, DG RTD has now encapsulated the principle in the following working definition:

*"EU policy and legislation should be developed, implemented and assessed in view of encouraging innovations that help realise the EU's environmental, social and economic objectives, and to anticipate and harness future technological advances"<sup>153</sup>.*

It is however unclear what the European Commission intends to do with this working definition.

Although the term 'innovation principle' suggest otherwise, the principle cannot be seen as a legal principle, as does it not meet the basic requirements of a legal principle (see above, section 2.3). It does not reflect a custom within society or the law, its provision is not general enough (it directly prescribes particular actions), it does not express a common sense or custom in the society or the legal community, and it does not express a requirement of justice or fairness or some other dimension in morality. It rather presents an objective or policy goal to be reached.

The principle does not exist in any of the Member States legal orders<sup>154</sup>, as underlined by Garnett, Van Calster and Reins.<sup>155</sup> It also cannot be found in any international treaties, decisions of intergovernmental organizations, jurisprudence and legal theory.

Since its proposition in 2013, there has been a vivid debate as to the purpose and application of this innovation principle among stakeholders.

Civil society organisations joined forces to call for the immediate and complete removal of the innovation principle from Horizon Europe.<sup>156</sup> Uni Europa, for instance, argues on its website that 'the innovation principle presents a new form of impact assessment to ensure that "whenever policy or regulatory decisions are under consideration the impact on innovation should be assessed and addressed". It is *not a principle of law, but a tool that creates more leverage for business interests in the early phase of decision making*. The innovation principle has the potential to severely risk undermining the precautionary principle and, in turn, EU social and environmental protection.<sup>157</sup> Civil society hence claims that the innovation principle has no legal basis and moreover is incompatible with the EU's precautionary principle.<sup>158</sup>

The European Risk Forum, who proposed the 'innovation principle' on the other hand explicitly stated: "The notion that the innovation principle is opposed to the precautionary principle is incorrect and misleading, especially as innovation will be increasingly important to achieve sustainability. The ERF considers both principles as being complementary and essential".<sup>159</sup>

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153 [https://ec.europa.eu/info/news/innovation-principle-makes-eu-laws-smarter-and-future-oriented-experts-say-2019-nov-25\\_en](https://ec.europa.eu/info/news/innovation-principle-makes-eu-laws-smarter-and-future-oriented-experts-say-2019-nov-25_en).

154 Although in Germany there have been attempts to incorporate an innovation principle in the legal order, but these have not been successful.

155 Garnett, K., Van Calster, G., Reins, L., 'Towards an innovation principle : an industry trump or shortening the odds on environmental protection?', *Innovation and Technology*, 2018, vol. 10, issue 1, p. 1.

156 <https://epha.org/removing-innovation-principle-from-horizon-europe/>.

157 <http://www.uni-europa.org/2019/03/13/uni-europa-calls-for-the-rejection-of-the-innovation-principle-from-horizon-europe/>.

158 <https://epha.org/removing-innovation-principle-from-horizon-europe/>.

159 <http://www.riskforum.eu/about-us.html>.

Business Europe argues in a Position Paper: "The EU will have to build a true culture of innovation, encouraging reasonable risk-taking rather than over-playing the precautionary principle, and balance it with an innovation principle".<sup>160</sup>

On the other hand, there is significant opposition to the innovation principle as it is formulated by the ERF, expressed by various civil society organisations, that worry especially about the impact an innovation principle could have on environmental regulation. The civil society organisations have a much more negative perception on the innovation principle.

The European Trade Union Confederation (ETUC), IndustriAll Europe and UNI Europa, all of them European trade unions, have serious concerns about the innovation principle because<sup>161</sup>:

- It is promoted as a counter-balance to, and could weaken the impact of, the existing precautionary principle that was adopted by the EU to prevent serious harm to human health or the environment;
- innovation is a means to achieve social, economic or environmental purposes, and is not a goal or "principle" in itself.

The civil society organisations moreover support innovation that benefits workers and citizens. They indicate that innovation not necessarily good because it is new. The real question, they argue, is whether the innovation benefits society and not vested interest.<sup>162</sup>

UNI Europa (the European services workers union) notes that 'defining innovation as an end-product, without any form of evaluation, is wrong, and could even be dangerous'.<sup>163</sup>

Corporate Observatory Europe (CEO), another European NGO, wrote a critical report on the innovation principle in 2018, by mentioning to it as 'the innovation principle trap'. Their main argument against the innovation principle is the lack of an official legal basis and the fact that it was introduced by industry. CEO comments that, by giving the innovation principle the same legal status as the precautionary principle, industry would exert a lot of influence on shaping European policy.<sup>164</sup> Additionally, CEO argues that there is no need for the innovation principle, because the precautionary principle already allows industry to innovate in the public interest. By applying the innovation principle instead of the precautionary principle, R&D and financial gains would get the upper hand over dealing with societal challenges.<sup>165</sup>

The consumer organisation BEUC describes the precautionary principle as the safety net for the European consumer, in cases where final proof is absent. Thereby, they acknowledge that science is central in the use of the precautionary principle and that precautionary measures are only temporary.<sup>166</sup> The frequently used argument that

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160 Business Europe Position Paper, 'A Breath of Innovation, Business Recommendations on Future of European Research and Innovation Policy' December 2014, <https://www.businesseurope.eu/sites/buseur/files/media/imported/2014-01116-E.pdf>, last accessed 4 May 2019, p.1.

161 <https://www.etuc.org/en/pressrelease/beware-innovation-principle>, last assessed 23 June 2019.

162 <https://www.etuc.org/en/pressrelease/beware-innovation-principle>, last assessed 23 June 2019.

163 <http://www.uni-europa.org/2016/05/31/innovation-principle-new-deregulatory-tool/> last assessed 23 June 2019.

164 <https://corporateeurope.org/en/environment/2018/12/innovation-principle-trap>.

165 <https://corporateeurope.org/en/pressreleases/2018/12/innovation-principle-trap-corporate-lobbies-attack-reach-and-precautionary>.

166 The European Consumer Organisation (2018) Precautionary principle under attack: please delete so-called 'Innovation Principle' from Horizon Europe research funding programme.

[https://www.beuc.eu/publications/beuc-x-2018-112\\_precautionary\\_principle\\_under\\_attack\\_please\\_delete\\_so-called\\_innovation\\_principle.pdf](https://www.beuc.eu/publications/beuc-x-2018-112_precautionary_principle_under_attack_please_delete_so-called_innovation_principle.pdf).

innovation would be limited by the precautionary principle is contradicted by BEUC, by stressing that the precautionary principle pushes industry towards more safe and sustainable alternatives and thereby the precautionary principle would actually promote innovation. BEUC feels that nowadays the European Commission seems to be more in favour of the innovation principle, and thereby the interest of the business is overruling the protection of consumers and the environment.<sup>167</sup>

Although academic literature on the innovation principle is limited, a few authors provide suggestions to reconcile innovation and precaution.

Garnett, Van Calster and Reins argue that the innovation principle – as currently phrased – is not a qualified principle; it focuses exclusively on jobs, growth and competitiveness. This is out of balance with EU primary and secondary law, which safeguards consumers and environmental needs alongside the need to foster jobs and growth.<sup>168</sup>

Further, the innovation principle appears incompatible with the EU's RRI objectives, namely to consider research and innovation as a 'dynamic, interactive process in which all stakeholders become mutually responsive and share responsibility for both the process and its outcomes'<sup>169</sup>.

Garnett, Van Calster and Reins believe that a comprehensive, qualified innovation principle that encourages reasonable risk-taking while accepting an element of responsibility could help square the EU's twin objectives of fostering innovation and offering a high level of environmental and consumer protection. By incorporating consumer and environmental safeguards and accepting that innovation goes hand in hand with precaution, it is argued that a revised principle could help to relieve the tension between the EU's core objectives. Garnett et al. argued that the principle can only reach its full potential if all stakeholders have a say in how innovation is shaped and formed. Failure to qualify the innovation principle could lead to the creation of irresponsible and potentially unnecessary innovations.<sup>170</sup>

Second, Garnett, Van Calster and Reins suggest introducing a needs assessment, to be better adapted to the challenges of the twenty-first century. Not all innovation is needed and not all innovation fosters the public good. However, there is no systematic assessment of whether a certain innovation is needed and by whom. Such a needs assessment would merit further research as to who and when it could be applied.<sup>171</sup>

Von Gleich and Petschow in turn have derived three different interpretations of how to relate an 'innovation principle' to the precautionary principle. They derived these interpretations from current debates around the introduction of an 'innovation principle'. The interpretations are presented as 1) 'One More Principle to be Considered', 2)

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167 The European Consumer Organisation (2017) Consumers let down by decision on hormone disrupting chemicals. <https://www.beuc.eu/publications/consumers-let-down-decision-hormone-disrupting-chemicals/html>.

168 Garnett, K., Van Calster G., Reins L., 'Towards an innovation principle: an industry trump or shortening the odds on environmental protection?', *Law, Innovation and Technology*, 2018, Vol. 10, Issue 1, p. 10.

169 Garnett, K., Van Calster G., Reins L., 'Towards an innovation principle: an industry trump or shortening the odds on environmental protection?', *Law, Innovation and Technology*, 2018, Vol. 10, Issue 1, p. 10.

170 Garnett, K., Van Calster, G., Reins, L., 'Towards an innovation principle : an industry trump or shortening the odds on environmental protection?', *Innovation and Technology*, 2018, vol. 10, issue 1, p. 10.

171 Garnett, K., Van Calster, G., Reins, L., 'Towards an innovation principle : an industry trump or shortening the odds on environmental protection?', *Innovation and Technology*, 2018, vol. 10, issue 1, p. 10.

'Systematic Assessment of Potential Threats and Benefits' and 3) 'Downgrading the precautionary principle'.<sup>172</sup>

#### 2.6.4. The innovation principle in EU Member States

To the best of our knowledge, it seems that an 'innovation principle' does not play at Member State level. In Germany, the past years have seen several attempts to incorporate an innovation principle into the country's legal framework. Although these attempts were unsuccessful, the debate is still ongoing.

In 2016, the Federal Government introduced the "Fourth Act to Amend the Genetic Engineering Act" to make use of the possibility offered by Directive (EU) 2015/412 to restrict or prohibit the cultivation of genetically modified organisms. In the explanatory memorandum for the act, the Federal Government added the innovation principle to the precautionary principle by stating it assumes 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.<sup>173</sup> This triggered the Research Service of the German Bundestag to publish a paper on the status quo of the innovation principle in 2016.<sup>174</sup>

In 2017 and 2018, the Federal Government published two position papers on Horizon Europe, the future research and innovation programme proposed by the European Commission in 2018.<sup>175</sup> While both position papers did not explicitly mention the innovation principle, they welcomed a stronger involvement of industry in research processes and the introduction of relevant institutions, such as the European Innovation Council. Nonetheless, both position papers also emphasize that the precautionary principle takes precedence over innovation.

The Federal Ministry of Education and Research regularly reports on the state of research and innovation in Germany, including the legal framework. The 2018 report states, that the Federal Government will examine how the innovation principle can be anchored in Germany in addition to the precautionary principle.<sup>176</sup> Similarly, the 2018 High-Tech Strategy states, that research and innovation requires a regulatory framework that includes innovation in impact assessments. Via impact assessments, the innovation

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172 For further elaboration see von Gleich, A., Petschow, U., Aktuelle Diskussion um die Einführung eines Innovationsprinzips und das Verhältnis zum Vorsorgeprinzip. Kurzstudie im Auftrag des NABU – Naturschutzbund Deutschland e.V.. Berlin, Institut für Ökologische Wirtschaftsforschung, 2017.

173 Gesetzesentwurf der Bundesregierung, Entwurf eines Vierten Gesetzes zur Änderung des Gentechnikgesetzes vom 28.11.2016, Bundestag-Drucksache 18/10459, S. 15, <http://dip21.bundestag.de/dip21/btd/18/104/1810459.pdf>.

174 Wissenschaftliche Dienste des Deutschen Bundestags, 2016, Sachstand: Das Innovationsprinzip, WD 5. – 3000 – 106/16, <https://www.bundestag.de/resource/blob/487670/cda05a4abdb39a95a8f9a3061ee22db2/wd-5-106-16-pdf-data.pdf>.

175 Bundesregierung, 2017, Leitlinien für das neue EU-Rahmenprogramm für Forschung und Innovation, Positionspapier, [https://www.bmbf.de/files/Bundesregierung\\_FP9\\_Leitlinienpapier\\_September\\_2017.pdf](https://www.bmbf.de/files/Bundesregierung_FP9_Leitlinienpapier_September_2017.pdf);

Bundesregierung, 2018, „Horizont Europa“ – Deutsche Position zum Entwurf der Europäischen Kommission, Positionspapier der Bundesregierung, [https://www.bmbf.de/files/Positionspapier\\_Horizont\\_Europa\\_Web.pdf](https://www.bmbf.de/files/Positionspapier_Horizont_Europa_Web.pdf).

176 Bundesministerium für Bildung und Forschung, 2018, Bundesbericht Forschung und Innovation, Forschungs- und innovationspolitische Ziele und Maßnahmen, S. 32, [https://www.bmbf.de/upload\\_filestore/pub/Bufi\\_2018\\_Hauptband.pdf](https://www.bmbf.de/upload_filestore/pub/Bufi_2018_Hauptband.pdf).

principle can ensure that potential impacts on research and innovation are always sufficiently taken into account when drafting and reviewing legislation in all areas.<sup>177</sup>

In April 2019, the German Liberals called on the Federal Government to amend the Joint Rules of Procedure of the Federal Ministries in order to install the innovation principle in all impact assessments for federal legislation.<sup>178</sup> They want the Federal Ministries to take into account potential effects of legislative projects on Germany's innovative capacity. Responding to this, with its motion of 10 April 2019, the German Green Party requested the Federal Government to clarify that the precautionary principle itself and its constitutional status must not be called into question at EU level and that it is therefore clearly superior to simple legislation.<sup>179</sup> It should be strengthened as a driver of innovation for sustainable development. Following a controversial debate in the German Bundestag, the motions were referred to the now leading Committee for Internal Affairs for further discussion.<sup>180</sup>

## 2.7. Responsible (Research and) Innovation

Recent times have seen the rise of the notion of 'responsible research and innovation' (RRI).

The term RRI, in a general sense, addresses the observation that innovation as a goal in itself does not always lead to results that are beneficial to society as a whole or are accompanied by negative side effects.<sup>181</sup>

Work on responsible innovation has developed ways through which innovation can be developed in the light of responsible aims and through responsible methods. Stilgoe et. al. thus define Responsible Innovation as taking care of the future through collective stewardship of science and innovation in the present.<sup>182</sup>

Emphasized is that technological development can contribute to societal or environmental problems, but that this does not happen automatically. RRI was developed out of empirical and theoretical research that challenges certain common ideas about the science-society interface. RRI is the on-going process of aligning research and innovation to the values, needs and expectations of society.<sup>183</sup> RRI can be defined as a "transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)".<sup>184</sup>

As such, RRI is a *process*, a *practice* of the highest integrity and quality, a reflective & critical *research culture*, and a force pushing for an internal *reform of science* to better

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177 Bundesregierung, 2018, Forschung und Innovation für die Menschen, Die Hightech-Strategie 2025, S. 50, <https://www.hightech-strategie.de/files/HTS2025.pdf>.

178 Antrag vom 09.04.2019 „Innovation und Chancen nutzen – Innovationsprinzip bei Gesetzgebung und behördlichen Entscheidungen einführen“, Bundestags-Drucksache 19/9224, <http://dip21.bundestag.de/dip21/btd/19/092/1909224.pdf>.

179 Antrag vom 10.04.2019 „Vorsorgeprinzip als Innovationsmotor“, Bundestags-Drucksache 19/9270, <http://dip21.bundestag.de/dip21/btd/19/092/1909270.pdf>.

180 See for a summary of the debate <https://www.bundestag.de/dokumente/textarchiv/2019/kw15-de-innovationsprinzip-633778>.

181 Owen, Richard, John R. Bessant, and Maggy Heintz, eds. Responsible innovation: managing the responsible emergence of science and innovation in society. John Wiley & Sons, 2013.

182 Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research policy*, 42(9), 1568-1580.

183 Rome Declaration on Responsible Research and Innovation in Europe, 2014 [https://ec.europa.eu/research/swafs/pdf/rome\\_declaration\\_RRI\\_final\\_21\\_November.pdf](https://ec.europa.eu/research/swafs/pdf/rome_declaration_RRI_final_21_November.pdf)

184 von Schomberg 2012

align science, technology and innovation with the values, goals and aspirations of society.<sup>185</sup>

Arnaldi and Gorgoni connect RRI with the precautionary principle. According to Arnaldi and Gorgoni, RRI takes the heritage of the precautionary approach one step further and merges two typically separated perspectives on responsibility, namely the legal and the political one.<sup>186</sup>

Furthermore, Arnaldi and Gorgoni argue that “what distinguishes RRI from the precautionary attitude of the safety paradigm, is not their respective inner logic and their underlying epistemology (they both refer to decisions in a context of uncertainty), but rather their goals. The precautionary principle was meant as a safeguard against the undesirable outcomes of innovation activities, serving as a tool for correcting their path, either by inverting, diverting, or blocking them. RRI focuses on orienting science and technology along a (morally and socially) ‘right’ trajectory”<sup>187</sup>.

## 2.8. Risk Governance Frameworks

It is important to link the debates on precaution, precautionary principle, innovation and innovation principle to existing frameworks on risk governance. Risk Governance can be defined as the “totality of actors, rules, conventions, processes and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken”.<sup>188</sup> Risk governance actually combines 2 distinct fields: 1) Risk analysis including risk assessment, management, and communication; 2) Governance of collectively binding decisions associated with regulation and specific context in which risk analysis take place<sup>189</sup>.

We view risk governance frameworks as an ideal place to address various aspects of Responsible Research and Innovation (RRI) as well as the dimensions anticipation, reflexivity, inclusion and responsiveness. In particular, part of our assessment of the usefulness of risk governance frameworks overall is in assessing how they can address RRI considerations. In addition to risk governance, consideration of another key aspect of RRI, gender, has been incorporated throughout the research. The importance of taking into account a gender and diversity perspective in all the phases of the project is also guaranteed by the presence of gender experts within the RECIPES consortium (K&I).

Different risk governance frameworks exist, and the RECIPES Consortium we will consider whether and how these frameworks can be used in the next WP’s. Potential guiding frameworks are the International Risk Governance Council (IRGC) framework and the Safe Foods Governance Framework.

### *IRGC Risk Governance Framework*

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185 J. van der Sluijs (2020) The Precautionary Principle, responsible innovation and post-normal science. Lecture at PNS5 2020, a digital journey – 24 September 2020 [https://www.uib.no/sites/w3.uib.no/files/pns5\\_pp\\_jvds.pdf](https://www.uib.no/sites/w3.uib.no/files/pns5_pp_jvds.pdf)

186 Arnaldi, S., Gorgoni, G. Turning the tide or surfing the wave? Responsible Research and Innovation, fundamental rights and neoliberal virtues. *Life Sci Soc Policy* 12, 6 (2016). <https://doi.org/10.1186/s40504-016-0038-2>

187 Arnaldi, S., Gorgoni, G. Turning the tide or surfing the wave? Responsible Research and Innovation, fundamental rights and neoliberal virtues. *Life Sci Soc Policy* 12, 6 (2016). <https://doi.org/10.1186/s40504-016-0038-2>

188 IRGC (2018). Guidelines for the Governance of Systemic Risks. Lausanne: International Risk Governance Center (IRGC).

189 Renn, O., Klinke A., and Schweizer, P.J., 'Risk Governance: Application To Urban Challenges' *International Journal of Disaster Risk Science*, 2019.

The IRGC framework recommends a holistic, multidisciplinary and multi-stakeholder approach to risk. It does so by providing policy makers, regulators, risk managers and other key decision-makers with evidence-based recommendations about risk governance. In contrast to traditional risk analysis, IRGC tries to understand the broader stakeholder, expert, and public context surrounding social and environmental risks. By including the stakeholder input and context of broader legal, political, economic and social contexts, risk governance aims at the “development of an integrated, holistic and structured approach, a framework, by which we can investigate risk issues and the governance processes and structures pertaining to them” (IRGC 2005)<sup>190</sup>. The IRGC framework has been applied to several relevant precautionary principle case topics: nanotechnology, pollination services, synthetic biology, GM crops, and precision medicine.<sup>191</sup>

The IRGC framework contains a 5-step framework: pre-estimation, interdisciplinary risk estimation, risk characterization, risk evaluation, and risk management.

#### *Food Safety Governance Framework*

In addition, the Safe Food project’s Food Safety Governance framework might also be relevant for the RECIPES project. The Food Safety Governance framework arose out of the challenges the EU was confronted with in the wake of various food crises in the late 1990s and 2000s. The Food Safety Governance framework is a design with four governance stages (framing, assessment, evaluation, management, with participation and communication as cross-cutting activities), and an organisation into four assessment and management tracks distinguishing between risk-, precaution-, concern- and prevention-based approaches.<sup>192</sup>

These frameworks offer inspiration for how the precautionary principle can be conceived as part of a general framework of risk governance which also includes stages (in particular risk evaluation) which appear suitable for linkages with innovation. Consideration of the IRGC or other risk frameworks might play an important part in the generation of scenarios (task 2.5) for the future of the precautionary principle-innovation principle, and in the new tools and guidelines to be developed in WP3.

## **2.9. Concluding remarks**

The objective of this chapter was to create a common understanding of the concepts used in RECIPES research. The chapter therefore presented our understanding of the key concepts precaution, precautionary principle, innovation and innovation principle by examining relevant literature on the relationship between risk, uncertainty, precaution and the precautionary principle, innovation and the innovation principle.

This chapter has shown that a universally accepted definition of ‘the’ precautionary principle does not exist. Different versions and interpretations of the precautionary principle are used at international, European and even national level.

Irrespective of how the precautionary principle is interpreted, we can say that 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 offer a predetermined solution. Rather, the precautionary principle is 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. Some

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190 International Risk Governance Council (IRGC) (2005). Risk governance. Towards an integrative approach. Geneva: IRGC. <https://www.irgc.org/risk-governance/irgc-risk-governance-framework/>

191 See <https://irgc.org/issues/>

192 Renn O., and Dreyer, M., Food Safety Governance, Springer, 2009

therefore argue that the strength of the precautionary principle precisely lies in its open-endedness and flexibility, which creates a possibility and an incentive for better regulation.

We also have observed that practice and literature operate several constituent elements of the precautionary principle. They identified a 'conceptual core'<sup>193</sup> of the principle, based on various definitions and understandings of the principle, that forms the main components of the precautionary principle.

*RECIPES takes scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and burden of proof to form the main components of the precautionary principle.*

In the remainder of this report, we will study the implementation and application of the precautionary principle at international, European level and national level in detail. We will pay particular attention to these main components.

In order to get a clear understanding of the possible tension between precaution and innovation and to create opportunities for aligning the goals of precaution and innovation, it was also necessary to create a common understanding of what is meant with 'innovation', and the 'innovation principle'.

Our research showed that it is important to note that 'innovation' is in the eye of the beholder. Something is called an innovation by someone because the person in question 'assumes' that it will be an improvement.

Therefore, RECIPES does not consider innovation as a goal in itself as this hides the factual uncertainties and different opinions that exist with regard to the desirability of a particular new technology.

*RECIPES will use the term innovation in the sense of responsible innovation. With responsible innovation we mean "taking care of the future through collective stewardship of science and innovation in the present".<sup>194</sup> Defined as such, innovation can be technological inventions and also other kinds of changes such as organizational innovations. This working definition reflects the fact that products of technological development can bring forth a wide range of (societal) benefits; as medical technology and health, electric cars and the environment or digital technologies and the free flow of information.*

The innovation principle on the other hand, was proposed by the European Risk Forum (ERF) in 2013. It defines the innovation principle as:

*"whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed".<sup>195</sup>*

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193 Cameron, J., 'The Precautionary Principle in International Law', in 'O Riordan, T., Cameron, J., Jordan, A., (eds.) Reinterpreting the Precautionary Principle, London: Cameron May 2001, p. 116.

194 Stilgoe, J., Owen, R., Macnaghten, P. (2013). Developing a framework for responsible innovation. Research Policy 42, 1568-1580, here p. 1570.

195 European Risk Forum, 'The Innovation Principle, Stimulating Economic Recovery', Open letter to Barroso, Van Rompuy and Schultz, 24 October 2013. Retrieved from [https://corporateeurope.org/sites/default/files/corporation\\_letter\\_on\\_innovation\\_principle.pdf](https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf), last accessed 5 May 2019, p. 2.

Furthermore, we explained the connection of the RECIPES research with Responsible Research and Innovation (RRI). Some authors have connected RRI with the precautionary principle. RRI could be considered as constituting a process, a practice of the highest integrity and quality, a reflective & critical research culture, and a force pushing for an internal reform of science to better align science, technology and innovation with the values, goals and aspirations of society. In this context literature points out to the different goals of RRI and the precautionary attitude of the safety paradigm; with RRI focusing on orienting science and technology along a morally and socially 'right' route and the precautionary principle to act as a tool against undesirable outcomes of innovation activities.

Finally, the chapter embedded the concepts of precaution, precautionary principle, innovation and innovation in two highly relevant existing risk governance frameworks that relate to risk and/or safety governance: IRGC risk governance framework and the General Safe Foods framework. It herewith aimed to connect RECIPES to the larger risk governance landscape in which enactment of the precautionary principle may take place.

The concepts and reflections developed in this Chapter will serve to further develop and design in Work Package 2 a conceptual framework for comparative multiple case study analysis. Nine case study topics will be analysed in order to get an in-depth understanding of the implementation and application of the precautionary principle.

## 3. Stakeholders of the precautionary principle

The precautionary principle gives direction to what is right and fair in situations of scientific uncertainty, and how interests should be weighed up. However, the principle does not establish *which* measures are linked to *which* situations of scientific uncertainty. The question of how and when the principle should be implemented is a balancing act under uncertain circumstances. When putting the precautionary principle into practice, decision-makers make various considerations, such as: is the danger serious enough? Is there in fact scientific uncertainty? And which measures are proportionate to the prevention of potential damage? Decisions of this kind must be made carefully, because they can have far-reaching consequences for on the one hand the producers of the substance/technology, and on the other hand the potential victims of the associated risks, such as nature and European citizens.

Within this balancing exercise, we distinguish four stakeholder groups. Firstly, there are parties who *formalize the precautionary principle* in laws, rules and measures. Secondly, there are parties who *implement* the precautionary measures. Thirdly, there are parties who are *directly affected* by the way in which the precautionary principle is applied. Fourthly, there are parties *indirectly affected*. On the basis of these four categories, we first describe the stakeholder landscape and their relation to the precautionary principle (section 3.1). Subsequently, we shortly describe different stakeholder groups and their desired involvement in the RECIPES project (section 3.2).

Because actors are involved with and affected by the precautionary in many different domains, on many levels, and in varying contexts, we do not provide an exhaustive list of stakeholders as part of this general analysis. However, in both sections we do name examples of specific actors within each stakeholder group. Further identification of specific stakeholders and their perspectives is part of the RECIPES case studies.

### 3.1. Outline of the stakeholder landscape

#### 3.1.1. Stakeholders who formalize the precautionary principle in laws, regulations and measures

The precautionary principle is a leading principle for how all kinds of risks are handled in our society. Moreover, as an internationally recognized, general principle of law it has an enormous effect on how regulations, decisions, policies and guidelines are formulated on all kinds of levels: international, EU, national and even local.

As a legal principle, the precautionary principle has been applied in a variety of ways within local, national and global governance levels. Legal principles can be deployed as a ground for interpreting laws, the changing of laws, formulating specific exceptions to laws, making new rules and even as the sole ground for action<sup>196</sup>.

In 1990, the *12 EU Heads of State or Government* gave their formal, political blessing to the principle in the Dublin Declaration of the *European Council*. In 1992, it was consequently included in the Maastricht Treaty and it became part of the 'acquis communautaire': rights and obligations deriving from EU treaties, laws and regulations. Today, the precautionary principle is enshrined in Article 191 (2) of the Treaty on the Functioning of the EU.

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196 Raz, J. (1971). Legal principles and the limits of law. Yale. LJ, 81, 823.

*Lawyers* have used it as 'generally applicable to all risk regulation activities in the EU'<sup>197</sup> and it is referred to in directives, *European Court of Justice* judgments and policy documents. As such, its significance in the EU has considerably expanded, for instance through case law stemming from the European Court of Justice. The principle has also been incorporated into a number of measures of secondary legislation (i.e. Regulations and Directives), which apply to *member states*, such as the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). In some applications, the principle is not mentioned as such, but a law seems to follow the main ideas behind it.

Many actors play a part in the creation, distribution and concretization of the principle for example in the jurisprudence in a country. These formalizations can be based on different interpretations of the principle, depending on answers given to questions like: does uncertainty justify action? Or is it enough to say that uncertainty does not justify inaction? How serious must a threat be to invoke the principle? Who has the burden of proof: does the developer need to prove its new product is safe or do those aiming for environmental protection need to prove it is not? Which measures are appropriate? In 2000, the European Commission released the *Communication on the Precautionary Principle*<sup>198</sup>, a guide to applying the principle as interpreted by the EU. It prescribes moderate precaution: uncertainty justifies precautionary action, regulation should be 'proportionate to the risk level', and the banning of substances is only a last resort.

### **Groups influencing the formalization of the precautionary principle in laws, regulations and measures**

Different European and global (advisory) organizations supporting policy and governance have further developed policy recommendations based on the precautionary principle. For example, the World Health Organisation (*WHO*)<sup>199</sup> has published a working document on the precautionary principle in 2003, in which an approach is developed for applying precaution in decision-making on environmental and health risks in order "to protect the health of children and future generations and make rational decisions under conditions of uncertainty" (WHO 2004). The UNESCO advisory body *COMEST* (World Commission on the Ethics of Scientific Knowledge and Technology) has also published a report aiming to clarify the precautionary principle in a pragmatic way, describing implications for science, policy and governance, industry and trade, and society at large. Finally, the *European Environment Agency's* Late Lessons from Early Warnings reports<sup>200</sup> have helped develop a broader, more proactive definition of precaution that clarifies its application to children's health and sustainable development<sup>201</sup>.

*Academic researchers* in areas of for example Science and Technology Studies, Risk Research, Law, Ethics and Sustainability Studies have also been involved in the formalization of the precautionary principle as they provide expertise on the management and assessment of risks to government institutions. This is done directly, through consultation, and indirectly, through the publication of articles for example. Academics have also taken a stand in public fora, such as a series of posts on the precautionary

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197 Fisher, E. 'Precaution, Precaution Everywhere: Developing a Common Understanding of the Precautionary Principle in the European Community', in *Maastricht Journal of European and Comparative Law* 9, 2002

198 <https://op.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en>

199 Martuzzi, M., & Tickner, J. A. (eds.) (2004), *The precautionary principle: protecting public health, the environment and the future of our children*, World Health Organization.

200 Gee, D., 'More or less precaution', in *Late lessons from early warnings II: Science, precaution, innovation*, European Environment Agency, EEA report no 1/2013; and *European Environment Agency* (2001), *Late Lessons from Early Warnings: The Precautionary Principle 1896–2000*, Environmental Issue Report No. 22 (Luxembourg: Office for Official Publications of the European Communities).

201 Working document (EUR/04/5046267/11, 28 April 2004) prepared by WHO Secretariat for the Fourth Ministerial Conference on Environment and Health, Budapest, June 2004

principle in The Guardian in 2013<sup>202</sup>, contributed to by Andrew Stirling, Steve Fuller, Nicolas Nasim Taleb, Tracey Brown, Jack Stilgoe and Andrew Maynard (among others). Academic research touches upon different aspects of decision making in relation to uncertain risks. Scholarly discussions are general or take place within specific domains such as GMOs, food safety, biodiversity conservation, chemicals management, climate, health, law etc.

Finally, actor groups such as *politicians, lobbyists* and *advocacy groups* influence the debate on how to formalize the precautionary principle, for example, to the degree that it is enacted in laws through parliament.

### 3.1.2. Stakeholders involved in formal precautionary principle procedures

The second group of stakeholders is made up of actors involved in the procedures that implement the precautionary principle. In other words: those who decide when and how the principle is invoked, who are (generally) involved in legal, policy and risk assessment procedures - establishing the seriousness of a given threat, its plausibility, uncertainty and who can be held responsible.

#### Outline of the general procedure

The precautionary principle serves as a general overarching principle for dealing with serious risks that are uncertain, complex and ambiguous. While the precautionary principle's application has been elaborated by, for example, the European Commission and, furthermore, in EU case law, the particularities of different cases would not be served with a set procedure. Procedures can, therefore, differ between regions, governance levels and types of innovation.

In general, the precautionary principle is implemented as follows: 1. A certain risk is brought to the attention. 2. It is associated with the precautionary principle. 3. Cost-benefit analysis/ accumulation of necessary knowledge 4. Judgement 5. Formulation of the measures that have to be taken.

When precaution has not sufficiently been taken, risks have frequently been brought to the attention fairly early by *individual researchers* (in the sense of whistleblowers), though this may differ throughout cases. The demand for action is often voiced to policy makers by *NGO's, advocacy groups, academics and journalists*<sup>203</sup>. *Advocacy groups, politicians, journalists and academics* assemble evidence of the risks and associate this risk with 'precaution' or 'precautionary principle'.

On the basis of existing evidence and sometimes additional research, countries adopt specific legislative or administrative acts with regard to a specific technology. In the EU, the introduction of a technology with potential risks is often accompanied by a 'comitology' procedure. Both with regard to consumer, health and environmental protection, the *European Commission* asks *scientific committees or agencies* to assess the potential risks, based on the available scientific evidence<sup>204</sup>. In the risk management phase, policy alternatives are weighed with the representatives of the *Member States* and the *Commission* who try to reach a unanimous decision.<sup>205</sup> In some cases, there is a need to adopt new or revise existing EU legislation, which needs to be discussed and adopted by the EU legislators: the *European Parliament* and the *Council of the EU*.

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202 <https://www.theguardian.com/science/political-science/2013/jul/12/precautionary-principle-science-policy>

203 European Environmental Agency, 2013

204 EC [http://ec.europa.eu/assets/sante/health/scientific\\_committees/risk\\_assessment/index\\_en.htm](http://ec.europa.eu/assets/sante/health/scientific_committees/risk_assessment/index_en.htm) infograph:

205 Hesselhaus, 2010.

Often the steps described above run parallel to each other and cannot easily be separated. For instance, as was the case with nanotechnology, the development of (fundamentally new) innovation is always in a certain sense accompanied by a certain degree of precaution that is also formalized and institutionalized, like keeping research closed off in a certain area. When the production of nano-materials increased, different countries, including the US, decided to investigate the magnitude of the use of Nano-materials which prompted US policy makers to expand investigations in possible effects (for instance with regard to local eco-systems), which in turn led to more detailed knowledge. This led to the *Organisation of Economic Co-operation and Development* (OECD), among others, to call for a precautionary approach to particular applications of nanotechnology.<sup>206</sup>

### Political considerations

Ultimately, political considerations determine whether and how the principle is implemented. The precautionary principle serves as a legal principle for dealing with situations that are ambiguous, complex, or without a definite relationship between activity/innovation and potential hazard. As stated in the 2000 *Communication on the Precautionary Principle*<sup>207</sup>, "the appropriate response in a given situation is thus the result of a political decision, a function of the risk level that is 'acceptable' to the society on which the risk is imposed" (p. 16). To 'apply' the precautionary principle can, therefore, mean different things, like a (temporary) moratorium banning a specific type of substance or innovation, or a case by case assessment of risks. Considerations that are often taken into account in the determination of actions are the proportionality and reversibility of precautionary measures.

The invocation and formalization of the procedures leaves room for lobby, power play and public relations campaigning by *lobby and interest groups*, as is seen for example in De Santo's analysis of European marine environmental decision making<sup>208</sup>. An example of an interest group that has lobbied against the innovation principle is the *Corporate European Observatory*.

On the basis of existing evidence and sometimes additional research on a specific technology, countries draft legislative or administrative acts. In the EU, the European Commission asks scientific committees or EU agencies to assess the potential risks, based on the available scientific evidence.<sup>209</sup> Policy alternatives are weighed representatives from Member States and the Commission trying to reach a unanimous decision.<sup>210</sup> In some cases draft-decisions are put for stakeholder consultation. In some cases, there is a need to adopt new or revise existing EU legislation, which needs to be discussed and adopted by the EU legislators: the *European Parliament* and the *Council of the EU*.

### 3.1.3. Stakeholders directly affected by its implementation

The third group of stakeholders consists of those that are directly affected by implementation of the precautionary principle: those involved in the introduction of new substances or products in the environment or the market. Actor groups that are forced to

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206 ((OECD, 2005) in (EC 2018))

207 <https://op.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en>

208 De Santo, Elizabeth. (2010). 'Whose Science?' Precaution and power-play in European marine environmental decision-making. *Marine Policy*. 34. 414-420. 10.1016/j.marpol.2009.09.004.

209 EC infograph: [http://ec.europa.eu/assets/sante/health/scientific\\_committees/risk\\_assessment/index\\_en.htm](http://ec.europa.eu/assets/sante/health/scientific_committees/risk_assessment/index_en.htm).

210 Heselhaus, S., 'Risk Management of Nanomaterials: Environmental and Consumer Protection under Existing EC Legislation on Chemicals, Pesticides and Biocides'. *Environmental Law Review*, 12(2), 2010, pp. 115-131.

take risk reducing measures on the basis of the precautionary principle include actors from industry and academic researchers.

*Actors from industry* can be directly affected by the precautionary principle- both large and small companies have to adapt their strategy in order to be “safe rather than sorry”. Industrial or technological accidents seldom only have one source of human failure; more typically they are the result of a chain of interrelated actions and systemic technological design.<sup>211</sup> That means that when the precautionary principle is implemented, it can have a large impact on the entire supply chain of a product.

Risks are generally already charted and prevented in company R&D, for instance in pre-clinical trials. In regulations such as REACH, which is explicitly underpinned by the precautionary principle, the producers of new chemicals are required to identify and manage the risks associated with the substances they manufacture and market in the EU. They have to demonstrate how the substances can be safely used, and must communicate health and safety information to the other users in the supply chain. Producers can also be required to inform consumers about possible health risks on their labels.

Invocation of the precautionary principle might lead companies to no longer invest in the R&D of a certain technology. Others might become retroactively liable to lawsuits. In order to prevent taking drastic measures after products are market-ready, companies can also take a precautionary approach already in the development of their innovation. This way, the principle can stimulate innovators to invest in different innovation pathways or to develop innovations that are safe by design.

Of course, in the complex daily reality of research and development, the precautionary principle is only one of many factors in decisions that innovators make. In addition, not all safety regulation is based on the precautionary principle. The way companies are affected is dependent on the regulations already in place.

*Large multinationals* have the power to influence the regulation of innovation. In the past years, in an effort to counterbalance regulations related to the precautionary principle, we have seen an increased lobby for an “innovation principle”, led by the *European Risk Forum* (ERF)<sup>212</sup>. However, other businesses see opportunity in reconciling precaution with innovation. Some companies can take pride in precaution, by integrating it into strategies for corporate social responsibility.

*Universities and research institutes* can also be directly affected by the precautionary principle, as precaution can put a halt to (the funding of) research activities, research applications, or the economic valorisation of research. Individual researchers and researchers from different countries can have different views on what kinds of research are acceptable. In an international research community, this can lead to contested outcomes.

#### **3.1.4. Stakeholders indirectly affected by its implementation**

The precautionary principle is a safety net for European citizens, who are represented by interest groups like *patient organizations, consumer organizations, unions and activist groups*. However, the group of stakeholders indirectly affected by the implementation of the precautionary principle is much broader than the EU citizen. The principle is often applied in cases of technology that might be produced and distributed on a global scale with possible irreversible effects, and, therefore, stakeholders effectively include the whole world and even future generations. Especially in the case of chain reactions, as is the case

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211 Perrow, C. *Normal accidents: Living with high risk technologies*-Updated edition, Princeton university press, 2011.

212 <https://www.politico.eu/article/consumer-protections-europe-big-business-sharks-circle>

with human induced climate change, a feedback loop can strengthen consequences for every generation that is to follow. The emergence of the precautionary principle has been inspired, amongst others, on the tenet that risk governance should account for both intra- and extragenerational equity: the needs of present generations should be met provided they do not impair the ability of future generations to meet their needs.<sup>213</sup>

Moreover, deliberations based on the precautionary principle are sometimes informed on the idea that the negative impacts that human activities may have on nature should be considered, even if these impacts do not pose direct risks for humans.<sup>214</sup><sup>215</sup> A technology that destabilizes an ecosystem can have ever wider consequences for all living things that are connected to it.

In light of the precautionary principle, the involvement of this fourth group of stakeholders in decisions under scientific uncertainty is very important. The ethical principle behind this idea is that decisions that affect parties other than the decision-maker should be consented to by these parties under conditions of transparent process and with freely accessible information.<sup>216</sup><sup>217</sup> However, in discussions involving uncertain risks, an adequate representation of stakeholders with less or even without voice or power, such as nature and future generations, is difficult.

An imbalance remains between those that are involved in its implementation and application and everything and everyone that will be affected in the long term, especially in relation to the kind or risks that the precautionary principle is meant for (irreversible and often with global implications). The precautionary principle protects people from technological risk, but can also prevent the world from benefiting from technology and the economic growth or geopolitical advantages that sometimes accompany it. Moreover, the effects of the application of the precautionary principle are difficult to assess.

### 3.2. Stakeholder involvement in the RECIPES project

The precautionary principle is an important general principle and is for example a general principle of EU law. Its application has an effect on the safeguarding of human health and the environment and innovation in a variety of ways. It aims to enable a response to uncertain serious risks that is appropriate and 'acceptable' to the society on which the risk is imposed. This analysis demonstrates a complex array of forces and interests around the implementation of this principle.

Because RECIPES takes place in the middle of this dynamic and often political arena, co-creation and stakeholder involvement play an important and unique role within the project. The partners of the consortium come from different European countries and have different (academic) backgrounds. Different interest groups are represented in the advisory board of the project. Above all, we involve stakeholders in the different steps of our methodology.

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213 Borowy, I., *Defining sustainable development for our common future: A history of the World Commission on Environment and Development (Brundtland Commission)*. 2013. Routledge.

214 Oughton, D., Forsberg, E.-M., Bay, I., Kaiser, M. & Howard, B., 'An ethical dimension to sustainable restoration and long-term management of contaminated areas', in *Journal of Environmental Radioactivity*, Vol. 74, Issues 1-3, 2004, pp. 171-183.

215 Kaiser, M. & Forsberg, E.-M., 'Consensus conference on environmental values in radiation protection: a report on building consensus among experts', *Science and Engineering Ethics*, vol. 8, (4), 2002, pp. 593-602.

216 Gethmann, C.F., Carrier, M., Hanekamp, G., Kaiser, M., Kamp, G., Lingner, S., Quante, M., Thiele, F., *Interdisciplinary Research and Trans-disciplinary Validity Claims*, Springer: Cham, Heidelberg, New York, Dordrecht, London, 2015, DOI 10.1007/978-3-319-11400-2.

217 Kaiser, M., Millar, K., Thorstensen, E., & Tomkins, S., 'Developing the ethical matrix as a decision support framework: GM fish as a case study'. *Journal of Agricultural and Environmental Ethics*, 20(1), 2007, pp. 65-80.

In the following section, we describe how different stakeholder groups are involved in the RECIPES project. We also provide examples of specific relevant actors.

### **1. Policy makers in the field of risk assessment, evaluation and management (at EU, national and local level)**

Policy and decision makers, as well as institutions on the European and national level working on human health, the environment, research and innovation represent a key target group for the RECIPES Project. As a direct target group, they can undertake relevant concrete policymaking. However, they are also important multipliers and strategic partners for the spreading of project results: they can ensure a constant communication with their national, regional and local level networks, influence the opinion and policymaking process, and, together with their network, support awareness raising about the implications and applications of the precautionary principle. I.e.: European Commission and European Parliament, specifically the Committee on the Environment, Public Health and Food Safety (EU level); Ministers of health, Ministers of the Environment, Ministers of Agriculture, Ministers of Food or Consumer safety, Ministers of Science (National level); regional administrative authorities, especially those governing natural reserves, Municipalities, Committees (Local level).

### **2. Agencies, authorities and public knowledge organizations in the field of risk assessment, evaluation and management (at a global, EU, national and local level)**

Agencies and authorities usually support and complement the activities and policies implemented by policy makers. Informing and involving agencies and authorities at different levels is of great importance. Large international organizations are important stakeholders because they have the power to set the global agenda. Municipalities and local authorities should also be involved since bottom-up data is, largely, to be collected on lower governmental levels. I.e.: the Organisation of Economic Co-operation and Development (OECD) the World Trade Organization (WTO), World Health Organization (WHO), UN organizations such as the Food and Agriculture Organization and UNESCO / COMEST, the United Nations Environmental Program (UNEP) and the International court of Justice (global level); the European Commission's Joint Re-search Centre (JRC), various Directorate-Generals of the EC, the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), the European Environment Agency (EEA), the European Medicines Agency (EMA), the European Systemic Risk Board, the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), the European Court of Human Rights (ECHR) (EU level); the Federal Institute for Risk Assessment of Germany, the German Environment Agency, The Food Safety authority of Ireland (National level).

### **3. Research/Academia**

Researchers/academics from different domains will have a different interest in the RECIPES project. Some researchers are involved in the formalization of the precautionary principle as they provide expertise on managing risk to government institutions. We distinguish three groups. Those interested in policy/law (political scientists, lawyers, public administrators) should be involved in WP1 and WP4. Researchers interested in risk analysis and associated methods and principles should be part of WP3. Those researching the relationship between science and society (STS researchers, ethicists, philosophers) can be involved in all WPs. The partners of this project are themselves relevant stakeholders, as are other research institutes in these fields, such as for example the partners of the European Parliamentary Technology Assessment network.

Furthermore, universities and research institutes can also be directly affected by the precautionary principle in their daily practice. Researchers interested in specific technologies should be involved in WP2. Examples of research institutes specific to a particular technology are the Dutch NanoLabNL or research institutions that are members of the NANOfutures network.

#### **4. Industry/Businesses**

In order for the RECIPES project to have impact, it is vital to involve both large companies (including for example Bayer, Syngenta and Dow Chemical) and SME's, (which can be represented by for example Business Europe, or Plantum) in this project. Primarily companies that are in the business of high-risk materials and/or technologies might be interested. Some of these companies have already organized themselves around their critical view of the precautionary principle in the European Risk Forum.

#### **5. Funding Sources/Finance**

Public and private funding organisation may apply the precautionary principle in their decisions on which research to fund. This audience will be targeted by the dissemination and communication activities of the project. (I.e.: Banks such as the European Central Bank (ECB), Governments and national research funding organizations such as NWO, the Deutsche Forschungsgemeinschaft etc.)

#### **6. NGOs, Associations and interest groups**

NGOs and interest networks are an important target group and act as multipliers for the RECIPES project. Active on both local and international levels, these organizations engage in activities that involve citizens in meaningful actions and foster sustainable lifestyles. International NGO's include the WWF, Greenpeace, and the Corporate Europe Observatory (focused on corporate lobbying over EU policy-making). Like NGOs, associations like ECOROPA bring forward ideas and activities with the support of their networks.

#### **7. Citizens and civil society organizations**

We involve citizens directly (by conducting citizen group interviews) and indirectly by communicating with civil society organizations such as Citizens for Europe (CFEU), consumer organizations such as BEUC, and trade and consumer organizations, like The European Trade Union Confederation (ETUC) and the European Consumers Union (ECU).

#### **8. Future generations and the world**

Unfortunately, we cannot include future generations or the whole world directly in the project. However, the question of how future generations can be adequately represented in discussions that involve uncertain risks should be an explicit part of RECIPES. Future generations and those without a voice can (partially) be represented by organizations like The World Future Council or by young people. An approach that could be used is for instance The Parliament of Things<sup>218</sup>.

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218 See <https://theparliamentofthings.org/>

## 4. The precautionary principle in International Law

### 4.1. Introduction

After analysing the nature and purpose of the precautionary principle, the innovation principle and the link -or absence of link- between both concepts, we will examine the application of the precautionary principle at various policy levels.

This chapter will look at the application of the precautionary principle in international law, in particular since 2000.

The main question that we will address in this chapter is whether the precautionary principle is a general principle of international law or whether its application depends upon the will of States.

It appears that, today, despite occurrences in more than fifty international treaties, the definition and legal status of the precautionary principle remain unclear (section 4.2.). 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 (section 4.3.). These different points of view could eventually be reconciled by means of 'new generation' bilateral trade agreements such as the recent Comprehensive Economic and Trade Agreement (CETA) concluded between the EU and Canada (section 4.4.).

### 4.2. The precautionary principle in the international legal framework

#### 4.2.1. The precautionary principle in international treaties

In the early 1980s, references to precaution, the precautionary principle or to a precautionary approach started to find their way into the international legal framework.<sup>219</sup> Yet, the principle was codified for the first time in 1992 in Principle 15 of the non-binding Rio Declaration on Environment and Development<sup>220</sup> which (as already stated in Chapter 2) states:

*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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.*

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219 For an overview see M. Bocchi, 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016* at: [http://www.ceje.ch/files/2314/5933/0264/Geneva\\_JMWP\\_02-Bocchi.pdf](http://www.ceje.ch/files/2314/5933/0264/Geneva_JMWP_02-Bocchi.pdf). See also Scott, J., 'Legal Aspects of the Precautionary Principle', *A British Academy Brexit Briefing*, November 2018, p.8.

220 The text of this is available at: <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>.

Since this time, the precautionary 'principle' or 'approach' has been included in more than 50 international treaties and instruments, only some of which use the formulation included in the Rio Declaration.<sup>221</sup> Consequently, it is closer to reality to refer to the 'precautionary principles' in international law rather than to a single, clearly defined and demarcated precautionary principle.

The lack of consistence and the vagueness of the precautionary principle has consequences on the legal status of the principle in international law.

The issue of the legal status of the precautionary principle in international law is fundamental, as it determines whether states are under the obligation to apply and to implement it and, if yes, which states.

Currently, there still is disagreement about the status of the precautionary principle or approach in international law. However, it seems that there is a trend towards making a precautionary approach part of customary international law.<sup>222</sup>

In this respect, the decisions of the International Tribunal for the Law of the Sea (ITLOS) and the International Court of Justice (ICJ) are of significant value in clarifying the status of the precautionary principle in international law.

#### 4.2.2. ITLOS and ICJ Case Law

A review of case law of the International Tribunal for the Law of the Sea (ITLOS) shows that ITLOS is very cautious in invoking the precautionary principle. The reason would not be the uncertain status of the precautionary principle, but the commercial interests of States involved in marine-environment disputes.<sup>223</sup>

Two cases are of interest. First, in the Bluefin Tuna Case of 1999<sup>224</sup>, the ITLOS found that there was "scientific uncertainty regarding measures to be taken to conserve the stock of southern bluefin tuna" and therefore granted provisional measures in favour of the claimant.<sup>225</sup> Hereby, the ITLOS implicitly lowered the burden of proof for invoking the precautionary principle and shifted it, in part, onto the defendants.<sup>226</sup>

In the MOX Plant Case<sup>227</sup> of 2001, the ITLOS followed a different reasoning. The ITLOS recognized that indeed possible risks should be avoided by taking proportional measures, but in the specific case the ITLOS decided that there was no urgent need to authorize them

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221 Scott, J., 'Legal Aspects of the Precautionary Principle', *A British Academy Brexit Briefing*, November 2018, p.8.

222 Scott, J., 'Legal Aspects of the Precautionary Principle', *A British Academy Brexit Briefing*, November 2018, p.8. See also Advisory Opinion, ITLOS Seabed Dispute Chamber, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area (2011, Case No. 17), para. 135.

223 See Sage-Fuller, B., *The Precautionary Principle in Marine Environmental Law*, Routledge, 2013; Tanaka, Y., *The International Law of the Sea*, Cambridge, 2012, and Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 17.

224 ITLOS, Southern Bluefin Tuna Cases (New Zealand/Japan; Australia/Japan), Provisional Measures, Judgment of August 3rd and 16th, 1999, ITLOS Report 1999.

225 See Kazhdan, D., 'Precautionary Pulp: Pulp Mills and the Evolving Dispute between International Tribunals over the Reach of the Precautionary Principle', *Ecology Law Quarterly*, 2011, pp. 527-552 and Trouwborst, A., 'The Precautionary Principle and the Ecosystem Approach in International Law', *Review of European Community and International Environmental Law*, 2009, pp. 26-37.

226 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 17.

227 ITLOS, MOX Plant Case (Ireland/United Kingdom), Provisional measures, Judgment of November 19th 2001, ITLOS Report 2001.

based on the reasons put forward by the State that invoked the precautionary principle (Ireland).<sup>228</sup>

The apparent risk was similar in MOX Plant and Bluefin Tuna cases. In both cases the states took action based on the precautionary principle and stressed that the defendant must offer proof that its action would not endanger the environment.<sup>229</sup> However, only in Bluefin Tuna ITLOS grant provisional measures under the precautionary principle.

Bocchi argues that the reason might be that the principle was invoked, not for the protection of human health or the environment, but for the States' economic interests.<sup>230</sup>

The International Court of Justice (ICJ) has also contributed to the evolution of the precautionary principle in international law. Yet, case law shows that also the ICJ took a very restrictive approach. In the view of the ICJ, the uncertainties and contradictions regarding the definition of the precautionary principle have hampered it to become a general principle of international law.<sup>231</sup>

The first time proceedings concerning the precautionary principle were introduced before the ICJ in was the *French Nuclear Test II* case.<sup>232</sup> And, although the Court eventually dismissed it as inadmissible, dissents opinions rendered by, respectively, Judge Weeramentry and Judge Palmer stated that the precautionary principle was gaining more support as part of international law and that it may even form part of customary international law.

In 1997, in the *Gabcikovo-Nagymaros* judgment, the state's parties to the dispute recognized that the precautionary principle constituted a new requirement of international environmental law; however, in reason of the variety of interpretations that were given to this principle, the Court did not discuss its content, letting the parties agree on an interpretation of it on their own.<sup>233</sup>

It must be remarked that in both cases the precautionary principle was mentioned solely in dissenting and separate opinions, never in the judgments themselves.<sup>234</sup>

The ICJ has dealt more directly with the precautionary principle in *Pulp Mills* (2008).<sup>235</sup> This was the first case in which the principle was mentioned in a judgment.

However, the Court took a very narrow interpretation of the precautionary principle, and pointed out what had already been implicit in *French Nuclear Test II* and *Gabcikovo-Nagymaros*: in the Court's view, the precautionary principle is not a rule of law that gives rise to obligations and, therefore, it cannot be invoked as a ground of justification for the adoption of precautionary measures.<sup>236</sup>

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228 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 17.

229 See Gillespie A., 'The Precautionary Principle in the Twenty-first Century: A Case Study of Noise Pollution in the Ocean', *The International Journal of Marine and Coastal Law*, 2007, pp. 61-87.

230 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 20.

231 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 18.

232 *Nuclear Tests (New Zealand v. France)*, Judgment ICJ Rep [1974], 457.

233 *Gabcikovo-Nagymaros Project (Hungary v. Czechoslovakia)*, ICJ Judgment, 37 ILM162 (1998).

234 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*.

235 ICJ, *Pulp Mills (Argentina/Uruguay)*, Judgment of April 20th 2010, ICJ Reports 2010.

236 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 17.

## 4.3. The precautionary principle in WTO law

### 4.3.1. The precautionary principle in WTO law

The status of the precautionary principle within WTO law is of particular importance because it can play a role in determining the lawfulness of restrictions on trade.<sup>237</sup>

In the WTO system, international trade law is based on the free movement of goods under Article IX of the GATT Agreement (1994). Only a few exceptions to this rule are permitted.<sup>238</sup>

Under the Sanitary and Phytosanitary Measures Agreement (SPS Agreement), adopted in 1995, States Parties are allowed to adopt sanitary and phytosanitary measures that may directly or indirectly affect international trade if such measures are deemed necessary to protect animal, plant or human life and health within their territory, and as long as they are consistent with the provisions of the Agreement.<sup>239</sup>

Article 5(7) of the SPS Agreement provides the possibility, under certain narrowly circumscribed conditions, to adopt national SPS measures in case of scientific uncertainty. Although it does not mention the word 'precaution' as such, Article 5(7) constitutes the 'clearest reflection of the precautionary principle in the SPS Agreement' and, more generally, the only explicit reflection of it in all WTO Agreements.<sup>240</sup>

It reads as follow:

*"In cases where scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."*

Four cumulative requirements can be drawn from this provision. First, there must be insufficient scientific evidence, which refers to a lack of scientific data on the subject matter concerned.<sup>241</sup> Second, the SPS measures adopted pursuant to this article have to be based upon available pertinent information. Third, the State Party concerned must seek to obtain all additional information necessary to conduct an objective assessment and, finally, it must also review the SPS measure accordingly within a reasonable period of time. In other words, SPS measures based on Article 5(7) are only provisional, and they must be reviewed

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237 Scott, J., 'Legal Aspects of the Precautionary Principle', *A British Academy Brexit Briefing*, November 2018, p. 8.

238 Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper 2/2016*, p. 14.

239 Article 1(1) and Article 2(1) SPS Agreement. 'Sanitary' measures relate to human and animal life and health, whereas 'phytosanitary' measures concern plant life and health.

240 J. Zander, *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 43.

241 See Van den Bossche, P and Prévost D., *Essentials of WTO LAW*, Cambridge University Press, 2018. See also D. Grimeaud, 'The precautionary principle in international environmental and trade law' in Faure M. and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 103; Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 62.

in the light of new scientific information, which the state concerned must actively look for.<sup>242</sup>

The TBT Agreement of 1994 covers all potential technical barriers to trade with the exception of SPS measures, namely all requirements imposed by states on products, processes and production methods in terms of, *inter alia*, terminology, labelling or packaging. The TBT Agreement functions in a more classic way than the SPS Agreement: as a principle, technical barriers to trade are forbidden, except where a State Party fulfils the requirements for derogation provided for by Article 2 of the Agreement. Pursuant to, in particular, Article 2(2), states are allowed to adopt or maintain technical regulations as long as those measures do not create unnecessary obstacles to international trade and that they are necessary to fulfil a legitimate objective, taking into account the risks non-fulfilment of such objective would create. Protection of human, animal and plant life and health, as well as the environment, are part of the non-exhaustive list of legitimate objectives listed under this provision. As to the risks that are referred to, the provision specifies that, when assessing them, 'relevant elements of consideration are, *inter alia*, available scientific information and technical information.'

Therefore, whereas SPS measures can only be adopted, according to Article 2(2) and Article 5(3) of the SPS Agreement, if they are based upon scientific evidence and upon a risk assessment taking all available scientific information into account, TBT measures do not compulsorily have to be supported by such information, since Article 2(2) of the TBT Agreement refers to scientific and technical information only as one of the elements to be taken into account. This means that, unlike the SPS Agreement, which constrains precautionary action to the strict cumulative conditions of Article 5(7), the TBT Agreement does not object to the adoption of precautionary technical measures in the face of scientific uncertainty, as long as the state concerned pursues a legitimate objective and fulfils the other conditions established by Article 2.<sup>243</sup>

Finally, Article XX of the 1994 General Agreement on Tariffs and Trade (GATT) Agreement<sup>244</sup> provides that measures that, for instance, States Parties deem necessary to protect human, animal or plant life or health (b) or that relate to the conservation of exhaustible nature resources (g) may be adopted as long as they do not constitute a means of arbitrary or unjustifiable discrimination between countries or a disguised restriction on international trade and that they comply with the conditions established by Article I and III of the Agreement.

However, the GATT is only meant to apply when the measure concerned does not fall either within the scope of the SPS Agreement nor that of the TBT Agreement, which itself only applies when the SPS Agreement does not.<sup>245</sup>

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242 Grimeaud, D., 'The precautionary principle in international environmental and trade law' in Faure M. and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 103.

243 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 44 to 46; D. Grimeaud, 'The precautionary principle in international environmental and trade law' in Faure M. and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 113 and 114; Zankl, M., 'The Effects of CETA on the Continuous Implementation of the Precautionary Principle within the European Union', *Global Trade and Customs Journal*, v. 14, n°4 (2019), 179-198, p. 188.

244 Grimeaud, D., 'The precautionary principle in international environmental and trade law' in Faure M. and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 113.

245 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p.45 and 46.

### 4.3.2. WTO Case law

The 1997 *Beef Hormone* case, which opposed the United States and Canada to the (then) European Communities ('EC'), gives an example of how WTO Panels and Appellate Bodies ('AB') have attempted to 'reconcile or not free trade and precautionary-based national health protection measures'.<sup>246</sup> Furthermore, it exemplifies the existing divergences between states in relation to precautionary action.

Indeed, while the European Union has always been a defender of a high level of precaution, US and Canada are proponents of a risk-based approach, requiring to only take action once scientific uncertainty has been cleared up or even once harm effectively occurred.<sup>247</sup>

The matter at stake concerned an EC Council directive that prohibited the import of meat and meat products derived from cattle that had been treated with one or more of six hormones for growth promotion purposes.<sup>248</sup> Affected by this measure, the US and Canada challenged it under the SPS Agreement: they argued, in particular, that the directive was not grounded either on a risk assessment based upon available scientific information [in breach of Article 5(1) and (2) of the Agreement] nor on scientific evidence [in violation of Article 2(2) of the Agreement]. In response, the EC, which explained having adopted the ban on meat based on the precautionary principle in order to protect human and animal health and food safety, argued that precautionary action was, alongside Article 5(7), also contained in Article 5(1) and (2) of the SPS Agreement. The EC had to bring this argument forward because the ban was intended to apply permanently, and not provisionally, as required by Article 5(7), and it was therefore unable to rely on this provision.

In the end, both the Panel and the Appellate Body concluded to the non-compliance of the EC ban with the SPS Agreement. Nevertheless, their conclusions departed from each other on several accounts and, most importantly, the AB report elaborated much more on the precautionary principle than the Panel.<sup>249</sup> First, the AB recognized that the precautionary principle was a central element of the dispute brought before it.<sup>250</sup> Second, it concluded that it could not merely base its decision on the principle, since it still had not been considered as being part of customary international law.<sup>251</sup> Third, it stated that the fact that the principle, even though it was not mentioned as such in the SPS Agreement, '[found] reflection' in Article 5(7) but also in Article 3(3) and in the sixth paragraph of the preamble of the Agreement and that, consequently, 'there was no need to assume that Article 5(7) exhaust[ed] the relevance of the precautionary principle'.<sup>252</sup> Finally, the AB made clear that, in spite of those findings, the precautionary principle '[did] not override the provisions of Article 5(1) and (2)' and consequently [did] not exempt a SPS Member

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246 Grimeaud, D., 'The precautionary principle in international environmental and trade law' in Faure M., and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 104.

247 Zankl, M., 'The Effects of CETA on the Continuous Implementation of the Precautionary Principle within the European Union', *Global Trade and Customs Journal*, v. 14, n°4 (2019), 179-198, p. 179.

248 Council Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, 29 April 1996 (OJ 1996 L125/3).

249 Grimeaud, D., 'The precautionary principle in international environmental and trade law' in Faure M. and Vos E. (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 105.

250 See Scott, J., On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO In: Weiler, J. (ed.), *The EU, the WTO, and the NAFTA: towards a common law of international trade*, 2000, IX/1, 125-168, Collected courses of the Academy of European Law Collected Courses of the Academy of European Law.

251 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 47.

252 AB Report, EC-Hormone I, §194; J. Zander, 'The Precautionary Principle in International Law', Chapter 3, *The Application of the Precautionary Principle in Practice, Comparative Dimensions*, Cambridge University Press, New York, 2010, p.46 and 47.

either from establishing a risk assessment nor, pursuant to Article 2(2), from basing its SPS measures on scientific evidence.<sup>253</sup>

In sum, the *Beef Hormones* case clearly showed the divergence between the states on the interpretation of the legal status of the precautionary principle, and whether the precautionary principle has to be considered as a 'real' international principle or merely 'an approach'.

The *Asbestos* case of 2001<sup>254</sup> could have been a milestone in the WTO's approach on the precautionary principle. In this case, the AB recognised that the assessment of risks to human health is a key consideration in the resolution of a dispute. The AB clarified that the precautionary principle should be taken into account in all cases in which there is significant evidence of a possible risk to human health. However, the *Asbestos* case did not become the starting point of a new interpretative approach to the precautionary principle in the WTO jurisprudence, but has remained an isolated case.

On 29 September 2006, the World Trade Organization (WTO) released its final decision in the longstanding dispute between the United States and Europe over the regulation of genetically modified food and seed (*EC Biotech Products*).<sup>255</sup> Much of the dispute precisely concerned the legal status of the precautionary principle. Whereas the European Commission recognizes the precautionary principle as a fully-fledged and general principle of international law, the United States strongly disagreed that 'precaution' has become a rule of international law and argued that the 'precautionary principle' could not be considered a general principle or norm of international law because it did not have a single, agreed formulation. Thus, the United States considers precaution to be an 'approach' (more limited, provisional and facts-oriented) rather than a 'principle' of international law.<sup>256</sup>

The Panel reaffirmed that WTO member countries concerned about the safety of specific biotech food-related imports must follow the specific terms of the WTO SPS Agreement. As stated above, pursuant to the SPS Agreement, countries may restrict imports of certain products in order to safeguard human or animal health, or to protect the environment, provided the regulations they enact either are in accordance with existing relevant international standards, or are narrowly drafted in order to protect against a genuine ascertainable risk, as determined by the application of best available science.

Hence, in the EC Biotech products case, the AB returned to the idea that restrictive measures could only be justified if the possibility of harm is scientifically proven, thus in effect demanding concrete evidence of a potential risk.<sup>257</sup>

The EC Biotech Products decision is especially significant for its discussion of the precautionary principle's legal status within the confines of WTO law. The Appellate Body previously acknowledged that SPS Article 5.7 reflects a Precautionary Approach as opposed to the precautionary principle. The WTO Panel, in the EC Biotech Products case, found that

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253 AB Report, EC-Hormone I, §125.

254 WTO Appellate Body, DS-135, Measures Affecting Asbestos and Products Containing Asbestos, judgment of March 5th 2001, WTO Report, 2001.

255 WTO Panel DS-291, Measures Affecting the Approval and Marketing of Biotech Products, judgment of September 29th 2006, WTO Report, 2006.

256 European Communities – Measures Affecting the Approval and Marketing of Biotech Products ("EC Biotech"). Doc WT/DS291-293/INTERIM. 29 September 2006. para. 4.541. See also Sirinskiene A., 'The Status of Precautionary Principle: Moving Towards a Rule of Customary Law', *Jurisprudence* 2009, 4(118), p. 349–364, p. 354.

257 See Prévost, D., 'The role of science in mediating the conflict between free trade and health regulation at the WTO: the EU - biotech products dispute', in van Asselt, M., Everson, M., Vos, E. (eds.), *Trade, Health and the Environment*. London: Routledge, 2014 and Bocchi, M., 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' *Geneva Jean Monnet Working Paper* 2/2016, p. 16.

the EU and the EU member states were ineligible to invoke the limited and provisional safeguard measures (a Precautionary Approach) afforded by SPS Article 5.7.

Moreover, the Panel refused to embroil itself in the continuing international debate over the legal status of the precautionary principle. As the EC Biotech Products decision noted, “there has, to date, been no authoritative decision by an international court or tribunal which recognizes the precautionary principle as a principle of general or customary international law.” The Panel also noted that there was not even a single, definitive formulation of the principle.

In sum, the restrictive approaches of the ITLOS, ICJ and WTO show that the precautionary principle still faces many obstacles to being recognized as a general principle of international law. Furthermore, it appears that these tribunals do not refer to the European courts in their judgments on questions related to the precautionary principle. Bocchi therefore argues that parallel monologues have developed. Only in the ICJ’s judgments, a certain degree of influence of the European Courts’ interpretation of this principle can be noted. In fact, while the ICJ initially did not take it into account in cases where a precautionary approach might have been relevant, after the CJEU judgments established it as a general principle of EU law, the Court began to recognize the legal existence of the precautionary principle, thus showing an awareness of the European jurisprudence. On the other hand, the low number of ICJ cases in which the precautionary principle has been applied, make its relevance very weak in the Court’s reasoning.<sup>258</sup>

There are also differences between the ICJ and the WTO and ITLOS judgments. In WTO and ITLOS cases, the precautionary principle often is diametrically opposed to the general principle of trade liberalization and States’ economic interests in marine environment disputes. It is not unthinkable that the principle is invoked before these courts for protectionist interests and not for the protection of human health or the environment, as the Asbestos and MOX Plant judgments illustrated. Hence, the precautionary principle could be ‘misused’ in certain situations in order to prevent the importation of certain products.<sup>259</sup> This precisely is the dispute in the EC Biotech case.

#### **4.4. The precautionary principle in new generation regional trade agreements, as CETA**

The CETA is a bilateral trade agreement concluded between the European Union and Canada, which was signed on 30 October 2016 and which provisionally entered into force almost a year later, on 21 September 2017.<sup>260</sup> The main objective of this treaty is to reconcile regulatory divergences between the two trade blocks in order to reduce non-tariff barriers to trade of goods and services. From the outset, concerns arose regarding the fundamentally different approaches defended by the Parties to the agreement. Indeed, as already mentioned in this chapter, whereas EU’s policies in the field of environment, health and consumers’ rights are based on the precautionary principle, Canada is a proponent of reactive action, requiring to only take action once scientific uncertainty has been cleared

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258 Bocchi, M., ‘The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?’ *Geneva Jean Monnet Working Paper 2/2016*, p. 20

259 Bocchi, M., ‘The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?’ *Geneva Jean Monnet Working Paper 2/2016*, p. 20

260 On 30 April 2019, the CJEU ruled, in its Opinion 1/17, that the CETA complied with EU law and that it could therefore enter into force. The text of the treaty is available, chapter by chapter and with comments, on <http://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/>.

up or even once harm effectively occurred.<sup>261</sup> This paragraph will only briefly analyse the CETA agreement with respect to the precautionary principle.

Of particular importance in the case of CETA is regulatory cooperation; besides being inserted in several Chapters of the agreement, including the SPS and the TBT Chapters, it has a whole Chapter, the number 21, dedicated to it, which shows that regulatory cooperation is an underlining feature of the agreement. Concretely, regulatory cooperation aims to enhance the Parties to a trade agreement's promotion and exchange of practices with the view to increase convergence. Under CETA, participation in such cooperation is voluntary, as provided for by Art. 21.2.6 of the Treaty.

Within the EU, concerns arose as to whether regulatory cooperation could eventually bring convergence to the lowest common denominator between the Parties and consequently weaken European high standards of environmental and health protection, as well as threaten the precautionary principle as it is applied by the Union.<sup>262</sup>

Concluding and without prophesying on the effective materialization of this assumption, we notice that, indeed, clashes between the opposite views of Canada and the EU on precaution could arise again in the context of regulatory cooperation. Nonetheless, in our view, it might also be that exchanging views could, on the contrary, incite Canada to review its own perspectives on the matter. After all, the insertion of Art. 24.8.2 is evidence that Canada took a small step towards its trade partner, but only a small one indeed, which is logical when one recalls that, next to the EU, Canada's most important trade partner remains the US. More generally, as underlined by A. Couvreur, regulatory cooperation, in that it provides for the creation of forums where practices and points of view can be exchanged, can only have rewarding outcomes.<sup>263</sup> In the case of CETA, this is even further enhanced by the place left to stakeholders' involvement in the process: pursuant to Art. 21.8 of the treaty, 'each Party or the Parties may consult, as appropriate, with stakeholders and interested parties, including representatives from academia, think-tanks, non-governmental organisations, businesses, consumers and other organisations.'

## 4.5. Perspectives on Innovation at International Level

It appeared that the status of the precautionary principle at International level is often studied in the academic literature. Academic literature on the relationship between the precautionary principle and innovation, or an innovation principle is not available. This seems to be a European discussion. Nevertheless, the CETA for instance contains the necessary tools to, if the States Parties are willing to use them, discuss and try to reconcile diverging views on, among other things, precaution. It moreover establishes mechanisms for public participation. This way, bilateral trade treaties might succeed where the WTO Agreements, in reason of their multilateral nature, have failed. More importantly in the context of the RECIPES project, they could constitute an interesting platform to discuss, at regional level and, progressively, international one, the precaution/innovation dichotomy. After all, sustainable development, which requires states to take into account environmental as well as social and economic concerns into consideration - in our view, alongside the precautionary principle, this could also include the concept of innovation - constitutes a part and even an underlining feature of the agreement and therefore, besides establishing its own public participation mechanisms, falls within the scope of regulatory

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261 Zankl, M., 'The Effects of CETA on the Continuous Implementation of the Precautionary Principle within the European Union', *Global Trade and Customs Journal*, v. 14, n°4, 2019, 179-198, p. 179.

262 Zankl, M., 'The Effects of CETA on the Continuous Implementation of the Precautionary Principle within the European Union', *Global Trade and Customs Journal*, v. 14, n°4, 2019, 179-198, p. 190.

263 Couvreur, A., 'New Generation Regional Trade Agreements and the Precautionary Principle: Focus on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union', *15 Asper Rev. Int'l Bus. & Trade L.* 265, 2015, p. 286.

cooperation altogether. The future will tell whether and how Canada and the EU decide to make use of the agreement's tools.

# 5. The precautionary principle in European Union Law

## 5.1. Introduction

This Chapter will examine how the precautionary principle has been applied in practice at EU level since 2000 when the European Commission issued its Communication on the Precautionary Principle.<sup>264</sup> To this end, it will briefly explain the development of the precautionary principle in EU law. The Chapter will moreover study whether and in how far the guidelines that were developed by the European Commission in its Communication have been applied in the legal practice. It will do this by a review of the literature and by an empirical study looking at all legal acts that mention the term precautionary principle.

Hence, first the Chapter will examine how the precautionary principle was codified and further developed in practice (section 5.2.) Subsequently, it will discuss the implementation of the precautionary principle since 2000 by the EU institutions in legal acts (section 5.3). Here, it will examine, taking a bird's-eye perspective, whether and how the precautionary principle is explicitly applied in EU legal acts. Hereby, it does not look into acts that apply the precautionary principle without mentioning the precautionary principle.

The Chapter will subsequently scrutinise how the EU Courts deal with conflicts that involve the application of the precautionary principle and how they apply the precautionary principle in their case law (section 5.4). In addition, it will examine how the European Ombudsman, who only started to look into this matter very recently, understands the precautionary principle (section 5.5). It subsequently also will examine what effects the constitutionalisation of the precautionary principle had in France, as the only European country in which this occurred, so as to seek insights for the EU to possibly further develop the precautionary principle (section 5.6) A summary of the findings and conclusions will be presented in section 5.7.

## 5.2. Codification and development of the precautionary principle

### 5.2.1 Codification of the precautionary principle by the Maastricht Treaty

Although the precautionary principle was formally introduced in the EC Treaty in the 1990s, the EU had already long before taken precautionary action. Following developments in international environmental law,<sup>265</sup> the first formulations of a precautionary principle, albeit without mentioning the word precaution, were included in policy documents and legislation pertaining to environmental concerns in the 1970s.<sup>266</sup> The initial Wild Birds Directive, for example, adopted in 1979, aimed to protect, alongside threatened species, those that did not face imminent danger of extinction, although not referring to precaution.<sup>267</sup> The first EU's Environmental Action Programme (1973-1976) too, without mentioning precaution as such, established that the lack of available and relevant scientific knowledge 'ought not

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264 Communication from the Commission on the precautionary principle, COM/2000/1, hereafter COM(2000) 1.

265 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 78-87.

266 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 80.

267 Directive 79/409/EEC on the conservation of wild birds (OJ 1979 L 103), 2 April 1979, p.1.

[...] to have any delaying effect on the application of emergency measures in cases where there is a real or potential danger to man or his environment', adding that, by any event, those measures would 'be reviewed and modified subsequently' in the light of new research carried out.<sup>268</sup> It was only the fourth Environmental Action Plan of 1987 that explicitly referred to precaution<sup>269</sup> and prescribed the adoption of precautionary approach in several sectors, including those of gene editing and nuclear power.<sup>270</sup> Finally, in the 1990 Dublin Declaration on the Environmental Imperative, the Heads of State of the Union stated that action by the EU and by its Member States should be 'developed on a co-ordinated basis on the principles of sustainable development and preventive and precautionary action.'<sup>271</sup>

The principle was formally included in the EU legal order in the same year as the Rio Declaration and its famous Principle 15 were adopted. As indicated above, the Maastricht Treaty inserted in 1992 the precautionary principle under the environmental chapter of the EC Treaty, which entered into force on 1<sup>st</sup> November 1993. Article 130r(2) (now Article 191 (2) TFEU) stipulated that the EU's environmental policy was to be based on inter alia the precautionary principle.

It also provided that 'environmental protection requirements must be integrated into the definition and implementation of other Community policies.' This obligation to integrate environmental requirements, which includes the precautionary principle, in all other EU policies was elevated to the rank of general principle of EU law and enshrined in a separate provision, Article 6 EC (now Article 11 TFEU) by the Treaty of Amsterdam, signed in 1997 and entered into force in 1999.<sup>272</sup>

Today's Article 191(2) TFEU has not been modified and leaves the precautionary principle undefined. It states:

*'Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.'*

Equally noteworthy in relation to precaution, Article 191 (1) TFEU includes a '*prudent and rational utilization of resources*' [emphasis added] among the objectives to be pursued by the Union environmental policy.

Hence, through the Maastricht Treaty, the precautionary principle has acquired a constitutional status. As of Maastricht, the precautionary principle found its way into EU

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268 Declaration of the Council of the European Communities and of the Representatives of the Governments of the Member States, meeting in the Council on the Programme of action of the European Communities on the Environment (OJ 1973, C112/1) ('EAP I').

269 The same year as the Brundtland Report on Sustainable Development, see <https://sustainabledevelopment.un.org/content/documents/5987our-common-future.pdf>.

270 Resolution of the Council and Representatives of the Governments of the Member States, meeting within the Council on the continuation and implementation of an EC policy and action programme on the environment (1987-1992) (OJ 1987, C328/1) ('EAP IV').

271 [http://www.europarl.europa.eu/summits/dublin/default\\_en.htm](http://www.europarl.europa.eu/summits/dublin/default_en.htm)

272 Morgera, E., 'Environmental law', Chapter 22 in C. Barnard and S. Peers (eds), *European Union Law*, Second Edition, Oxford University Press, 2018, p. 663.

environmental measures,<sup>273</sup> without however a concrete understanding of its meaning.<sup>274</sup> The breakout of the so-called mad cow or BSE crisis in 1996, which put into question the EU system of regulation on food safety, was pivotal in understanding the reach and meaning of the precautionary principle beyond the field of environmental protection.<sup>275</sup>

### 5.2.2 Beyond Environmental Protection

The BSE or 'mad cow' crisis concerned the free movement of beef from cows that were affected with a neurodegenerative disease, bovine spongiform encephalopathy ('BSE') and the protection of health of EU citizens. Although BSE had already been discovered in 1985, it was not until 1996 that the United Kingdom, which had so far allowed the placing on the market and the exportation of meat from ill cows, revealed to the public scientific findings conceding that a link between BSE and the Creutzfeldt-Jakob disease, which affected humans, could not be entirely ruled out.<sup>276</sup> At EU level, the Commission imposed a ban on the importation of British beef in the rest of the EU's internal market. When the British government challenged this ban before the European Court, the Court upheld the ban argued that the precautionary principle applied also to human health protection, stating that:

*'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.'*<sup>277</sup>

Where public trust in the Union's ability to guarantee the safety of food products had dramatically decreased, the EU institutions were forced to rethink their decision-making process and to install general principles of food safety. At the same time, they prominently declared the precautionary principle to be key in the new EU food safety legislative regime, adopted in 2002.<sup>278</sup> The new EU General Food Law thus consolidates the Court's case law that the precautionary principle was not merely limited to the field of environmental protection (see further section 5.3).

### 5.2.3 The Commission's Communication on the precautionary principle of 2000

Following the BSE crisis and faced with trade conflicts on the EU's prohibition on hormone treated beef at the WTO level,<sup>279</sup> the European Commission designed various guidelines

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273 Luis Da Cruz Vilaca, J., 'The Precautionary Principle in EC Law', *European Public Law*, Vol. 10, Issue 2, 2004, pp. 369-406, p. 371; Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 88.

274 Wiener, J., 'Precautionary Principle' in Faure M., (ed.), *Elgar Encyclopedia of Environmental Law*, Vol. VI, Chapter 13, 2018, p. 176.

275 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 88.

276 Vos, E., 'EU Food Safety Regulation in the Aftermath of the BSE crisis', *Journal of Consumer Policy*, 23:227-255, Kluwer, 2000, p. 232.

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

278 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 89.

279 See on the latter conflict: Scott, J., 'On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO', in: Weiler, J. (ed.), *The EU, the WTO, and the NAFTA: towards a common law of international trade*, 2000, IX/1, pp. 125-168.

for the application of the precautionary principle in its Communication of 2000.<sup>280</sup> In this document, the Commission does however not give a definition of the precautionary principle. Instead, it intends to give guidance but not to give 'the final word, rather, the idea is to provide input to the ongoing debate both at Community and international level'.<sup>281</sup>

Although a non-binding instrument, the Communication constitutes an important codification of the views of the EU institutions at the time it was adopted. The addressees of the document are the EU institutions, the Member States and the EU trading partners. As regards the latter, it contains several references to the WTO, in particular to the SPS Agreement, and expressly stipulates that the Union's approach of precautionary action is in line with WTO rules, that allow WTO Members to seek to achieve the level of environmental and health protection they desire.<sup>282</sup>

To be sure the guidelines mostly target the EU institutions when they apply the precautionary principle. Indeed, the document does not make any mention of the principle as it is or should be applied by the Member States. The latter nevertheless have had multiple times recourse to it in order to derogate from the free movement of goods in non-harmonised areas, under Article 36 TFEU, and in harmonised areas, by invoking Article 114(4) and (5) TFEU or safeguard clauses established in that regard by specific pieces of secondary legislation.<sup>283</sup>

Accordingly, the Commission thus describes the situations in which the precautionary is 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".<sup>284</sup>*

Important hereby is that the Commission requires the presence of 'reasonable grounds' for considering 'potentially dangerous effects'. In order to invoke the precautionary principle, the Communication requires the identification of possible negative effects, the performance of a scientific evaluation and the existence of 'scientific uncertainty'. However, crucial terms, such as 'scientific uncertainty' are left undefined.<sup>285</sup>

The Communication draws an important distinction between, on the one hand, the decision to make use of the precautionary principle; i.e. the factors that trigger the application of the precautionary principle, and, on the other hand, the decision as to which kind of precautionary measures are to be adopted in each case under which conditions.<sup>286</sup> Both decisions are eminently political by nature, depending on the level of risk society is willing to accept, but must however be based on science. Furthermore, the Commission recommends adopting a structured approach of precautionary action, divided into three distinct stages: risk assessment, risk management and risk communication. According to

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280 COM(2000) 1.

281 COM(2000)1, p. 8.

282 COM(2000)1, p. 2.

283 See further below.

284 COM(2000)1, p. 2.

285 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), 145.

286 COM(2000)1, p. 12.

the Commission, it is at the level of risk management that the precautionary principle has a role to play.<sup>287</sup>

### **1. Factors triggering the precautionary principle**

Firstly, the Commission focuses on the factors able to trigger recourse to the principle. In that regard, it states that such triggering '*presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty*'.<sup>288</sup>

This sentence echoes the definition of the principle established by the Court (or seen as such by the legal doctrine) in the 1996 BSE case, which referred to the circumstances under which the principle could be triggered.<sup>289</sup> The Commission insists that, in any event, the principle cannot be invoked in order to justify the adoption of arbitrary decisions, which could happen if, in the face of a crisis, the policy-maker felt forced to adopt urgent measures to respond to increased public concerns and should be based on the strongest possible scientific evaluation.<sup>290</sup>

As such, the Communication provides three prerequisites for invoking the precautionary principle<sup>291</sup>:

- the identification of possible negative effects;
- the performance of a scientific evaluation;
- the existence of scientific uncertainty.

Importantly, while the Commission acknowledges that the uncertainty precludes the performance of a comprehensive and conclusive risk assessment, it insists that, where feasible, a scientific evaluation should anyway be performed in order to identify the extents of such uncertainty and, where possible, also identify the topics for further scientific research which could eventually put an end to the uncertainty. The inclusion of the words 'where feasible' seems to indicate that the decision whether to proceed to a risk assessment is already a political one.<sup>292</sup>

Most notably, the Communication states that risk assessment consists of four components, namely hazard identification, hazard characterisation, appraisal of exposure and risk characterisation, and that an attempt to complete those four steps should be performed before any decision to act is adopted.<sup>293</sup> The risk assessment can give the policy-maker a more concrete idea of the extent of uncertainty and by which means it might eventually be solved. In that regard, the Communication prescribes that due attention should also be given to advice given by a minority fraction of the scientific community, provided that the credibility and reputation of this fraction are recognized.<sup>294</sup>

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287 COM(2000)1, p. 12.

288 COM(2000)1, p. 3.

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

290 COM(2000)1, p. 13

291 COM(2000)1, p. 13.

292 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 95.

293 COM(2000)1, p. 13 and Annex III. As a reminder and to draw a brief comparison, Article 5(7) SPS Agreement, the clearest reflection of the precautionary principle within the WTO framework, allows for the adoption of precautionary measures only where scientific uncertainty resulting from a lack of available data precludes the performance of a risk assessment. Where drafting an assessment appears to be possible, it is not Article 5(7), but Article 2(2) and Article 5(1) and (2) of the Agreement that apply.

294 COM(2000)1, p. 16.

## **2. Kinds and conditions of precautionary measures**

Secondly, the Communication elaborates on the types of measures to be adopted once the decision to have recourse to the precautionary principle is taken. In that regard, it specifies from the outset that precautionary measures must not under all circumstances be designed to produce legal effects and to be amenable to judicial review. A broad range of measures are conceivable, such as funding research programmes, informing the public about the potential risk surrounding a certain product or substance or even, in some cases, decide not to take action at all.<sup>295</sup> Furthermore, the Commission establishes guidelines in relation to those precautionary measures, to be followed by the policy-maker, and which consist of six components<sup>296</sup>:

- proportional to the chosen level of protection;
- non-discriminatory in their application;
- consistent with similar measures taken;
- based on an examination of the potential benefits and costs of action and inaction;
- subject to review in light of new scientific data;
- capable for assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

First, the Communication provides that precautionary measures should be proportional to the chosen level of protection.<sup>297</sup> This involves not trying to reach a 'zero-risk' situation, which does not constitute a realistic goal, although, under certain circumstances, the state of uncertainty is such that drastic measures such as bans have to be imposed. Second, the measures should be non-discriminatory in their application.<sup>298</sup> Third, especially where it proves impossible to characterize the risk in reason of a lack of data, they should be consistent in scope and nature with similar measures already taken in equivalent areas where all the scientific data is available.<sup>299</sup>

Fourth, where appropriate and possible, the Communication states that a cost-benefits analysis should precede their adoption, which implies weighing both economic and non-economic concerns when considering their consequences.<sup>300</sup> In that regard, the Communication specifies that, in line with the Court's case law, the protection of health must take precedence over economic considerations. Once again, having added that the analysis should only take place 'where appropriate and possible' seems to indicate that it is the policy-maker who decides whether to proceed to it.<sup>301</sup>

Fifth, the measures should be subject to review in the light of new scientific data. This implies, on the one hand, that even though they are meant to be only provisional, they should not be revoked as long as the uncertainty cannot be resolved; and, on the other hand, that scientific research ought to be continued, and that the measures could be subsequently reviewed and potentially modified in light of those new developments.<sup>302</sup>

As final guideline for the adoption of precautionary measures, the Communication prescribes that the latter should be capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.<sup>303</sup> This is the question of to whom the burden of proving the safety of a product, substance or process

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295 COM(2000)1, p. 15.

296 COM(2000)1, p. 3.

297 COM(2000)1, p. 17.

298 COM(2000)1, p. 18.

299 COM(2000)1, p. 18.

300 COM(2000)1, p. 18 and 19.

301 COM(2000)1, p. 19.

302 COM(2000)1, p. 20.

303 COM(2000)1, p. 21.

should be assigned. In that regard, the Commission indicates that in cases where approval mechanisms prior to the putting on the market were established, the burden was placed, a priori, on the manufacturer. Prior approval schemes are frequent and uncontroversial precautionary measures in the EU Member States but also in third countries. Although they involve going through burdensome procedures, they give producers the chance to, before putting the product or substance on the market, reconsider whether to proceed to it. If the producer went through the whole process and that the product was eventually recognized as being safe and commercialized, he benefits from a situation of sensible legal certainty.<sup>304</sup> Where no prior approval system was established, the Communication prescribes that *ad hoc* precautionary measures could nevertheless be adopted with the effect of reversing the burden of proof onto the producer. According to the Commission, this should not, however, constitute a general rule.<sup>305</sup>

#### 5.2.4 Reflections on the 2000 Communication in the academic literature

Although the Communication was generally welcomed by the Council, the European Parliament, Member States and stakeholders, academic literature published in the early 2000's has been quite critical about the Communication.<sup>306</sup> The main criticisms regarding the Communication raised in the academic literature are:<sup>307</sup>

- The Communication does not provide a definition of the precautionary principle. Hence, it does not give proper guidance on how the precautionary principle can then best be used;<sup>308</sup>
- Contrary to its declared goals, the Communication does not place meaningful and effective constraints on the application of the precautionary principle. While imposing a 'balancing' activity in deciding whether to have recourse or not to the principle, the communication apparently tipped in favour of adopting preventive measures. Hence, it failed to set a risk threshold triggering its invocation<sup>309</sup>.
- It is naive to assume that decisions based on the precautionary principle can be reversed when new scientific findings become available, as this ignores the problem of technical stigma;<sup>310</sup>
- The Commission does not provide a means to assess and determine which hazards should be prioritized over others using the precautionary principle;<sup>311</sup>
- The Communication does not address the problematic issue of risk-risk trade-offs;<sup>312</sup>
- Although the Commission, in principle, favours cost-benefit analysis, it argues that it should not only consider the costs to the EU as a whole but also to a number of non-

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304 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 97.

305 COM(2000)1, p. 4.

306 Löfstedt R., 'The precautionary principle in the EU: Why a formal review is long overdue'. *Risk Management* 16(3), 2014, p. 143-145.

307 Ibid.

308 Graham, J., and Hsia, S. 'Europe's precautionary principle: promise and pitfalls', *Journal of Risk Research* 5(4), 2002; Majone, G., 'What price safety? The precautionary principle and its policy implications', *Journal of Common Market Studies* 40(1), 2002, pp. 89-109; Zander, J., *The Application of the Precautionary Principle in Practice Comparative Dimensions*, Cambridge, 2010.

309 McNelis, N., EU Communications on the precautionary principle, in *J. Int. Economic Law*, 2000, 3, p. 545-551.

310 Graham, J., and Hsia, S., 'Europe's precautionary principle: promise and pitfalls', *Journal of Risk Research* 5(4), 2002.

311 Graham, J., and Hsia, S., 'Europe's precautionary principle: promise and pitfalls', *Journal of Risk Research* 5(4), 2002.

312 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge, 2010.

economic considerations such as public acceptability, leaving the Commission plenty of vague language for interpretation.<sup>313</sup>

Importantly the literature has criticized the Commission's view that the precautionary principle pertains to *risk management* and not also to *risk assessment*". In this context we agree that the precautionary principle should be seen as a general governance principle employed throughout the overall process of framing, assessment, evaluation and management.<sup>314</sup>

Below we will examine in how far the EU Institutions have complied with the Communication in the adoption of legal acts (section 5.3.3).

## 5.3. Implementation of the precautionary principle in legal acts by the European institutions from 2000 to 2019

### 5.3.1 Facts and figures

In order to understand how the precautionary principle is used in practice by the EU institutions in legal acts, the context of its use must first be understood. Therefore, we will first look at in how many legal acts the precautionary principle is used or referred to. We will do this from a bird's-eye perspective in order to grasp whether and how the precautionary principle is used over the years. To this end, we will conduct an advanced search on the Eur-Lex portal for the term 'precautionary principle' in EU legal acts. Our analysis is twofold: we differentiate in instruments used: regulations, directives and decisions; whilst we also differentiate into the various types of legal acts: legislative acts adopted by the Council and the European Parliament according to the ordinary legislative procedure and non-legislative acts adopted by the Commission (since Lisbon delegated acts<sup>315</sup> and implementing acts<sup>316</sup>). To provide for a complete overview, the time span between January 2000 and July 2019 is covered and the data provided by Eur-Lex, such as directory codes have exported. The Eur-Lex search allows for an inductive analysis to understand when and how precautionary principle is used.

#### **Number of acts**

The search for the term 'precautionary principle' initially yielded 47 regulations, 41 directives and 47 decisions, in total 135 legal acts. As indicated in Table 1, these acts are spread over the years 2000 until 2019 relatively evenly, with a notable decrease as from 2017.

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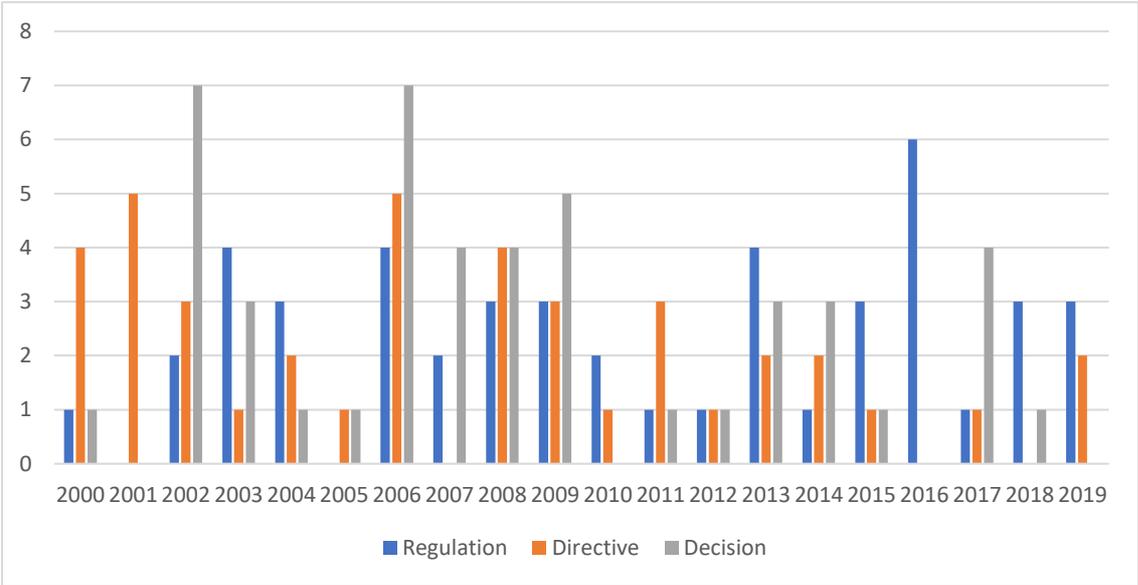
313 Majone, G., 'What price safety? The precautionary principle and its policy implications', *Journal of Common Market Studies* 40(1), 2002, p. 89–109.

<sup>314</sup> See e.g. Renn, O. and Dreyer, M. (eds.) *Food Safety Governance*. Springer 2009.

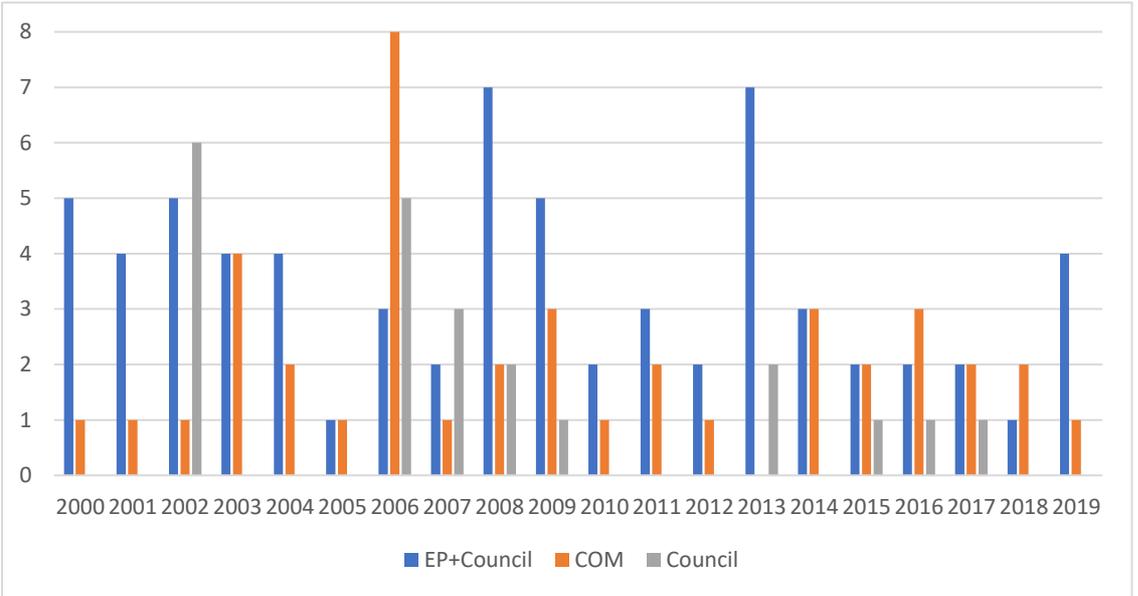
<sup>315</sup> According to the procedure laid down in the relevant legislative acts based on Article 290 TFEU.

<sup>316</sup> Adopted by the Commission in accordance with comitology, Article 291 TFEU.

**Figure 1 - Overview of legal acts containing the term 'precautionary principle' from 2000 to 2019 (according to instrument)**



**Figure 2 - Overview of legal acts containing the term 'precautionary principle' from 2000 to 2019 (according author)**



We subsequently refined our search and those acts that were no longer in force were left out. This was necessary to avoid duplications, because some of the acts found might have been recasts of previously existing acts and would otherwise be counted twice. In addition, for the present evaluation only those acts could be taken into account that have been classified by means of the directory codes used by Eur-Lex. The search for legal acts resulted in a total of 94 documents (40 regulations, 27 directives and 27 decisions) which were in force in July 2019 which then formed the basis of our further analysis.

A few observations need to be made as regards the number of acts. It is first clear that the total number of acts found, i.e. 135 acts in a period of 19 years (with 94 of these being still in force), is quite a low number in view of the fact that yearly the EU legislator adopts currently approximately 150 legislative acts and that the Commission adopts almost 2000

executive acts (both delegated and implementing) per year. Here, it is important to underline here, as stated above, that we did not look into acts that apply the precautionary principle without mentioning the precautionary principle. This would be in particular relevant for acts concerning food safety (because of the General Food Law) and the environment (in view of Article 1919 TFEU). This means that in practice there may be more situations where the precautionary principle is being applied. For example, a study on the precautionary principle in EU environmental policies carried out by Milieu, reveals that whilst some legal instruments referred to the precautionary principle in their recitals or in their main articles, other instruments referred to the precautionary principle only via indirect reference, e.g., by relying on concepts such as risk assessment or uncertainty.<sup>317</sup> This means that the total number of acts that apply the precautionary principle in practice is definitely higher. For example, out of the 15 regulations and directives in the field of environmental policy, Milieu found that five acts lacked explicit reference to the precautionary principle, but nonetheless integrated a precautionary approach in practice.<sup>318</sup> It is therefore acknowledged that the bird's-eye perspective, and hence the search for the term precautionary principle in legal acts, is an important starting point but is not able to precisely grasp the actual application of the precautionary principle in EU legal acts. It is therefore important to undertake an in-depth study in the practice to find out the actual application of the precautionary principle. We will do this by means of in-depth study of the case studies in Work Package 2.

Second, it is important to signal a trend the Milieu study points to: namely that in particular since 2000 (when the Commission adopted its Communication on the Precautionary principle) there has been an overall increase in the inclusion of the precautionary principle in EU environmental legislation.<sup>319</sup> Seen in this context, 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 than comparing it to the actual numbers of legal annually adopted.

### ***Authors of acts***

As regards the authors of the act, we can observe that with regards to potential variations of the use of the precautionary principle in legislative acts (by the legislator: the European Parliament and the Council) and non-legislative acts (by the executive: the European Commission, often the risk manager), our analysis reveals no particular patterns. Most acts remain vague on the precautionary principle, with the exception of the General Food Law and individual decisions on the basis of Article 114 TFEU.

### ***Policy fields***

Furthermore, we may observe that the precautionary principle as a general principle of EU law has gained relevance also in other policy fields.<sup>320</sup> In this respect, the Eur-Lex directory codes can give a helpful indication. This directory classifies each act by means of codes on different levels in order to indicate the subject matter it covers. Importantly, acts which cover different policy areas at the same time are categorized with more than one directory

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317 European Commission, Study on the precautionary principle in EU Environmental Policies, Final Report – Study, Milieu, November 2017, p. 22-27.

318 European Commission, Study on the precautionary principle in EU Environmental Policies, Final Report – Study, Milieu, November 2017, p. 28-29.

319 European Commission, Study on the precautionary principle in EU Environmental Policies, Final Report – Study, Milieu, November 2017, p. 78.

320 Case C-180/96 UK vs. Commission.

code. Whilst the number of codes does therefore not necessarily correspond with the number of acts, it can nonetheless provide for a good impression of subject areas covered.

**Table 2 - Policy fields containing references to the precautionary principle**

year	00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	SUM	
Competition	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Industry	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Regional Devel.	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Services	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Transport	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Area of Freedom, Security & Justice	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2
Institutional issues	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	2	1	0	0	5
Free movement of workers	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	2	0	1	0	5
Fisheries	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	2	1	0	0	6
External Relations	0	0	1	0	0	0	2	1	0	0	0	0	0	2	0	0	0	1	0	0	0	7
Consumer prot.	0	1	1	3	1	0	1	0	1	2	1	1	0	1	2	1	3	0	1	0	0	20
Agriculture	0	0	2	2	1	0	1	1	0	5	0	0	1	0	0	3	2	0	1	2	0	21
Internal market	0	1	0	4	1	0	4	0	3	3	0	0	1	1	0	1	2	0	1	1	0	23
Environment	1	3	2	2	0	0	4	2	5	1	1	2	1	4	2	2	0	2	0	1	0	35
<b>SUM</b>	<b>1</b>	<b>5</b>	<b>6</b>	<b>13</b>	<b>6</b>	<b>0</b>	<b>13</b>	<b>5</b>	<b>10</b>	<b>11</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>10</b>	<b>6</b>	<b>8</b>	<b>8</b>	<b>9</b>	<b>5</b>	<b>5</b>		

In principle, codes at first level were used for this evaluation. Yet, two modifications were made. The code for 'Environment, consumers and health protection' was broken down into its component part with the help of the second level codes in order to allow for more precision: 'environment' and 'consumer protection'.<sup>321</sup> Similarly, the code 'Industrial policy and internal market' was specified in two separate codes: 'industry' and 'internal market'.

Unsurprisingly, the code for *environmental* acts was used most often (35 times) to describe legislation containing the precautionary principle, followed by acts in the field of the *internal market* (23), *agriculture* (21) and *consumer protection* (20).

There were, however, also seven decisions for which the code *external relations* was used.<sup>322</sup> Five of these cases involved documents which were also classified under the

321 The subject 'health' did not appear on the first level of codes analysed here.

322 Regulation (EU) 2018/975 of the European Parliament and of the Council of 4 July 2018 laying down management, conservation and control measures applicable in the South Pacific Regional Fisheries Management Organisation (SPRFMO) Convention Area;  
 Directive 2008/101/EC of the European Parliament and of the Council of 19 November 2008 amending Directive 2003/87/EC so as to include aviation activities in the scheme for greenhouse gas emission allowance trading within the Community\*;  
 Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision');  
 2007/799/EC: Council Decision of 12 October 2006 on the signature, on behalf of the Community, of the Protocol on the Implementation of the Alpine Convention in the field of transport (Transport Protocol) [+ENVI]  
 2006/871/EC: Council Decision of 18 July 2005 on the conclusion on behalf of the European Community of the Agreement on the Conservation of African-Eurasian Migratory Waterbirds\*;  
 Council Decision (EU) 2017/758 of 25 April 2017 on the position to be adopted, on behalf of the European Union, at the eighth meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants, as regards the proposals for amendments to Annexes A, B and C\*;  
 2013/332/EU: Council Decision of 10 June 2013 on the conclusion on behalf of the European Union of the Protocol on the implementation of the 1991 Alpine Convention in the field of transport (Transport protocol);

environment-code and mostly refer to international environmental agreements and protocols. In recent years, there was an increased reference to the precautionary principle in the fields of fisheries and employment. In the *fisheries* sector, four regulations and one Commission decision concern the common fisheries policy<sup>323</sup> and one regulation is linked to an international agreement on fisheries.<sup>324</sup> The cases related to the free movement of *workers* concern a regulation on health and safety at work,<sup>325</sup> as well as four directives on the protection of workers from carcinogens and mutagens.<sup>326</sup>

Interestingly, the code for *general, financial and institutional matters* was used five times as well.<sup>327</sup> These generally refer to the establishment of institutional structures in policy

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2006/507/EC: Council Decision of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants\*;

2002/628/EC: Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety\*;

\*External Relations code used together with Environmental Policies code.

323 Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture;

Regulation (EU) 2017/1004 of the European Parliament and of the Council of 17 May 2017 on the establishment of a Union framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the common fisheries policy and repealing Council Regulation (EC) No 199/2008;

Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC;

Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104;

Commission Decision (EU) 2017/2112 of 6 March 2017 on the measure/aid scheme/State aid SA.38454 — 2015/C (ex 2015/N) which Hungary is planning to implement for supporting the development of two new nuclear reactors at Paks II nuclear power station (notified under document C(2017) 1486).

324 Regulation (EU) 2018/975 of the European Parliament and of the Council of 4 July 2018 laying down management, conservation and control measures applicable in the South Pacific Regional Fisheries Management Organisation (SPRFMO) Convention Area.

325 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

326 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC);

Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work;

Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work;

Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

327 Commission Implementing Regulation (EU) 2015/207 of 20 January 2015 laying down detailed rules implementing Regulation (EU) No 1303/2013 of the European Parliament and of the Council as regards the models for the progress report, submission of the information on a major project, the joint action plan, the implementation reports for the Investment for growth and jobs goal, the management declaration, the audit strategy, the audit opinion and the annual control report and the methodology for carrying out the cost-benefit analysis and pursuant to Regulation (EU) No 1299/2013 of the European Parliament and of the Council as regards the model for the implementation reports for the European territorial cooperation goal;

areas where the precautionary is of substantive relevance, such as the creation of a special EP committee on the EU's authorisation procedure for pesticides, or a regulation establishing guidelines for reporting and cost-benefit analyses.

Two cases in which the precautionary principle appeared in relation to the *area of freedom security and justice* again concern environmental and health concerns.<sup>328</sup> Reference to the precautionary principle is only made briefly in the introduction. Moreover, there are isolated instances of use of the precautionary principle in the fields of *transport*<sup>329</sup>, *services*<sup>330</sup>, *regional policy*<sup>331</sup>, *industrial policy*<sup>332</sup> and *competition*.<sup>333</sup>

On the basis of these data it can be observed that, although the precautionary principle is used in a broad range of topics, it is still mainly in the traditional sectors, such as environmental, consumer and health protection that the precautionary principle is resorted to. This coincides with the Commission's Communication.<sup>334</sup> Academic research moreover shows that for the invocation of the precautionary principle it matters which *Directorate General (DG)* is responsible for addressing the risk issue in question. For example, DG Environment has been found to be more willing to propose precautionary policies than DG Industry.<sup>335</sup>

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Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II);

European Parliament decision of 6 February 2018 on setting up a special committee on the Union's authorisation procedure for pesticides, its responsibilities, numerical strength and term of office (2018/2534(RSO));

Decision of the Authority for European political parties and European political foundations of 20 July 2017 to register European Green Party;

Commission Decision of 19 January 2012 on setting up of the European Union Offshore Oil and Gas Authorities Group.

328 Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II);

Council Decision 2008/206/JHA of 3 March 2008 on defining 1-benzylpiperazine (BZP) as a new psychoactive substance which is to be made subject to control measures and criminal provisions.

329 Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships.

330 Directive 2014/51/EU of the European Parliament and of the Council of 16 April 2014 amending Directives 2003/71/EC and 2009/138/EC and Regulations (EC) No 1060/2009, (EU) No 1094/2010 and (EU) No 1095/2010 in respect of the powers of the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority).

331 Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006.

332 2003/653/EC: Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty (Text with EEA relevance) (notified under document number C(2003) 3117).

333 2014/274/EU: Commission Decision of 20 March 2013 on State Aid No SA.23420 (11/C, ex NN40/10) implemented by Belgium for SA Ducroire/Delcredere NV (notified under document C(2013) 1497).

334 COM (2000) 1, p. 8.

335 Tosun J., and Pesendorfer, D., 'EU environmental policy under pressure: chemicals policy change between antagonistic goals?', *Environmental Politics* 15(1), 2006, p. 101.

### 5.3.2 Implementation of the precautionary principle in legal acts

Furthermore, it is important to understand for which purpose the precautionary principle is used. Of all 94 acts in which the precautionary principle was mentioned, a majority of 63% referred to the precautionary principle only in the recitals of the acts. In these cases, it is mostly used with reference to the objective of the act in question or simply in the context of Article 192 TFEU.<sup>336</sup>

In 8% of cases, the precautionary principle appears in the Annexes of legal acts. There, it does not only vaguely refer to the objective of the act, but it instructs decision-makers to take the precautionary principle as a basis and thus has more a functional purpose.<sup>337</sup> The principle is mentioned in a very broad range of topics; for example in the assessment of veterinarians,<sup>338</sup> as basis for the requirement to eliminate copolymers,<sup>339</sup> as requirement in the information form for major projects<sup>340</sup> and in the requirements for the Ecolabel for textile products and paint.<sup>341</sup>

Finally, in only in 29% of acts (in 27 acts) the precautionary principle is mentioned in the provisions of the acts. The arguments for mentioning the principle, however, vary. While some of the references detected in the provisions include *i)* a definition, *ii)* others name the principle as object of the act or *iii)* mention the precautionary principle as guiding principle for those implementing the act (*iii*). Finally, in some individual Commission decisions the principle is used *iv)* as an argument by either the Commission or Member States.

We will have a closer look at these arguments mentioned in the provisions.

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336 Whilst the European Court sometimes refers to the recitals when analysing the purpose of a certain act, the recitals do not have the same legal value as the Articles.

337 The only exception is the Decision of the Authority for European political parties and European political foundations of 20 July 2017 to register European Green Party, in which the Manifesto of the European Greens is annexed. The latter makes reference to the precautionary principle.

338 Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve mollusks in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council.

339 Commission Delegated Regulation (EU) 2015/1576 of 6 July 2015 amending Regulation (EC) No 606/2009 as regards certain oenological practices and Regulation (EC) No 436/2009 as regards the registering of those practices in the wine sector registers.

Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions.

340 Commission Implementing Regulation (EU) 2015/207 of 20 January 2015 laying down detailed rules implementing Regulation (EU) No 1303/2013 of the European Parliament and of the Council as regards the models for the progress report, submission of the information on a major project, the joint action plan, the implementation reports for the Investment for growth and jobs goal, the management declaration, the audit strategy, the audit opinion and the annual control report and the methodology for carrying out the cost-benefit analysis and pursuant to Regulation (EU) No 1299/2013 of the European Parliament and of the Council as regards the model for the implementation reports for the European territorial cooperation goal.

341 2014/350/EU: Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (notified under document C(2014) 3677)

2014/312/EU: Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes (notified under document C(2014) 3429).

### **(i) Definition**

Only six of these legal acts contain definitions of the precautionary principle. The first notable attempt to define the precautionary principle was made in the General Food Law in 2002. Article 7 of this Regulation emphasises the use of the precautionary principle in response to scientific uncertainty and as part of the 'risk management'. It also clearly establishes the provisional nature of precautionary measures by stating that they are adopted 'pending further scientific information for a more comprehensive risk assessment' (Art. 7(1)) and subject to review 'within a reasonable period of time' (Art. 7(2)). The trigger for the use of the principle, specified here as 'possibly harmful effects on health', must necessarily remain imprecise. This definition corresponds to the definition and criteria established in the Commission's 2000 Communication.

#### **Box 1: Definition of precautionary principle laid down in the General Food Law**

*1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.*

*2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.*

Article 7, General Food Law (Regulation 178/2002)

As this is one of the rare instances, in which a clear definition of the precautionary principle is spelled out, it is not surprising that references to the General Food Law are also contained in other legal acts. This is the case in two other food-related Regulations as well as the Regulation on plant protection products.<sup>342</sup> This definition sees to the moderate to strong precaution interpretation, as defined in Chapter 2.3.

Besides this, the precautionary principle is identified only in one other act of general application revealed by our search: a Council Decision on the Protocol on the Implementation of the Alpine Convention in the field of transport (Transport Protocol). Article 2 of this document defines the precautionary principle. Compared to the definition laid down in the General Food Law, the threshold to trigger the precautionary principle seems lightly higher in the Transport Protocol, which makes reference to 'serious irreversible effects on the health and the environment', albeit indicating that this also means 'potential harmfulness'. The General Food Law, by contrast, departs from 'potential harmful effects on health'.

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<sup>342</sup> Reg.2015/2283, Art. 12+18, Reg 1107/2009, Art. 13 (plant protection products), Reg 609/2013, Art. 5 (food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control).

## Box 2: Definition of the precautionary principle in the Transport Protocol

*The precautionary principle is the principle whereby measures intended to avoid, control or reduce serious or irreversible effects on health and the environment should not be postponed by arguing that scientific research has not yet strictly proven the existence of a cause-and-effect relationship between the substances concerned and their potential harmfulness to health and the environment.*

*Article 2, Council Decision 2007/799/EC.*

The definition provided in the Transport Protocol bears similarities with the 'triple negative definition'<sup>343</sup> laid down in Principle 15 of the Rio Declaration (see Chapter 2.3). This seems evident as the Transport Protocol implements international law.

With regards to the requirement of scientific uncertainty, both legal acts show similarities. The Transport Protocol refers to situations where 'research has not yet strictly proven the existence of a cause and effect relationship' between substances and potential harm whereas the General Food Law mentions that 'scientific uncertainty persists'. The measures to be taken in such situations are those 'intended to avoid, control or reduce effects' of the harm (Transport Protocol) or 'risk management measures' necessary to ensure health protection (General Food Law).

The formulation of the action to be taken differs slightly. Whilst Transport Protocol links with the triple negative formulation of the Rio Declaration in stating that measures 'should not be postponed' by reference to uncertainty, the General Food Law holds that measures 'may be adopted'.

Moreover, the General Food Law clearly states that the measures are of a 'provisional' nature and 'pending further scientific information', no such indication is given in the Transport Protocol definition. This is one of the requirements foreseen in the 2000 Communication (see Chapter 5.2.3)

Definitions of the precautionary principle are also provided in some individual decisions taken by the Commission where Member States indicate their willingness to derogate from EU harmonising acts pursuant to paragraphs 4 and 5 of Article 114 TFEU. In these cases, it is usually the Commission that emphasises specific parts of the precautionary principle to justify its decision. In three decisions found in our analysis, the Commission is notably concerned with the threshold of scientific information about potential harm, which is necessary to trigger the principle. By reference to its 2000 Communication, it holds that the precautionary principle 'presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty'.<sup>344</sup> Member States have an interest to lower this threshold, which would allow them more leeway in deviating from the policies on Union-level. The Netherlands, for example, argued that 'it cannot be expected to wait until a serious problem occurs.'<sup>345</sup>

In conclusion it can be said that there is no uniform, one-size-fits-all, definition of the precautionary principle in the EU legal acts. For example, EU food safety legislation has

<sup>343</sup> As this is called in the literature, see e.g. Bergkamp, L., *European Community law for the new economy*, Intersentia, 2003, p. 163.

<sup>344</sup> 2003/653/EC: Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty.

<sup>345</sup> 2003/549/EC: Commission Decision of 17 July 2003 extending the period referred to in Article 95(6) of the EC Treaty in relation to the national provisions on the use of short-chain chlorinated paraffins notified by the Netherlands under Article 95(4).

expressly defined the precautionary principle for application in that area. According to Milieu, there is no such definition for EU secondary environmental legislation, although the TFEU directly refers to the precautionary principle as a basis for EU environmental policy.<sup>346</sup> This has left the precautionary principle open to interpretation within the individual environmental policy area. This is advantageous as it allows for flexibility and the possibility to adapt to individual needs of environmental problems. Commentators have generally viewed the lack of general definition of the precautionary principle at EU level positively as the principle's application differs across the range of policies and must be context-specific. Quite evidently, this has led to different approaches and interpretations. This is why both the literature and the Commission instead of giving a firm definition prefer to speak of the 'constituent parts'<sup>347</sup> of the precautionary principle. In Chapter 8 of this report we will elaborate on the conceptual core of the precautionary principle.

Whilst it is not necessary nor possible to strive for a general legal definition of the precautionary principle in EU law, it is important 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, are similar and predictable.<sup>348</sup>

### **(ii) The precautionary principle as objective of an act**

In ten legal acts, the precautionary principle serves to define the *objective of the act in question*. Some acts state, for instance, that they are 'underpinned by the precautionary principle'.<sup>349</sup> Others set out the objectives of the act 'in accordance with' or 'taking into account' the precautionary principle.<sup>350</sup> Again others simply state that the precautionary principle 'shall apply' as for example stipulated in Regulation 609/2013 on food for infants and young children (Art. 5).<sup>351</sup>

Remarkable, all of the legal acts identified have in common that they remain vague and do not specify the precautionary principle. It remains unclear why the precautionary principle is invoked and which consequences this should have.

### **(iii) The precautionary principle as guiding principle**

Furthermore, the precautionary principle serves as *guiding principle for actions by authorities at Union or Member State level* in 12 cases. Where these actors are asked to take action on the basis of the legal act, they should take into account the precautionary principle as guidance for their actions. This is applied to Member States,<sup>352</sup> the Commission,<sup>353</sup> the Union,<sup>354</sup> or Overseas Countries and Territories.<sup>355</sup> Where these actors

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346 European Commission, Study on the precautionary principle in EU Environmental Policies, Final Report – Study, Milieu, November 2017, p. 93-94

347 COM(2000)1, p. 12.

348 European Commission, Study on the precautionary principle in EU Environmental Policies, Final Report – Study, Milieu, November 2017, p. 93-94.

349 See for example: Regulation 528/2012 (Article 1), Regulation 1107/2009 (Article 1(4)), Regulation 1907/2006 (Article 1(3)).

350 See Regulation 1946/2003 Article 1, Regulation 2019/1021 (Art. 1), Directive 2001/18 (Art. 1).

351 Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

352 COM Dec. 2017/848, Art. 4, Dir 2001/18, Art. 4, Dir. 2001/95, Art. 8, Dir. 2009/48, Art. 39.

353 Reg 2015/2283, Art. 12+18, Dir 2011/65, Art. 6.

354 Council Dec. 2013/755.

355 Council Dec. 2013/755, Art. 58.

implement the legal acts or adopt authorisation decisions for products, they are expected to take their decisions in accordance with the precautionary principle. It is, however, only in few cases that the acts provide for additional guidance as to how the precautionary principle is to be applied.

One exception is the General Product Safety Directive (Directive 2001/95). This Directive specifies that the precautionary principle can be used under certain conditions (Article 8(2)). These conditions are further specified in paragraph 1 of the same article. Member States are expected to take measures 'in particular' where products 'could be dangerous' (Art. 8(1)(d)), are 'dangerous' (Art. 8(1)(e)) or where 'dangerous products [are] already on the market' (Art. 8(1)(f)). In the first case, a temporary ban is foreseen; the second scenario allows for a ban on marketing, and in the latter case, an organised withdrawal from the market and a recall from consumers and possibly destruction of the product are the available options.

### Box 3: General Product Safety Directive

1. *For the purposes of this Directive, and in particular of Article 6 thereof, the competent authorities of the Member States shall be entitled to take, inter alia, the measures in (a) and in (b) to (f) below, where appropriate:*
  - (a) *for any product:*
    - (i) *to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;*
    - (ii) *to require all necessary information from the parties concerned;*
    - (iii) *to take samples of products and subject them to safety checks;*
  - (b) *for any product that could pose risks in certain conditions:*
    - (i) *to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present;*
    - (ii) *to make its marketing subject to prior conditions so as to make it safe;*
  - (c) *for any product that could pose risks for certain persons:*  
*to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;*
  - (d) *for any product that could be dangerous:*  
*for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;*
  - (e) *for any dangerous product:*  
*to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;*
  - (f) *for any dangerous product already on the market:*
    - (i) *to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;*
    - (ii) *to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions.*
2. *When the competent authorities of the Member States take measures such as those provided for in paragraph 1, in particular those referred to in (d) to (f), they shall act in accordance with the Treaty, and in particular Articles 28 and 30 thereof, in such a way as to implement the measures in a manner proportional to the seriousness of the risk, and taking due account of the precautionary principle.*

Article 8, Directive 2001/95.

The guidance provided in the Directive for the use of the precautionary principle partly corresponds to the criteria imposed by the Commission on the use of the precautionary principle as set out in the 2000 Communication. The severity of harm is indicated in the different levels, such as 'could pose risks to certain persons', 'could be dangerous', 'dangerous'. The concept 'dangerous product' is further defined in Article 2 of the same directive. Moreover, proportionality is explicitly mentioned in that Article and non-

discrimination can be established by reference to what is today Article 34 and 36 of the TFEU. The nature of the precautionary measures is also set out in the Directive. However, no indication is made with regards the provisional nature of the reaction. Only the ban in case of products that 'could be dangerous' is explicitly temporary. In paragraphs (e) and (f) the measures seem to be permanent. Furthermore, no requirement for scientific evidence is imposed.

Interestingly, Directive 2009/128 on the use of pesticides presents the precautionary principle as a possibility for Member States to deviate from harmonisation, albeit to a limited extent.<sup>356</sup> Article 2(3) states that 'The provisions of this Directive shall not prevent Member States from applying the precautionary principle in restricting or prohibiting the use of pesticides in specific circumstances or areas.' This formulation indicates that such deviations cannot be of a general nature but only limited to individual, very specific cases. Yet, no mention is made of scientific evidence or the temporary nature of such measures. The legislator apparently relies on the national authorities' knowledge and rightful application of the precautionary principle.

#### **(iv) The precautionary principle invoked in derogation decisions**

Finally, the precautionary principle is invoked as argument in individual Commission decisions by either the Commission or a Member State in situations where Member States wish to derogate from an EU harmonisation measure. Various of these decisions contain precautionary language by the Commission in response to the derogation requests from the Member states. Whilst the Commission does, in some cases, not analyse the precautionary principle in detail, even when it is relied upon by Member States,<sup>357</sup> there are a few cases in which it engages in substantive argumentation.

Austria invoked the precautionary principle when notifying measures to the effect of banning the use of GMOs in Upper Austria pursuant to Article 114(5) TFEU.<sup>358</sup> The problem in this case was that Austria produced scientific evidence which, in the view of the Commission and the EFSA, was not new and that nothing in the report relied on by Austria would 'justify taking action on the basis of the precautionary principle at Community or national level' (paragraph 73). Austria was therefore unsuccessful in invoking the precautionary principle.

A similar problem occurred with regards to France which tried to rely on the precautionary principle in order to limit the import and sale of certain NK fertilisers pursuant to Article 114(5) TFEU. The French authorities unsuccessfully tried to rely on the precautionary principle in order to limit the import and sale of certain NK fertilisers pursuant to Article 114(5). France argued that the production of these fertilisers occurred in ways which had not been foreseen when the Directive was adopted, was not accepted. The Commission, however, rejected France's request as the Member State was unable to present any *new scientific* evidence, as required under Article 114(5) TFEU. This confirms the finding by

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356 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

357 See, for example: 2008/62/EC: Commission Decision of 12 October 2007 relating to Articles 111 and 172 of the Polish Draft Act on Genetically Modified Organisms, notified by the Republic of Poland pursuant to Article 95(5) of the EC Treaty as derogations from the provisions of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms.

358 2003/653/EC: Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty.

scholars that 'recourse to the precautionary principle does not appear to mitigate the stringent criteria of Article 114(5).'<sup>359</sup>

In all these cases, especially concerning the derogation under Article 114(5) TFEU, we may observe a rather weak precaution. This is also confirmed by scholarly research.<sup>360</sup>

### 5.3.3 Strength of the implementation of the precautionary principle

As stated above, the precautionary principle is not applied very consistently in EU legal acts. Our analysis of legal acts reveals that the invocation of the precautionary principle is diverse and seems to leave gaps with regards to a precise definition and application of the principle. Scholarly analyses confirm these findings. Garnett and Parsons reviewed a small sample of directives and regulations and came to the conclusion that the precautionary principle in EU law was applied differently with very little consistency across cases regarding the conditions for taking precautionary action and the basis for imposing regulation.<sup>361</sup> Their review of a limited numbers of legal acts (4 regulations, 4 directives and 3 decisions of the EU legislators and the Commission) reveals so that the strength of the application of the precautionary principle varies from weak to moderate and strong precaution (see section 2.3).

### 5.3.4 Impact of the 2000 Communication

The above shows that the guidelines laid down in the Commission's Communication are not followed consistently in the legal practice. These findings could cast doubt on the impact of the 2000 Communication. Löfstedt, for example, argues that the Communication has been little used in practice, referring to the example of the endocrine disrupters case and asks for a review of the Communication.<sup>362</sup> These results moreover largely correspond with the results of a study on the use of the precautionary principle in EU Environmental policies performed by Milieu for the European Commission in November 2017. It, for example, shows that certain aspects such as methodologies for assessing risk and the question as to when precautionary action needs to be taken vary across the different environmental sectors. This can be explained by the different content-specific approaches taken.<sup>363</sup> As indicated above, this makes a coherent application of procedures of fundamental importance.

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359 Vos E., and Weimer, M., 'Differentiated Integration or Uniform Regime? National Derogations from EU Internal Market Measures', in B. de Witte, A. Ott and E. Vos (eds.), *Between Flexibility and Disintegration, The Trajectory of Differentiation in EU law*, Edward Elgar, 2017, p. 317.

360 Garnett, K. and Parsons, D. J., 'Multi-Case Review Of The Application Of The Precautionary Principle In European Union Law And Case Law.' *Risk Analysis: an official publication of the Society for Risk Analysis*, 2017, p. 37.

361 Garnett, K and Parsons, D. J., 'Multi-Case Review Of The Application Of The Precautionary Principle In European Union Law And Case Law.' *Risk Analysis: an official publication of the Society for Risk Analysis*, 2017, p. 37.

362 Löfstedt R., 'The precautionary principle in the EU: Why a formal review is long overdue'. *Risk Management* 16(3), 2014, p. 149.

363 European Commission, Study on the precautionary principle in EU Environmental Policies, Final Report – Study, Milieu, November 2017, DOI 10.2779/58953 KH-07-17.198-EN-N.

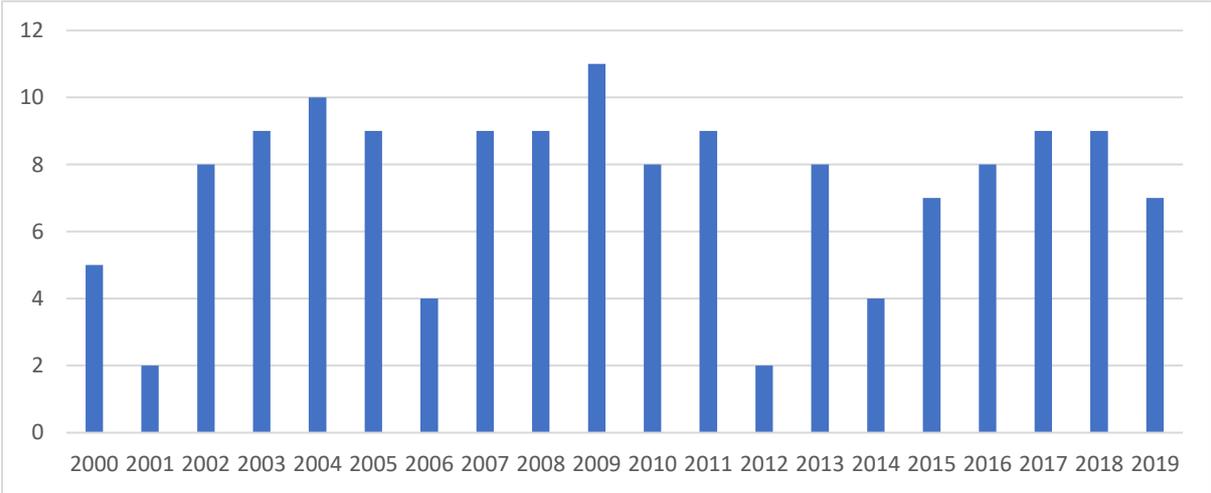
# 5.4. Application of the precautionary principle by the European Courts in Court rulings from 2000 to 2019

As the 2000 Communication did not provide a definition of the precautionary principle, the Court of Justice of the European Union’s case law has been crucial in determining when, how and by whom the precautionary principle may be relied upon in the EU legal order.<sup>364</sup> Yet, as will be set forth below, the Courts visibly struggle with this role and certain inconsistencies have arisen.

## 5.4.1 Facts and figures

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.<sup>365</sup>

**Figure 3 - Judgments containing the expression ‘precautionary principle’ between 2000 and 2019**

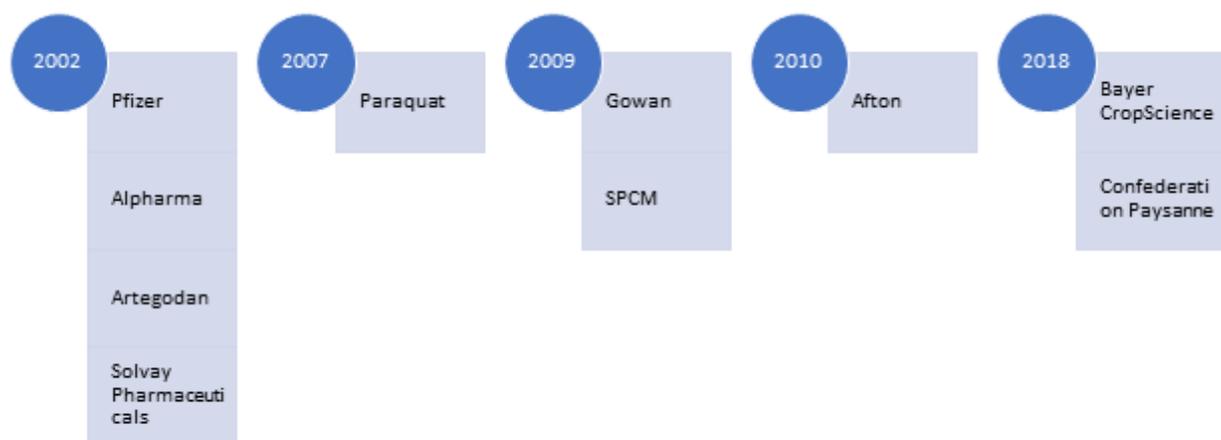


In a few cases, the Courts have made important contributions to the understanding of the precautionary principle. We see them as milestone cases, and we will use these cases to show tendencies in the EU Courts’ application and interpretation of the precautionary principle. Below, the milestone cases are represented. We will come back to these cases separately when discussing the compliance with the 2000 Communication (see section 5.4.6 of this Chapter).

364 Alemanno, A., ‘The shaping of the precautionary principle by European courts: from scientific uncertainty to legal certainty’, *Bocconi Legal Studies Research Paper*, 2007.

365 As in the case of legislation, several descriptors were sometimes used for one document. The number of descriptors does therefore not correspond to the total number of judgments.

**Figure 4 - Milestone cases in the EU Courts' application of the precautionary principle**



#### 5.4.2 Definitions of the precautionary principle

The Courts have given various definitions of the precautionary principle. These definitions of the precautionary principle have been formalized over time. Generally, we can observe that the Courts use three different formulations of the precautionary principle, one of which is further differentiated depending on whether it is the Commission or a Member State that make use of the precautionary principle.

Above, we already reported on the Court's definition of the precautionary principle to be applied by the EU institutions in the BSE case, that 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, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent'.<sup>366</sup>*

A similar formulation is used for the Member States:

*'It is clear that such an assessment of the risk could reveal that scientific uncertainty persists as regards the existence or extent of real risks to human health. In such circumstances, it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated'.<sup>367</sup>*

<sup>366</sup> Case C-180/96, para 99. See later cases C-343/09, para 62; C-77/09, para 73; T-429/13, para 110; T-13/99, para 139; T-70/99, para 152; T-141/00, para 185; C-269/13, para 57; T-108/17, para 281; T-584/13, para 59; T-257/07, para 68; C-78/16, para 47; T-392/02, para 122; T-817/14, para 51; T-31/07, para 135; C-151/17, para 38; C-157/14, para 81; T-334/07, para 116; C-477/14, para 47; C-236/01, para 111.

<sup>367</sup> See cases C-41/02, para 52; C-282/15, para 60; C-446/08, para 67; C-333/08, para 91.

In other cases, the Court stated that:

*'The precautionary principle allows the adoption of provisional risk management measures necessary to ensure a high level of health protection when, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists [pending further scientific information]'*.<sup>368</sup>

And

*'Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persist should the risk materialise, the precautionary principle justifies the adoption of restrictive measures'*.<sup>369</sup>

These definitions have in common that they point to scientific uncertainty as the main factor that triggers the use of the precautionary principle, allowing for restrictive measures. Moreover, case law that was issued after the 2000 Communication makes mention of the provisional character of the risk management measures whilst also pointing out that precautionary action may only be taken following an initial assessment of the available information. Our analysis reveals that no explicit evidence of risks is necessary in order for the regulator to rely on the precautionary principle.

#### 5.4.3 Limited review of the precautionary principle in Court rulings

We reviewed moreover the cases in which the precautionary principle was invoked, in order to define commonalities with respect to the Courts' review of these cases.

It appears that with regards to the success of the arguments, it is notable that the regulator is usually the successful party in cases in which the precautionary principle is invoked. In 28 cases, the regulator's (i.e. the Commission or Member States) decisions were confirmed by the Court. Only in three cases, measures were declared incompatible with the precautionary principle.<sup>370</sup>

In Case C-282/15 referred by the *Verwaltungsgericht Braunschweig*, the Member State had breached the precautionary principle by adopting a regulatory measure whose scope was broader than the underlying risk assessment without allowing for derogations.<sup>371</sup> The Court of Justice referred the precautionary principle and emphasised that Member States are generally entitled to rely on this principle in order to take protective measures. However, it emphasised that:

*'the risk analysis and the resulting application of the precautionary principle appear to concern only certain amino acids, which would be insufficient to justify a prior authorisation scheme, such as that laid*

<sup>368</sup> See cases T-257/07, para 67; C-282/15, para 54; C-111/16, para 44; C-192/01, para 49.

<sup>369</sup> See cases C-343/09, para 61; C-77/09, para 76; T-429/13, para 119; C-192/01, para 52; C-95/01, para 48; C-41/02, para 54; C-333/08, para 93; C-446/08, para 70; T-31/07, para 142; C-269/13P, para 58; C-157/14, para 82; T-817/14, para 51; C-477/14, para 47; C-78/16, para 47; C-78/16, para 47; C-282/15, para 57; T-584/13, para 68; C-151/17, para 38; C-489/17, para 58; T-108/17, para 282.

<sup>370</sup> In the remaining two cases, the precautionary principle was invoked and discussed by the applicants but not defined or applied by the court.

<sup>371</sup> CJEU, C-282/15 *Queissner Pharma v Bundesrepublik Deutschland* [2017], ECLI:EU:C:2017:26.

*down in the LFGB, which applies without distinction to all amino acids'* (para 65).

In Case C-111/16 referred by the *Tribunale di Udine*, it was the reference by the national court that pointed to the precautionary principle.<sup>372</sup> The case arose in a situation in which the national authorities tried to rely on the precautionary principle thereby deviating from the special system for emergency measures provided by Regulation 1829/2003, whose conditions were not fulfilled. The Court held that the Regulation at issue:

*'does not give Member States the option of adopting, in accordance with Article 54 of Regulation No 178/2002, interim emergency measures solely on the basis of [the precautionary] principle, without the conditions set out in Article 34 of Directive No 1829/2003 being satisfied'* (para 54).

The national measure was therefore not deemed to be in compliance with EU law.

Finally, among the cases analysed there was one rare instance in which the individual applicant invoked the precautionary principle and succeeded. In Case T-584/13, BASF argued that a Commission decision should be annulled because the Commission had not completed an impact assessment.<sup>373</sup> By reference to the 2000 Communication, the Court emphasises that the precautionary principle requires to conduct an impact assessment. The failure to provide an impact assessment was therefore deemed to be a breach of the precautionary principle.<sup>374</sup>

It is interesting to note that all of these cases related to procedural issues. Where the substance of the decision to invoke the precautionary principle is challenged the Court frequently emphasises the broad discretion given to the regulator which the Court only reviews in cases of 'manifest errors of assessment'. This has been subject to critique by scholars of the precautionary principle. Alemanno and Zander argue that the Commission and the Member States gained a significant amount of leverage under the argument of protecting human health. Indeed, the willingness of the Courts to accept the Commission's risk measures and their refusal to demand proper risk assessments confirms Alemanno's view that 'the Court [the CJEU in Gowan] seems ready to surrender its function of gatekeeper of precautionary action,<sup>375</sup> thereby relinquishing more power to the Commission.

In this light, it is perhaps surprising that applicants nonetheless invoke the precautionary principle frequently to support their arguments. The precautionary principle is invoked by a variety of parties in cases. Where applicants claim that the precautionary principle should not have been used because the level of uncertainty raised by scientific evidence was insufficient, the applicants' argumentation is usually to no avail. In the Case T-31/07, the applicant, Du Pont, relied on an understanding of the scientific information available which differed from the Commission's assessment. The Court attempted to review the scientific information and ultimately supported the Commission's assessment. In various cases, it repeatedly emphasised the regulator's discretion and held that it would only engage in judicial review of these decisions in cases of manifestly inappropriate assessments.<sup>376</sup> The

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372 CJEU, C-111/16, Criminal proceedings against Giorgio Fidenato and Others [2017], ECLI:EU:C:2017:676.

373 CJEU, T-584/13 BASF Agro BV and Others v European Commission [2018], ECLI:EU:T:2018:279.

374 Case T-584/13, para 171.

375 Alemanno, A., 'The shaping of the precautionary principle by European courts: from scientific uncertainty to legal certainty', *Bocconi Legal Studies Research Paper*, 2007.

376 See for example Cases C-78/16, T-817/14.

Commission emphasised that this should also hold for its decision not to use the precautionary principle.<sup>377</sup>

Applicants therefore try to establish arguments to prove that the regulator has exceeded its margins of discretion. One possible argument is to claim that the risk relied on by the regulator was purely hypothetical. The Court has repeatedly held that mere hypothetical risks and the so-called 'zero-risk approach' could not be a basis to invoke the precautionary principle.<sup>378</sup> It is, however, difficult for applicants to prove that this was indeed the regulator's aim. Even in a case where the Council pursued a 'policy of zero tolerance with regards to the potential risks to human health' the Court interpreted this as different from 'zero risk'.<sup>379</sup> Moreover, the Court has held that it is for the regulator to balance economic interest on the one and precaution on the other hand.<sup>380</sup> Importantly though, the Court has consistently held requirements related to the protection of public health, safety and the environment have precedence over economic interest.<sup>381</sup>

Thus, where applicants invoke a substantive breach of the precautionary principle, this is mostly rejected by the Court. The analysis of the cases selected shows that review is limited to a small number of potential factors.

#### 5.4.4 Factors that play a role in judicial review of the Precautionary Principle

These factors can be broadly divided into three categories: *i*) reasons for triggering the use of the principle, *ii*) the considerations that the regulator has to take into account in the decision-making phase, and *iii*) requirements that the legal acts based on the principle have to comply with. These factors are summarised in Figure 1.

First, the Courts have to decide whether the invocation of the precautionary principle was justified. In this step, the Court attempts to define the precautionary principle and examines the elements that justify the use of the precautionary principle. In this stage, the Court only reviews whether the conditions for applying the precautionary principle are fulfilled, i.e. the sufficiency of scientific uncertainty and ensures that the regulator does not base its decision on purely hypothetical risks.

Second, the decision-making itself requires a complicated assessment of scientific data on the one hand and societal preferences on the other, both of which are difficult to review for a court. Hence review of the Court in this phase is therefore limited to manifest errors.

Third, the measures resulting from the decision-making are mainly reviewed by the court to make sure that they are proportional and do not aim for a 'zero-risk approach'.

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377 See case T-304/01 in which applicants claimed that the Commission should have adopted stronger control mechanisms. The Commission claimed that the PP does not oblige institutions to follow all scientific information without its own assessment. In this case under article 340 TFEU, the court analysed the existence of a causal link between the alleged breach of EU law and the damage incurred by the applicant first and, failing to establish this, dismissed the case without assessing the PP in detail.

378 See for example Cases C-269/13P and T-392/02.

379 Case T-392/02, para 150.

380 Case T-108/17, para 284.

381 See below.

**Figure 5 - Factors taken into account in judicial review of acts involving the precautionary principle**



Like the definitions, these requirements have become embedded in standard formulations in the Court’s jurisdiction over time. The definitions of the precautionary principle and target points for review are laid down in paragraphs which have increasingly been repeated by the Court over the past years.

These formulations may be considered as a kind of standard formulations that the Courts use to either provide a definition of the precautionary principle or cover one of the three phases identified above. We will elaborate on each of these three phases below.

**(i) Review of preconditions triggering the application of the precautionary principle**

In the milestone case *Pfizer*, the Court of First Instance (now General Court) for the first time discussed the interpretation and the correct application of the precautionary principle and defined the *conditions for triggering* the application of the precautionary principle.<sup>382</sup>

According to the Court:

*‘in case of scientific uncertainty as to the existence of a risk to human health, the EC institutions as well as the Member States may invoke the precautionary principle in order to adopt protective measures, in spite of the fact that a proper risk assessment showing conclusive scientific evidence cannot be conducted’.*<sup>383</sup>

More specifically, the *factors for triggering* the precautionary principle are further described with regards to two different elements. First, the requirement that the risk on which the action is based may not be hypothetical is emphasised. As has been demonstrated before, this is one of the elements the Court is indeed willing to review.

The Court moreover applies the definition of the precautionary principle to very specific authorisation procedures and emphasises above all the need for *‘solid evidence’*. Thus, the Court requires sufficient evidence in order to conclude that there is insufficient scientific information about the prevalence of certain risks. This is what Van Asselt and Vos have

382 Janssen, A. and Van Asselt, M., ‘The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law’, in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, UK: Routledge, 2013, p. 199.

383 Case T-13/99, *Pfizer Animal Health SA v. Council*, ‘Pfizer’, 2002.

referred to as the 'uncertainty paradox'.<sup>384</sup> Whilst an insufficient amount of evidence can, in principle, be a reason for the Court to review decisions, this had an effect in the decisions analysed only where procedural mistakes were made. The precise level of uncertainty needed is difficult to assess and therefore, in practice, only subject to a very limited review.

In procedural terms, it is important for the regulator to conduct a risk assessment in order to provide the required level of 'solid evidence'. In practice, however, this requirement is not always fulfilled. In several cases (*Alpharma, Solvay*) no risk assessment was performed, and the Court did not reprimand the Commission or the Council, for not performing a risk assessment. Instead, the Court 'acted as a super risk assessor', while it ought to determine whether the risk manager conducted a risk assessment and if this had been done according to the procedural requirements. In its place, the Court *constructed uncertainty as the absence of full safety*.<sup>385</sup>

Academic literature emphasizes that other cases show the same lack of a proper risk assessment.<sup>386</sup> In *Afton*, the Commission did not conduct a risk assessment to determine the negative impact of MMT on pollution abatement techniques.<sup>387</sup> In *Bayer CropScience*, the Court accepted expert consultations as sufficient as a risk assessment.<sup>388</sup> Furthermore, Alemanno and Zander argue that in the *Paraquat* and *Gowan* court cases the European court has supported (and for Paraquat the Court even found that the Commission *must* act in a precautionary manner) the use of the precautionary principle to ban substances without proper scientific evidence.<sup>389</sup>

In various cases the Court however states that

*'In the domain of [human health], the existence of solid evidence which, while not resolving scientific uncertainty may reasonably raise doubts as to the safety of a substance justifies, in principle, [the refusal to include that substance...] The precautionary principle is designed to prevent potential risks'*.<sup>390</sup>

The Court has therefore repeatedly held that:

*'The risk assessment cannot be based on purely hypothetical considerations'*.<sup>391</sup>

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384 van Asselt, M., and Vos, E., 'The precautionary principle and the uncertainty paradox', *Journal of Risk Research*, 9(4), pp. 313-336.

385 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E., (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, 2013, p. 213.

386 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), p. 150.

387 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), p. 150.

388 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), p. 150. See also Alemanno, A., 'The Science, Law and Policy of Neonicotinoids and Bees: A New Test Case for the Precautionary Principle'. *European Journal of Risk Regulation*, 2013.

389 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge, 2010, 130. See also Alemanno, A. (2011). Annotation of European Court of Justice case C-79/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute (Precautionary Principle)*, *Common Market Law Review*, 48, pp. 1329-1348.

390 Established in T-141/00, para 192. See further cases C-236/01, para 113; T-392/02, para 129; T-326/07, para 166; T-334/07, para 180; T-71/10, para 75, T-429/13, para 116.

391 See cases C-192/01, para 49; C-41/02, para 52; C-269/13P, para 58; T-584/13, para 65.

Van Asselt and Vos argue that in *Pfizer*, the Court equated scientific uncertainty with diverging opinions and thereby it constructed its own definition of uncertainty.<sup>392</sup> They pointed out to the risk that in this manner the precautionary principle might be applied whenever one qualified scientist holds a diverging opinion.<sup>393</sup>

Janssen and Van Asselt<sup>394</sup> examined post-Pfizer case law to determine whether the problematic ruling of the Court in *Pfizer* had set a precedent. They identified several tensions and inconsistencies in the Court's rulings of *Pfizer*, *Alpharma*, *Artegoda*n and *Solvay Pharmaceutical*, all rulings of 2002, both respect to the prerequisites for invoking to precautionary principle as for the measures eventually taken. Janssen and Rosenstock furthermore criticize the Court's lack of vision on how to deal with uncertainty and precaution.<sup>395</sup> Janssen and Van Asselt hold that, in *Pfizer*, the General Court has used scientific disagreement as a way to construct uncertainty about the risk in question. The Court referred to diverging opinions between the experts, which was subsequently used to legitimise the application of the precautionary principle.<sup>396</sup>

Moreover, in *Alpharma*, uncertainty was not only constructed through a lack of scientific consensus, the Court also argued in terms of analogy with other antibiotics. In this case, there were no risk assessments performed on the specific substance of bacitracin zinc. The Court, however, ruled that 'all antibiotics and all nitrofurans have similar characteristics and should be treated in the same way'.<sup>397</sup> As Janssen and Van Asselt argued, this argumentation entails that substance-specific characteristics are no longer needed in the risk assessment and commonalities suffice.<sup>398</sup> Analogy was also applied in the *Solvay* case on Nifursol and later in the *Gowan* case and the *Bayer CropScience* case. Janssen and Rosenstock argue that with this approach of establishing uncertainty, the precautionary principle could easily become a tool to prohibit marketing of products.<sup>399</sup>

## **(ii) Review of Decision-making**

Second, the *decision-making* itself requires a complicated assessment of scientific data on the one hand and societal preferences on the other, both of which are difficult to review for a court. Review in this phase is therefore limited to manifest errors.

Another set of formulations covers this decision-making phase under the precautionary principle. Interestingly, the Court states in various cases that the precautionary principle

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392 van Asselt, M., and Vos, E., 'The Precautionary Principle And The Uncertainty Paradox', *Journal of Risk Research*, 9, 2006.

393 van Asselt, M., and Vos, E., 'The Precautionary Principle And The Uncertainty Paradox', *Journal of Risk Research*, 9, 2006.

394 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, UK: Routledge, 2013, p. 199.

395 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), 2016.

396 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, 2013, p. 199.

397 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, UK: Routledge, 2013, p. 207.

398 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, 2013, p. 207.

399 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), 2016, p. 146.

can 'require' the institutions to take action. This is in sharp contrast to other cases in which the Court held that the precautionary principle 'may warrant the adoption of a restrictive measures by an institution' but 'does not require it to do so'.<sup>400</sup> The Commission has also stated that, in its view, the precautionary principle 'does not... oblige the Community institutions to follow all scientific opinion without any margin for assessment'.<sup>401</sup>

In other cases, the Court's formulations are variants of the same starting point: both state that the regulator must follow certain steps when applying the precautionary principle. The regulator must identify the risk and then conduct an assessment relying on relevant data. The Court views that, thirdly, risk management measures can be taken on this basis:

*'Within the process leading to the adoption by an institution of appropriate measures to prevent specific, potential risks to public health, safety and the environment by reason of the precautionary principle, three successive stages can be identified: firstly, identification of the potentially adverse effects arising from a phenomenon, secondly, assessment of the risks to public health, safety and the environment which are related to that phenomenon; thirdly, when the potential risks identified exceed the threshold of what is acceptable for society, risk management by the adoption of appropriate protective measures'.<sup>402</sup>*

This is also confirmed by the Court where it states that:

*'The correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the substances or foods concerned, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research'.<sup>403</sup>*

These step-by-step conditions give another, much clearer possibility of review to the Court. Whilst the substantive decisions are difficult to review, these seemingly clear procedural issues can be assessed in a comprehensive way and have, as seen in the *BASF* case, led the Court to annul a Commission decision.<sup>404</sup>

Importantly the Court views that measures to protect human health and safety and the environment take precedent over economic interests.

*'The precautionary principle is a general principle of EU law requiring the authorities in question, in the particular context of the exercise*

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400 Case T-108/17 *ClientEarth v European Commission* [2019], ECLI:EU:T:2019:215, para 284.

401 Case T-304/01 *Julia Abad Pérez and Others v Council of the European Union and Commission of the European Communities* [2006], ECLI:EU:T:2006:389, para 80.

402 See cases T-429/13, para 111; T-257/07, para 69; T-31/07, para 136; T-584/13, para 60.

403 See cases C-343/09, para 60; C-77/09, para 75; C-192/01, para 51; C-41/02, para 53; C-333/08, para 92; C-446/08, para 69; C-282/15, para 56; C-489/17, para 57; T-108/17, para 281.

404 Case T-584/13 *BASF Agro BV and Others v European Commission* [2018], ECLI:EU:T:2018:279.

of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment by giving precedence to the requirements related to the protection of those interests over economic interest'.<sup>405</sup>

### (iii) Review of the Outcome

Finally, with regards to the *outcome*, the Court also imposes clear conditions: non-discrimination, proportionality and objectivity are central in the judicial review of decisions.

'Such measures must not be allowed unless they are non-discriminatory [, proportional] and objective'.<sup>406</sup>

Moreover, the Court repeatedly emphasised that the regulator should not aim for a 'zero-risk approach'. Studies have confirmed that *proportionality* is subject to a more thorough review than other criteria, such as the need for new scientific data.<sup>407</sup> Rogers highlights that this should not be surprising considering that proportionality is a topic that has been long discussed in European circles, while the fact that precautionary actions should be subject to review has to date never been tested in the courts.<sup>408</sup> The proportionality principle is well-established in EU law and the Courts have considerable practice in applying it,<sup>409</sup> so much that in *Pfizer* the fourth criterion (action should be subject to costs and benefits of the proposed action) was effectively subsumed by the Court under the proportionality test.<sup>410</sup>

Moreover, whilst the Court emphasizes that a *zero-risk policy* is not acceptable, it has been repeatedly criticized for its own stance on this issue. Another requirement with regards to the outcome which is clearly mentioned in the Communication but significantly less subject to judicial review, is the requirement to *review the measure* in light of new scientific data. It appears that in various cases the Court has ignored the temporary nature of precautionary measures. However, such re-evaluations are necessary to prevent precautionary measures to become permanent. Instead of demanding a substantive review of the latest scientific findings, the Court found in *Solvay* that an administrative review is sufficient when deciding on precautionary measures. Consequently, 'by not insisting on a new risk assessment of the substances, the Court disregards the temporary character of the precautionary principle'.<sup>411</sup>

The ruling of the Court in the *Artogodan* case however, was different from the ruling in *Solvay*. The Court explicitly argued that old data which has been used in previous

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405 Established in T-141/00, para 184. See further cases T-429/13, para 109; T-141/00, para 184; T-392/02, para 121; T-584/13, para 58; T-817/14, para 51; T-257/07, para 66; T-433/13, para 102; T-31/07, para 134.

406 See cases C-77/09, para 76; T-429/13, para 117; C-192/01, para 53; T-392/02, para 125; C-333/08, para 93; C-446/08, para 67; T-71/10, para 76; T-817/14, para 51; C-477/14, para 48; C-78/16, para 48; C-282/15, para 57; T-584/13, para 68; C-489/17, para 58; T-108/17, para 282.

407 Rogers M., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, p. 467-484.

408 Rogers M., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, p. 478.

409 See e.g. Tridimas, T., *The General Principles of EU Law* (2006).

410 Rogers M., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, p. 480.

411 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, 2013, p. 213.

assessments may not constitute a sufficient basis upon which to establish scientific uncertainty in the present.<sup>412</sup>

#### 5.4.5 Inconsistencies in the case law

Academic literature reveals that there are several inconsistencies in the Courts' rulings in dealing with uncertain risks, which has led to several problematic patterns which are effectively using the precautionary principle as a tool of risk management. The academic literature displays a number of reoccurring issues.

First, with respect to the prerequisites to invoke the precautionary principle, the Courts define in some cases uncertainty as contrasting scientific opinions, or the lack of consensus between experts.<sup>413</sup> This is delicate as this could open up for protectionism, as in many uncertain risk cases a divergent opinion can be found. Therefore, requirements as to the production of such scientific opinions that form the basis of regulatory measures, which experts participate, etc. become here of key importance.

Second, in various cases, the Courts are not consistent in requiring proper scientific evidence to support measures based on the precautionary principle. Literature has criticized the Court for that.<sup>414</sup> Moreover, authors have pointed out that analogy between substances and consultations with experts was deemed to be enough by the Courts in cases where no risk assessments had been performed by independent bodies or risk assessments were ignored.<sup>415</sup>

Moreover, it has been argued that the application of proportionality is often insufficiently strict.<sup>416</sup> It has been moreover asserted that the Courts also disregarded the temporary nature of risk measures by failing to insist on new risk assessments or ignoring new information, while each case must be reviewed based on the latest scientific evidence available. Rogers so holds that EU Courts could make a provisional or interim order pending further research, but so far, they have not done so.<sup>417</sup>

#### 5.4.6 Application of the 2000 Communication by the Court

Surely, as the 2000 Communication is a non-binding guidance document, the Courts are not bound to apply the criteria proposed by the Commission. We note however that, notwithstanding that, the Courts do pay attention to the 2000 Communication.

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412 Janssen, A. and Van Asselt, M., 'The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law', in van Asselt, M., Versluis, E., Vos, E. (eds.), *Balancing between Trade and Risk, Integrating Legal and Social Science Perspectives*, London, 2013, p. 212-213.

413 Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*; van Asselt, M., and Vos, E., 'The Precautionary Principle And The Uncertainty Paradox', *Journal of Risk Research*, 9, 2006.

414 See Löfstedt R., 'The precautionary principle in the EU: Why a formal review is long overdue', *Risk Management*, 2014; 16(3), p. 147. See also Zander, J., *The Application of the Precautionary Principle in Practice*, Cambridge University Press, New York, 2010 and Alemanno, A., Annotation of European Court of Justice case C-79/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute (Precautionary Principle)*. *Common Market Law Review*, 48, 2011, pp. 1329-1348.

415 Janssen, A., Rosenstock, N., 'Handling Uncertain Risks: an Inconsistent Application of standard? The Precautionary Principle in Court Revisited', *European Journal of Risk Regulation*, 7 (1), 2016, p. 150.

416 Alemanno, A., Annotation of European Court of Justice case C-79/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute (Precautionary Principle)*. *Common Market Law Review*, 48, 2011, pp. 1329-1348.

417 Rogers M., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, p. 481.

For 8 judgments we examined whether the criteria of the Communication were followed. The results are represented in Table 1 in Annex 1.

From the analysis of these 8 judgments, it can be inferred that the Court does not follow the 2000 Communication consistently. It appears that in particular the criteria to perform a proper risk assessment or a proper cost-benefit analysis are not consequently checked.

Furthermore, whereas the sample is too small to provide a definite conclusion, it seems that in most cases the Court agrees with a ban or upholds the restrictions. It seems that the Court generally adopts a moderate to strong interpretation of the precautionary principle.

## 5.5. The application of the precautionary principle by the European Ombudsman

A new actor in the field of the precautionary principle is the European Ombudsman. The European Ombudsman was first introduced in the EU's institutional system by the Maastricht Treaty in order to deal with complaints by citizens or natural or legal persons about cases of maladministration in the activities of EU institutions, bodies, office and agencies.<sup>418</sup> A relatively new phenomenon are complaints about infringement of the precautionary principle that arrive at the Ombudsman's office. Of particular interest are a few decisions of the Ombudsman where she explicitly addressed the precautionary principle. In 2013, the Pesticides Action Network Europe filed a complaint with the Ombudsman alleging that the practices of the Commission for approval of pesticides were unsafe and/or not in accordance with the relevant legislation. The Ombudsman held here that:

*[...], the precautionary principle which, according to Regulation 1107/2009, must be applied, is also to be regarded as a principle of good administration. It requires the Commission to ensure that it does not approve active substances in cases where public health or the environment could be endangered.*<sup>419</sup>

This phrasing was repeated in a more recent decision of the Ombudsman concerning chemical testing under the REACH regulation.<sup>420</sup> Of interest here is that the Ombudsman also refers in a footnote to the precautionary principle as 'a form of preventative decision-making, which essentially implies that a decision should not be taken where there is a potential risk'.<sup>421</sup>

To consider the precautionary principle as a principle of good administration may very well link with the view that the precautionary principle needs to be flexible and that one should

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418 According to Articles 20(2), 24 and 228 (1) TFEU. See N. Vogiatzis, *The European Ombudsman and Good Administration in the European Union*, Palgrave, 2018.

419 Para 10 of Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides), <https://www.ombudsman.europa.eu/en/decision/en/64069>.

420 Decision in case 23/2018/SRS on how the European Commission updates EU rules on chemical testing when alternative test methods are identified; <https://www.ombudsman.europa.eu/en/decision/en/109429>.

421 Harremoës, P. et al., *Late lessons from early warnings: the precautionary principle 1896-2000*, European Environment Agency, Copenhagen, 2001

more look into having similar and predictable procedures for the application of the precautionary principle.

## 5.6. Constitutionalisation of the precautionary principle in France: what can be learned?

In one European country the precautionary principle has been constitutionalized too: viz. France. It is therefore important to analyse what the EU can learn from the constitutionalisation of the precautionary principle in France. This section will therefore examine this question. To this end, it will foremost review the literature on the effects of the '*constitutionnalisation*' of the precautionary principle in French law. Before doing so, we would like to briefly clarify how the precautionary principle was inserted in this Charter and what the legal value of this Charter is.

### 5.6.1. The inclusion of the precautionary principle in the French '*Constitutional block*' ('*Bloc de constitutionnalité*')

The precautionary principle first appeared in French law with the Barnier Act of 1995, which incorporated Article L 110-1 into the Environmental Code.<sup>422</sup> It was due to the former president Jacques Chirac who personally committed himself to the protection of environment, that the Constitutional Charter of the Environment was adopted in 2005. This Charter included the precautionary principle in its Article 5.<sup>423</sup> Whilst the precautionary principle is thus not inserted in the French constitution as such, it does belong to the so called '*constitutional block*', ('*Bloc de constitutionnalité*') and thus has constitutional value. This constitutional block consists of the 1958 Constitution, the 1789 Declaration of the Rights of Man and of the Citizen, the preamble to the 1947 Constitution, and the Constitutional Charter of the Environment. To this block are also added the '*fundamental principles recognized by the laws of the Republic*'.<sup>424</sup>

### 5.6.2. Article 5 of the Constitutional Charter

Article 5 of the Charter reads:

*Where the occurrence of damage, although uncertain in the light of scientific knowledge, could seriously and irreversibly affect the environment, public authorities shall ensure, by application of the precautionary principle and within their areas of responsibility, that risk assessment procedures are carried out and that provisional and proportionate measures are adopted to prevent the occurrence of damage*<sup>425</sup>

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422 Loi no 95-101 du 2 février 1995 relative au renforcement de la protection de l'environnement (Loi Barnier).

Retrieved <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000551804&fastPos=3&fastReqId=158787804&categorieLien=id&oldAction=rechTexte> from,

423 Loi constitutionnelle n° 2005-205 du 1er mars 2005 relative à la Charte de l'environnement

424 In French : Les principes fondamentaux reconnus par les lois de la République.

425 Translation by Clara Ferron, of the French text: Lorsque la réalisation d'un dommage, bien qu'incertaine en l'état des connaissances scientifiques, pourrait affecter de manière grave et irréversible l'environnement, les autorités publiques veillent, par application du principe de précaution et dans leurs domaines d'attributions, à la mise en oeuvre de procédures d'évaluation des

It requires a combination of three criteria: the existence of a risk to the environment, the uncertainty of scientific knowledge about whether that risk exists, and the likelihood that the risk will result in serious and irreversible damage to the environment. Once these three criteria are cumulated, the precautionary obligation is to be borne by 'public authorities'. Yet, the Article 5 remains an obligation of means, not of goal, as the duty bearers have to 'implement risk assessment procedures' and 'adopt provisional and proportionate measures to prevent the occurrence of the damage'.

One can observe that the 'letter' of Article 5 presents both an improvement and a step backwards compared to its predecessor, Article L 110-1, the former being the disappearance of 'economically acceptable costs', the latter being the restraint of the obligation of precaution to the 'public authorities'.<sup>426</sup> Yet authors have argued that Article 5 of the Charter is not exempt from economic considerations.<sup>427</sup>

### 5.6.3. Effects of the constitutionalisation in French law

The elevation of the precautionary principle to the Constitutional Charter led many authors to expect a greater use of the precautionary principle.<sup>428</sup> Yet, we may observe that some years after the introduction of the principle into the Constitutional Charter, the majority of the authors views that the constitutionalisation did not have a real impact on the use and application of the precautionary principle in French law. Doctrinal debates on the implementation of the precautionary principle remain rather limited.

Only very few authors actually think that it brought a change in that the precautionary principle is now also used for town planning and private property.<sup>429</sup> Most authors however view that nothing has really changed. They are rather disappointed as they had expected Article 5 of the Charter to create, so to speak, miracles in French law. Some even speak of 'a constitutional (and jurisdictional) illusion'.<sup>430</sup> They had hoped that it would address legal insecurity concerning the unclear delimitation of the duty bearer of the precautionary obligation, and prevent the misuse of the principle by various groups.<sup>431</sup> They however feel that there has not been an increase in the application of the precautionary principle. One author even condemns the judicial inaction to better apply the precautionary measures, particularly in the implementation of emergency procedures.<sup>432</sup>

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risques et à l'adoption de mesures provisoires et proportionnées afin de parer à la réalisation du dommage'.

426 Kast, R. (2007). Calcul économique et mise en pratique du principe de précaution. *Économie publique*, 21(2), p. 632.

427 Deguergue, M. (2006). Les avancées du principe de précaution en droit administratif français *Revue internationale de droit comparé*, 48( 2), pp. 621-641.

428 Prieur, M. (2014). Promesses et réalisations de la Charte de l'environnement. *Nouveau Cahiers du Conseil Constitutionnel N° 43*. Deguergue, M. (2006). *Les avancées du principe de précaution en droit administratif français* *Revue internationale de droit comparé*, 48(2), pp. 621-641.

429 Laquière, A. (2012). L'introduction du principe de précaution dans la Constitution: sens ou non-sens? *Revue de Métaphysique et de Morale*, No 4/2012, pp. 549-562, p. 560. Prieur, M. (2014). *Promesses et réalisations de la Charte de l'environnement. Nouveau Cahiers du Conseil Constitutionnel N° 43*.

430 Capitani, A. (2005). La Charte de l'environnement, un leurre constitutionnel ? *Revue française de Droit constitutionnel*, 2005/3 (n° 63), pp. 493 - 516.

431 See Godard, O. (2009). *Le principe de précaution : bilan de son application quatre ans après sa constitutionnalisation* Paper presented at the Audition publique organisée par Claude Biraux et Jean-Claude Etienne, Sénat. *Les Petites Affiches*, no 16, pp. 43 - 51, at p. 44.

432 Capitani, A. (2005).

And, in the cases in which it was applied by French courts, it was not applied correctly.<sup>433</sup> This was in particular the case in disputes over telephone relay antennas.<sup>434</sup> Some authors thus view that the improper use of the precautionary principle deteriorates the effectiveness of its application.<sup>435</sup>

Some authors believe however that Article 5 of the Charter could be better applied in French Law. They give suggestions to solve what they call the currently 'floating' nature of the precautionary principle, which lacks of a defined legal framework and suffers from a great deal of legal insecurity.<sup>436</sup> Some authors, for example, calls for the creation of a specialised scientific body to draw orientation for the implementation of the risk assessment and 'provisional and proportionate' measures to be adopted, to call for an 'active knowledge-based approach to remove scientific uncertainties', and improve the monitoring of 'the duration of the actions undertaken under the aegis of the principle'.<sup>437</sup> Others suggest to rethink the interpretations made of Article 5 today.<sup>438</sup>

#### 5.6.4. Lessons?

From the above it becomes clear that the constitutionalisation of the precautionary principle in France has not changed a lot in its application in French law. The French doctrine is critical of the effects of the constitutionalisation of the precautionary principle in French law, noting in particular its incorrect application.<sup>439</sup> The precautionary principle, by the constitutionalisation placed at the top of the French hierarchy of norms, prevails now over European law that is included in the so-called sub-constitutional and supra-legislative block, the conventionality block ('*bloc de conventionnalité*'). In this respect, it is interesting to note that a French parliamentary report assessing the application of Article 5 of the Charter has pointed out that the gaps in the interpretation of the precautionary principle in French law could be filled by the French courts insofar as they could apply the precautionary principle in the light of EU law, especially the guidelines adopted by the

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433 See Godard, O. (2009). *Le principe de précaution : bilan de son application quatre ans après sa constitutionnalisation Paper presented at the Audition publique organisée par Claude Biroux et Jean-Claude Etienne, Sénat. Les Petites Affiches*, no 16, pp. 43 – 51. Boutonnet, M. (2014). L'influence du principe de précaution sur la responsabilité civile en droit français : un bilan en demi-teinte. *McGill International Journal of Sustainable Development Law and Policy*, 10(10), pp. 105-136. Other authors mentioned in this context scientific institutions recognised at national and/or European level, such as the IPCC. See AUVERLOT, Dominique; Hamelin, Joel PUJOL, Jean-Luc Commissariat Général à la Stratégie et à la Prospective. (C.G.S.P.). Paris, France, *Le principe de précaution : quelques réflexions sur sa mise en oeuvre*. 2013, 22 p., ref : dissem, Illustration.

434 See CA Versailles, 4 février 2009, n° 08/08755, and TGI Nanterre le 18 septembre 2008.

435 Godard, O. (2010). *Quid de la gestion des risques après la constitutionnalisation du principe de précaution ? Annales des Mines - Responsabilité et environnement*. doi: 10.3917/re.057.0038, Godard, O. (2009). *Le principe de précaution : bilan de son application quatre ans après sa constitutionnalisation Paper presented at the Audition publique organisée par Claude Biroux et Jean-Claude Etienne, Sénat. Les Petites Affiches*, no 16, pp. 43 – 51, Boutonnet, M. (2014). L'influence du principe de précaution sur la responsabilité civile en droit français : un bilan en demi-teinte. *McGill International Journal of Sustainable Development Law and Policy*, 10(10), pp. 105-136.

436 Ibid. Godard, O. (2009).

437 Ibid. Godard, O. (2009) See : 'Il faudrait par exemple instituer une instance à saisir, définir les conditions d'une saisine, organiser la mise en oeuvre de ces deux directions désignées dans le texte constitutionnel, d'une part l'évaluation des risques, d'autre part la prise de mesures provisoires et proportionnées, donc révisables, appelant une démarche active de connaissance pour lever les incertitudes scientifiques et de suivi dans la durée des actions engagées sous l'égide du principe'.

438 Ibid. Boutonnet, M. (2014). See. p 133: '(...)il est possible de réfléchir la manière dont les conditions qui s'en dégagent aujourd'hui peuvent être interprétées demain en faveur d'une subsistance du principe de précaution'.

439 Inter alia, Ibid. Capitani, A. (2005). Ibid. Godard, O. (2009). Ibid. Boutonnet, M. (2014). Ibid. Deguerge, M. (2006).

European Commission.<sup>440</sup> As such the constitutionalisation of the precautionary principle in France does therefore not really reveal important lessons to be learned for the EU. On the contrary, some authors even argue that it would help to follow and apply the guidelines by the European Commission. What could be of interest is the suggestion of authors to set up a specialised scientific body to draw orientation for the implementation of the risk assessment and provisional and proportionate measures to be adopted and to improve the monitoring of temporary character of precautionary measures.

## 5.7. Conclusions

Although the EU had already since long taken precautionary action, it was only the Maastricht Treaty that formally introduced the precautionary principle in the EC Treaty in 1992. As the Treaty did not give a definition of the precautionary principle, the definition and meaning of the precautionary principle have been further taken shape in EU legal acts, soft law documents and case law of the EU courts. This Chapter therefore examined how the precautionary principle has developed in EU law, how it is defined and what criteria are operated to trigger the precautionary principle. It also examined in how far we can draw lessons for the EU from the constitutionalisation of the precautionary principle in France, being the only European country where the precautionary principle has constitutional value.

To this end, we examined EU legislative and non-legislative acts from 2000 to 2019. Our empirical analysis has revealed that precautionary principle is used in a variety of policy areas, albeit still with a focus on environmental, consumer protection and internal market policies. Express references to the precautionary principle in legal acts are relatively modest: a total of 135 acts in a period of 19 years, of which today 94 acts still in force. This is quite a low number in view of the fact that annually the EU legislator adopts currently approximately 150 legislative acts and that the Commission adopts almost 2000 executive acts (both delegated and implementing) per year.

Hereby, it is important to bear one caveat in mind: this study took a bird's eye perspective and did not look into acts that apply the precautionary principle without mentioning the precautionary principle. This would be in particular relevant for acts concerning food safety (because of the General Food Law, Regulation 178/2002) and the environment (in view of Article 191 TFEU). This means that in practice there may be more situations where the precautionary principle is being applied. It is therefore acknowledged that the overall, bird's-eye perspective taken in this study, viz. the search for the term precautionary principle in legal acts, is an important starting point but is not able to precisely grasp the actual number of cases in which the precautionary principle is applied in EU law, nor does it tell us how precisely the precautionary principle is applied. This study looked therefore also into the judicial practice of the EU Courts to see how the precautionary principle has been relied upon in practice and how the EU Courts have dealt with conflicts in this respect and applied the precautionary principle. Moreover, the RECIPES project will carry out nine case studies in Work Package 2, in which precisely the application of the precautionary principle will be investigated in detail. In addition, 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 to be more elevated when seeing this in the context before the Communication was adopted in 2000.

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440 Rapport d'information (n° 2719), Comité d'évaluation et de contrôle des politiques publiques, *sur l'évaluation de la mise en œuvre de l'article 5 de la Charte de l'environnement relatif à l'application du principe de précaution* (Rapport Gest and Tourelie), issued on the 17 of Novembre 2010.

Retrieved from, [http://www.assemblee-nationale.fr/13/rap-info/i3970.asp#P616\\_205925](http://www.assemblee-nationale.fr/13/rap-info/i3970.asp#P616_205925)

Our study discloses that there is no single definition of the precautionary principle in the EU legal acts. The principle is used in different areas, sometimes even as guiding principle for Member States or the Commission. In such cases, it is often poorly explained. This corresponds to the views expressed in the academic literature. Moreover, there are few acts which attempt to provide a definition of the precautionary principle. An exception to this is the EU's food safety legislation that has expressly defined the precautionary principle for application in that sector. EU secondary 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 prefer to speak of the 'constituent parts'<sup>441</sup> of the precautionary principle, instead of giving a firm definition. Hereby 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.

An important soft law document is therefore the Commission's Communication on the precautionary principle of 2000 that gives guidance on the application of the precautionary principle but fails to define it. In this document, the Commission distinguishes between the decision to make use of the precautionary principle; i.e. the factors that trigger the application of the precautionary principle, and the decision as to which kind of precautionary measures are to be adopted in each case under which conditions.<sup>442</sup> It furthermore highlights that precautionary measures should be proportional, non-discriminatory, consistent, based on an examination of the potential benefits and costs of action and inaction, subject to review in light of new scientific data and capable for assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment. Our empirical analysis discloses that these guidelines are not followed consistently in the legal practice.

Our study of the application of the precautionary principle before and by the EU Courts shows that the Courts have taken up the challenge of defining the precautionary principle. Over time, they even have codified definitions and requirements for application of the principle into standard formulations which it uses repeatedly. At the same time, our analysis reveals that 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 examination of the EU Courts' case law moreover reveals that the precautionary principle is dealt with in quite some detail in many cases decided by the CJEU. Importantly, the Court has consistently held that health and environmental concerns take precedence over economic concerns; something that is repeated by the European Commission in its 2000 Communication. Our analysis confirms on a broader scale what the literature suggested for individual cases.<sup>443</sup> The Court's review of the application of the precautionary principle is strongly limited to a small number of potential factors and often lacks consistency. This makes it difficult for applicants to successfully challenge any measure which was based on the principle. Unless there are procedural mistakes or manifest errors

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441 COM(2000) 1, p. 12.

442 COM(2000)1, p. 12.

443 See the case-study analysis performed by Garnett, K. and Parsons, D.J., 'Multi-Case Review Of The Application Of The Precautionary Principle In European Union Law And Case Law.' Risk Analysis: an official publication of the Society for Risk Analysis, 37, 2017.

of assessment, the Court is reluctant to annul precautionary decisions in view of the large discretion the Commission has in these cases. Importantly the Court has largely ignored the need, laid down in the Communication and in some laws, 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 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.<sup>444</sup>

On the one hand, this formal attitude makes it easier for applicants to identify the potential factors when challenging a decision. On the other hand, however, this limits the Court's focus to 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 that the Courts leave the EU legislator and the Commission large 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 thought that one would accept that no general legal definition of the precautionary principle in EU law would be developed and that one should more look into having similar and predictable procedures for the application of the precautionary principle.

Our analysis reveals that the criteria for precautionary action, as described in the Communication are not consequently followed by the EU policy makers and EU Member States. This ranges from inconsistent applications to complete disregard of the 2000 Communication.<sup>445</sup> The inconsistencies in the application 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 seems desirable. To explore ideas in this direction this study also looked in the impact the constitutionalisation of the precautionary principle had in France. Our study reveals that here not a lot has changed.

What could be of interest is the suggestion of authors to set up a specialised scientific body to draw orientation for the implementation of the risk assessment and provisional and proportionate measures to be adopted and to improve the monitoring of temporary character of precautionary measures.

Some scholars have called for a revision of the 2000 Communication.<sup>446</sup> They view a need to define what is meant by the precautionary principle, 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 further 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 need for a general uniform definition of the precautionary principle, 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. At the same time, it needs to be examined how the requirement of carrying out an impact assessment prior to adopting a precautionary measure should be implemented -the lack of which, as the Court has ruled

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444 See Rogers M., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, 481.

445 Löfstedt R., 'The precautionary principle in the EU: Why a formal review is long overdue'. *Risk Management* 16(3), 2014, 149-151.

446 As suggested by Löfstedt, Garnett, Alemanno, Zander, Rogers, Janssen and Rosenstock, cited above.

in its case law, is a breach of the precautionary principle-, and the recognition of the precautionary principle as a principle of good administration.

## 6. The precautionary principle in selected countries

This paragraph will provide an analysis of the implementation of the precautionary principle in four selected Member States and one EEA country:

- Denmark
- Italy
- Bulgaria
- The Netherlands
- 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. These will be the same countries as where the interviews in the public discourse will take place to allow for a comparison between the legal and policy interpretation and citizen's perspective on the precautionary principle in these countries.

### 6.1. Implementation and application of the precautionary principle in Denmark

This section provides a short review on perceptions and implementation of the precautionary principle in Denmark. It gives an overview of the legal status and applications of the concept and it explores how it is used in policies, strategies and administrative practices.

#### 6.1.1. The implementation and status of the precautionary principle in Denmark

Precaution has been a key part of Danish health and environmental policies and practices for the last three decades. Denmark is a treaty member of the Rio Declaration and a party to the Climate and Biodiversity conventions and their protocols. Denmark is also a member state of the EU where the precautionary principle is a central principle in the Union's legislative framework for health and environmental matters.

Traditionally Denmark has been active in the negotiations and formulation of both the international instruments and the EU legislation and in many instances the precautionary principle has been integrated into the Danish health and environmental policies, legislation and practices.

What best describes the use of the precautionary principle in Danish laws, policies and practices is a precautionary approach.

#### The Constitution

The Danish Constitution is from 1849 and is one of the oldest in the world. It was created at a historical time where transition from absolute to a constitutional monarchy took place and a more democratic society began to take shape. The constitution therefore defines the distribution of power between the monarch and the government and is designed to provide a legal frame for a political and legal system which ensures the rights of the individual.

Generally, the constitution frees citizens from government intrusion, rather than ensuring their rights to governmental assistance. The development of law and justice therefore has

not been, and still is not, guided by environmental principles laid down in the constitution.<sup>447</sup>

The constitution has only been amended a few times and then very little. During the last few years, however, a debate has arisen on the need for a new and modern constitution, and citizens' rights related to health and environment are central elements in this discussion. More on this at the end of this section.

## Laws

The precautionary principle is indirectly included in several Danish laws, but it is not explicitly mentioned. Therefore, there does not exist a precise legal definition of the precautionary principle and it is also not perceived a specific legal principle in Danish law.<sup>448</sup>

As the precautionary principle is not a principle which occurs directly in the Danish laws and statutory orders and as it is not a well-defined legal concept, there are no court decisions made in Danish courts which explicitly invoke the precautionary principle.

Furthermore, the precautionary principle is also usually not elaborated much on in the most commonly used textbooks for environmental law students at the Danish universities.<sup>449</sup>

However, in the next sections, it will be demonstrated that the principle is indirectly implemented in several pieces of the national legislation and also, and more directly, applied in many political strategies and decisions and in a large number of administrative decisions and rulings made by ministerial agencies, municipalities or appeal boards.

### The Environmental Protection Act

The Danish Environmental Protection Act is from 1974 and has been amended considerably over time. The act aims at prevention of pollution.<sup>450</sup> It regulates protection of air, water, noise, waste etc. The law contains environmental principles such as "the polluter pays principle" and "the principle of the use of the best available technology". The law has been amended many times since it was first enacted in 1992. The amendments have ensured the national implementation of EU directives, primarily the Integrated Pollution, Prevention and Control (IPPC) Directive which is based on the precautionary principle.<sup>451452</sup>

The precautionary principle is reflected in paragraph 3.2.1 of the law: "*When determining the extent and nature of measures to prevent pollution consideration shall be given to: The nature of the physical surroundings and the likely impact of pollution there on*".

The law with its statutory orders determines threshold values for pollution which are adopted in EU or through national processes which include considerations on the

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447 Basse E.M., 'Denmark', in de Sadeleer, N. (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*. Earthscan, London, 2007.

448 Resumé from Miljøstyrelsens conference on the precautionary principle: "Forsigtighedsprincippet - Udtrykt i national regulering, Den Natur- og Miljøpolitiske redegørelse 1995 og gennem eksempler på internationale erklæringer". Miljøstyrelsen, May 1998.

449 Professor, dr. Jur. Peter Pagh. Forsigtighedsprincippet – fra luftighed til hard law. Ugeskrift for retsvæsen, no. 15, 12. April 2003.

450 Present version: Lov bekendtgørelse nr. 241, 13. March 2019.

451 Helle Tegner Anker. Miljøret – miljøbeskyttelse, vandløb og vandforsyning, Kap. 1 (rev.) Baaner, Lasse; Anker, Helle Tegner. Københavns Universitet, Absalon, 2009.

452 Resumé from Miljøstyrelsens conference on the precautionary principle: "Forsigtighedsprincippet - Udtrykt i national regulering, Den Natur- og Miljøpolitiske redegørelse 1995 og gennem eksempler på internationale erklæringer". Miljøstyrelsen, May 1998.

precautionary principle and aim to ensure that scientific doubt concerning risks come to benefit the environment and the citizens.

### The Chemical Substances and Products Act

The Danish Chemical Substances and Products Act is from 1979 and has been amended many times since.<sup>453</sup>

Paragraph 2 of this act says: *“The Act aims at ensuring that the necessary information is provided on chemical substances and products which are sold in Denmark, and that the sale and use of chemical substances and products which present, or on the basis of available investigations or experience are suspected to present, hazards to health or the environment can be regulated».*

With its reference to “suspected” this paragraph refers to the precautionary principle.

Except for this formulation the precautionary principle is not referred to in the act. The act, however, ensures compliance with the relevant EU-regulations and directives. The most notable of these being the 2007 Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which has integrated the precautionary approach. REACH aims to establish total harmonization amongst member states and shifts the responsibility from public authorities to the industry for ensuring that chemicals in the EU are safe.

### Act on Nature Protection

The Danish Act on Nature Protection is from 1992 and has also been amended many times.<sup>454</sup> The act is primarily to ensure nature protection, nature restoration and citizens access to nature. There is no references in the law or its statutory orders to the precautionary principle.

Regulations on biodiversity conservation and sustainable use, however, in general can be said to be based on precaution for nature and human health. The act, together with a number of other newer laws, ensures the Danish implementation of EU’s Birds and Habitats directives, which are amongst the EU legislation with the highest degree of implementation of the precautionary principle.

### Act on Environment and Gene Technology

The Danish Act on Environment and Gene Technology is from 1986.<sup>455</sup> At the time, it was one of the very first laws in the world on regulation of risks from gene technology. Over time it has been amended and supplemented to implement the later EU directives on deliberate release and contained use of genetically modified organisms as well as the legally binding protocols under the Convention on Biological Diversity (the Cartagena Protocol on transboundary movements of living modified organisms and biosafety and the Nagoya Protocol on sustainable use and benefit sharing of genetic resources).

Although the precautionary principle is not mentioned directly in the law it ensures that the precautionary principle is used according to both the international agreements and the two EU directives where the concept of precaution is dominant.

### Act on Growing etc. of Genetically Modified Crops

Although there has not been and is no cultivation of genetically modified crop plants in Denmark the Danish Parliament, in an expression of precaution, adopted this Act on Growing etc. of Genetically Modified Crops in 2004.<sup>456</sup> The act establishes a system for

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453 Present version: Lov Bekendtgørelse nr. 115, 26. January 2017.

454 Present version: Lov Bekendtgørelse nr.240, 13. March 2019.

455 Present version: Lov Bekendtgørelse nr. 9, 4. January 2017.

456 Present version: Lov bekendtgørelse nr. 28, 4. January 2017.

protection of non-genetically-modified-crop-growing-farmers (traditional and organic farmers) against spreading of genetically modified crops through requirements of minimum distances for cultivation of genetically modified crops and for liability and compensation in cases of pollution of non-genetically-modified-crop materialism with genetically-modified-crop-materials.

### Act on Environmental Goals and Objectives

The Danish Act on Environmental Goals and Objectives is from 2003 and it implements the EU Water Framework Directive and the Birds and Habitats directives.<sup>457</sup> Although the precautionary principle is not mentioned in the law its provisions are closely aligned with the provisions of these EU directives in which the precautionary principle is strongly integrated.

In particular, article 6(3) of the Habitats Directive installs a situation of reverse burden of proof. Accordingly, applicants must provide scientific assessments of risks which may potentially harm protected species and nature types in Nature 2000 areas and if negative impacts cannot be rejected, on the grounds of sufficient scientific evidence, doubt is to benefit the nature protection.

There have been many both political strategies and administrative decisions made in Denmark with respect to these special provisions of the two directives and in the official guidelines to the law it is also stated clearly that decisions are to be based on the precautionary principle.<sup>458</sup>

### Decisions can be appealed

Most projects and cases are dealt with and decided upon by national or municipal authorities. Their decisions can be challenged by citizens, companies and organizations etc. who can arraign their appeals to the authorities or to appeal boards.

In general, decisions adopted under environmental, nature and planning legislation can be appealed to the Environmental and Food Appeal Board which are empowered to make final administrative decisions within these areas. Access to the board is generally easy and cheap. A large number of associations and organisations, as well as any person with a considerable interest in the outcome of the case, can appeal to the board. Most types of appeals are free of charge although some categories of appeals will cost a moderate amount of money (Danish Kroner 900 for individuals and Danish Kroner 1,800 for companies and organisations).<sup>459</sup>

The former appeal board, Nature Protection Board of Appeal, (which later was merged with another appeal board to become the Environmental and Food Appeal Board), made direct reference to the precautionary principle in a well-known case in 2003 regarding the reintroduction of beavers in two nature protection areas (Flynder Å and Omme Å). The Board decided against the reintroduction in arguing that the beavers, due to their potential physical changes of the hydrology of creeks, could maybe have a negative impact on protected populations of local salmon populations.

This decision was overruled by the Danish High Court, which did not find that there was sufficient evidence to invoke the precautionary principle as basis for the board's decision.<sup>460</sup>

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457 Present version: Lov Bekendtgørelse nr. 119, 26. January 2017.

458 Vejledning til bekendtgørelse 408 af 1. juni 2007 om udpegning og administration af internationale naturbeskyttelsesområder samt beskyttelse af visse arter. Miljøministeriet, Naturstyrelsen, June 2017.

459 <https://naevneneshus.dk>, accessed 7. July 2019.

460 Basse, E.M., 'Denmark', in de Sadeleer N. (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*. Earthscan, London, 2007.

Subsequently, however, the board started to refer to and apply the precautionary principle in several cases related to the EU Nature 2000 directives (the Birds Directive and the Habitats Directive) after an EU court verdict in 2004 in a case from the Netherlands (C-127/02 Waddenzee, "The Mussel Case"). In this ruling the EU Court of Justice clearly based its judgement on the precautionary principle and also very clearly reverted the burden of proof (of little or no risk) to the operator.<sup>461462</sup>

Apart from the option of appeal to the appeals boards, stakeholders can also take cases to Danish courts and it is also possible to arraign an administrative decision to the Ombudsman.<sup>463</sup>

The Ombudsman may raise cases on his own initiative or respond to complaints being brought to him, according to the Ombudsman Act. It is a requirement that the options for administrative appeal have been exhausted before bringing a case to the Ombudsman. It is up to the Ombudsman to determine whether a complaint should lead to further investigations. The Ombudsman cannot make decisions with legally binding effect, but he can raise criticism of and make recommendations to the respective authorities.

Finally, if a citizen or an NGO considers that a criminal offence has taken place and violates environmental legislation the matter can be reported to the police/public prosecutor.

## **Policies and strategies**

The significance and visibility of the precautionary principle in governmental policies and strategies has varied over time. After the Brundtland Commission released the report "Our common Future" in 1987 and after the Rio de Janeiro Earth Summit in 1992 the principle frequently occurred in Danish policy papers, and particularly in the Danish government's Nature and Environmental Policy Presentation which was promoted by the social democratic minister for the environment at the time, Svend Auken.<sup>464</sup>

Formulations in this policy presentation such as "The government is aware of the development's long term impacts on health and welfare and will apply the precautionary principle in order not to hand over poorer nature and environmental conditions to the next generations" characterized the environmental policies at the time.

As the precautionary principle emerged in international fora and in EU legislation as well as on the national scene the principle was also often mentioned in media and in scientific and analytical literature on health and environmental policies and issues. In the Danish media at the time the term most frequently occurred in relation to pesticides, drinking water, GMOs and endocrine disruptors.<sup>465</sup>

During the preparation of this chapter it has become clear that the principle has gradually been addressed less often in policy documents, media and in the scientific literature since the late 90's and first years of the 21st century.

Since year 2000 till now mostly liberal/conservative parties have held governmental power in Denmark and this has, most observers agree, resulted in ambitious environmental and nature policies being less prioritized.

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461 <https://docplayer.dk/39033408-Forsigtighedsprincippet-professor-dr-jur-peter-pagh-juridisk-fakultet-koebenhavns-universitet.html>, accessed 7. July 2019.

462 Miljøministerens besvarelse af spørgsmål nr. 47 stillet af Folketingets Miljø- og Planlægningsudvalg (MPU alm del). Miljøministeriets Departement, 25 august 2005.

463 <https://www.ombudsmanden.dk>, accessed 7. July 2019.

464 Regeringens natur- og miljøpolitiske redegørelse 1995. Miljøministeriet, 1995.

465 Forsigtighedsprincippet i praksis. Institut for Miljøvurdering (Danish Centre for Environmental Assessment, which was an independent institution under the Danish Ministry for the Environment in 2002 to 2006), December 2003.

After a liberal/conservative government came into power in 2000 replacing the social democratic one, the Danish Environmental Protection Agency shortly after announced on its homepage a fundamental change: "In the future, the Government will let market-based instruments and improved cost-effectiveness guide its environmental policy."<sup>466</sup>

Since then the Danish Ministry for the Environment has undergone frequent restructuring and was from 2015 to June 2019 merged with the Ministry for Agriculture to become a Ministry for Environment and Food. The ministry's administrative agencies have also been subject to annual reduction in budgets and numbers of staff and some of its agencies (the Environmental Protection Agency and the Agency for Forest and Nature) have been moved out of Copenhagen, the capital, to towns in Jutland or Fyn.

Due to the requirements of the EU legislation and the jurisprudence of the EU Court in rulings related to health and environment and also due to the long term traditions of high national health and environmental ambitions in certain sectors the precautionary principle, however, continues to be present in a number of national policies and strategies.

One such strategy is the Danish Action Plan on Pesticides 2017-2021 which is the outcome of a political agreement established in April 2017 between the liberal/conservative government, the Danish People's Party, the Social Democratic Party, the Social-Liberal Party and the Socialist People's Party.<sup>467</sup>

Although pesticides are regulated by a large body of EU legislation, which ensures that pesticides cannot be placed on the EU market and used without prior risk assessment and authorisation, the Danish governments have regularly adopted national pesticide strategies and action plans and in this way emphasised an extended national use of the precautionary principle.

This is already indicated in the subtitle of the present national pesticide strategy "*Facts, Caution and Consideration*". Explicit references to the utilization of the precautionary principle is also found in the foreword to the strategy by the Minister for Environment and Food and in the text of the political agreement which creates the basis for strategy. The principle is primarily used in the strategy in relation to protection of groundwater against percolating pesticides.

This strategy demonstrates a strong application of the precautionary principle in an area of particularly high national interest. For many years Danish citizens have been able to drink extracted ground water straight from the tap but in recent years an increasing number of wells extracting drinking water have become contaminated with pesticides and closed.

There has existed a broad and long term political consensus to clean ground water and previous strategies have aimed to regulate and reduce the application of pesticides primarily by taxation based on a principle of placing the highest taxes on the pesticides with the highest load on health and environment.

Due to the increasing number of pollution cases a new protective element has been included in the present plan, which enforces protection against pesticides in protection zones around water wells by introduction of a ban on farmers filling and mixing pesticides and cleaning of pesticide sprayers in these particular zones.

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466 Tharan, D., Denmark Case Study - Analysis of National Strategies for Sustainable Development. Unedited working Paper. Prepared by: Environmental Policy Research Centre, Freie Universität Berlin, by Berlin, Germany, June 2004.

467 «Danish National Plan on Pesticides 2017-2021. Facts, Caution and Consideration». Ministry for the Environment and Food, 2017.

## **Public involvement and consultation of organizations and authorities**

Denmark has been instrumental in the propagation and creation of the Aarhus Convention which was adopted in the Danish town Aarhus in 1998. The convention lays down international principles, rules and standards for how national authorities can ensure citizens access to environmental information, their participation in decision-making processes as well as provide concerned individuals and entities access to impartial complaint bodies, which shall be empowered to make binding legal decisions.

Public participation has become a mandatory requirement in many parts of environmental decision-making in Denmark. This includes the Danish land use planning system with a system of prior public consultations prior to the presentation of plan proposals, as well as consultation processes after the plans are proposed. These procedures are defined in the Danish Planning Act.<sup>468</sup>

Procedures for environmental impact assessment (EIA) of land- and offshore based activities and projects also include public participation procedures allowing citizens to become informed and provide input at early, midway and final stages of the assessment processes.<sup>469</sup>

The Aarhus Convention contains a special provision on the involvement of the public in cases of deliberate release of GMOs. Here it is to a large extent up to the individual countries to decide if this is considered appropriate. In Denmark the Environmental and Genetic Engineering Act contains special rules on public involvement and remarkably, the parliament's standing Committee for Environment and Food must be informed by the acting minister in all cases of deliberate release of GMOs. This contributes to ensuring that decisions in such cases rest on a broad political majority and not solely on the position of the government at the time (possible consequences of this is deliberated on in section 7.2.2 – Case law).

## **Administrative decisions and practices**

The precautionary principle is traditionally integrated into the provisions for risk assessments and impact assessments required by the Danish authorities. When deciding to approve or reject projects, any individual, organization or others wishing to initiate a project is in most cases expected to supply information that proves that there will be no or only acceptable harm to nature, environment or health. The burden of proof generally rests on the applicant and the precautionary principle is in many instances well entrenched in the authorities' decision-making.

Numerous cases have been handled by the administrative bodies (i.e. public agencies, municipal divisions and appeal boards) in which the precautionary principle has played a role.<sup>470</sup>

Although the precautionary principle is used by the authorities in their approvals, rejections or in the process of setting certain preconditions or requesting certain mitigating measures, specific conditions or guidelines for the use of the principle mostly do not exist.<sup>471</sup>

In general, there seems to be much variation in the way cases are approached in terms of both processes and decision-making in the different ministries and municipalities and within and across their respective agencies and divisions.

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468 Gældende: Lov Bekendtgørelse nr. 287, 16. April 2018.

469 Gældende: Lov Bekendtgørelse nr. 1225, 25. October 2018.

470 Helle Tegner Anker. Miljøstyrelsen Implementering af EU's miljølovgivning i national lovgivning. Miljøstyrelsen 2013.

471 Professor, dr. Jur. Peter Pagh. Forsigtighedsprincippet – fra luftighed til hard law. Ugeskrift for retsvæsen, no. 15, 12. April 2003.

In situations where the EU Court of Justice have made rulings on the importance and effect of the precautionary principle the Danish authorities use these rulings as guidance for their own decision-making. Some EU court verdicts, in cases where Denmark has played an active role, are particularly well-known by staff in the respective agencies and appeal boards and can therefore especially influence practices and decisions.

One such case is a specific EU court ruling, also called "the Pfizer ruling" of 2002. In this case the Danish Agency for Environmental Protection suspected that some specific antibiotic growth stimulants, which were added to animal feed, could result in development of resistance to the antibiotics of certain bacteria, and that this could result in risks to the antibiotic treatments in humans. After dialogue with the Danish authorities and amongst the EU member states the EU Council adopted a new EU regulation which banned the use of the stimulants. A medical company (Pfizer), which produced growth stimulants took the decision to the EU court which after thorough analysis supported the Council's decision.<sup>472,473</sup>

Nonetheless, it seems that officers in the ministerial and municipal agencies and offices in many cases may have limited knowledge on the principles and rulings of the EU court and make decisions which, if submitted to the EU court, would have had different outcomes.<sup>474</sup>

An in-depth study was conducted in 2003 on the role and importance the precautionary principle had had in the Danish media and on how the authorities had interpreted and applied the concept in four specific cases.<sup>475</sup>

The four cases analysed in detail were about: Mad cow disease (bovine spongiform encephalopathy, BSE), where there was suspicion that the disease could spread from cattle to humans during the process of slaughter, sunscreen, where UV-filtering chemical ingredients were suspected to have female hormone effects, straw shorteners, applied on fields to inhibit growth of grain stems where chemical residues in animal feed were suspected to result in smaller numbers of litter in pigs and potentially to have negative effects on humans' seed quality, and finally phthalates, which are chemicals used to soften PVC plastic, where there was suspicion related to human hormonal disruptions, especially in relation to toys and kids.

The analysis showed that the decision-processes in all four cases had been very long and complicated in terms of the interactions between the EU Commission and the Danish authorities and sometimes intensely involved both the respective Danish Ministers and sometimes the EU Parliament as well. In fact, some of the cases are still unsettled.

The analysis further looked into to which extent the cases were handled by the Danish institutions in accordance with the five guiding principles provided by the EU Commission from February 2000 in its communication to member states on the precautionary principle.<sup>476</sup>

These guiding principles, which are not to be explained here, relates to: Proportionality, non-discrimination, compliance, analysis of benefits and costs, insight into the scientific development and application of new scientific knowledge.

The four cases all reflected some degree of scientific uncertainty and was surrounded by both scientific and political disagreements which led to different positions and conclusions

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472 <https://www.advokatsamfundet.dk/Service/Publikationer/Tidligere%20artikler/2006/Advokaten%202/Forsigtighedsprincippet.aspx>, accessed 7. July 2019.

473 [http://europa.eu/rapid/press-release\\_CJE-02-71\\_en.htm](http://europa.eu/rapid/press-release_CJE-02-71_en.htm), accessed 7. July 2019.

474 Professor, dr. Jur. Peter Pagh. Forsigtighedsprincippet – fra luftighed til hard law. Ugeskrift for retsvæsen, no. 15, 12. April 2003.

475 Forsigtighedsprincippet i praksis. Institut for Miljøvurdering (Danish Centre for Environmental Assessment, which was an independent institution under the Danish Ministry for the Environment in 2002 to 2006), December 2003.

476 COM(2000)1 -EU-Kommissionen on the Precautionary Principle, 2000.

regarding the use of the precautionary principle amongst the involved Danish and EU institutions. In all four cases, however, the EU authorities' rulings determined the outcome of the conflicts while the study at the same time illustrated a certain degree of national flexibility, which in cases where national non-approval would be in conflict with the EU provisions in some instances instead could result in voluntary national agreements made with the industry.<sup>477</sup>

The analysis concluded that one or more of the EU principles had not been sufficiently considered by the Danish politicians and administrative authorities and also found that there existed a large degree of variation in use of and compliance with the EU guiding principles in the four cases.

The study therefore recommended that the precautionary principle should be better defined by the national authorities and should also be applied more systematically and in accordance with the 5 EU principles in order to achieve transparency and ensure the long term support from the industries and the public.

### 6.1.2. Case law

In the following two recent cases of application of the precautionary principle in Denmark are presented. The cases illustrate the long duration and complexity of cases and also how political and public attitudes, will and pressure impact on decisions and outcomes.

#### Cultivation of genetically modified maize

In 2015 the Danish Minister for the Environment and Food forwarded a suggestion to the national parliament's Commission for Environment and Food to allow varieties of genetically modified maize for cultivation in Denmark: Maize Bt11 from Syngenta, maize Mon810 from Monsanto and maize 1507 from Pioneer. In the case of maize Bt11 and maize 1507 the application was for a 10 year cultivation duration, while the application regarding maize Mon810 was for a 10 year renewal of an existing cultivation approval). The crop plants were genetically modified to be herbicide-tolerant (Roundup-tolerant) and/or insect-resistant against the pest maize borer. Maize borer is not yet common in Denmark but is expected to become so in the near future as a result of global warming.

The EU approval process had started much earlier than 2015. For instance, Syngenta handed in its application for cultivation of the Bt11 maize in EU already in 1996, but the scientific assessment by EU's Food Safety Authority (EFSA) and national research institutions as well as the coordinated political approval process amongst the EU Commission and the member states is today still unsettled.

In 2015 the relevant and involved Danish health and environmental scientific institutions had, in parallel to EFSA, made updated risk assessments and concluded that the plants would not pose any significant risks to health or environment. On this basis the Danish minister wanted to allow the plants for cultivation in Denmark.

According to an EU Directive ("The Barroso Directive" from 2015<sup>478</sup>) this national process would represent the first step in a process that in the end would determine if the crops could achieve an EU approval. According to the new directive EU member states were given the opportunity to say no to cultivation of varieties of genetically modified crops in their own country ("to opt out"). This entailed that a subsequent and coordinated EU approval could be given for cultivation in member states who wanted the crop while it would not be

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477 Søren Løkke and Per Christensen, 'The Introduction of the Precautionary Principle in Danish Environmental Policy: The Case of Plant Growth Retardants', *Journal of Agricultural and Environmental Ethics* (2008) 21:229–247 DOI 10.1007/s10806-007-9080-7, Springer 2007.

478 EU 2015/412 ("Barroso Directive").

grown in the member states who had said no to cultivation on their own territory. According to the Barroso Directive member states could opt out without provision of scientific evidence of environmental or health risks. Reasons such as reference to “public order” or other broad and rather unprecise terms would be sufficient for members states to ask for an opt out.

This rather unique legal construction was established to motivate countries not to vote against genetically modified crops in the coordinated EU voting and thus to overcome the year long stalemate in EU on the coordinated approval process on cultivation of genetically modified crops where there almost never could be established a majority for or against a particular genetically modified crop plant. This construction in reality provides the individual EU member states an option to disregard the legal “principle of proportionality” which in many other situations must be applied to counter balance the precautionary principle.

In the current case the Danish minister, after public hearings and reception of negative comments from green NGOs and positive responses from agricultural sector organisations, was faced with a political consensus in the Danish parliament’s Commission for the Environment and Food against the national approval. Despite the available EU and national risk assessments the opponents expressed that they felt that too little was known about GMOs and that doubt should benefit the environment and human health.<sup>479</sup>

The minister therefore had to reply to the EU Commission that Denmark wanted to opt out (i.e. wanted a “geographical exemption” from cultivation of the maize varieties according to the provisions of the Barroso Directive).

Next step in the EU process was then a coordinated voting amongst member states in October 2016 in Brussels in the EU Standing Committee for the Directive on deliberate release of genetically modified organisms. Also, here the Danish political majority forced the minister to vote against her own position, so Denmark voted against the possibility of cultivating the crops in all member states.

As the formal reason for the negative vote Denmark referred to a minor and specific condition in the approval text for the cultivation which determined that growers had to respect a security distance from the genetically modified crops to other crops in order to protect protected butterflies from a theoretical risk of being harmed in case the butterflies fed on plants with pollen from the genetically modified maize on their leaves or flowers. With reference to the precautionary principle Denmark called for moderately larger security distances.

Today, several years later, these maize varieties have still not been decided upon in the EU. There has been no majority for or against approval of the plants in the standing EU committee or the appeal committee, and the EU Commission, who in such cases holds the power to make a decision, has not yet managed to do so.

This case illustrates how the precautionary principle has been applied in the national decision-making process and how sceptical public and political attitudes, which were not based on scientific evidence, have not only been determining for decisions regarding approval of products in Denmark, but have also influenced other EU countries who would have preferred to approve use in their own territories.

Based on this and similar experiences the independent Danish Board of Ethics in a public communication of May 2019<sup>480</sup> expressed that the Danish government’s decisions related to cultivation in Denmark of genetically modified crops could no longer be said to rest on scientific reasoning related to risks for health and nature. The board stated that the

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479 <https://www.ft.dk/samling/20151/almdel/MOF/bilag/658/1669693.pdf>, accessed 7. July 2019.

480 Udtalelse fra det Ethiske Råd, GMO og etik i en ny tid, det Ethiske Råd. ISBN: 978-87-92915-15-3, May 2019.

predominant attitude of disapproval of all kinds of genetically modified crops was unethical and strongly recommended that such crops should be assessed and determined upon by a case by case risk assessment and on proper scientific analyses.

The board had reached this conclusion after involvement and advice from a broad range of scientists at the Danish research institutions and universities.

### Neonicotinoids

The European populations of honey bees have declined during recent years and scientific studies indicated that one of the factors causing this development could be the widespread use of pesticides in the form of neonicotinoids used against a broad variety pests. Scientific research found that neonicotinoids were very persistent and widespread in the environment.

Following risk assessments by the EU Food Safety Authority (EFSA) and voting by member states in EU's Standing Committee on Plants, Animals, Food and Feed, the EU Commission, based on the precautionary principle, posed a partial ban on the use of a number of neonicotinoids in EU in 2013.

Although member states were only left with limited opportunities to make national exemptions from the rule, Denmark made exemptions regarding the use of certain nicotinoids, for instance stain winter oilseed rape seeds. Winter oilseed rape makes up a large proportion of the cultivated area of Danish crop farming.

The EU ban was intensified in the end of 2018 to become a total ban on specific neonicotinoids<sup>481</sup> and possibilities to make exemptions were further restricted. Only few EU member states (i.e. Denmark, Romania, the Czech Republic and Hungary) voted against an overwhelming majority of other EU member states.<sup>482</sup>

Due to the strengthened ban, the Danish Environmental Protection Agency in the Ministry for Environment and Food had to withdraw its earlier approvals of utilization of neonicotinoids for staining winter rapeseed seeds, but insisted that neonicotinoids could be used by Danish farmers to stain beet seeds in order to avoid an estimated loss of the national sugar beet harvest of about 10-23 %.<sup>483</sup>

The involved scientific institution and the agency reasoned that bees and other pollinators are not put at any significant risk by this decision because the chemicals are used at low dosages and on seeds of plants that are harvested before flowering.

Despite this justification, this use of neonicotinoids was criticized by international and national green organisations who wanted an absolute ban and were concerned that Denmark in this way would contribute to a situation where more member states could want to apply exemptions.<sup>484</sup>

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481 <https://www.nature.com/articles/d41586-018-04987-4>, accessed 7. July 2019.

482 <https://www.euractiv.com/section/agriculture-food/news/invoking-science-europe-shuts-the-door-to-neonics/>, accessed 7. July 2019.

483 Science letters 2019: [https://www.sciencemagazinedigital.org/sciencemagazine/01\\_march\\_2019/MobilePagedArticle.action?articleId=1467479#articleId1467479](https://www.sciencemagazinedigital.org/sciencemagazine/01_march_2019/MobilePagedArticle.action?articleId=1467479#articleId1467479), accessed 7. July 2019.

484 <http://cphpost.dk/news/sale-of-bee-killing-insecticide-up-big-time-in-denmark.html>, accessed 7. July 2019.

### 6.1.3. Precautionary principle mechanisms incorporated in Danish policy making

As described in the previous sections the precautionary principle has been incorporated more or less in an ad hoc manner in policy-making. A more systematic approach to this integration has not been established.

In recent years, however, a national debate has started on the need for a revision of the old Danish Constitution so that it would include rights related to nature, health and sustainability. The Danish Nature Conservation Association, an NGO with 130.000 members, and also some of the most successful Danish companies (e.g. Novozymes and Grundfos) have publicly argued for a revision of the constitution in order for it to directly reflect citizens' rights to a clean environment and a sustainable managed nature. Some of the political parties, and in particular a new green party, the Alternative, are also amongst the current proponents of such a revision of the constitution.

A revised national constitution with ingrained citizens' health and environmental rights could possibly contribute to a situation where the precautionary principle would be revitalized and gain more political and administrative importance - and where its application could move beyond *ex ante* application in the regulation of new products and projects to be considered more in active management and regulation of existing circumstances and activities.

Awareness of environmental and health matters has increased recently and dominated a recent general election in Denmark while economics and immigrant policy for the first time in more than about 15 years moved down on the political agenda. This shift in voters' attitudes was a major reason that a greener government came into power in June 2019.

The Ministry for Environment and Food also launched an analysis of the Danish environmental laws in 2015 in order to provide recommendations regarding a process which could lead to a revision of the law structure and provide for more simplicity, clearness and coherence.<sup>485</sup> Many of the experts cited in this chapter on the Danish implementation of the precautionary principle were strongly involved in this analysis and a revision could provide an option for reflections on a much more consistent and systematic inclusion of the precautionary principle in the legislation.

#### The precautionary principle vis-à-vis innovation

At present the precautionary principle, dependent on the specific circumstances, can in some situations be expected to hinder and, in some cases, stimulate innovation. For instance, very strict implementation of the principle can in some cases encourage the discovery of other solutions – e.g. to the development of new alternative and less harmful chemicals. In other cases, such as in the case of cultivation of genetically modified crops, it may rather stifle innovation and hinder climate adaptation and food security by blocking cost effective development of more robust crop plants with reduced need for pesticides and fertilizers and a lesser carbon footprint.

To our knowledge, however, no scientific analysis of whether the precautionary principle stimulates or hinders innovation in different fields and sectors has been undertaken in Denmark.

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485 LOVKOMPASSET - Rekommandationer fra ekspertpanelet vedrørende en fremtidig struktur for miljø- og fødevarelovgivningen. Miljø- og Fødevareministeriet, December 2017.

## 6.2. Implementation and application of the precautionary principle in Italy

This section provides a short review on perceptions and implementation of the precautionary principle in Italy. It gives an overview of the legal status and applications of the concept and it explores how it is used in policies, strategies and administrative practices.<sup>486</sup>

### 6.2.1. The implementation and status of the precautionary principle in Italy

In Italy there is no constitutional/general norm on the precautionary principle that provides a general definition of it. Nevertheless, some authors believe that the strong emphasis in the Constitution on certain fundamental values/rights (i.e. the fundamental right of individuals to health - which encompasses environmental well-being - and the respect of the human person mentioned in Art. 32; and the prevalence of human dignity and safety over the freedom of economic initiative in Art. 41) represents the constitutional foundation of precaution in the Italian legal system.<sup>487</sup>

Besides the constitutional references, the principle operates in Italy due to the content and effect of (now) Article 191 Treaty of the Functioning of the European Union of 2012.<sup>488</sup>

The precautionary principle entered the Italian legal system for the first time through the Electromagnetic pollution law (Law 22 February 2001, no. 36) in Art. 1, bearing the general aims of the law, which explicitly refers to it.<sup>489</sup>

The principle is also mentioned in Law 5 March 2001, no. 57, regarding the opening and regulation of the markets, and in legislative decree 21 May 2004, no. 172, dealing with the safety control of products, which was merged into Part IV, Title I, of Legislative Decree 6 September 2005, no. 206, the so-called Consumer Code.

*Article. 107, paragraph 4, provides, in fact, that the competent administrations on such control "when they adopt measures (...), taking into account the precautionary principle, act in compliance with the Treaty establishing the European Community, in particular with articles 28 and 30, to implement them in a manner proportionate to the gravity of the risk".*

*The following paragraph establishes that: "the competent administrations, in the context of the measures adopted on the basis of the precautionary principle and, without further burdens for the public finance, encourage and favour the voluntary action of the producers and the distributors of adaptation to the obligations*

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486 The translations from Italian to English of laws and literature are all by K&I.

487 See Follieri F., Decisioni precauzionali e stato di diritto. La prospettiva della sicurezza alimentare (Parte I), in *Rivista italiana di diritto pubblico comunitario*, AnnoXXXVINFasc.N6N-N2016, ISSN1121-404X, 2016.

488 Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - Consolidated version of the Treaty on the Functioning of the European Union - Protocols - Annexes - Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007 - Tables of equivalences, Official Journal C 326 , 26/10/2012 P. 0001 – 0390.

489 Patrizi E., Il principio di precauzione nella società del rischio, Doctoral thesis, 2014, p. 99.

*imposed by the present title, also through the possible creation of codes of good conduct and agreements with industry specialists.*<sup>490</sup>

A further normative reference is Legislative decree 8 July 2003 no.224 transposing Directive 2001/18/CE concerning the deliberate release into the environment of genetically modified organisms, whose Art. 1 aims to establish "in compliance with the precautionary principle, measures to protect human health, animal health and the environment in relation to the release of genetically modified organisms, hereinafter referred to as GMOs, against: a) deliberate issue for purposes other than placing on the market; b) placing on the market of GMOs as such or contained in products".

Article. 5, paragraph 3, of the aforementioned decree states that the competent national authority will ensure that all measures are taken, in compliance with the precautionary principle, to avoid negative effects on human and animal health and on the environment that could derive from the deliberate release of genetically modified organisms.<sup>491</sup>

A more extensive review of the precautionary principle is included in Legislative Decree no. 152 of 3 April 2006, the so-called Environmental Code.<sup>492</sup> Its Article 3-ter, in providing the "Principle of environmental action", establishes that:

The protection of the environment, environmental ecosystems and cultural heritage shall be ensured by all public and private entities and public and private legal and natural persons, by an adequate action informed by the principles of **precaution**, preventive action, correction, priority at the source, of the damages caused to the environment and the "polluter pays principle" which, according to Article 174, para 2, of the Treaty on European unions, govern the community policy in environmental matters.

In the same Environmental Code, the precautionary principle is recalled also in Articles

- 144, para 4-bis (Protection and use of water resources);
- 178 (Principles of waste management);
- 179 (Priority criteria in waste management);
- **301 (Implementation of the precautionary principle)**, paras 1 and 4;
- 307 (Notification of preventive and restoration measures);
- 308 (Costs of prevention and restoration activities), paras 2 and 4;
- 309 (Request for state intervention), para 1;
- 310 (Appeals), para 1.

Currently, the precautionary principle in Italian legislation is often stated but not well defined. Nevertheless, it permeates various sectors of intervention linked to human and environmental health (such as the food and pharmaceutical sectors), through various branches and partitions of law, as Quagliarella, Giliberti and others state.<sup>493</sup>

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490 Stanzone M.G., 'Principio di precauzione, tutela della salute e responsabilità della P.A. Profili di diritto comparato', in *Comparazione diritto civile*, 2016, [comparazionedirittocivile.it](http://comparazionedirittocivile.it), last accessed: July 27, 2019.

491 Stanzone M.G., 'Principio di precauzione, tutela della salute e responsabilità della P.A. Profili di diritto comparato', in *Comparazione diritto civile*, 2016, [comparazionedirittocivile.it](http://comparazionedirittocivile.it), last accessed: July 27, 2019.

492 <https://www.camera.it/parlam/leggi/deleghe/06152dl.htm>.

493 Quagliarella D.B. Principio di precauzione: alcune applicazioni, [www.quagliarella.com](http://www.quagliarella.com), 2012, (last accessed: July 27, 2019) and Giliberti B., 'Il principio di precauzione nel Diritto alimentare e farmaceutico'. In Giustamm, *Rivista di diritto pubblico*, n. 3, 2013, [www.giustamm.it](http://www.giustamm.it) (last accessed: July 27, 2019).

*The Italian legal system has used the principle in the Consumer Code (law 6 November 2005, no. 206), in Art. 107, paragraph 4, concerning product safety controls) (...) (this is not the only normative trace in the Italian legal system). Making this quotation of our legal system on a different subject than the one made in the Community framework means recognizing that the principle has greater value and has the intrinsic limitation of not affecting the principles of free competition, freedom of establishment and freedom to provide services.<sup>494</sup>*

*Whoever practices the study of the precautionary principle will immediately come across a strongly characterizing element: general principles rarely present an interdisciplinary dimension as wide as that which characterizes the operation of the precautionary principle. In fact, the precautionary principle is concerned at least with international law, community law, administrative law and civil law. If on the one hand it proves the importance of the values underlying the principle (intangibility and dignity of the human person), on the other hand it has made it more difficult to ascribe to unity, since, without a common conceptual core, in the context of the individual legal sectors, the precaution has peculiar features, inevitably descending from the contact of the principle under examination with the peculiar characteristics of each specific context.<sup>495</sup>*

### **Duty to take precautionary action in the face of uncertainty (duty to act)**

In the text of the aforementioned Electromagnetic pollution law, duties to act are established in relation to exceeding threshold values of electromagnetic pollution (Art 9); the Ministry of the Environment is asked to continue the research on possible damages (Art 4) and the Regional administrations are also given a supporting role in such research (Art 8).

Duty to act in relation to potential risks is also stated in the already mentioned Environmental Code. **Article 301** (Implementation of the precautionary principle) establishes that:

- (1) In application of the precautionary principle referred to in Article 174, paragraph 2 of the EC Treaty, a high level of protection must be ensured in the event of dangers, even if only potential, for human health and the environment.
- (2) The application of the principle referred to in paragraph 1 concerns the risk that can anyway be identified following a preliminary objective scientific evaluation.
- (3) The interested operator, when the aforementioned risk emerges, must inform without delay, indicating all the aspects relevant to the situation, the municipality, the province, the region or the autonomous province in whose territory the damaging event lies, as well as the Prefect of the province who, in the next twenty-four hours, informs the [Minister for the Environment and the Protection of the Territory and the Sea].
- (4) The [Minister for the Environment and the Protection of the Territory and the Sea], in application of the precautionary principle, has the right to adopt at any time preventive measures, pursuant to Article 304, which are: a ) proportional to the level of protection to be achieved; b) non-discriminatory in their application and

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494 Quagliarella D.B. Principio di precauzione: alcune applicazioni, [www.quagliarella.com](http://www.quagliarella.com), 2012, (last accessed: July 27, 2019).

495 Giliberti B., 'Il principio di precauzione nel Diritto alimentare e farmaceutico'. In Giustamm, *Rivista di diritto pubblico*, n. 3, 2013, [www.giustamm.it](http://www.giustamm.it) (last accessed: July 27, 2019).

consistent with similar measures already adopted; c) based on the examination of potential benefits and charges; d) updatable in the light of new scientific data.

- (5) The [Minister for the Environment and the Protection of the Territory and the Sea] promotes public information on the negative effects of a product or process and, taking into account the financial resources provided for under current legislation, can finance research programs, make use of environmental certification systems and take any other initiative aimed at reducing the risks of environmental damage”.

Also, in the Environmental code, this duty to act, as established by Art. 3-Ter reported above, thanks to a correction inserted in 2008, is attributed not only to public authorities at all levels, but also to private entities.<sup>496</sup>

Moreover, without being explicitly mentioned, the precautionary principle, together with all the other principles of the EU legal order, has become one of those that must inform Italian administrative activity through the 2005 changes to Law 7 August 1990, no. 241 "New rules on administrative procedures and right of access to administrative documents" (hereinafter "Law on administrative procedure").

Art. 1 (General principles of administrative activity)

1. Administrative activity pursues the purposes determined by the law and is governed by criteria of economy, effectiveness, impartiality, publicity and transparency, according to the methods provided for by this law and by the other provisions governing individual proceedings, as well as by the principles of Community legislation.

### **Goal setting to improve health or environmental quality, even to reverse trend lines**

As said before, in Italian law the Constitution states in Arts 9 and 32 the objectives of protecting citizens' health, as well as landscape and environment quality.

The aforementioned Electromagnetic pollution law aims to "protect the environment and the landscape, promote technological innovation and recovery actions for the minimization of electromagnetic fields according to the best available technologies". The law also promotes scientific research with the aim of assessing long-term effects and "activating precautionary measures to be adopted in application of the precautionary principle".

The Environmental Code, which "has as its primary objective the promotion of quality levels of human life, to be achieved through the safeguarding and improvement of environmental conditions and the prudent and rational use of natural resources", in respect of the international obligations and community law, confirms the aforementioned purposes, linking them to the respect of community principles.

### **Proving the potential risk (burden of proof)**

In the mentioned Environmental Code, Art. 307 "Notification of preventive and restoration measures" states that:

Decisions requiring precautionary measures, prevention or restoration, adopted pursuant to the sixth part of the present decree, are adequately motivated and communicated

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496 Allena M., 'Il principio di precauzione: tutela anticipata v. legalità-prevedibilità dell'azione amministrativa', in *Il diritto nell'economia*, vol. 29, n. 90 (2-2016), issn 1123-3036.

without delay to the interested operator with indication of the means of appeal available to him and of the relative terms.

In the same decree this obligation (art. 309) is also extended to those who require state intervention.

*ART. 309 (Request for state intervention)*

*The regions, the autonomous provinces and the local bodies, even associated, as well as the natural or legal persons who are or who could be affected by environmental damage or who have a legitimate interest in participating in the procedure relative to the adoption of the measures of precaution, prevention or restoration provided for by the sixth part of this decree **may present** to [Minister for the Environment and the Protection of the Territory and the Sea], depositing them at the Prefectures - Territorial Government Offices, **complaints and observations, accompanied by documents and information concerning any case of environmental damage or imminent threat of environmental damage** and requesting state intervention to protect the environment pursuant to the sixth part of this decree.*

### **Structures to ensure democratic decision-making in public decisions**

In the Environmental Code, also in Art. 301, there is talk of the duty of the competent authorities to inform those who could be affected of the current and potential environment and health risks.

As reported by the Ministry of the Environment and the Protection of the Territory and the Sea, the Environmental Code is in compliance with the obligation, stipulated in Article 6 of the Aarhus Convention, to involve the public in decisions concerning the authorization of activities that can have significant effects on the environment.

In particular, it is the most important legislative act regulating public participation in Environmental Impact Assessments (EIA) and in Strategic Impact Assessments (SEA). These are the evaluation processes that the public authority must necessarily take into consideration before authorizing certain works, plans or programs that can have a significant impact on the environment.

The Environmental Code states that anyone can participate in the environmental assessment procedures by expressing their observations and requests in the manner established by law. At the end of the evaluation procedure, an independent technical commission called "VIA and VAS Commission" issues an opinion based also on the comments sent by the public. On the basis of this opinion, the Ministry of the Environment issues an environmental compatibility decree. A similar procedure for public participation is provided by the Environmental Code with reference to the Integrated Pollution Protection and Control (IPPC) system.

Another fundamental area in which the public participation of citizens in environmental decision making is promoted concerns the deliberate release of Genetically Modified Organisms (GMOs). Legislative Decree 243/2003 identifies the Ministry of the Environment as the competent national authority with the task of informing and consulting the public about each deliberate release of GMOs for experimental purposes. The consultation is conducted through a dedicated section of the portal of the Italian Biosafety Clearing House (BHC).

The framework law on protected areas (Law 394/1991) also provides for public participation in the preparation of the plan for the creation and management of the area.

At the local level, further public participation mechanisms are envisaged, based on regulatory and/or statutory provisions on a regional, provincial or municipal basis.

Examples of public involvement at the local level can be found in wastewater management plans, acoustic impact and atmospheric pollution, in urban planning, in territorial plans.

In Italy, however, participation in administrative proceedings (including, for example, the Decision on the layout of a power line or on the plans to recover from electromagnetic pollution, see Electromagnetic pollution law, Art. 11) is sanctioned by the aforementioned Law on administrative procedure, Chapter III, Art. 9 and Art. 10.

*(Intervention in the proceeding) "Any person, bearer of public or private interests, as well as widespread interests in associations or committees, which may result in a prejudice by the provision, has the right to intervene in the proceeding"*

*(Rights of participants in the proceeding) 1. The subjects referred to in Article 7 and those intervening pursuant to Article 9 have the right: a) to examine the proceeding, except as provided in Article 24; b) to submit written briefs and documents, which the administration is obliged to assess where they are relevant to the subject matter of the proceeding".*

This extension of precautionary responsibility to other subjects outside the state is considered by some jurists to be typical of the tendency of public authorities, in contemporary societies, to transfer the costs of precaution and risk management to other parties.<sup>497</sup> This would be particularly true in the Italian case, where a lack of clarity of national legislation would give rise to over-interpretations of the precautionary principle by peripheral administrations (regions, municipalities). They, in the name of this principle, would tend to increase the obligations of private entities, restricting their prerogatives more than those required by the national laws in force and, in some cases, generating conflicts between administrative decisions and the principle of legality.

### **Careful and structural analysis of alternatives**

The analysis of the alternatives is an integral part of the procedures envisaged in the second part of the Environmental Code, i.e. the aforementioned Strategic Environmental Assessment (SEA), Environmental Impact Assessment (EIA) and Integrated Environmental Authorization (IPPC).

### **Flexibility to update decisions as new information is received**

The enunciation of the precautionary principle in the Environmental Code, in Art. 301 paragraph 4 d) refers to measures "updatable based on the availability of new scientific data".

### **Reference to innovation in relation to precaution**

The aims of the aforementioned Electromagnetic pollution law (Art. 1) include the promotion of technological innovation to minimize the damage of electric and electromagnetic fields. This law, as mentioned, represents the first explicit reference to the precautionary principle in Italian legislation, carried out, according to some authors, with

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497 Allena M., 'Il principio di precauzione: tutela anticipata v. legalità-prevedibilità dell'azione amministrativa', in *Il diritto nell'economia*, vol. 29, n. 90 (2-2016), issn 1123-3036.

a clear reference to the German version of this principle, which considers precaution and technological innovation as being linked by necessity.

*The precautionary principle thus becomes the rationale justifying the legislative provision (...), constituting a clear reference to the original German configuration of the precautionary principle that required innovative technologies, anticipating and avoiding the production of damage through the progressive reduction of pollutants released into the environment, regardless of the evidence of their harmfulness to the ecosystem.<sup>498</sup>*

The Environmental Code does not explicitly refer to innovation, but, as already mentioned, like the Electromagnetic pollution law, it gives the Ministry of the Environment the power to promote research aimed at minimizing damage to the environment.

### **Innovation principle**

No separate formulation of the principle of innovation was found in current Italian legislation.

In the 2018 program report "The participation of Italy in the European Union" drafted by the Department of Community Policies of the Presidency of the Council of Ministers, as in that of the previous year, there was talk of implementing the principle of innovation, in relation to legislative production, "as a factor to be taken into account in examining the proposals for regulation and in reviewing the existing legislation, in order to define a "future-proof" regulatory framework that promotes research and development by facilitating the relaunch of investments without reducing the level of protection of public and private interests".

The reference is instead absent in the 2019 report (drafted by the new government).

### **6.2.2. Case law**

Multiple judgments of courts of various levels have referred to the precautionary principle, even before it was explicitly defined in Italian legislation. As Stanzione states, "administrative jurisprudence on the subject of precaution is very consistent, especially in areas such as electromagnetic pollution and food security, and appeals concern indiscriminately state, regional and municipal measures."<sup>499</sup>

These judgments, as mentioned above, concerned different issues, even beyond the provisions of national laws in the matters pertaining to the judgments themselves, and in many cases have raised the levels of health and environmental protection required by the current law. Some examples illustrate the variety of topics in which the precautionary principle is applied.

**Concentration of pollutants in groundwater.** The Administrative Court of Trentino before the appeal of E.R.G. Petroli SpA against the provision of the Provincial Health Services Company with sentence dated 8 July 2010 no. 171 stated that the non-inclusion of methyl tert-butyl ether (MTBE) in the table attached to the Environmental Code (2006) does not represent per se an element that precludes the assertion of its dangerousness. The contested provision had prescribed to follow, for the preparation of the characterization

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498 Patrizi E., *Il principio di precauzione nella società del rischio*, Doctoral thesis, 2014.

499 Stanzione M.G., 'Principio di precauzione, tutela della salute e responsabilità della P.A. Profili di diritto comparato', in *Comparazione diritto civile*, 2016, [comparazionedirittocivile.it](http://comparazionedirittocivile.it), last accessed: July 27, 2019.

plan, as regards the substance MTBE (methyl tert-butyl ether), the V.C.G. (guide concentration value) for groundwater, 10 micrograms / litre.<sup>500</sup>

**Solar showers.** The Regional Administrative Court for Piedmont (Section II) before the appeal of a company against an order of the Mayor with which it had been warned against using two solar showers, as they cannot be classified in the so-called type 2 <>; on 14 December 2011, pronounced sentence no. 14/2012 with which the same company was ordered to carry out a series of requirements better specified in the order in which it was noted that the maximum irradiance limit of 0.3 w / sq. m. allowed by the "CEI EN 60335 - 2-27 ".<sup>501</sup>

**Arsenic pollution in drinking water.** The Regional Administrative Court for Lazio, Section II Bis, sentence no. 664 of 20 January 2012, dealt with the delay of the Italian State in transposing the European directive on the thresholds for the presence of arsenic in drinking water.<sup>502</sup>

*1. The behaviour of the State Administration, which has delayed in fulfilling a Community Decision that limited the use of water contaminated with arsenic, constitutes an illegal conduct, resulting in a violation of the principles of good performance and impartiality, economy, effectiveness, advertising and transparency.*

*2. From this unlawful conduct comes the responsibility, justified by the precautionary principle, of the Administration to compensate for non-pecuniary damage, consisting in the probability of real damage to health.*<sup>503</sup>

**Toxic food additives.** The Court of Cassation with the sentence of 10 July 2014 no. 15824, concerning the supply to the company Saclà, by a supplier company, of a large quantity of red pepper revealed to have been altered by a carcinogenic dye, overturned the traditional hermeneutic setting of similar cases, affirming the duty of a buyer company of a defective good to analyse specific risk factors of the transferring company in order to obtain full compensation for the damage suffered.<sup>504</sup>

In the Italian case Saclà, Cass. 10 July 2014, n. 15824, the importance of the precautionary logic in the agri-food sector is stressed "which translates into reasons of general expectation of social security, as well as self-control obligations for individual companies, into controls by the subjects that interact with these companies along the supply chain" (Lucifero, 2017, quoted in Guerra, 2017).<sup>505</sup>

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500 Quagliariella D.B. Principio di precauzione: alcune applicazioni, [www.quagliariella.com](http://www.quagliariella.com), 2012, (last accessed: July 27, 2019).

501 Quagliariella D.B. Principio di precauzione: alcune applicazioni, [www.quagliariella.com](http://www.quagliariella.com), 2012, (last accessed: July 27, 2019).

502 Quagliariella D.B. Principio di precauzione: alcune applicazioni, [www.quagliariella.com](http://www.quagliariella.com), 2012, (last accessed: July 27, 2019).

503 Benedetti A.P., 'Superamento dei limiti di arsenico negli acquedotti comunali e violazione del principio di precauzione: responsabilità da fatto illecito o sanzione di una condotta negligente dell'amministrazione?', in *Nel diritto*, Marzo 2012 - n. 3 [www.neldiritto.it](http://www.neldiritto.it) (last accessed: July 27, 2019).

504 Vaccaro G., Il principio di precauzione e la responsabilità delle imprese nella filiera alimentare, *rivista di diritto alimentare*, Anno IX, numero 4, Ottobre-Dicembre 2015, [www.rivistadirittoalimentare.it](http://www.rivistadirittoalimentare.it), (last accessed: July 27, 2019).

505 Lucifero N., 'La responsabilità per le informazioni al consumatore di alimenti tra regole di validità, regole di comportamento e doveri informativi', in *Contratto e impresa*, 2017, 2 and Guerra G. Alimenti, tecnologie e obblighi di etichettatura. Riflessioni comparatistiche sulla convergenza legislativa tra Europa e U.S.A., [www.comparazionediritto.civile.it](http://www.comparazionediritto.civile.it), 4/2017.

**Genetically modified organisms** (this topic will be dealt with in para. 7.3.3).

In some cases, the courts have ruled to counter too extensive (or, according to some authors, imaginative) conceptions of the precautionary principle.

**Environmental impact assessment of a gas pipeline.** The Regional Administrative Court (TAR) of Lazio, section III, 17 February 2016, no. 2107 rejected the appeal brought by an Apulian municipality against an environmental impact assessment that had authorized the construction of a gas pipeline aimed at transporting transboundary natural gas from Azerbaijan to Italy (with landfall in Puglia) and Western Europe. In this ruling the judges of the first instance ruled that the precautionary principle cannot become "a canon of interpretation of industry legislation" with the effect of subjecting the construction of the plant to much more severe prescriptions than those provided for by the law even though there is no scientific uncertainty about the risks associated with a specific activity (in this case, the construction of the pipeline); in fact, the Lazio TAR specifies, it is only "the lack of scientific certainties due to insufficient information and scientific knowledge concerning the extent of the potential negative effects of an organism or a substance that requires the adoption of appropriate measures in order to avoid or limit potentially negative effects".<sup>506</sup>

As stated, the precautionary principle, although not explicitly mentioned in the Italian Constitution, protects universal values and rights expressed in it. Whether or not this reference makes the precaution mandatory for the legislator is a matter of discussion.<sup>507</sup>

*However, the constitutional provision does not seem to oblige the legislator to take precautions against these values. However, it allows an early protection (model of the allowed precaution). So, if the legislator directly adopts precautionary measures or delegates the administration to the exercise of precautionary powers for human dignity / health or for the environment, he would do so legitimately. The absence of the constitutional obligation of the precautionary attitude, however, prevents from sanctioning the constitutional illegitimacy of a discipline of primary rank that omits the precautionary attitude for health or the environment (except for unreasonable profiles). This absence, combined with the principle of legality, also prevents the administration from deciding according to precaution if not expressly provided for by the legislator: if there is a 'precautionary permit' for the legislator and he does not exercise the relative power, deeming the precautionary approach unsuitable, the administration cannot replace the legislator. Therefore in our Constitution the precaution for health or the environment (axiological dimension) depends on a decision by the legislator (subjective dimension), in the sense that the legislator decides whether to resort to it and whether to subject the administration to it - a model of the precaution allowed. (...)*

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506 Allena M., 'Il principio di precauzione: tutela anticipata v. legalità-prevedibilità dell'azione amministrativa', in *Il diritto nell'economia*, vol. 29, n. 90 (2-2016), issn 1123-3036.

507 Gagnani A., 'Il principio di precauzione come modello di tutela dell'ambiente, dell'uomo, delle generazioni future', in *Riv. dir. civ.*, 2003 and Follieri F., Decisioni precauzionali e stato di diritto. La prospettiva della sicurezza alimentare (Parte I), in *Rivista italiana di diritto pubblico comunitario*, AnnoXXXVIFasc.N6N-N2016, ISSN1121-404X, 2016, p. 20.

*In matters falling within the jurisdiction of the internal system (...) the precaution is permitted for the legislator who has made it mandatory for administration by referring to the principles of the EU system as criteria of administrative activity (Art. 1, c. 1, law 241/1990) - obviously discretionary - within the limits of the powers attributed to the administration by the law.<sup>508</sup>*

Other authors note that the formulation of the principle by the Italian legislator (referred to more than defined) gives rise to wide margins of discretion in the implementation of the same principle in administrative law.<sup>509</sup>

It emerges from the above a dialectical relationship between legislator and administrators regarding the adoption of precautionary measures in the field of environment, technologies, health and food safety, all areas that are in continuous evolution, as well as the scientific knowledge that concerns them. In the Italian legal and administrative system, characterized by high complexity, there are therefore conflicts of competences and interpretations between the various levels of the administration (e.g. state and regions), which have given rise to numerous causes and subsequent pronouncements of the Constitutional Court aimed at restoring the balance between the different principles that are the basis of Italian law (e.g. protection of health and the environment, legality, freedom of economic initiative) and balancing interests in the field.

The Constitutional Court therefore ruled on precautionary measures for the environment and health that had as their object psychiatric therapies considered harmful to health, emissions of dangerous and polluting substances, electromagnetic pollution, animal vaccination, coexistence between GMOs and traditional crops, mandatory vaccinations (see para 6.3.4.). In most cases, the Constitutional Court has rejected regional regulations that are in contrast with national legislation. Exceptions are two judgments relating to GMOs in 2005 and 2006. The first rejected the state's request to declare two regional laws of Puglia and Marche that opposed the cultivation of GMOs unconstitutional, the second, at the request of the Marche region itself against the state has declared unconstitutional parts of legislative decree no. 279 of 2004, adopted to implement Commission Recommendation 2003/566 / EC.

### **6.2.3. Precautionary principle mechanisms incorporated in Italian policy making**

As far as agriculture and food are concerned, Italian politics seems mostly inspired by an extremely precautionary approach with respect to potential risks to health, the environment and the biodiversity of plant and animal species typical of the Italian territory.

Perhaps the clearest example is the Italian approach to GMOs, considered a threat to native species, notoriously more restrictive than that of the EU. Italy, as a member of the EU, has implemented EU directives and regulations, so it cannot restrict the import of GMO products authorized at the European level, nor prohibit their cultivation except for scientifically supported reasons. The penetration of GM crops, however, was strongly opposed by the agriculture ministers of the various Italian governments who succeeded one another between 2000 and 2004, regardless of their opposing political alignment. In

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508 Follieri F., *Decisioni precauzionali e stato di diritto. La prospettiva della sicurezza alimentare (Parte I)*, in *Rivista italiana di diritto pubblico comunitario*, AnnoXXXVIFasc.N6N-N2016, ISSN1121-404X, 2016.

509 Stanzone M.G., 'Principio di precauzione, tutela della salute e responsabilità della P.A. Profili di diritto comparato', in *Comparazione diritto civile*, 2016, [comparazionedirittocivile.it](http://comparazionedirittocivile.it), last accessed: July 27, 2019.

subsequent years, although implementing directives and regulations, Italian politics has maintained its opposite position, which is shared by a wide and heterogeneous group of stakeholders.

The case of the Friulan farmer Giorgio Fidenato, the protagonist of a long legal dispute that ended recently, concerning the cultivation of genetically modified maize species authorized by the EU but not by Italian law is significant in this respect. In 2014 Fidenato had carried out GMO maize seeding in his fields in three locations in Friuli, but in addition to being targeted for sabotage and physical assault by activists opposed to GMOs, he had been the subject of measures by the regional court of Friuli Venezia Giulia for violation of the regional law of 5/2014. This law prohibited the cultivation of GMO varieties pending the definition by the EU of a standard on the coexistence between traditional and GMO varieties. For this reason, the authority had intervened by destroying Fidenato's crops and the Regional Administrative Court had rejected the farmer's appeal. Following the ruling of the European Court of Justice in 2017, in 2019 the State Council declared the regional law illegitimate and, consequently, the subsequent sentences, sentencing the Region to compensate the farmer.

There are also areas in which applying the precautionary principle by balancing the interests in the field has proved particularly difficult, as in the case of the ILVA of Taranto, an important Italian iron and steel hub that is the subject of an ongoing complex political and judicial affair, which has involved Italian and European institutions and courts (Court of Assizes of Taranto, Court of Milan, Regional Administrative Court of Lazio, Constitutional Court, EU Court of Justice in Luxembourg and Court of Human Rights of Strasbourg) in trying to balance the right to a healthy environment for citizens and workers, already severely compromised, and the economic interest of the country and the entrepreneurs involved.<sup>510</sup>

Analysing two sentences of the Constitutional Court that recalled the precautionary principle in the hypotheses of balancing constitutional interests, Di Cosimo<sup>511</sup>, taken up by Bertuzzi and Tedaldi<sup>512</sup> compares the differences between the strategies adopted by the Court with regard to GMOs and the ILVA of Taranto.

In the first decision, the Court, called to rule on the constitutional legitimacy of Legislative decree no. 279/2004 ("Urgent provisions to ensure the coexistence between the forms of transgenic, conventional and biological agriculture"), underlines how the question of the regulation of transgenic crops involves and requires a synthesis between divergent interests of constitutional relevance: the freedom of economic initiative of the agricultural entrepreneur, on the one hand, the need for this freedom not to be exercised in contrast to social utility, and in particular by causing disproportionate damage to the environment and health, on the other. It is precisely in the context of the elaboration and conciliation of these guidelines, an operation that falls under the law of the State and cannot be derogated from regional legislation, that the precautionary principle plays an important role. It can in fact intervene "in the interest of the environment and human health", in order to constitutionally justify the imposition of limits on the exercise of freedom of economic initiative. The precautionary principle, therefore, does not constitute a new and autonomous term in the balancing performed by the Constitutional Court, representing, on

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510 For a synthetic reconstruction of the complex history of the ILVA steelworks in Taranto, see "The ILVA case: a brief history of the judicial story. Article", taken from the magazine *Ambiente e Sviluppo*, Ipsoa, dated 14/06/2018 <https://www.altalex.com/documents/biblioteca/2018/06/13/caso-ilva-estratto-rivista> (last accessed: July 28 2019).

511 Di Cosimo, Corte costituzionale, bilanciamento di interessi e principio di precauzione, in *Forum costituzionale*, [www.forumcostituzionale.it](http://www.forumcostituzionale.it), 2015 (last accessed: July 27, 2019).

512 Bertuzzi R., Tedaldi A. Il principio di precauzione in materia ambientale. Tentativi di definizione a partire dal livello sovranazionale e dagli esempi italiano e francese, in *Lex ambiente, Rivista giuridica a cura di Luca Ramacci*, [www.lexambiente.it](http://www.lexambiente.it), 2017 (last accessed: July 27, 2019).

the contrary, the tipping point that causes one of the interests under examination (the protection of the environment and health) to prevail over the other (freedom of economic initiative).

The role played by precaution in the well-known case of Ilva of Taranto is more complex. The Constitutional Court was asked to rule on the legitimacy of some provisions of legislative decree no. 207/2012, a text adopted urgently to allow the continuation of the activities of the industrial plant. Also, in this case, as in the previous one, the precautionary principle plays an arbitrator role, defining which of the interests at stake (production and right to economic freedom, on the one hand, the right to health and the environment, on the other) should prevail. Unlike the GMO affair, however, this balance is not already implemented by the legislator, who, instead, has delegated it to the adoption of the Integrated Environmental Authorization (so-called AIA). The Court emphasizes, in fact, that, from the point of view of the legislator, the procedure that culminates in the release of the AIA represents, for its characteristics of participation and publicity and as a "result of multiple, technical and administrative contributions", the best tool in identifying the balance point with regard to the acceptability and management of the risks deriving from an industrial activity. And it is precisely within this procedure that the precautionary principle is inserted.

The Integrated Environmental Authorization will then be able to be "challenged before the competent judge, in the case of defects of legitimacy of the act by citizens who consider themselves injured in their legitimate rights and interests" due, for example, to an excess of power in the application of the precautionary principle.<sup>513</sup>

Several authors, analysing the political decisions and the sentences of the Constitutional Court, highlight the risk that, in the absence of sufficient scientific evidence (recurrent condition in cases where the precautionary principle is invoked), or when there are particularly difficult conflicts between opposing interests to be protected, the decision regarding the acceptable degree of risk for a given community with respect to potential harmful events, necessarily political in nature, is delegated to the technical-scientific level.<sup>514</sup>

Summarising, the precautionary principle is being applied to different subjects, not only in environmental law, but also in health, agri-food law and pharmaceutical law.

The precautionary attitude in political decisions has often been adduced as an inspiring principle by opposing parties that were opposed in cases between public bodies of different levels, or between citizens and administrations. Often, however, especially in the last decade, the debate on the precautionary principle applied to urgent questions of a health or environmental nature has been the place where conflicts of another nature have flared up (between state administrations at different levels, between magistracy and

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513 Bertuzzi R., Tedaldi A. Il principio di precauzione in materia ambientale. Tentativi di definizione a partire dal livello sovranazionale e dagli esempi italiano e francese, in *Lex ambiente, Rivista giuridica a cura di Luca Ramacci*, [www.lexambiente.it](http://www.lexambiente.it), 2017 (last accessed: July 27, 2019).

514 Di Cosimo, Corte costituzionale, bilanciamento di interessi e principio di precauzione, in *Forum costituzionale*, [www.forumcostituzionale.it](http://www.forumcostituzionale.it), 2015 (last accessed: July 27, 2019); Follieri F., Decisioni precauzionali e stato di diritto. La prospettiva della sicurezza alimentare (Parte I), in *Rivista italiana di diritto pubblico comunitario*, AnnoNXXVIN Fasc.N6N-N2016, ISSN1121-404X, 2016; Allena M., 'Il principio di precauzione: tutela anticipata v. legalità-prevedibilità dell'azione amministrativa', in *Il diritto nell'economia*, vol. 29, n. 90 (2-2016), issn 1123-3036. Marchese, 2015 Il PRINCIPIO DI PRECAUZIONE TRA LUCI ED OMBRE, in *Comparazione diritto civile*, [www.comparazionediritto.it](http://www.comparazionediritto.it), Last accessed: July 27, 2019; Scialò A. 'Il principio di precauzione: da principio cardine delle politiche ambientali ad alibi delle Amministrazioni per affidare alla supponenza giudiziaria decisioni "impopolari"', in *Diritto e giurisprudenza agraria alimentare e dell'ambiente*, 2/2016.

administration; between civil society and state organizations, etc.) linked to the way of understanding local autonomies; the relationships between the different powers; the predominance of the common good over that of individuals and, more generally, the relationship between state and citizens.

In recent times, the precautionary principle has also been invoked by adopting points of view of extreme mistrust towards the scientific community, or at least of the scientific authorities called into question in support of the provisions of the law, as in the case of the controversy over mandatory vaccinations which was the centre of attention especially in 2017, on the occasion of a stricter state policy in this sector undertaken by the then Minister Lorenzin, operationalized by law 31 July 2017 no. 119. The obligation for the population from 0 to 16 years of age of 10 vaccinations (compared to the four previously prescribed) had been adopted to counteract the decrease in the vaccination coverage of the population, detected above all in some Italian regions.

Several public and private stakeholders have moved against the law (first of all, the Veneto region), requesting opinions from the Council of State.

The applicants, inter alia, have appealed to the precautionary principle. The Council of State disputed the interpretation of the principle they provided.

The position taken by the Council of State undoubtedly adheres to the theory that refuses to see the precautionary principle as a useful tool for the total elimination of risk (so-called zero risk), which, moreover, would prevent any technological progress and of medical science.

In particular, it is reiterated that the precautionary principle does not necessarily imply the adoption of choices with "zero risk", but induces to prefer a median solution that, in other words, makes possible the balance between the minimization of risks and the maximization of advantages.

And again, the precautionary principle has no anti-scientific bias, but it is the basis for the progress of science and medicine, otherwise rendered impossible by the logic of eliminating, at any cost, any risk factor.<sup>515</sup>

The law has also been accused of unconstitutionality in an appeal to the Constitutional Court, which once again recalls the precautionary principle. The Court rejected the appeal, reiterating that the principle itself is one of the prerequisites for state action in this area.

Faced with an unsatisfactory vaccination coverage in the present and prone to critical issues in the future, this Court considers that it falls within the discretion - and political responsibility - of the government bodies to appreciate the urgency to intervene, in the light of new data and as epidemiological phenomena emerged, also in the name of the precautionary principle that must preside over such a delicate area for the health of every citizen as is prevention.<sup>516</sup>

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515 Marino, 'Note su obbligo vaccinale e principio di precauzione. A proposito di un certo indirizzo del Consiglio di Stato', in *Ordines* ISSN 2421-0730 NUMERO 1 – GIUGNO 2018'.

516 Constitutional Court, Judgment of 18 January 2018 no. 5.

## 6.3. Implementation and application of the precautionary principle in Bulgaria

This section provides a short review on perceptions and implementation of the precautionary principle in Bulgaria. It gives an overview of the legal status and applications of the concept and it explores how it is used in policies, strategies and administrative practices.

### 6.3.1. The implementation and status of the precautionary principle in Bulgaria

Desk research results show that the precautionary principle has been addressed in the Bulgarian legislation to a certain extent. It has been incorporated in two national acts - the Waste Management Act<sup>517</sup> and the Genetically Modified Organisms Act.<sup>518</sup> There are two other laws – the Bulgarian Food Law and the Bulgarian Feed Law – that refer to the essence of the precautionary principle, however without directly mentioning the term. No precise definition of the principle has been accepted by Bulgarian legislation. Instead, the principle is generally referring to the concept presented in Art. 191 of the Treaty on the Functioning of the European Union.<sup>519</sup>

The Waste Management Act includes two provisions (Art. 6, par. 3 and Art. 49, par. 2) that address general environmental principles that should be taken into account when applying the Act. What Art. 6, par. 3 says is that when applying the waste management hierarchy, the competent authorities and persons whose operations involve the generation and/or treatment of waste shall take into account “*the general environmental protection principles of precaution and sustainability, technical feasibility and economic viability, protection of resources as well as the overall environmental, human health, economic and social impacts[...]*”. Art. 49, par. 2 addresses the same environmental protection principles, emphasizing that the Minister of Environment and Water shall take into account those principles in the development of the National Waste Management Plan and submit it for adoption to the Council of Ministers. An article (Penchev, G. (n.d.))<sup>520</sup> focused on the principles of the Bulgarian environmental law, argues that the two provisions mentioned above have some weaknesses. Among them is the claim that the explicitly stated principles must be clearly and precisely formulated in order to avoid difficulties in their interpretation and application. With regard to the precautionary principle, Penchev, G. (n.d.) states that in its essence it coincides with the precautionary principle under Art. 191, par. 2 of the Treaty on the Functioning of the European Union.<sup>521</sup>

The Genetically Modified Organisms Act of Bulgaria, in turn, also refers to the precautionary principle, providing a short statement of what it encompasses. The General dispositions of the Act define the principle as “[...] *priority protection of human health and the environment if any potential harmful effects are likely to occur, regardless of the existing economic interests or the unavailability of sufficient scientific data.*” (Art. 1, par. 2). It is emphasised that the GMO Act of Bulgaria aims to protect human health and the environment,

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517 Waste Management Act. Retrieved from: <https://www.me.government.bg/en/library/waste-management-act-342-c25-m258-1.html>.

518 Genetically Modified Organisms Act. Retrieved from: [http://plantbiotech.bg/wp-content/uploads/2017/02/GMO\\_en\\_26\\_07\\_2016.pdf](http://plantbiotech.bg/wp-content/uploads/2017/02/GMO_en_26_07_2016.pdf).

519 Consolidated version of the Treaty on the Functioning of the European Union (2012). Retrieved from: [https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC\\_2&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC_2&format=PDF).

520 Penchev, G. (n.d.). Particular principles of the Environmental Law of the Republic of Bulgaria. (In Bulgarian: Пенчев, Г. (n.d.). Специалните принципи на екологичното право на Република България) Retrieved from: <http://web.uni-plovdiv.bg/paunov/Stidia%20Iuris/broi%202%20-%202016/Georgi%20Penchev.pdf>.

521 Consolidated version of the Treaty on the Functioning of the European Union (2012). Retrieved from: [https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC\\_2&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC_2&format=PDF).

considering the precautionary principle when carrying out activities associated with use, release, placing on the market, transfer, import, export, and transit of GMOs.

Other legal documents that touch upon the concept of the precautionary principle are the Bulgarian Food Law and the Bulgarian Feed Law. Although the two laws do not directly mention the particular principle, they talk about temporary precaution measures that shall be applied when the assessment of the available information indicates a possibility of adverse health effects, but there is no reliable scientific evidence of their occurrence.

A study of the application of the precautionary principle in scientific and ecological policy in Bulgaria identifies a few more examples from the Bulgarian eco-legislation that take into consideration the precautionary principle. The author of the study mentions the Environmental Protection Act which explicitly states that environmental protection shall be based on particular principles among which is the principle of "priority of pollution prevention over subsequent elimination of pollution damage". A number of provisions in sectoral laws such as the Law on Biological Diversity, the Water Act and the Clean Air Act are also given as examples of precautionary principle application areas. At statutory level, the precautionary principle is found to be implemented in the Environmental Impact Assessment of the Ministry of Environment and Water.<sup>522</sup>

The National Environmental Strategy 2009 - 2018 is another legislative document discussed in the study mentioned above that is claimed to provide key points regarding the application of the precautionary principle. It calls for avoiding activities that according to the precautionary principle pose a potential threat to the environment and human health. It further states that the principle is applied through an environmental impact assessment and the use of the most advanced available technologies. The lack of reliable scientific data is considered not to be a reason for not taking measures to prevent environmental degradation in case of potential or existing impacts on it.<sup>523</sup>

### 6.3.2. Case law

The precautionary principle has been taken into account when issuing court decisions in Bulgaria in contexts such as waste management and environment protection (fuel quality, air quality, destruction of plant and animal species habitats). Applying the precautionary principle enables environmental control authorities to act at an earlier stage, ahead of the existence of firm scientific evidence of harm, and to prevent them from occurring. Administrative courts in different cities in Bulgaria have addressed the precautionary principle (referring to Art. 191, par. 2 of the Treaty of the Functioning of the European Union) when making decisions about issues that are expected to have impact on the environment or on people's health. All court decisions consider the condition that "[...] *harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons*[...]"

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522 Ivancheva, L. 'The precautionary principle in scientific and environmental policy and its application in Bulgaria'. (In Bulgarian: Иванчева, Л. (2014). Принципът на предпазливостта в научната и екологична политика и приложението му в България. In Екологическа етика, природа и устойчиво развитие на България), 2014.

523 Ibid.

### 6.3.3. Precautionary principle mechanisms incorporated in Bulgarian policy making

#### The precautionary principle and the shale gas extraction

The precautionary principle has been addressed in the debates (both public and in the Bulgarian Parliament) addressing the topic of shale gas extraction in Bulgaria that started in 2011. By 2012, the debate was defined by two main issues – one related to economic and political concerns (considering shale gas as an opportunity to break dependency on Russian natural gas supply), and the other being mostly environmental (questioning the impact of the technologies used to extract the gas from underground shales).<sup>524</sup> As a result, highly effective campaigns were organised by environmentalists, expressing local communities concerns that the specific technology used in the process of shale gas extraction (known as “fracking”) was harmful to the land areas where it was applied which in turn was believed to have long-term negative effect on the environment as well as on the human health. The lack of information about the benefits and potential risks of shale gas production has given impetus to the campaigns.<sup>525</sup>

The widely expressed public concerns made the Government introduce the issue of shale gas extraction in the parliamentary agenda in late 2011. One of the key criticisms that emerged in result of the Parliamentary debate on the shale gas issue had to do with the lack of public awareness about what shale gas is and how it is being extracted. The responsible ministries were criticised for negotiating with a foreign corporation without studying the possible impact on the environment and on human health. It was also argued that the negotiating Ministry had not taken into account the availability of international studies proving the hydraulic fracturing technology as dangerous and harmful.<sup>526</sup>

In 2011, the Institute of Biodiversity and Ecosystem Research at the Bulgarian Academy of Sciences came out with a conclusion regarding risk assessment of shale gas exploration and extraction, stating that taking into account the available scientific information, the environmental risk of applying the hydraulic fracturing technology for research and exploitation of shale gas fields cannot be assessed as negligible or permissible in all possible cases. The assessment further claims that in case of adverse impacts resulting from the contamination of deep aquifers, the possibilities for taking counter-measures would be very limited and poorly effective.<sup>527</sup>

The sustained pressure from environmental groups and political scene actors combined with the growing public opposition resulted in the adoption of the decision to ban shale gas extraction through the method of hydraulic fracturing on the territory of the Republic of Bulgaria. The complete ban was introduced in January 2012 by the Bulgarian Parliament. It was adopted on the grounds of particular articles of the Constitution of the Republic of Bulgaria and the Rules of Organisation and Activities of the National Assembly and based on the precautionary principle regarding the protection of human health and the environment.<sup>528</sup> Fracking has been claimed to be a highly risky activity that influences

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524 PACITA Case Study.

525 PACITA Case Study; Dąborowski, T. and Groszkowski, J., Shale gas in Bulgaria, the Czech Republic and Romania, 2012 Retrieved from: [http://aei.pitt.edu/58010/1/shale\\_gas\\_in\\_bulgaria\\_the\\_czech\\_republic\\_and\\_romania\\_net\\_0.pdf](http://aei.pitt.edu/58010/1/shale_gas_in_bulgaria_the_czech_republic_and_romania_net_0.pdf).

526 PACITA Case Study.

527 Opinion of the Institute of Biodiversity and Ecosystem Research at the Bulgarian Academy of Sciences (In Bulgarian: Становище на Института по биоразнообразие и екосистемни изследвания при БАН (2011)) Retrieved from: [http://www.iber.bas.bg/sites/default/files/Stanovishte\\_IBER\\_shistov\\_gaz.pdf](http://www.iber.bas.bg/sites/default/files/Stanovishte_IBER_shistov_gaz.pdf)

528 Dąborowski, T. and Groszkowski, J. Shale gas in Bulgaria, the Czech Republic and Romania, 2012, Retrieved from: [http://aei.pitt.edu/58010/1/shale\\_gas\\_in\\_bulgaria\\_the\\_czech\\_republic\\_and\\_romania\\_net\\_0.pdf](http://aei.pitt.edu/58010/1/shale_gas_in_bulgaria_the_czech_republic_and_romania_net_0.pdf); National Assembly (2012). Decision to ban the application of the hydraulic fracturing technology for exploration and/or extraction of gas and oil on the territory of the Republic of Bulgaria. (In Bulgarian:

human health and the environment and thus an activity that is contrary to the obligations of the Treaty for the Functioning of the EU, including Art. 191 and the precautionary principle.<sup>529</sup>

### ***The precautionary principle and its relation to neonicotinoids and bee population***

Another topic of debate in Europe (and respectively in Bulgaria) in the recent years has been the declining bee population and its link with the increased use of pesticides. A number of scientific studies in this field have shown contradictory opinions, supporting and opposing the role of pesticides for reducing the bee population. The lack of solid and conclusive scientific evidence on the issue, made the European Commission request from the European Food Safety Agency (EFSA) to provide a risk assessment analysis of the impact of neonicotinoids on bees. Since the results of the analysis showed a high acute risk for bees from certain crops that have been treated with the pesticides in hand, the EC, taking into account the precautionary principle, has proposed to introduce measures to restrict the use of neonicotinoids. At the end of 2013, the EC introduced a partial ban on the use of three of the most popular neonicotinoid products.<sup>530</sup> However, the Regulation provided for an exception of the rule (derogation) if strictly supervised by the local authorities. In Bulgaria, the derogation of the ban on neonicotinoids was applied in the period 2014 – 2016.<sup>531</sup>

In 2017, Greenpeace Ecological Organization in Bulgaria called upon the Ministry of Agriculture, Food and Forestry (MAFF) and the Bulgarian Food Safety Agency (BFSA) to ban the use of neonicotinoids in the country and not to apply the derogation. The organisation was concerned that despite the prevailing scientific data on the harm that neonicotinoids pose, the BFSA considers to allow their use. In a letter to the MAFF and the BFSA, Greenpeace Bulgaria referred to the EU's precautionary principle approach, arguing that it was important Bulgaria to apply the respective principle to the use of neonicotinoids and to take measures to avoid health hazards of bees and ecosystems as well as of humans.<sup>532</sup>

In the beginning of 2018, the EFSA presented results of its updated risk assessment analysis of the three neonicotinoids showing that they represent a risk to wild bees and honeybees. Considering the conclusions of the analysis, the EC introduced amendments to

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Народно събрание (2012). Решение за забрана върху прилагането на технологията хидравлично разбиване при проучване и/или добив на газ и нефт на територията на Република България) Retrieved from: <http://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=60677>.

529 Declaration on Shale Gas, Bituminous Shale Oil, Coal Gas and Hydraulic Fracking (2012). (In Bulgarian: Декларация относно шистовия газ, нефта от битуминозни шисти, газа от въглищни пластове (CBM) и хидравличното разбиване (фракинг) (2012)) Retrieved from: [http://www.foodandwatereurope.org/wp-content/uploads/2012/04/FoodandWaterEuropeBulgarianNGOs\\_joint\\_statement\\_against\\_shale\\_gas\\_BG.pdf](http://www.foodandwatereurope.org/wp-content/uploads/2012/04/FoodandWaterEuropeBulgarianNGOs_joint_statement_against_shale_gas_BG.pdf).

530 Vogoeva, I., Dimitrova, R., Stefcheva, M. and Velichkov, A., Opinion on the issue neonicotinoids-bees, 2013. (In Bulgarian: Боевеева, И., Димитрова, Р., Стефчева, М. и Величков, А. (2013). Становище по проблема неоникотиноиди-пчели) Retrieved from: [http://bah.government.bg/uploads/File/COR\\_Aktualno/040613/Stanovishte-Pcheli-Neonikotinoidi.pdf](http://bah.government.bg/uploads/File/COR_Aktualno/040613/Stanovishte-Pcheli-Neonikotinoidi.pdf).

531 Radoslavova, S., An enemy in the hive, 2017. (In Bulgarian: Радославова, С. (2017). Врар в кошера) Retrieved from: [https://www.capital.bg/biznes/kompanii/2017/03/10/2931951\\_vrag\\_v\\_koshera/](https://www.capital.bg/biznes/kompanii/2017/03/10/2931951_vrag_v_koshera/).

532 Greenpeace Bulgaria, Greenpeace - Bulgaria urged the Ministry of Agriculture and Food and the Bulgarian Food Safety Agency not to allow the use of neonicotinoids in Bulgaria in 2017, 2017 (In Bulgarian: Greenpeace Bulgaria (2017). „Грийнпийс“ – България призова Министерството на земеделието и храните и Българската агенция по безопасност на храните да не разрешават използването на неоникотиноиди у нас през 2017 година) Retrieved from: <http://www.greenpeace.org/bulgaria/bg/novini/2017/pismo-zabrana-neonikotinoidi/>.

the current restrictions on the use of these pesticides and announced to completely ban their use by 2019.<sup>533</sup>

### ***The precautionary principle and the GMO***

Bulgaria is claimed to be among the countries with the richest biodiversity in Europe, with the cleanest environment and traditions in growing oilseed rose, tobacco, fruit trees and vegetables. The country is also famous for the production of Bulgarian yoghurt, sheep cheese and nutritious honey. All these give opportunities for developing the bio-products sector in the country. This, in turn, calls for the Bulgarian government to pursue a highly responsible policy in this area.<sup>534</sup>

Considering the GMO as a threat in this regard, Toshev advocates for the precautionary principle to be strictly applied when working with GMOs in order to prevent the releasing of such organisms into the environment. The author of the article has been among the activists in promoting the ban of growing GMOs not only in Bulgaria but also in Europe. He has submitted recommendations on the right of countries in Europe not to grow GMOs and these recommendations have been considered in the adoption of a GMO resolution by the Parliamentary Assembly of the Council of Europe (PACE). On national level, in 2000 the author submitted a draft moratorium on the cultivation of GMOs in Bulgaria. The moratorium has been withdrawn in favour of the adoption of the GMO Act in 2005.<sup>535</sup>

In 2009 the government of Bulgaria submitted a proposal for changes to the GMO Act, aiming at liberalising the regime for GMO cultivation for agricultural purposes. However, in result of wide public debates and strong public opposition to the release of GMOs into the environment, in 2010 the National Assembly of Bulgaria adopted a decision on a five-year moratorium on changes to the GMO Act.<sup>536</sup>

Despite the five-year moratorium, the anti-GMO coalition in Bulgaria insisted on the adoption of a new and quality law, compatible with EU regulations and much more respective and effective than the one introduced in 2005. They advocated for developing and adopting a law that allows public participation and restricts the intervention of administration authorities to decision-making. Also, a law that ensures control and observance of the precautionary principle under the Cartagena Protocol (to note, in 2000 the Bulgarian National Assembly became the first in the world to ratify the Cartagena Protocol on Biosafety to the Convention on Biological Diversity). The anti-GMO coalition proposed the promotion of bio-production as an alternative to industrial GMO-farming, aiming at both creating opportunities for competitive agriculture and preserving the Bulgarian nature.<sup>537</sup>

To conclude, the precautionary principle is becoming increasingly widespread in international and national level legislation as well as in environmental regulatory

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533 EFSA, Neonicotinoids: risks to bees confirmed. Retrieved from: <https://www.efsa.europa.eu/en/press/news/180228>, 2018.

534 Ivancheva, L., The precautionary principle in scientific and environmental policy and its application in Bulgaria, 2014. (In Bulgarian: Иванчева, Л. (2014). Принципът на предпазливостта в научната и екологична политика и приложението му в България. In Екологическа етика, природа и устойчиво развитие на България).

535 Toshev, L., . The precautionary principle and the GMO issue, 2013. (In Bulgarian: Тошев, Л. (2013). Проблемът ГМО и принципът на предпазливостта. Лечител, № 14).

536 Ivancheva, L., The precautionary principle in scientific and environmental policy and its application in Bulgaria, 2014. (In Bulgarian: Иванчева, Л. (2014). Принципът на предпазливостта в научната и екологична политика и приложението му в България. In Екологическа етика, природа и устойчиво развитие на България)

537 Ibid.

mechanisms, providing an adequate framework for the prevention of potential environmental risks.<sup>538</sup>

Finally, desk research results did not show the existence of any opposing to the precautionary principle narratives (as an innovation principle) or any counterarguments in the Bulgarian context.

## 6.4. Implementation and application of the precautionary principle in the Netherlands

### 6.4.1. The implementation and status of the precautionary principle in the Netherlands

This section provides a short review on perceptions and implementation of the precautionary principle in the Netherlands. It gives an overview of the legal status and applications of the concept and it explores how it is used in policies, strategies and administrative practices.

#### The emergence of the precautionary principle in Dutch law

After the Second World War the risk governance in the Netherlands was characterized by standard setting and standard testing (*normstelling en normtoetsing*).<sup>539</sup> The starting point of policy was guaranteeing legal certainty for companies and an equal minimum level of protection for all citizens through scientifically underpinned certainty. However, the defects of a governance that only focusses on (quantitative) certainty, increasingly became recognized by policy makers, partly due to the emergence of the complex and uncertain risks in relation to environmental degradation.

The role of legal principles in relation to environmental law moreover gradually emerged from the 1970's in international laws, treaties and policies.<sup>540</sup> As a formal principle in (international) environmental law the precautionary principle first emerged in Germany, a neighbour of the Netherlands. The influence of the principle was consequently early noticed in the Netherlands due to, for example, the implementation of the principle in the context of nature reserves that touched the Dutch border.<sup>541</sup>

The integration of the precautionary principle, alongside other closely related environmental principles like the ALARA-principle,<sup>542</sup> the principle of prevention and the principle of sustainable growth, in the Dutch law was started with the so-called National Environmental Policy Plans (1989-2001). The first time the precautionary principle was mentioned in a Dutch policy document was the Third Policy Document on Water Management (1989).<sup>543</sup> Environmental principles were translated into the procedures and provisions of the main (environmental) legislation of the 1990's, such as the Environmental

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538 Ibid.

539 Gezondheidsraad, *Voorzorg met rede* (Den Haag, 2008), 61.

540 Douma W. Th., *The Precautionary Principle: Its Application in International, European and Dutch Law*, Groningen: s.n., 2003, 472 p. 55-186.

541 See for instance the First North Sea Conference in 1984.

542 ALARA is an acronym for As Low As is Reasonably Achievable. It is especially often employed in relation to reducing risks concerning radiation.

543 Douma (see above), *The Precautionary Principle*, p. 382.

Management Act (*Wet Milieubeheer: EMA*), Nature Protection Act (*Natuurbeschermingswet*) and the Flora and Fauna Act (*Flora- en Faunawet*).

Codification of the principles in the Dutch law however remained absent. This can partly be explained by the fact that the Dutch legal system is characterized by 'pragmatic realism', and that Dutch environmental law often relies on procedures and on a delegation of standard-setting (*gelede normstelling*). A codification of general normative principles has in this sense always been at odds with traditional Dutch legislative practices.<sup>544</sup>

Since the 1990's the need for codification of the principle in Dutch laws became however a reoccurring theme in policy documents.<sup>545</sup> In 2001 the Minister of Housing, Spatial Planning and the Environment sent a green paper (*discussienota*) to the Parliament about how the precautionary principle, among other environmental principles, could be codified in the Dutch law.<sup>546</sup> During the discussion in the parliament this proposal could count on significant support.<sup>547</sup>

In 2000 the precautionary principle was established as a general principle in European law in a directive of the European Commission.<sup>548</sup> This document encouraged national legislators and policy makers to harmonize their approach to precaution according to a common framework, though it did not contain a definition of the principle. In 2001 the National Environmental Policy Plan 4 (*Nationaal Milieubeleidsplan 4*) was published. This plan was meant to set environmental policy goals for the next thirty years. Precaution was posed as one of the guiding principles, partly as an extension to Article 174 of the EU Treaty. It was also mentioned in relation to health, radiation, GMO's, food safety and in the field of fisheries.<sup>549</sup>

The Ministry of Housing, Spatial Planning and the Environment gave the order to establish a research consortium to investigate ways to codify the principle.<sup>550</sup> A general conclusion of the report delivered by the consortium was that the principle should be codified in the Environmental Management Act and that it has to be applied primarily in relation to actions of the authorities under this act, but should also govern the action of citizens and companies. It was stated that codification in national law could contribute to an explanation of the national law in conformity with EU law, but that this was not deemed absolutely necessary.

In 2008 two government advisory bodies brought out and advice that also suggested the government to codify the principle in national laws. In 2004 the Cabinet had asked the Scientific Council for Government Policy of the Netherlands (*De Wetenschappelijke Raad voor het Regeringsbeleid: WRR*) for advice on issues about physical safety. The WRR requested to examine in particular how the responsibility of the society in this respect can be strengthened. The WRR noted that duty of the government to take care of the physical safety of its citizens is confronted with two problems today: the increasing complexity and lack of clarity of the regulatory systems and secondly, increasing uncertainties in relation

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544 Verschuuren, J., 'Naar een codificatie van beginselen in het milieurecht,' *Environmental Law*, 1995.

545 Douma, *The Precautionary Principle*, p. 381-390.

546 Kamerstukken II, 2000/01, 27664, nr. 2.

547 The Ministry of Housing, Spatial Planning and the Environment, 'Codificatie van milieurechtelijke beginselen in de wet milieubeheer', Onderzoek naar Toekomstige Regelgeving Algemene Milieubeginselen (TRAM) Onderzoeksreeks milieuwetgeving 2001/1.

548 COM(2000)1.

549 Douma, *The Precautionary Principle*, p. 392.

550 The Ministry of Housing, Spatial Planning and the Environment, 'Codificatie van milieurechtelijke beginselen in de wet milieubeheer', Onderzoek naar Toekomstige Regelgeving Algemene Milieubeginselen (TRAM) Onderzoeksreeks milieuwetgeving 2001/1.

to the knowledge about new technologies that is necessary for optimal risk assessment and prevention.<sup>551</sup> A new distribution of responsibility is thus needed, so argued the council.

To stress the (renewed) importance of the principle and the associated widening of responsibilities, the WRR argued that the principle should be included in both the Dutch constitution and The General Administrative Law Act (*Algemene wet bestuursrecht*). The Council also advised the government to add a formulation in the Civil Code (*Burgerlijk Wetboek*) to stimulate that, when establishing what reason and fairness demand in the domain of physical safety, it must be taken into consideration if a juridical person, given his position in society, has accounted for the vulnerability of man, society and the natural environment and the uncertainties (*onzekerheden*) that are at issue. The Health Council of the Netherlands (*Gezondheidsraad*) also published an advice in 2008 about what the precautionary principle encompasses, as well as a guide on how it can be applied in the domains of health care, working conditions, nutrition and environment.<sup>552</sup>

As a response to these two reports, the Cabinet wrote a letter to the Dutch parliament about its vision towards the implementation of the precautionary principle.<sup>553</sup> The Cabinet stated that it did not see additive value in anchoring the precautionary principle in a general law such as the Civil Code because the meaning of the principle requires a specific interpretation. The Cabinet stated that the notion of (physical) safety is too undefined and possible safety hazards cannot be established objectively. It would thus be better to formulate the obligations of citizens towards (physical) safety in various sector-specific laws.

In 2013 the Dutch Senate argued that there exists considerable differences in how risks that fall under the different domains of the Ministry of Infrastructure and Water Management are handled.<sup>554</sup> The Ministry of Infrastructure and Water Management has subsequently worked, from 2013 until 2018, on a more uniform and integral risk assessment framework that prescribes roles of municipalities, provinces, environmental services, safety regions, industry and knowledge institutes in this domain.<sup>555</sup> This framework seems to place the precautionary principle firmly at the forefront of Dutch risk governance and indicates a broadening of the responsibilities that are deemed necessary for precaution. We will analyse this framework in more detail in the section 'policy documents'.

## **Implementation and application of the precautionary principle in Dutch law**

Codification of the precautionary principle in the Dutch law has remained absent. It is not mentioned in the constitution, the main laws concerning the environment or acknowledged as a principle for reviewing laws.<sup>556</sup>

International and EU treaties and policy documents, like the Rio declaration, the EU treaty, the Communication Directive of the European Commission on the Precautionary Principle and verdicts of the European court of Justice have however provided a background against

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551 Wetenschappelijke Raad voor het Regeringsbeleid (WRR), *Onzekere veiligheid: Verantwoordelijkheden rond fysieke veiligheid* (Amsterdam, 2008).

552 Gezondheidsraad, *Voorzorg met rede* (Den Haag, 2008).

553 Ministerie Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer, Brief minister met een reactie op het advies van de WRR 'Onzekere veiligheid' en van de Gezondheidsraad 'Voorzorg met rede' (2009), 28089, nr. 23.

554 Handelingen I 2012/2013, nr. 33. Item 2, p. 2-15; behandeling Wet Basisnet in de EK op 2 juli 2013.

555 Ministerie van Infrastructuur en Waterstaat, *Bewust Omgaan met Veiligheid: Op weg naar een schone, gezonde en veilige leefomgeving – Eindrapportage* (Den Haag, 2018), 5.

556 Faure M., Vos E., (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*. Den Haag: Gezondheidsraad, 2003.

which the precautionary principle took shape in 'the application' of the Dutch law. In this sense the concrete use of the principle in the Dutch law has been characterized by a 'pragmatic' approach. Its significance has consequently been concretized in relation to specific topics<sup>557</sup> and/or regions.<sup>558</sup> The precautionary principle or precautionary thinking has consequently found its way in the application and implementation of the law in the Netherlands through other means than codification.

Some national laws contain, first of all, precautionary elements or have been interpreted in a precautionary manner. Secondly, the precautionary principle has been invoked in policy documents. Thirdly, the principle has been codified in regional ordinances (*verordeningen*). It has moreover also been invoked in the application of the law, in court cases. Some jurist furthermore argue that it can consequently also be seen as a legal custom.

Before we analyze each of these aspects, we will describe how generally is dealt with uncertain risks in the Dutch law. This will make clear how the responsibility with regard to uncertain risks has been distributed in the Netherlands.

## Uncertain risks in the Netherlands

The final responsibility with regard to uncertain risks has been placed with the Dutch government, since it carries a duty to care (*zorgplicht*) for the physical safety of its citizens and the (living) environment.<sup>559</sup> The precautionary principle has been acknowledged by the European Court of Human Rights (EHRM) in relation to these rights.<sup>560</sup> Based on judgments by the European court and the fact that these judgements are binding for the Dutch law, the duty to care can be translated in obligations with regard to intervention, research, the enactment of new rules, supervision and the distribution of information to citizens.<sup>561</sup> However, in its decisions the EHRM takes into account the complexity of monitoring a modern society and of making the right choices. Not every risk leads to a duty to act and the measures have to be proportionate.<sup>562</sup>

In relation to securing a safe and healthy living environment for everyone in the Netherlands, the Dutch government carries the responsibility for the system as a whole (*systeemverantwoordelijkheid*). The government provides legislation and regulations, information, enforcement and supervision, infrastructure and system interventions in the event of permanent failure. However, the government does not carry this responsibility alone. The Ministry of Infrastructure and Water Management states that other parties also play important roles in the implementation of precaution, and they also have responsibility or even a duty to which they can be addressed.<sup>563</sup> The government must set the frameworks in which these parties can fulfill their responsibility and must ensure supervision and enforcement. The Ministry confirms in this respect the chain-responsibility that is also written down in REACH.

The scope of the duty to care (in general) is in Dutch law also given by the so-called Kelderluik-criteria.<sup>564</sup> The duty to care is proportional to the extent that inattention or carelessness can be expected, the plausibility and seriousness of accidents that this may

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557 For instance: biotechnology, nanotechnology, climate change.

558 For instance: Antartica, the Wadden Sea, the province of Flevoland, the municipality of Bergeijk.

559 Art. 2 and 8 EVRM. art. 21 en 22 Grondwet.

560 Tătar EHRM 27 januari 2009, ECLI:CE:ECHR:2009:0127JUD006702101 (Tătar/Roemenië).

561 Leerstoelgroep Staats- en bestuursrecht Faculteit der Rechtsgeleerdheid UvA, *Jurisprudentie Veiligheid en gezondheid* (Amsterdam, 2007), 11.

562 UvA, *Jurisprudentie Veiligheid en gezondheid*, 11.

563 Ministerie IenW, *Bewust Omgaan met Veiligheid*.

564 UvA, *Jurisprudentie Veiligheid en gezondheid*, 11.

cause and the objectionability (*bezwaarlijkheid*) of the safety measures that have to be taken. These criteria are based on a judgment by the Dutch High Council, which have often been used as a standard in similar cases.

Dutch public law is however grounded on the legality principle (*legaliteitsbeginsel*), which means that the government can only do things if the law proscribes it. An administrative body is consequently not allowed to do anything, unless it is proscribed by the law. Thus, though the precautionary principle is connected to a duty to care of the government, this duty can only be exercised on the basis of explicit laws and regulation. Since the precautionary principle is not codified in the Dutch law, both duties and restrictions based on precaution have mainly been implemented and applied through policy documents.<sup>565</sup>

The execution of such policy is bound by principles of good governance. Such principles, though not all of them, are codified in the General Administrative Law Act. Some jurists claim that the precautionary principle can be understood as a principle of good governance that has not (yet) been codified.<sup>566</sup> Others argue that a variety of principles of good governance seem to express thoughts that show similarity with the main line of thinking of the precautionary principle, such as the principle of due care,<sup>567</sup> the principle of proportionality,<sup>568</sup> the principle of fair play<sup>569</sup> and most importantly: the principle of motivation.<sup>570</sup>

Among some jurists has recently grown the opinion that the duty of the government to care for its citizens, can also be enforced by private individuals.<sup>571</sup> Precaution may consequently be instigated by citizens themselves. Recently, in Dutch law a practice is reoccurring in which liability-based procedures result in regulation that go further than the procedure itself. In such cases, the state was accused of alleged government failure and the responsibility of the state towards the risk has widened. This has happened on the topics of Q-fever, Asbestos, air pollution, tobacco, CO<sub>2</sub>-emissions and gas extraction in the province of Groningen.

Precautionary action towards uncertain risks posed by private actors has been organized considerably different. A private actor is in principle, according to Dutch law, allowed to do anything unless the law forbids it. The government thus has to explicate on the specific activities for which it deems precaution necessary. In the Netherlands this has mainly been done through the delegation of standard-setting to lower administrative bodies (*gelede normstelling*). Precaution has consequently been applied through the way permits have

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565 Every action of an administrative body furthermore has to be related to a provision in the Constitution or an international treaty.

566 C. Lambers, 'Het voorzorgsbeginsel, Vluchten kan niet meer' in: P.C. Gilhuis, A.H.J. van de Biesen, *Beginselen in het milieurecht*, Kluwer, 2001, p. 65; Marjan Peeters, 'Risicobeheer, milieuvergunningen ende rechtspraak van de Nederlandse Raad van State', in van Calster G, Vos, E., *Koersen in de mist, wie staat aan het roer?*, Intersentia, 2004, p. 114.

567 The principle of due care (*zorgvuldigheidsbeginsel*) requires that all relevant facts and interests are taken into account before a decision (art. 3: 2 and 3: 9 Awb) and that they are involved during the decision-making (article 3: 4 paragraph 1 Awb).

568 The provision that 'consequences of a decision for one or more stakeholders must not be disproportionate in relation to the objectives to be served by the decision' (awb article 3.4 2).

569 This principle stipulates that the government is not allowed to deprive citizens of their possibilities to defend its interests. (art. 2:4 Awb).

570 The principle of motivation states that a decision has to be (explicitly) motivated and based on a sound justification (*deugdelijke motivering*). This has sometimes been interpreted in terms of certainty, in the sense that a justification is not sound when uncertainty exists about the outcome of the decision (article 3.45 AWB).

571 Elbert de Jong, *Rechterlijk risicoregulering en het EVRM: over drempels om de civiele rechter als risicoreguleerder te laten optreden*, NTM|NJCM-Bull. jrg. 43 [2018], nr. 2.

been issued, the implementation of general rules and (extra-judicial) covenants with companies.<sup>572</sup>

## Precautionary elements in national legislation

Especially when some national laws are read in combination with the core thought of environmental law and sustainable growth, they show clear precautionary elements.<sup>573</sup> Article 8.11 (3) of EMA for instance states that a 'license shall be made subject to such additional regulations as may be necessary to provide the greatest possible protection to the environment from the said effects, unless this cannot reasonably be required.' The formulation of 'the greatest possible protection to the environment' has been interpreted on the basis of the precautionary principle in relation to the ALARA-principle. According to the government, the provision means that every time when this is reasonably possible, the best technical means for protection will have to be chosen.<sup>574</sup> The precautionary principle is moreover included in regulations that are based on this law. The principle has for instance been placed inside the Establishments and licensing decision (*Inrichtingen en vergunningbesluit*) as a consequence of the implementation of the IPPC-guideline.<sup>575</sup>

Another example of precautionary thinking in national legislation is in the Nature Protection Act (*Natuurbeschermingswet*). This law states that a permit is only granted to activities that can have significant consequences for nature if it is certain that these activities do not affect the natural features of the protected natural monument, unless compelling reasons of great public interest necessitates such a permission.<sup>576</sup> An often cited example of how this clause in the nature protection act should be interpreted is the case of the 'Kokkelvisserij-arrest'.<sup>577</sup> This means that during the judgement, on the basis of the available information, certainty has to exist that the natural features of the area will not suffer harmful consequences due to the activities of which a permit is requested.<sup>578</sup> This is the case when scientifically no reasonable doubt exists that there are no harmful consequences. This very strict interpretation of the precautionary principle, however, seems to be softened recently in a variety of cases due to the 'hand-aan-de-kraan-principe'. This means, more or less, that an exception can be made with regard to the application of the precautionary principle if a process is closely monitored and measures are taken that can quickly stop it.<sup>579</sup> Similar provisions about burden of proof can be found in the Pesticides Act (*Bestrijdingsmiddelenwet*), the Environmentally Hazardous substances Act (*De Wet milieugevaarlijke Stoffen*) and the Medicines Supply Act (*Wet op de geneesmiddelenvoorziening*).<sup>580</sup>

The principle is also indirectly included in a future Dutch law, that will have far-reaching consequences for the system of legislation for the development and management of the

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572 Peeters, M. G. W. M., in de Braek, D., & Huitema, D. (2005). Onzekere milieurisico's. Een onderzoek naar de wijze van omgaan met onzekere milieurisico's door de wetgever, bestuur en de rechter. Deel 1: inleidend rapport. (STEM-project). Arnhem: Ministerie van VROM, 11.

573 Douma, *The Precautionary Principle*, p. 397-407.

574 Douma, *The Precautionary Principle*, p. 405.

575 Article 5a.I *Inrichtingen en vergunningbesluit*.

576 Article 16.3, *Nbwet 1998*.

577 HvJEG 7 september 2004, zaak C-127/02 (*Kokkelvisserij*), *Jur* 2004.

578 Barkhuysen and Onrust, 'De betekenis van het voorzorgsbeginsel voor de Nederlandse (milieu)rechtspraak.' *Kansen in het Omgevingsrecht* (Amsterdam, 2010), 65.

579 Barkhuysen and Onrust, 'De betekenis van het voorzorgsbeginsel voor de Nederlandse (milieu)rechtspraak,' 65.

580 Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer, 'Codificatie van milieurechtelijke beginselen in de wet milieubeheer,' 57.

living environment: The Environment and Planning Act (*de Omgevingswet*).<sup>581</sup> The precautionary principle is only used in the law in relation to the requirements of the so-called Environment strategy (*Omgevingsvisie*). This environment strategy is at issue at three levels; the municipal council must determine a municipal environmental strategy, the Provincial Council shall determine a provincial environmental strategy, and the relevant Minister has to determine a national environmental strategy in agreement with Ministers whom it concerns.<sup>582</sup>

The Environment strategy has to contain a description of the main features of the quality of the physical living environment, the broad outlines of the proposed development, the use, management, protection and preservation of the territory, and the principal aspects of the entire policy to be pursued in relation to the physical environment. Article 3.3 of the law mentions the precautionary principle as one of the principles that have to be accounted for with regard to the environment strategy. A Statutory instrument will elaborate on how there has been accounted for, amongst others, the precautionary principle.<sup>583</sup>

The Dutch government emphasizes that the European Union and the Central Government (Het Rijk) have already taken the precautionary principle in consideration when they drew up and developed certain norms that underlie the Environment and Planning Act as a whole, such as the so called 'omgevingswaarden' and 'instructieregels'.<sup>584</sup> 'Omgevingswaarden' are norms that concern for instance, air quality, water quality and water safety. An 'Instructieregel' is a general rule with which an administrative body indicates to another administrative body *how* that body should perform a task or power. Above these 'minimal norms' the role of the precautionary principle in the Environment and Planning Act is that it concerns not already set (*niet-genormeerde*) risks. To this extent it is upon the authority in question to indicate how relevant the uncertain risks are in his area and how it handles this. The EU Communication Directive from the year 2000 about the precautionary principle is advised as a guideline for the motivations and choices that consequently have to be made.

Another national law in which the precautionary thinking was implemented is the Animal feed framework law (*Kaderwet diervoeders*).<sup>585</sup> This law states that 'in situations in which after evaluation of the available information the possibility of harmful consequences for the health of humans, animals or the environment has been ascertained, but scientific uncertainty exists, can, awaiting further scientific data for a more complete risk assessment, provisional risk management measures be established to ensure the chosen level of health protection.'<sup>586</sup>

Partly as a consequence of the implementation of European guidelines in Dutch law, the distribution of responsibility towards risks has changed; the duty to care and the burden of proof have increasingly been laid down by companies themselves. But though the precautionary principle is explicitly mentioned in the General Food Law, REACH and The General Product Safety Directive, the principle seems not to be mentioned in the related adaptations in Dutch national law.<sup>587</sup>

Another domain of application of the precautionary principle is employment law. The Working Conditions Act knows a provision about control at the source (*bestrijding bij de bron*). Dangers and risks concerning the safety and health of the employee have to be

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581 This law will replace 26 existing laws that cover provisions about environmental law (concerning a.o building, environment, water, spatial planning and nature).

582 Article 3.1 Environment and Planning Act.

583 Article 23.6 of the Environment and Planning Act.

584 'Voorzorg in de Omgevingswet' Website aan de slag met de Omgevingswet, <https://aandeslagmetdeomgevingswet.nl/omgevingswet/uitgangspunten-en/voorzorg/>.

585 Expired on 01-01-2013.

586 Article 38, 1. Animal feed framework law.

587 <https://wetten.overheid.nl/BWBR0021929/2008-06-13>.

<https://zoek.officielebekendmakingen.nl/stb-2005-590.html#IDAZHEFB>.

prevented or limited as much as is possible at its source, unless this cannot reasonably be required.<sup>588</sup> This is sometimes associated with the principle of prevention and the precautionary principle.<sup>589</sup> The precautionary principle has in this domain been invoked in relation to the general duty of care which can be attributed to the employer.<sup>590</sup> In a letter to the Parliament, the Minister of Social Affairs and Employment has for instance, amongst others, stressed the duty for precaution in relation to the conditions of people that work with nano-particles.<sup>591</sup> In 2013 a judge decided moreover that the airline company KLM had to execute a request for research from an employee on possible toxins in a working environment.<sup>592</sup>

## Policy documents

The precautionary principle has been applied in the Dutch law through policy documents since the 1990's.<sup>593</sup> We will however, just like with the legal analyses in the other countries, focus on policy documents that have been published after 2000.

In 2000 the Cabinet published a note in which it stated that the precautionary principle should play a central role in considerations about the possible risks and the intended social benefits of biotechnology.<sup>594</sup> Because genetic modifications to organisms can be irreversible and in principle multiplying, one ought to be cautious and careful during research and application of the organisms or products based on it in the environment and society. In the note it is stated that the Netherlands is positive about the European Commission's initiatives towards the precautionary principle, to the extent that the importance of it is fully recognized and underlined. The Cabinet agreed with the position of the Commission that the principle is applicable to not only the environment, but to the protection of the environment, nature and health of humans, animals and plants. It notes that the application of the principle on these terrains can differ and that this has to be worked out.

In 2001 the cabinet published a note<sup>595</sup> in which it, amongst others, formulated that anchoring of responsibility of companies and the improvement of quality within companies were a necessary condition for a precautionary approach. In relation to a new approach towards risks, especially environmental risks, the cabinet developed a vision in 2006.<sup>596</sup> The cabinet emphasized in this document that political decision-making has to be transparent, that the responsibilities of government, business and citizens have to be made explicit, that that threats and risks of an activity have to be measured against its costs and benefits, that the role of the citizen in the decision-making has to be strengthened and that the accumulation of risks has to be taken into account in the decision making. This document functioned, amongst others, as a guideline for the action plan of the Cabinet towards Nanotechnology.<sup>597</sup>

From 2013 until 2018 the Ministry of Infrastructure and Water Management, on request of the senate, developed an assessment framework for risk and safety issues in the living

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588 Article 3.1.b Working Conditions Act.

589 Gezondheidsraad, Voorzorg met rede (Den Haag, 2008), 51.

590 Artikel 3 a-c: <https://wetten.overheid.nl/BWBR0010346/2019-01-01>.

591 <https://zoek.officielebekendmakingen.nl/kst-25883-161.html>.

592 Rechtbank Amsterdam 18 september 2013, ECLI:NL:RBAMS:2013:5980, KLM-piloot.

593 Examples are: Third Policy Document on Water Management (Derde Nota Waterhuishouding) 1989, National Environmental Policy Plan 2 (Nationaal Milieubeleidsplan) 1994, Key National (Physical) Planning Decision on the Wadden Sea (Nota Waddenzee) 1994. For a full overview see, Douma, 2003).

594 Beleidsnota Biotechnologie, p. 6.

595 Strategienota Omgaan met Stoffen (SOMS).

596 RIVM rapport, Nuchter Omgaan met Risico's.

597 Actieplan Nanotechnologie.

environment. One of the ten core principles that were formulated by the Ministry was 'Apply the precautionary principle for new, still uncertain risks.'<sup>598</sup> These type of risks are defined as: 'serious indications of one or more risks, but with so many scientific and methodological uncertainties, that these are not easily determined through the usual methods of risk analysis.'<sup>599</sup> It is the explicit task of the government to check which actors have a responsibility and/or should be involved. The ministry emphasizes Safe-by-Design as an instrument for precaution. Already in the design phase of new technologies should uncertain risks be identified and possible alternatives for raw materials, basic techniques and applications be examined.<sup>600</sup> The ministry argues that this requires a new safety awareness of scientists, laboratory people, product developers, senior management in companies that direct investment decisions and a different way of working together in sharing (partly confidential) research data.<sup>601</sup>

The end report in which the assessment framework was published stated that judgements in court can clarify what must be expected from the government in relation to the precautionary principle.<sup>602</sup> Relevant guidelines that are mentioned are warranting a basic level of protection and a certain level of ambition. In its policies and use of different instruments the government must ensure that situations do not become more unsafe or unhealthier than the current level of basic protection and, where possible and desired, the government strives towards a cleaner, healthier and safer environment.

The Ministry states that cases of precaution require a scientific risk-evaluation, an evaluation of the potential consequences of inaction, a transparent procedure aimed at arriving at control measures (*beheersmaatregelen*) in collaboration (*samenspraak*) with all parties involved and looking out for risk-reports (*risicomelding*). The government is stated to be responsible for establishing if risks are handled responsible and carefully.

In relation to new technological developments, where the possible risks are unclear and specific legislation is absent, two options are said to exist. If there exists public law, it applies to the innovation in question. If that is not the case, civil liability law applies based on the unlawful act<sup>603</sup> (*onrechtmatige daad*). The Ministry moreover argues that a judgement of risk requires knowledge of both the physical, the social-psychological and the 'paper' reality (of rules, laws, norms, risk assessments etc.).

## Regional law

The precautionary principle has occasionally been codified in local ordinances (*verordeningen*) with regard to the environment, for instance in relation towards exemptions of cutting down trees, livestock farming and public health, and even an ordinance of the province of Flevoland about regulations concerning the physical living environment.<sup>604</sup>

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598 Ministerie van IenW, Bewust Omgaan met Veiligheid, p. 5.

599 Ministerie van IenW, Bewust Omgaan met Veiligheid, p. 27.

600 Ministerie van IenW, Bewust Omgaan met Veiligheid, p. 28

601 Ministerie van IenW, Bewust Omgaan met Veiligheid, p. 28

602 Ministerie van IenW, Bewust Omgaan met Veiligheid,, p. 6.

603 This is defined as: 'The act or omission with which someone is unlawful or improper harm another person'.

604 [https://www.overheid.nl/zoekresultaat/5/2/10/tekst%5B0%5D%3Dvoorzorgsbeginsel%26geldend\\_op%5B0%5D%3Dnow%26sortBy%3Dalternative%3AASC](https://www.overheid.nl/zoekresultaat/5/2/10/tekst%5B0%5D%3Dvoorzorgsbeginsel%26geldend_op%5B0%5D%3Dnow%26sortBy%3Dalternative%3AASC).

### 6.4.2. Case law

The precautionary principle has also been invoked in court cases. Judgments in which the precautionary principle is invoked often refer to the verdicts of the European court of Justice or European and International Treaties. When the principle is mentioned in a policy document it can moreover play a role when the execution of the policy is reviewed.<sup>605</sup> We will illustrate the use of the precautionary principle in case law by describing how it was applied in two cases.

#### Case: Q-fever

On 25 January 2017 the court of The Hague judged that the Dutch state is not liable towards the victims and relatives of the victims of the Q-fever epidemic.<sup>606</sup> The judge decided that the State had not omitted its legal obligation to take measures and inform the population.

The question, more precisely, was if the State had acted unlawful towards 297 of the (relatives of) the victims in waiting too long for taking adequate measures to protect the public health and informing them insufficiently about the dangers of the Q-fever. The plaintiffs referred to Article 2 (the right to live) and 8 (the right to privacy) of the European Convention on Human Rights. The position of the court was first of all that not what the state *could* have done, but what the state *should* have done was at issue, since it can always be said afterwards that things could have been done better. In this context, the judge tried to ascertain if the state took the right decisions in relation to the uncertainties that existed surrounding the disease.

It can be said that the state could have implemented a vaccination programme or it could have made the so-called 'melktank-test' mandatory. Because during the time uncertainties (*onduidelijkheden*) existed about the effectiveness, availability and risks surrounding the vaccination, the state was not legally mandated to use it. The 'melktank-test' moreover, in hindsight proved to be a useful instrument, but the policy towards Q-fever was till summer 2009 mainly focused on preventing further diffusion of the disease, for instance by making regulations for the spreading of manure. Only when this proved to be ineffective, so argued the court, did sufficient reason exist to make the 'melktank-test' mandatory, especially since the effectiveness of the it was uncertain ('onzeker').

On the basis of the precautionary principle, the delay for taking more uncertain and invasive measures while the ineffectiveness of the original measures was not yet clear, was judged legitimate ('rechtmatig'). It was also judged that the dissemination about the risks of Q-fever on the website of the government sufficed the duty of the state to inform its citizens.

#### Case: Urgenda

In 2015 the court of the Hague decided that the state has to do more to reduce the emission of greenhouse gasses.<sup>607</sup> It was the first and as yet the sole case in which a state was obligated to take measures against climate change.

The case was brought forward by the Urgenda Foundation, a citizen platform which concerns itself with the development of plans and measures to prevent climate change.

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605 Faure and Vos E, Juridische afbakening van het voorzorgsbeginsel, p. 213.

606 ECLI:NL:RBDHA:2017:587.

607 ECLI:NL:RBDHA:2015:7196.

During the case the foundation represented 886 persons. The state went into appeal, but the decision was confirmed by the High Court of the Netherlands in 2018.<sup>608</sup>

Referring to the European Convention on Human Rights, the court deduced that the Dutch state has a duty to care ('zorgplicht'), which is directly at issue due to the consequences of climate change. The judge argued that the protection of life, the protection of a living space and private life are in danger (Article 2 and 8 EVRM).

It was decided that the state has not taken sufficient measures to contribute to the prevention of the global problem of climate change, also in relation to the intentions it has explicated in, among others, the Paris agreement. The court established a certain negligence of the state in relation to achieving these goals, from which the court deduced that the state had acted unlawful.

The High Court referred to the precautionary principle to counter the arguments of the state that it has to take into account the uncertainties around climate change and other possible accidental events ('ongewisheden'). The court refers to it in relation to the climate treaty of the UN and jurisprudence of the European Court of Human Rights (Tătar/Roemenië, EHRM 27 januari 2009, nr. 67021/01 paragraaf 120).

## 6.5. Implementation and application of the precautionary principle in Norway

This section provides a short review on perceptions and implementation of the precautionary principle in Norway. It gives an overview of the legal status and applications of the concept and it explores how it is used in policies, strategies and administrative practices.

### 6.5.1. The implementation and status of the precautionary principle in Norway

Precaution has been an important part of Norwegian health and environmental policies for the last 30 years.<sup>609</sup> The Rio Declaration, which Norway has signed, solidified the precautionary principle as an internationally important principle. This definition has become the most dominant definition of the precautionary principle used in Norwegian policy and legal texts. However, Norwegian authorities had by that time already been involved in international fora such as the series of the North Sea Conference (1984, 1987, 1990, later also 1995) and the UN EC Conference in Bergen in 1990, both arenas that had discussed and suggested a principle of precaution.

The Rio Declaration has been influential in shaping Norwegian policies on precaution (Article 15).

Generally, the precautionary principle is considered one of several environmental principles that guide the public sector in decision-making on environmental issues in Norway. In 1997 the National Committee for Research Ethics in Science and Technology (NENT; [www.etikkom.no](http://www.etikkom.no)) published a policy report on the Precautionary Principle, addressed to the interface of science with policy. Since the 2000s, a precautionary approach has been promoted in many areas of policy and in policy documents, and the precautionary principle

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608 ECLI:NL:GHDHA:2018:2610.

609 Bugge, H.C., 'Norway' in de Sadeleer, N., (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*, Earthscan, London, 2007, p 104.

has also been implemented in a few legal acts since 2001. However, the actual application of the precautionary principle in practice seem to face several challenges.

### **The precautionary principle in the Norwegian Constitution**

The Norwegian constitution does not contain a principle of precaution. Though one of the oldest constitutions in the world, its flexibility regards to amendments suggests that including precaution in the constitution in the future may be easier, compared to other political systems with less flexibility. When discussing precaution and the Norwegian constitution, Article 112 (previously 110b) is generally considered the most relevant article. Article 112 (previously 110b), aims at securing citizens' rights to a healthy living environment and wellbeing. It states:

*"Every person has the right to an environment that is conducive to health and to a natural environment whose productivity and diversity are maintained. Natural resources shall be managed on the basis of comprehensive long-term considerations which will safeguard this right for future generations as well".<sup>610</sup>*

### **The precautionary principle in national acts**

The precautionary principle mentioned explicitly in two Norwegian acts: Svalbard Environmental Protection Act and the Nature Diversity Act (Naturmangfoldsloven).

The precautionary principle was first introduced into Norwegian legislation<sup>611</sup> in the 2000s. The first act that included the precautionary principle was the Svalbard Environmental Protection Act<sup>612</sup>. The basis of the environmental policy for Svalbard was to be based on the precautionary principle. It was the first law in Norway to include the precautionary principle. Its article 7 states:

*"When an administrative body lacks adequate information on the effects that an undertaking may have on the natural environment or cultural heritage, its authority under this Act shall be exercised in a manner designed to avoid possible damage to the environment".<sup>613</sup>*

The Svalbard Environmental Act replaced previous law on natural protection in Svalbard and set ambitious goals for preservation on the island. Stated in the purpose of the act, it aims at maintaining an *"almost untouched environment"* and to keep it one of the *"best protected wilderness areas in the world"*. The protection of Svalbard is an example of a restrictive precautionary policy that favours environmental concerns higher than other concerns. A guiding document on land planning on Svalbard highlights government

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610 Norwegian Constitution 1814. <https://lovdata.no/dokument/NLE/lov/1814-05-17?q=grunnloven>.

611 The process behind the passing of a bill in the Norwegian political system contains drafting a bill, launching a proposition along with a draft bill, completing hearings with stakeholders, redrafting the bill, presenting it to the King in council and finally to the Storting for approval. The inclusion of experts in drafting the bill and having a hearing that includes stakeholders and redrafting the bill assures that both civilians and elected representatives have a say in the drafting of the bill.

612 Svalbard Environmental Protection Act [2001]. <https://lovdata.no/dokument/NL/lov/2001-06-15-79?q=svalbard>.

613.Svalbard Environmental Protection Act 2001: Art. 7.

responsibilities to Svalbard, stating that the Norwegian government has a “moral obligation” to protect the islands’ wilderness and cultural heritage.<sup>614</sup>

The second act that included the precautionary principle was the Nature Diversity Act (Naturmangfoldsloven) in 2009. The Nature Diversity Act’s purpose is “to protect biological, geological and landscape diversity and ecological processes through conservation and sustainable use, and in such a way that the environment provides a basis for human activity, culture, health and well-being, now and in the future, including a basis for Sami culture.”<sup>615</sup> When interpreting the Nature Diversity Act, authorities are advised to consider possible conflicts of project plans with natural landscapes, biodiversity and species using an eco-systems approach.<sup>616</sup> The act upholds the precautionary principle as one of five environmental principles that guides environmental management within the public sector, and in article 9, titled the precautionary principle, it states:

*“When a decision is made in the absence of adequate information on the impacts it may have on the natural environment, the aim shall be to avoid possible significant damage to biological, geological or landscape diversity. If there is a risk of serious or irreversible damage to biological, geological or landscape diversity, lack of knowledge shall not be used as a reason for postponing or not introducing management measures.”<sup>617</sup>*

In comparison to the Svalbard Environment protection Act, the inclusion of the precautionary principle in the Nature Diversity Act affects application in a wide number of sectors. Important areas for biodiversity protection are forest, flora and fauna. The law is important in areal management, and the precautionary principle is discussed with regard to preservation of species, introduced species, conservation of nature areas, and genetic diversity, where it is suggested that the precautionary principle can be applied even if there is no specific threat of extinction.<sup>618</sup>

Further, although the precautionary principle is not directly stated in the Marine Resource’s Act 2008 (Havressurslova), there is reference to a ‘precautionary approach’<sup>619</sup>. In preparations of the law, a proposition to the parliament recommended the use of the precautionary principle<sup>620</sup>, but the principle itself did not make into an article of the law. Instead, a ‘precautionary approach’ is mentioned in § 7 as one of the principles for management of wild living marine resources:

*The Ministry shall evaluate which types of management measures are necessary to ensure sustainable management of wild living marine resources. Importance shall be attached to the following in the*

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614. Norwegian Ministry of Climate and Environment. ‘Veileder: Arealplanlegging og konsekvensutredning i planområdene på Svalbard’ [2007] p. 3-4.

615 Nature Diversity Act 2009 (naturmangfoldloven), LOV-2009-06-21-54 <https://lovdata.no/dokument/NL/lov/2009-06-19-100>.

616 Norwegian Ministry of Climate and Environment. ‘Naturmangfoldsloven Kap II’ [2016]. p. 7.

617 Nature Diversity Act 2009. Article 9.

618 Ministry of the Environment (2009) Om lov om forvaltning av naturens mangfold (naturmangfoldloven), Ot.prp. nr. 52 (2008–2009), Oslo.

619 Mel d. St. 14 (2015–2016) Nature for life — Norway’s national biodiversity action plan (Chapter 4–9). White paper to the Storting from Ministry of Climate and Environment.

620 Ot.prp. nr. 20 (2007–2008), <https://www.regjeringen.no/no/dokumenter/otprp-nr-20-2007-2008-/id493975/sec4?q=f%c3%b8re-var#kap4-2-1>.

*management of wild living marine resources and genetic material derived from them:*

*a) a **precautionary approach**, in accordance with international agreements and guidelines* <sup>621</sup>

This implies that regarding the precautionary principle and duty to act, the law only *recommends* use of a *precautionary approach* to be taken in regard to managing the resources of the sea in a sustainable manner. This law is important because Norway has a long seafaring tradition and marine industries still make up a large part of national revenue. The role of the Norwegian government is important as the main authority on resource management. The act dictates management of all marine resources and replaced similar previous law focused mostly on the fishing industry. The law is considered both an environmental and industry regulating law. However, other laws are also relevant to marine resources. The fish farming industry in Norway is large and growing, and the Aquaculture Act of promotes profitability, competitiveness and innovation of the aquaculture industry.<sup>622</sup> This indicates that the precautionary principle in the marine resource act may be in competition with values of profitability and cost-efficiency in highlighted in other acts.

A *precautionary approach* has also been influential in the preparation of several laws and is present in the preparations, accompanying legal texts or guiding documents to many laws such as the Food Act (article 6 on prevention of danger)<sup>623</sup>, the Gene Technology Act (Appendix 4)<sup>624</sup>, the Product Act<sup>625</sup>. The idea of precaution also heavily influences the Pollution Control Act<sup>626</sup> and the Forestry Act<sup>627</sup>.

There are also acts relevant to the use of the precautionary principle, underlining that the burden of proof generally falls on the person, organization or business that wishes to start an activity with possible effects on natural environments.<sup>628</sup> The Product Control Act state that individuals, organizations and authorities who wish to launch a product have a responsibility to investigate and prove unlikelihood of possible harm created from the product.<sup>629</sup> When deciding to approve or reject projects, any individual, organization or other wishing to initiate a project is generally expected to supply information that proves the absence of harm to environment and health. In addition, the Environmental Information Act (based on EU directive 2003/4/EC on Public Access to Environmental Information) was passed in 2004. Together with the Århus Convention it secured an expansion of the right to information and added a duty for public and private firms to supply information on environmental effects of an activity or initiative.<sup>630</sup> Precaution is also represented through the duties of care present in both the Svalbard Environmental Act

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621 Havressurslova (Marine Resources Act) 2008. <https://lovdata.no/dokument/NL/lov/2008-06-06-37>.

622 Norwegian Ministry of Fisheries and Coastal Affairs (2005). The Aquaculture Act [https://www.regjeringen.no/globalassets/upload/kilde/fkd/reg/2005/0001/ddd/pdfv/255327-I-0525\\_akvakulturloveneng.pdf](https://www.regjeringen.no/globalassets/upload/kilde/fkd/reg/2005/0001/ddd/pdfv/255327-I-0525_akvakulturloveneng.pdf).

623 The Food Act 2003. <https://lovdata.no/dokument/NL/lov/2003-12-19-124?q=matloven>

624 The Gene Technology Act 1993. <https://lovdata.no/dokument/NL/lov/1993-04-02-38?q=genteknologi>.

625 The Product Control Act 1976. <https://www.regjeringen.no/en/dokumenter/product-control-act/id172150/>.

626 Pollution Control Act 1981. <https://www.regjeringen.no/en/dokumenter/pollution-control-act/id171893/>.

627 Forestry Act 2005. <https://www.regjeringen.no/en/dokumenter/Act-relating-to-forestry-Forestry-Act/id87139/>.

628 Bugge, H.C., 'Norway', in de Sadeleer, N., (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*, Earthscan, London 2007.

629 Ibid.

630 Jerkø, Markus (2012). En taksonomi over rettslige prinsipper. Tidsskrift for rettsvitenskap. ISSN 0040-7143..(1-2), s 1- 48

(article 5) and in the Nature Diversity Act (article 6). This lays the foundation for a responsibility to act cautiously to not inflict harm or negative consequences upon the environment.

### **The precautionary principle in National policies and policy documents**

In addition to national acts, the precautionary principle has since 2000 featured in a large number of Norwegian government policy documents like government white papers, reports to the Parliament and Norwegian Official Reports. Especially white papers on protection of biodiversity and climate change<sup>631</sup> often refer to the precautionary principle. An example can be found in the 2001 White papers on Biological Diversity, where ambitious precautionary goals are posed that placed the precautionary principle at the centre of decision making in a variety of sectors. Further, several white papers states the precautionary principle as a part of the approach in the management plan for Norwegian seas and marine environment.<sup>632</sup>

The precautionary principle is also mentioned in several White Papers on climate policy.<sup>633</sup> In the Norwegian Climate strategy for 2030 (White paper 41. 2016), it is stated that policy climate strategy foremost needs to be cost-effective, but that principles of precaution also are important:

*"The principle that policies and measures to deal with climate change should be cost-effective in order to ensure global benefits is set out in the UNFCCC. Other key principles of climate policy that are set out in the Convention are the precautionary principle and the principle of common but differentiated responsibilities. The precautionary principle is also important in Norwegian environmental policy."*<sup>634</sup>

It seems that the precautionary approach is a part of risk and impact assessments completed by Norwegian ministers. It can be said that generally, the precautionary approach is well entrenched in decision-making processes by public management.

However, Norway has a high dependency on natural resources, and balancing industrial development and sustainability can be challenging. The Norwegian Sea is an important resource for fish stock used in trade, the home of fish farms and the petroleum industry. Hydraulic power is an important source of energy and agriculture has an important place in society.

Although it has been a goal for Norwegian authorities to maintain sustainable practices in many of these sectors, the road from policy to implementation is not always straight, and

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631 Meld. St. 10 (2010–2011) Report to the Storting from Ministry of Climate and Environment Meld. St. 33 (2012-2013), Climate Change adaptation in Norway. White paper to the Storting from Ministry of Climate and Environment. Innst. 497 S (2012-2013).

632 St.meld. nr. 12 (2001-2002). 'Protecting the Riches of the Seas.' White paper to the Storting from Ministry of Climate and Environment.

Meld. St. 35 (2016–2017) 'Update of the integrated management plan for the Norwegian Sea.' White paper to the Storting from Ministry of Climate and Environment.

Meld. St. 22 (2016–2017) 'The place of the oceans in Norway's foreign and development policy.' White paper to the Storting from Ministry of Climate and Environment.

Meld. St. 37 (2012-2013) 'Integrated Management of the Marine Environment of the North Sea and Skagerrak' (Management Plan). White paper to the Storting from Ministry of Climate and Environment.

633 Meld. St. 10 (2010–2011) Report to the Storting from Ministry of Climate and Environment Meld. St. 33 (2012-2013), Climate Change adaptation in Norway. White paper to the Storting from Ministry of Climate and Environment. Innst. 497 S (2012-2013).

634 Meld. St. 41 (2016–2017) Norway's Climate Strategy for 2030: a transformational approach within a European cooperation framework. White paper from Ministry of Climate and Environment.

the practical application of national acts is not always clear, as will be further discussed in section 7.5.3.

Further, the precautionary principle is also relevant as a guiding principle to addressing scientific uncertainty in chemical policy. White paper no.14 from 2006: "Working together towards a non-toxic environment and a safer future – Norway's chemicals policy"<sup>635</sup> states:

*"When a specific threat to health or the environment from chemicals is identified, the precautionary principle calls for action to be taken to reduce or eliminate this threat, even if there are uncertainties in the knowledge base. Thus, application of the precautionary principle does not mean that scientific facts are ignored, nor that we fail to make scientific risk assessments. On the contrary, it provides a guideline for the situations where we lack full scientific certainty. Since there is often uncertainty about the risks associated with chemicals, the precautionary principle is particularly relevant in chemical policy" (Norwegian Ministry of the Environment, 2006, p. 15)<sup>636</sup>.*

Although white paper n. 14 refers to the precautionary principle in a rather broad sense, the paper also stresses that any Norwegian regulation based on the precautionary principle will have to follow the guideline of the EU's Communication on the precautionary principle (i.e. regulatory measures have to be proportional, non-discriminatory, based on a cost-benefit analysis and reviewed in light of scientific developments).

### 6.5.2 Case law

Until 2007, there had not been a case in the national Norwegian courts where the precautionary principle had played a significant part.<sup>637</sup> However, a recent court trial between environmentalists and Norwegian authorities on petroleum extraction in the Arctic is a landmark case in Norwegian environmental law more generally. The so-called 'klimasøksmålet' case marks the first civil court case in Norway where civic groups (in this case, a coalition of environmental NGOs) filed a lawsuit against authorities<sup>638</sup>, similar to the climate change trial in the Netherlands. This case is relevant to precaution as the article 112 generally is viewed as the closest to a 'precautionary article' found in the constitution. The background for the climate change trial was that on the 10th of June 2016, after years of political debate, the Norwegian government gave permission to open up 10 areas in the Norwegian Arctic for future petroleum activity. The decision was controversial and on the 18<sup>th</sup> of October the same year, a coalition of environmental groups filed a lawsuit against the Norwegian government. The motivation for the lawsuit was what environmental groups claimed to be a violation of the constitution's Article 112, which aim is to safeguard environmental and health interest of the people and for future generations.<sup>639</sup>

The case is the first to deal with possible violations of article 112 due to growing concerns of effects on climate and environment in light of climate change. It illustrates an ongoing debate on Norway's position as a contributor to climate change and discussions on moving

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635 Norwegian Ministry of the Environment, 2006. Available at: [https://www.regjeringen.no/contentassets/abe386e25e0e4d788e868d5f7f991362/en-gb/pdfs/stm200620070014000en\\_pdfs.pdf](https://www.regjeringen.no/contentassets/abe386e25e0e4d788e868d5f7f991362/en-gb/pdfs/stm200620070014000en_pdfs.pdf).

636 Ibid.

637 Bugge, H.C., 'Norway' in de Sadeleer N., (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*, Earthscan, London, 2007.

638 <http://www.klimasøksmål.no/en/>.

639 Ibid.

towards an economy based less on petroleum activity. Despite the lack of use of the precautionary principle in the court trail (apart from notions of precaution inexplicitly apart of article 112), the case illuminates the increasingly relevant role of precaution in Norway's management of its own resources due to climate change. In a major newspaper after the trail, Supreme Court lawyer Pål Lorenzen claimed that the precautionary principle could have played a larger role than what was the case during the trail and questioned why environmental groups had not made use of the precautionary principle.<sup>640</sup>

### 6.5.3. Application of the precautionary principle in practice

Although the Precautionary Principle is stated in several national acts and is referred to in many policy documents, studies have shown that applying the precautionary principle has been challenging also in Norway<sup>641</sup>. In the following sections, some of these challenges will be indicated through outlining how the precautionary principle has been applied in three different areas.

#### Conserving bio-diversity

Desktop research on formal policy papers, public hearing documents, reports and newspaper articles mentioning the precautionary principle, shows that the most frequent cited act in relation to precautionary principle is the Nature Conservation Act. Government officials, politicians and environmental NGOs mention this act and the precautionary principle in relation to a broad range of cases on conserving bio-diversity. Policy papers and government officials underline that in the interpretation of the nature conservation act, it is generally understood that a project which negatively impacts red listed species may be rejected on the basis of the precautionary principle. In 2017, the government listed several examples where projects have been rejected, such as rejection of road construction and wind power plants due to impact on the red listed Hubro owl and power plants due to effect on biological diversity and wild salmon<sup>642</sup>. However, environmental NGO's claim that the government intentionally has reduced the significance of the nature conservation act, and that bio-diversity has decreased during the five years under a conservative government.<sup>643</sup> In a report, they display that the (conservative right party) prime minister several times has stated that the nature conservation act should be revised as it blocks developments, and that industrial and residential developments should be given more weight.<sup>644</sup> Further, the report argues that the government has reduced the role of the Ministry of Climate and Environment<sup>645</sup> by shifting the task of overseeing spatial developments to the ministries of spatial development, which is likely to favor other values than precaution and conservation. Another reason for that the application of the precautionary principle as stated in the act may be limited is that the responsibility for doing so often fall on local governments (who are responsible for spatial development and

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640 Pål W. Lorentzen. 'Rettmessig klimasøksmål' (Dagbladet, 18 Jan 2018) <https://www.dagbladet.no/kultur/rettmessig-klimasoksmal/69344639> Accessed 14 March 2019.

641 Bugge, H.C., 'Norway' in de Sadeleer N., (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*, Earthscan, London, 2007.

642 Norwegian Ministry of Climate and Environment. 'Fakta om regjeringens innsats for naturmangfold'.(Regjeringen, 29 August 2018) <https://www.regjeringen.no/no/aktuelt/fakta-om-regjeringens-innsats-for-naturmangfold/id2568704/> Accessed 13 March 2019.

643 WWF, Sabima, Norges Naturvernforbund (2018) *Naturpolitisk resultatliste 2013-2017*. [https://d1rirzyrd4ly69.cloudfront.net/downloads/naturpolitisk\\_resultatliste\\_regjeringen\\_2013\\_2017\\_wwf\\_sabima\\_nnv.pdf](https://d1rirzyrd4ly69.cloudfront.net/downloads/naturpolitisk_resultatliste_regjeringen_2013_2017_wwf_sabima_nnv.pdf).

644 Ibid.

645 Norwegian Environment Agency which is under the Ministry of Climate and Environment is the most central body that is supposed to implement and follow up the nature conservation act including the PP (see <https://tema.miljodirektoratet.no/en/About-us/>).

the use of local natural resources). A report from 2013 evaluates local governments experiences with implementing the Natura conservation act, and finds that many municipalities do not have sufficient competencies to follow up on the act generally and the precautionary principle specifically<sup>646</sup>. Therefore, the actual use of the precautionary principle varies greatly in cases of spatial development projects. In some newspaper articles from 2018 and 2019, environmental NGOs, spatial planners and scientists argue that some local governments neglect the precautionary principle in favour of development projects or industries that could benefit the local economy<sup>647</sup>.

Marine and coastal conservation is another area where several acts and policies indicate the relevance of the precautionary principle. The nature conservation act, the marine conservation act and several white papers indicate that the precautionary principle is central in the management plans for Norwegian seas and marine environment. The precautionary principle could thereby play a role in regulating seafood, aquaculture and oil industry operating in the Norwegian sea. There are several debates on the finishing and fish farming industries. In the fish farming industry, the precautionary principle is particularly relevant due to chemicals treating the fish is spreading to its environment and due to the diseases escaped farmed salmon can bring to the environment. Sometimes interrelated, there are also debates around the precautionary principle in relation to the offshore oil industry. Offshore oil is by far Norway's largest and most important industry. Since 1970s there have been several rounds of public discussions on the expansion of this industry. Particularly plans to extend petroleum operations in the Lofoten area with its valuable and vulnerable marine ecosystem, received public attention, and the precautionary principle is often drawn in<sup>648</sup>. A research paper on this case shows that proceeding with precaution is problematic given the fact that, while some uncertainties regarding the impacts of routine operations can be quantified statistically and reduced through more research with adequate time and resources, other uncertainties can be described as 'epistemological'<sup>649</sup>. This implies that the complexity of the issue results in inconclusive knowledge regarding long-term effects. Further, the study shows that these uncertainties lead to conflicts between the petroleum industry and the fishery sector on how to frame the issue<sup>650</sup>.

Another challenge in following the precautionary principle as stated in the act, is that the responsibility of doing often fall on local governments, as matters of spatial development are local and involves the use of local natural resources. A report by an independent research institute from 2013 evaluates local governments experiences with implementing the act and finds that many municipalities do not have sufficient competencies on the act generally and the precautionary principle specifically.<sup>651</sup> Therefore, the actual use of the precautionary principle varies greatly in cases of spatial development projects. Further, in some recent newspaper articles from 2018 and 2019, environmental NGOs, spatial planners and scientists have argued that local governments neglect the precautionary

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646 NINA rapport (2013). *Naturmangfoldlovens virkninger i kommunene*

<https://www.nina.no/archive/nina/PppBasePdf/rapport/2013/964.pdf>.

647 <https://www.dagbladet.no/kultur/et-veiskille-for-naturvernet-i-norge/70464919>

<https://www.dagbladet.no/kultur/naturforvaltning---et-spill-for-galleriet/70579480>

<https://www.dagbladet.no/kultur/innsigelse-i-arealsaker-er-blitt-det-store-fy-ordet/70623357>.

648 See e.g. the public hearing reply by a coalition of environmental NGOs:

[https://www.regjeringen.no/contentassets/6a8dd93c76a747a7946994ad8b0dd8be/folkeaksjonen\\_oljefritt\\_lofoten\\_vesteralen\\_senja.pdf?uid=folkeaksjonen\\_oljefritt\\_Lofoten,Vester%C3%A5len\\_og\\_Senja-Det\\_faglige\\_grunnlaget](https://www.regjeringen.no/contentassets/6a8dd93c76a747a7946994ad8b0dd8be/folkeaksjonen_oljefritt_lofoten_vesteralen_senja.pdf?uid=folkeaksjonen_oljefritt_Lofoten,Vester%C3%A5len_og_Senja-Det_faglige_grunnlaget)

649 Blanchard, A., Hauge, K. H., Andersen, G., Fosså, J. H., Grøsvik, B. E., Handegard, N. O., ... & Vikebø, F. (2014). Harmful routines? Uncertainty in science and conflicting views on routine petroleum operations in Norway. *Marine Policy*, 43, 313-320.

650 See also <https://fiskeribladet.no/nyheter/?artikkel=62877>.

651 NINA rapport (2013). *Naturmangfoldlovens virkninger i kommunene*  
<https://www.nina.no/archive/nina/PppBasePdf/rapport/2013/964.pdf>

principle in favour of development project and industries they believe would benefit the local economy.<sup>652</sup>

### Food production: GMOs and pesticides

An area where Norway is especially restrictive and the precautionary principle plays a large role, is the subject of genetically modified organisms (GMOs). Although Norway is a member of the EU approval scheme for GMOs, the Norwegian authorities have the opportunity to reserve themselves for sales if it is considered that the product poses a risk to health and the environment, or is contrary to the other purposes of the **Gene Technology Act**. In other words, Norwegian authorities have the freedom to reject products believed to have health or environmental risks, even though they have been approved in the market in other EFTA countries<sup>653</sup>. In the Gene technology act and the Food act, the precautionary principle is central even if it is not directly stated in any of the laws<sup>654</sup>. If the precautionary principle is evoked, the possible measures are a permanent ban, a time-based ban to gather additional information, step-by-step strategies with clear aims, a cautionary slow strategy or surveillance<sup>655</sup>. The Norwegian government has denied the introduction of several GMO foods and it has passed laws to lower hazardous chemicals (in line with REACH goals) such as prohibiting lead bullets for hunting use, to minimize the amount of lead found in the environment. In 2012 the Norwegian government rejected the introduction of GMO rapeseed (GT73) from recommendations from the Norwegian Directorate for Nature Management.<sup>656</sup> In a study from 2015, it is argued that the backdrop to Norway's strict GMO regulation, in comparison to other European nations, is a public perception that strongly oppose the use of GMOs, a considerably weaker GMO industry than the rest of Europe and a lack of industry lobbyism in favour of GMO.<sup>657</sup>

However, a challenge here is that the interpretation of the precautionary principle may vary, and that the interpretation may have direct consequences on the actions that follow to reduce risk. A study from 2002 shows that two government-appointed expert commissions, one on the health consequences of genetically modified products and one on xenotransplantation, had to two very different outcomes in dealing with the precautionary principle<sup>658</sup>. In the commissions on xenotransplantation, the presence of scientific evidence for possible risk (though an analogy) was an important precondition in the application of the precautionary principle. The commission on GMO products on the other hand, focused on the lack of possible evidence for risk, though high uncertainty was present, and found

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652 <https://www.dagbladet.no/kultur/et-veiskille-for-naturvernet-i-norge/70464919>

<https://www.dagbladet.no/kultur/naturforvaltning---et-spill-for-galleriet/70579480>

<https://www.dagbladet.no/kultur/innsigelse-i-arealsaker-er-blitt-det-store-fy-ordet/70623357>.

653 Fauchald, O.K., 'Genetically Modified Organisms and Precaution in Norwegian Law' in N. de Sadeleer (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA*, Earthscan, London, 2007, p. 233.

654 <https://www.regjeringen.no/no/dokumenter/nou-2000-29/id143253/sec7>.

655 Bioteknologirådet: Forslag til oppmyking av regelverket for utsetting av genmodifiserte organismer.

<http://www.bioteknologiradet.no/filarkiv/2010/07/2018-12-03-Komplett-genteknologiloven-Bioteknologiradet-publisert.pdf>.

656 Ministry of Climate and Environment (2012). 'Forbyr innførsel av genmodifisert raps'.

<http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Nyhetsarkiv/2012/12/Forbyr-innforsel-av-genmodifisert-raps/> Accessed 20 March 2019.

657 Roger, A. (2015). In the Public Interest? A Comparative Analysis of Norway and EU GMO Regulations. *Review of European, Comparative & International Environmental Law*, 24(3), 264-277.

658 Kaiser, M., 'Ethics, Science and Precaution: A View from Norway' in Joel Tickner (ed) *Precaution, Environmental Science and Preventive Public Policy*, Island Press, Washington 2003, p. 41.

that the risk was not enough to evoke the principle. The comparison of the two commission reports underline that interpretations of the precautionary principle may be either narrow or wide, and this relates to different interpretations of what scientific uncertainty entails. It also shows that the interpretation of the precautionary principle is linked to different values (eg the value of nature), and that the use and understanding of the precautionary principle may vary between sectors and actors.

Regarding **pesticides**, the Norwegian Food Safety Authority is the main governmental body assessing and approving plant protection products before they can be released on the market<sup>659</sup>. For regulating plant protection products, they adhere to the **Food Safety Act** generally and more specifically **the Norwegian Regulation on Plant protection (2015)**<sup>660</sup> which implements the **European Parliament and Council Regulation (EC) No 1107/2009** on plant protection. In the regulation, it is stated that the precautionary principle should be applied in the sense that the industry has to prove that the substance is not harmful. Although the regulations allow the Norwegian Food Safety Authority to dispense with the provisions of the Regulations, cf. Regulations on Pesticides Section 31 and Regulation (EC) No 1107/2009 Art. 53, the Food Agency has been critiqued for simply following EFSA's risk assessments. In a public hearing, several environmental NGOs argue that the Food Agency has not considered the precautionary principle to a satisfying degree, and that it is not sufficient to rely on EFSA's risk assessment<sup>661</sup>. The impression from this first hand desktop research thereby seem to indicate that the precautionary principle is applied to a lesser degree by Norwegian authorities in the case of pesticides than in the case of GMOs.

### **Chemical regulations and the case of PFOA's**

Shortly after the release of white paper n. 14,<sup>662</sup> the Ministry of Environment commissioned the Norwegian Environmental Agency to work on a national ban for 21 hazardous substances in consumer products. This ban was related to the regulatory objectives presented in the white paper, namely that the use and emission of the hazardous substances that were included in the national priority list were to be substantially reduced or eliminated by 2020 (an objective that is also known as the generation goal). Given that Norway is not a EU member state, the environmental agency submitted an impact assessment for this regulation to the EFTA (European Free Trade Association) Surveillance Authority<sup>663</sup>. The environmental agency highlighted that there were large uncertainties and that it was impossible to quantify the possible health and environmental damage using the available knowledge - and that an extremely long time would be required to gather reliable evidence of the long-term effects of such substances. At the same time, the exact costs of the regulation were difficult to predict but the agency considered that the benefits would outweigh the costs in the long term<sup>664</sup>. The assessment also stressed the importance of being precautionous and referred to the Norwegian Government Agency for Financial

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659 Mattilsynet (2015) Authorisation of plant protection products

[https://www.mattilsynet.no/language/english/plants/plant\\_protection\\_products/authorisation\\_of\\_plant\\_protection\\_products.20905](https://www.mattilsynet.no/language/english/plants/plant_protection_products/authorisation_of_plant_protection_products.20905).

660 <https://lovdata.no/dokument/SF/forskrift/2015-05-06-455>.

661 Mattilsynet (2012) Sammenstilling og vurdering av høringsuttalelser om utkast til forskrift om endring av forskrift om rester av plantevernmidler i næringsmidler og fôr

[https://www.mattilsynet.no/om\\_mattilsynet/sammenstilling\\_av\\_horing.8860/binary/Sammenstilling%20av%20h%C3%B8ring](https://www.mattilsynet.no/om_mattilsynet/sammenstilling_av_horing.8860/binary/Sammenstilling%20av%20h%C3%B8ring).

662 Norwegian Ministry of the Environment, 2006. Available at:

[https://www.regjeringen.no/contentassets/abe386e25e0e4d788e868d5f7f991362/en-gb/pdfs/stm200620070014000en\\_pdfs.pdf](https://www.regjeringen.no/contentassets/abe386e25e0e4d788e868d5f7f991362/en-gb/pdfs/stm200620070014000en_pdfs.pdf).

663 [www.eftasurv.int/?1=1&showLinkID=11660&1=1](http://www.eftasurv.int/?1=1&showLinkID=11660&1=1).

664 It was also noted that exemptions would be considered for those products where no adequate alternatives were available, where the use of the substances posed no risk to health or the environment, or when the regulation introduced costly barrier to trade.

Management (DFØ)'s guidance criteria for evaluating when to use the precautionary principle. These four point criteria related to the treatment of uncertainty in socio-economic analyzes include: 1) Large and non-quantifiable uncertainty in relation to future consequences, 2) Dramatic damage, 3) Irreversible damage, 4) No time to observe the development and gather more information<sup>665</sup>. The agency explained how the risk profiles of the selected hazardous substances fulfilled these criteria and proposed that as a result of the serious consequences and based on the precautionary principle, the ban ought to be carried out as soon as possible based on the existing information. During the consultation period, the agency received a large number of objections including strong criticism from the EFTA Surveillance Authority (also known as ESA). In particular, the question of whether or not Norway could introduce national restrictions in the context of the European Economic Area Agreement<sup>666</sup> (EFTA, 2007). After the consultation, the ban proposal was reduced to 18 substances, then to 10 and later to 4. Finally, in the summer of 2014, the first national ban based on this regulatory initiative entered into force concerning the chemical Perfluorooctanoic acid (PFOA). This time, the environmental authorities also received a warning from ESA. In its opinion document<sup>667</sup>, ESA challenged Norway for not presenting a risk assessment proving that the ban was necessary and proportional and in particular for infringing the laws of the internal market: "Norway is required to identify the specific risks associated with the substance and demonstrate that a ban on the product is the least restrictive measure possible".<sup>668</sup> Norway argued that PFOA was widely recognized as a hazardous substance and that this chemical's occurrence in the environment, the food chain and in humans constituted a potential risk to human health and the environment. The Norwegian authorities also explained that the establishment of European wide regulations under the European chemical legislation REACH was an inefficient process. They saw this unilateral measure on PFOA as necessary to ensure the phasing out of this chemical in Norway. In their opinion, such regulation was justified by the public health exception under Article 13 of the European Economic Area (EEA). However, for ESA, Norway's arguments were not sufficient to fulfil the burden of proof under Article 13 and the case was sent to the EFTA court.

In the meantime, Norway together with Germany had initiated a restriction procedure for PFOA under the REACH legislation. In July 2017, the EFTA court ruled that Norway had the right to maintain its national regulation while awaiting the result of the ongoing restriction procedure<sup>669</sup>. When the result become available, the European Commission echoed Norway's position from 2014, namely that the manufacture, use and placing on the market of PFOA posed an unacceptable risk to human health and the environment – and that those risks needed to be addressed through a PFOA restriction (this time via the REACH legislation)<sup>670</sup>. Which in practice meant that Norway's national regulation was going to be extended to the rest of the EU from 2020. At the end of 2018, the latest PFOA risk assessment conducted by the European Safety Agency also revealed that this chemical was considerably more hazardous than originally thought (reflected in a safety daily intake reduction from 1,500 nanograms per kilogram of body weight per day – to 6 nanograms per week). The agency also expressed concern about the fact that the PFOA's exposures in considerable portions of the population exceeded the new safety limits<sup>671</sup>.

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665 [www.eftasurv.int/?1=1&showLinkID=11660&1=1](http://www.eftasurv.int/?1=1&showLinkID=11660&1=1).

666 Under the EEA Agreement, Norwegian and EU chemicals legislation is harmonized, meaning that the same requirements apply for both Norway and the EU. However, there is some room for national regulation and Norway has most room for maneuver in areas where the legislation is not fully harmonized. It is more difficult for Norway to lay down stricter rules than the EU for substance and areas of use that are specifically regulated in fully harmonized regulations and directives, although there are possibilities for doing so (Norwegian Ministry of the Environment, 2006, p73).

667 <http://www.eftasurv.int/media/esa-docs/physical/759496.pdf>.

668 Ibid: (p.14).

669 [https://eftacourt.int/wp-content/uploads/2019/01/9\\_16\\_PR\\_EN.pdf](https://eftacourt.int/wp-content/uploads/2019/01/9_16_PR_EN.pdf).

670 Commission Regulation (EU) 2017/1000. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R1000>.

671 <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5194>.

## Summary

Comparing the three selected cases show that the precautionary principle could come into effect in a broad variety of sectors. It must be underlined that this review is limited in scope, and that further research is needed to properly analyze the effects- and implementations of the precautionary principle in Norwegian law and regulation policies.

However, the brief insights into the different cases indicate that the actual implementation of the precautionary principle varies between cases and fields, and that applying the precautionary principle in practice seem to face several challenges: First, the principle may be interpreted both broadly and narrowly, and different expert groups may interpret the principle differently, as shown in one of the studies of GMOs. It is generally indicated that both the expert groups that are appointed, but also the ministries that the tasks are delegated to, may impact on how and when the precautionary principle is followed up. Secondly, it is indicated that the level of competencies on the precautionary principle may vary between local governments. Third, the cases of pesticide and chemical regulation shows that although Norway's policy in this field is based on a precautionary approach, the actual implementation of precautionary regulatory measures in Norway is limited. A main reason seems to be that there is very little room for precautionary-based national regulations in the chemical sector, due to the rules of the European internal market. At the same time, the work at EU level and through EU legislation (the REACH procedures) is very demanding (economically and in terms of expertise) and lengthy.

## 6.6. Comparison and conclusion

In this paragraph, the implementation of the precautionary principle in 4 Member (Denmark, Italy, Bulgaria and the Netherlands) states and one EEA Country (Norway) was examined. 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.

We can now compare and draw four conclusions from this research.

First, in the countries that we examined, the precautionary principle was not incorporated in the constitution. Furthermore, the precautionary principle 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.

An attempt to define the precautionary principle could be found in the Norwegian Nature Diversity Act, in which it is stated that:

*"When a decision is made in the absence of adequate information on the impacts it may have on the natural environment, the aim shall be to avoid possible significant damage to biological, geological or landscape diversity. If there is a risk of serious or irreversible damage to biological, geological or landscape diversity, lack of knowledge shall not be used as a reason for postponing or not introducing management measures."<sup>672</sup>*

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672 Nature Diversity Act 2009. Article 9.

Second, in the countries that we examined, no reference to an innovation principle could be found.

Third, the precautionary principle is applied to a large variety of topics in the countries under examination. Some topics are reoccurring, as neonicotinoids and GMOs. However, there are also country-specific topics as for example the application of the precautionary principle to shale gas in Bulgaria, or to climate change (Urgenda) in The Netherlands. These are topics that are high on the political agenda of the respective countries.

The fourth conclusion is therefore connected to the third conclusion. Whether a weak versus moderate or strong approach was taken, seemed to be influenced by the political stance of the government. Furthermore, it also seemed to be influenced by the politization of the topic (see especially the report of Denmark and Italy). The precautionary principle in political decisions has often been used by opposing parties in cases between public bodies of different levels, or between citizens and administrations (see the report of Italy). This finding corresponds to the findings in Chapter 2, in which it was argued that the use of the precautionary principle is highly political.

In sum, the examination of the implementation and use of the precautionary principle in selected countries confirmed to a larger extent the research in the previous chapters.

## 7 Conclusions and Reflections

### 7.1 Overview of main findings

The objective of this report was to give an overview of the application of the PP since 2000 and herewith to create a **knowledge basis** on the effect and the application of the precautionary principle since 2000 and **to clarify our understanding of the key concepts** precaution, precautionary principle, innovation and innovation principle.

Chapter 2 of this report is therefore dedicated to an examination of the concepts precaution, precautionary principle, innovation and innovation principle.

First, the concepts precaution and the precautionary principle are examined. The history and the various interpretations of the precautionary principle -ranging from weak to strong formulations- are examined as well as the controversies surrounding the precautionary principle. We show that the precautionary principle is a legal principle, but that a universally accepted definition of 'the' precautionary principle does not exist. Different versions and interpretations of the precautionary principle are used at international, European and even national level.

Yet, irrespective of how the precautionary principle is interpreted, we can say that 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 offer a predetermined solution. Rather, the precautionary principle is 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. Some therefore argue that the strength of the precautionary principle precisely lies in its open-endedness and flexibility, which creates a possibility and an incentive for better regulation.

We also have observed that practice and literature operate several constituent elements of the precautionary principle. In this manner a 'conceptual core'<sup>673</sup> of the principle was identified, based on various definitions and understandings of the principle, that forms the main components of the precautionary principle.

*RECIPES takes scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and burden of proof to form the main components of the precautionary principle.*

Next, we examined the concept of innovation, its relation to the precautionary principle and the rise of an 'innovation principle'.

Also for innovation no single definition exists. It is important to note that 'innovation' is in the eye of the beholder. Something is called an innovation by someone because the person in question 'assumes' that it will be an improvement.

Therefore, RECIPES does not consider innovation as a goal in itself as this hides the factual uncertainties and different opinions that exist with regard to the desirability of a particular new technology.

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673 Cameron, J., 'The Precautionary Principle in International Law', in 'O Riordan, T., Cameron, J., Jordan, A., (eds.) Reinterpreting the Precautionary Principle, London: Cameron May 2001, p. 116.

*RECIPES will use the term innovation in the sense of responsible innovation. With responsible innovation we mean "taking care of the future through collective stewardship of science and innovation in the present".<sup>674</sup> Defined as such, innovation can be technological inventions and also other kinds of changes such as organizational innovations. This working definition reflects the fact that products of technological development can bring forth a wide range of (societal) benefits; as medical technology and health, electric cars and the environment or digital technologies and the free flow of information.*

The innovation principle on the other hand, was proposed by the European Risk Forum (ERF) in 2013. It defined the innovation principle as:

*"whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed".<sup>675</sup>*

More recently the European Commission's DG RTD has operated a different definition of the innovation principle, viz.:

*"EU policy and legislation should be developed, implemented and assessed in view of encouraging innovations that help realise the EU's environmental, social and economic objectives, and to anticipate and harness future technological advances"<sup>676</sup>.*

Furthermore, we explained the connection of the RECIPES research with Responsible Research and Innovation (RRI). Some authors have connected RRI with the precautionary principle. RRI could be considered as constituting a process, a practice of the highest integrity and quality, a reflective & critical research culture, and a force pushing for an internal reform of science to better align science, technology and innovation with the values, goals and aspirations of society. In this context literature points out to the different goals of RRI and the precautionary attitude of the safety paradigm; with RRI focusing on orienting science and technology along a morally and socially 'right' route and the precautionary principle to act as a tool against undesirable outcomes of innovation activities.

Finally, the chapter embedded the concepts of precaution, precautionary principle, innovation and innovation in two existing risk governance frameworks that relate to risk and/or safety governance: IRGC risk governance framework and the General Food Safety framework. It herewith aimed to connect RECIPES to the larger risk governance landscape in which enactment of the precautionary principle may take place.

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674 Stilgoe, J., Owen, R., Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy* 42, 1568-1580, here p. 1570.

675 European Risk Forum, 'The Innovation Principle, Stimulating Economic Recovery', Open letter to Barroso, Van Rompuy and Schultz, 24 October 2013. Retrieved from [https://corporateeurope.org/sites/default/files/corporation\\_letter\\_on\\_innovation\\_principle.pdf](https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf), last accessed 5 May 2019, p. 2.

676 [https://ec.europa.eu/info/news/innovation-principle-makes-eu-laws-smarter-and-future-oriented-experts-say-2019-nov-25\\_en](https://ec.europa.eu/info/news/innovation-principle-makes-eu-laws-smarter-and-future-oriented-experts-say-2019-nov-25_en).

Chapter 3 presented the RECIPES stakeholder landscape. The precautionary principle gives direction to what is right and fair in situations of scientific uncertainty, and how interests should be weighed up. However, the principle does not establish *which* measures are linked to *which* situations of scientific uncertainty. The question of how and when the principle should be implemented is a delicate balancing act to be made by decision-makers under uncertain circumstances. Within this balancing exercise, we distinguish four stakeholder groups. Firstly, there are parties who formalize the precautionary principle in laws, rules and measures. Secondly, there are parties who implement the precautionary measures. Thirdly, there are parties who are directly affected by the way in which the precautionary principle is applied. Fourthly, there are parties indirectly affected. On the basis of these four categories, we first described the stakeholder landscape and their relation to the precautionary principle. Subsequently, we shortly described different stakeholder groups and their desired involvement in the RECIPES project.

Chapter 4 studied the implementation of the precautionary principle at international level. The restrictive approaches of the ITLOS, ICJ and WTO show that the precautionary principle still faces many obstacles to being recognized as a general principle of international law.

Chapter 5 provided insights in the implementation and use of the precautionary principle at the EU level since 2000, the year of the adoption of the Commission's Communication on the Precautionary principle. Through the Maastricht Treaty, the precautionary principle has acquired a constitutional status. Hence, as of Maastricht, found its way into the precautionary principle EU environmental measures, without however a concrete understanding of its meaning. The breakout of the so-called mad cow or BSE crisis in 1996, which put into question the EU system of regulation on food safety, was pivotal in understanding the reach and meaning of the precautionary principle beyond the field of environmental protection.

A literature review combined with an empirical study looking at all legal acts that used or referred to the term precautionary principle provides for a bird's-eye perspective as to 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 still exists a lot of acts that apply the precautionary principle without expressly mentioning it. This means that in practice there are likely to be many more situations where the precautionary principle is being applied. To this end, 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.

The precautionary principle is recognised as a general principle of EU law. However, there is no single definition of the precautionary principle in the EU legal acts. The principle is used in different areas. For example, EU food safety legislation has expressly defined the precautionary principle for application in that sector. EU secondary environmental legislation however provides no equivalent definition, though 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.

Our analysis also showed that the European Courts have codified the definitions and requirements for application of the principle over time into standard formulations which are used repeatedly. Nonetheless, the Court is at times inconsistent in applying the

principle and visibly struggles with the application of the precautionary principle in specific cases. Furthermore, the Court's review of the application of the precautionary principle is limited and leaves ample room for the Commission to exercise its discretionary powers. 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 that the Courts leave the EU legislator and the Commission much discretion to do so. However, the Court's review looks at manifest errors and often lacks consistency. Importantly, the Court has largely ignored reviewing the temporary nature of a precautionary measure. This leads to the conclusion that although the EU courts have followed the 2000 Communication in general, some judgments seem to overlook the dynamics of science. In this way, the requirement set forth in 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.<sup>677</sup>

Our analysis also 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 need for a general uniform definition of the precautionary principle, 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. At the same time, it needs to be examined how the requirement of carrying out an impact assessment prior to adopting a precautionary measure should be implemented -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 as a general governance principle and a principle of good administration and how the precautionary principle could fit within a broader risk analysis framework.

To explore ideas in this direction, this study also looked in the effects the constitutionalisation of the precautionary principle had in France, being the only European country that has constitutionalized the precautionary principle. Our study reveals that here not a lot has changed. The French doctrine is critical of the effects of the constitutionalisation of the precautionary principle in French law, noting in particular its incorrect application.<sup>678</sup> What could be of interest is the suggestion of authors to set up a specialised scientific body to draw orientation for the implementation of the risk assessment and provisional and proportionate measures to be adopted and to improve the monitoring of temporary character of precautionary measures.

Chapter 6 looked into the implementation of the precautionary principle in four Member States (Denmark, Italy, Bulgaria and the Netherlands) and one EEA Country (Norway).

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677 See also Rogers M.D., 'Risk management and the record of the precautionary principle in EU case law', *Journal of Risk Research*, 14 (4), 2011, p. 481.

678 *Inter alia*, Ibid. Capitani, A. (2005). Ibid. Godard, O. (2009). Ibid. Boutonnet, M. (2014). Ibid. Deguerge, M. (2006).

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 these countries the precautionary principle is not incorporated in the constitution. The precautionary principle also mostly does 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. Furthermore, in the countries that we examined, no reference to an 'innovation principle' could be found.

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 be influenced by the political stance of the government and the politicisation 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.

We will now provide some reflections to feed into the next phase of the RECIPES project.

## 7.2 Conceptual Core of the precautionary principle

This study has shown that a universally accepted definition of 'the' precautionary principle does not exist. Different versions and interpretations of the precautionary principle are used at international, European and national level. For further research in this project, and especially the case studies research, however, a common understanding of the precautionary principle, that we will operate throughout the project, is desirable.

In the European Union, the precautionary principle is recognised a general principle of EU law. At international level, however, the restrictive approaches of the ITLOS, ICJ and WTO show that the precautionary principle still faces many obstacles to being recognised as a general principle of international law. The country studies show also a diverse picture of the application and use of the precautionary principle.

Our analysis shows that although the precautionary principle has been used in a variety of policy areas, it focuses on environmental, health and safety and consumer protection, and where it has been used on other policy areas, it here again dealt with health and safety matters. This holds for both the EU level as for the country studies.

Our analysis moreover reveals that, in EU law making, that the principle is used in different areas, sometimes even as guiding principle for Member States or the Commission, but hardly ever defined or explained with regards to the particular situation covered by the legal act in question. This leaves ample room for flexibility and *ad hoc* solutions. With respect to European Courts rulings, it was shown that the precautionary principle is dealt with in detail in various cases decided by the Courts.

We may therefore conclude in this report that there is no one single definition of the precautionary principle, not in legal practices nor in the literature. We have explained in Chapter 5 of this report that the lack of a general definition even for example at EU level, results from a need felt in the regulatory practice for a flexible and content-specific approach of the principle which is needed in order to make it implementable to the different subject areas.

## Conceptual core of the precautionary principle

We have thus observed that practice and literature operate several constituent elements of the precautionary principle. Literature has identified a 'conceptual core'<sup>679</sup> of the principle, based on various definitions and understandings of the principle, that forms the main components of the precautionary principle: scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and burden of proof.

### *Scientific uncertainty and risk*

Stirling describes the conventional science-based understanding of risk as the combination of what may happen – the hazards, possibilities, outcomes – with the likelihood that it might happen.<sup>680</sup> This conventional view implies that the outcomes and likelihoods of those outcomes are known, and thus that level of risk can be calculated by combining probability and severity. However, invoking uncertainty surrounding both the likelihoods and outcomes of technological risks, we define risk as uncertainty about and severity of the consequences or outcomes of an activity with respect to something that humans value.<sup>681</sup> It is this latter type of uncertain risk that is of relevance in the context of the precautionary principle.

These elements are considered to be important, because they point to the added value of the precautionary principle in relation to other principles. For instance, the precautionary principle can only be invoked in relation to threats of which scientific uncertainty exists, because if scientific certainty has been established and a threat is significant, the prevention principle is applicable instead.

At the core of the precautionary principle lies indeed scientific uncertainty, the 'key foundation' of the principle. Uncertainty is a necessary condition for the application of the precautionary principle. No clear consensus however exists about the exact requirements of the uncertainty-dimension.<sup>682</sup> Most definitions of the precautionary principle refer to 'scientific' uncertainty. This denotes to what extent it is possible to give a definitive answer on different aspects of a risk on the basis of the available scientific knowledge.<sup>683</sup> As indicated in Chapter 1, scientific uncertainty can stem from more than a lack of data or inadequate models of risk assessment. Scientific uncertainty might also exist in the form of indeterminacy, when not all the factors influencing the causal chains are known. Equally, scientific uncertainty might arise when there is ambiguity or contradicting data. Finally, it is possible that certain risks are still unknown, which often is labelled as 'unknown unknowns'.<sup>684</sup>

Uncertainty is what differentiates precaution from prevention, which is a separate and broader principle.<sup>685</sup> It raises two main questions, that of the types of uncertainty concerned and that of the scope of those uncertainties. Regarding the latter, the various national, EU and international instruments provide for different answers. Principle 15 of the Rio Declaration, for example, states that only a 'lack of *full* scientific certainty' may

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679 Cameron, J., 'The Precautionary Principle in International Law', in 'O Riordan, T., Cameron, J., Jordan, A., (eds.) Reinterpreting the Precautionary Principle, London: Cameron May 2001, p. 116.

680 Stirling, A., 'Science, precaution, and the politics of technological risk: Converging implications in evolutionary and social scientific perspectives', *Annals of the New York Academy of Sciences* 1128 (1):95 – 110, May 2008, p. 98.

681 Aven, T., and Renn, O., *Risk Management And Governance*, Springer, Berlin, Heidelberg, 2010.

682 Aven, T., 'On Different Types of Uncertainties in the Context of the Precautionary Principle'. *Risk Analysis*, Vol. 31, No. 10, 2011, p. 1516.

683 van Asselt, M., Vos, E., and Rooijacker, B., 'Science, Knowledge And Uncertainty In EU Risk Regulation', *Uncertain Risks Regulated*, 2019.

684 Donald Rumsfeld, U.S. Secretary of Defense, Defense Department Briefing, February 2002.

685 Zander, J., *The Application of the Precautionary Principle in Practice, Comparative Dimensions*, Cambridge University Press, New York, 2010, p 14-17.

conduct to impose on states a duty to adopt precautionary measures. The EU legislator does not seem to operate such a threshold and speaks merely of 'scientific uncertainty'.

#### *Some form of scientific analysis*

The fact that in cases of scientific uncertainty no full risk assessment can be carried is no leeway to adopt measures not being based on science. Some form of scientific evaluation or analysis is mandatory; imaginary issues are not enough to trigger the precautionary principle. Grounds for concern that can trigger the precautionary principle are limited to those concerns that are plausible or scientifically tenable. The European Commission talks in its Communication about 'reasonable grounds'. The European Court requires in Pfizer 'as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue'.<sup>686</sup>

#### *Threshold of damage*

The common element of the precautionary principle definitions is a threshold of damage to health or the environment that should be reached before any precautionary measure has to be adopted by the EU authorities or Member States. The establishment of such threshold was indispensable in order to avoid that 'an unsustainable utopian element enters into the discourse of the precautionary principle', which would force states to act even when they are facing only small and negligible damage.<sup>687</sup> Numerous international instruments, such as the Rio Declaration or the 1990 Bergen Declaration, refer to threats of 'serious' or 'irreversible' damage, which constitutes a very high threshold. Others only require the existence of a 'significant' damage, like the World Charter for Nature.<sup>688</sup> What these different clauses have in common is that they express a moral judgement about the acceptability of the harm. The formulation by the EU legislator is more loose and speaks of the 'possibility of harmful effect', whilst the also the European Courts frame this in loose terms, speaking of 'the existence or extent of risks to human health', 'the possibility of harmful effects on health' and likelihood of real harm to public health'.

#### *Cost-effective measures/proportionality*

Most definitions require an evaluation of the different possible actions, and hold that cost-effective measures should be taken, as for example provided for by Principle 15 of the Rio Declaration. According to some, in the specific context of Principle 15, this obligation would constitute the obligation of the regulator of an activity to opt for the 'least economically cumbersome' precautionary measures.<sup>689</sup> The EU legislator and Courts are silent on this point. Overall, actions taken on the basis of the precautionary principle should be proportional to the chosen level of protection and the magnitude of the possible harm. This is in line with the Commission's Communication and the Courts' case law.

#### *Burden of proof*

Some definitions of the precautionary principle also entail a reversal of the burden of proof. Indeed, contrary to the traditional approach, some precautionary provisions require that the person engaging in a given activity or action, either it be a polluting state or a manufacturer releasing potentially dangerous products or substances into the environment, prove that it will not harm it. The World Charter for Nature, for example, imposes on the person wishing to engage in a certain activity to demonstrate that the benefits of this activity will outweigh its costs – and that, consequently, results in a shift

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686 Case T-13/99 Pfizer, para 162.

687 Cameron J. and Wade-Gerry, W., *Addressing Uncertainty: Law, Policy and the Development of the Precautionary Principle*, 1992, p. 9.

688 Grimeaud, D., , 'The precautionary principle in international environmental and trade law' in Faure, M., and Vos E., (eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen*, The Hague, 2003, p. 71.

689 Zander, J., *The Application of the Precautionary Principle in Practice, Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 37.

of the burden of proof 'from the regulator and onto the regulated party'.<sup>690</sup> The Commission views that with prior approval mechanisms, the burden of proof is placed on the manufacturer, whilst in absence of such mechanisms, this should not be the general rule; but may be *ad hoc* the case.

#### *Provisional character*

Both the analyses of international and EU law make plain that the precautionary principle instructs to adopt only temporary measures that will be reviewed after a certain period of time.

## 7.3 Reflections

Based on the findings of this report, we would like to make a few reflections to feed into the next phase of the RECIPES project.

### **Stock-taking of the application of the precautionary principle in literature, law and practice**

This report aimed to clarify our understanding of key concepts and 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 Work Package 1 did not have the ambition to offer a conceptual framework. It is clear though that the RECIPES project will benefit from conceptual guidance. In Chapter 2, we proposed to look more into existing frameworks on risk and/or safety governance for the purpose of the next, analytical phase of the project, that will be carried out in Work Package 2.

### **Existing frameworks on risk and safety governance and RRI**

Therefore, it will be 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, as explained in Chapter 2. In the latter Chapter we thus highlighted two important frameworks: the International Risk Governance Council (IRGC) framework and the Safe Food project's Food Safety Governance framework<sup>691</sup> as a relevant way of linking up risk governance with the precautionary principle. Reflecting on this will be helpful in drafting the research design of the empirical research to be carried out in Work Package 2. We will therefore come back to this in Work Package 2. It should be emphasised, that the RECIPES project will not adopt up front 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.

In this context we would like to underline the relevance of RRI. RRI could be considered as constituting a process, a practice of the highest integrity and quality, a reflective & critical research culture, and a force pushing for an internal reform of science to better align science, technology and innovation with the values, goals and aspirations of society.

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690 Zander, J., *The Application of the Precautionary Principle in Practice. Comparative Dimensions*, Cambridge University Press, New York, 2010, p. 36 and 37.

691 Renn O., and Dreyer, M., *Food Safety Governance*, Springer, 2009.

## 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 also was applied by the Commission and the EU legislator for general, financial and institutional matters, for the area of freedom, security and justice and in the fields of transport, services, regional policy, industrial policy and competition. In the analytical phase, 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 how to apply the precautionary principle

Whereas the EU Treaties do not provide for a definition of the precautionary principle, the EU legislator, the European Commission and the European Courts have tried to further define the precautionary principle and the conditions for its use. These definitions however, have slight differences. For example, as was illustrated in Chapter 5 of this Report, the threshold to trigger the precautionary principle seems slightly higher in the Transport Protocol, which makes reference to '*serious irreversible effects on the health and the environment*' (albeit indicating that this also means 'potential harmfulness') than the General Food Law, which by contrast, departs from '*potential harmful effects on health*'.

The formulation of the action to be taken also differs slightly. Whilst the Transport Protocol links with the negative formulation of the Rio Declaration in stating that measures '*should not be postponed*' by reference to uncertainty, the General Food Law holds that measures '*may be adopted*'. Furthermore, the General Food Law clearly states that the measures are of a 'provisional' nature and 'pending further scientific information', no such indication is given in the Transport Protocol definition.

The European Courts also have struggled with the definition and application of the precautionary principle. As was shown in Chapter 5, the Courts have formalized definitions of the precautionary principle in standard formulations. The commonalities between these definitions are a description of the situation that allows for the use of the precautionary principle (scientific uncertainty), a hint at the type of risk (to human health), the action to be taken (protective measures/ risk management measures), and an assessment of the available information. There is however no clear indication of what threshold is necessary to trigger the precautionary principle, or what the assessment of the available information should entail. 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 how to apply the precautionary principle, a view 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 an important element in the decision-making process at the EU level is the impact assessment. Our analysis in Chapter 5 reveals that the case law of the Courts highlights the importance of carrying out an impact assessment. Impact assessments are carried out when in/during proposals for legislative acts or implementing and delegated acts or financial programmes, recommendations for the negotiations of international agreements 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.

In the case of risk regulation, for non-legislative regulatory initiatives, impact assessments are carried out where there is sufficient discretion and/or the decision deviates from the advice of risk assessors.<sup>692</sup> As Maria Weimer underlines, the purpose of an impact assessment in the field of risk is to control discretion especially in cases where risk managers decide to deviate from the advice of risk assessors.<sup>693</sup> She states that '... , unsurprisingly, every decision to invoke the precautionary principle is treated as falling within this category. In this way, economic expertise is expected to step in where scientific expertise falls short of controlling discretionary choices.'<sup>694</sup> Where regulatory initiatives entail significant impacts the results of risk assessment will feed into the impact assessments in assessing and selecting different policy options. In this way, both risk assessments and impact assessments aim to control the Commission's discretion and to 'rationalise' its choice for a specific risk management (precautionary) measure by subjecting it to scientific and economic expert scrutiny.<sup>695</sup>

Therefore, in the case studies, especially the ones that do research at the EU level, it should be carefully analysed how discretion is controlled and how decisions have been drafted and whether and how impact assessments were made. Such impact assessments potentially could also include a 'needs assessment'.<sup>696</sup>

### Precautionary principle 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 and innovation at this stage of the project.

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692 European Commission, Better regulation Toolbox; [http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

693 Weimer, M., Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology, Oxford, 2019, Oxford University Press, p. 77.

694 Weimer, M., Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology, Oxford, 2019, Oxford University Press, p. 77

695 Weimer, M., Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology, Oxford, 2019, Oxford University Press, p. 77.

696 Garnett, K., Van Calster G., Reins L., Towards an innovation principle: an industry trump or shortening the odds on environmental protection?, Law, Innovation and Technology, 2018, Vol 10, Issue 1, p. 10.

Therefore, the case-studies should 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.

## 8 Literature

### 8.1. International legal framework

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## 9 Annexes

### 9.1 Application of the precautionary principle in practice: in-depth analysis of eight seminal EU Court Judgments

Case	Subject of protection	Justification of the use of the precautionary principle  Severity of potential harm and level of uncertainty	Application of the criteria in the Communication of 2000					Review of measure foreseen	Responsibility assigned for producing scientific evidence	Nature of regulation (precautionary action)
			Proportionality	Non-discrimination	Consistent	Based on examination of costs and benefits				
<b>Case T-13/99</b>  <b>Pfizer Animal Health SA v. Council</b>  'Pfizer' (2002)	Health	Uncertainty on the link between the use of antibiotic <i>virginiamycin</i> in feedstuffs and resistance to it in humans. The Court set <b>precedent by interpreting uncertainty as contrasting scientific opinions</b> to justify use of precautionary principle	✓	✓	✓	The Court considered that a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management.  <b>Hence the Court subsumed this criterion within proportionality</b>	No	No	Ban on the use of <i>virginiamycin</i> upheld	
<b>Case T-229/04</b>  <b>Sweden v. Commission</b>  'Paraquat' (2007)	Health	Uncertainty regarding consequences of exposure to paraquat for human and animal health. By contrast with previous case law, the Court does not confine itself to a marginal review of the use made by the Commission of its discretionary powers, but rather thoroughly reviews the scientific data	/	/	/	/	/	/	Authorization of <i>paraquat</i> overturned  <b>[\$223]</b>	

Case	Subject of protection	Justification of the use of the precautionary principle  Severity of potential harm and level of uncertainty	Application of the criteria in the Communication of 2000					Responsibility assigned for producing scientific evidence	Nature of regulation (precautionary action)
			Proportionality	Non-discrimination	Consistent	Based on examination of costs and benefits	Review of measure foreseen		
<b>Case T-75/06</b>  <b>Bayer CropScience</b>  ‘Endosulfan’ (2008)	Health & Environment	Uncertainty regarding the consequences of exposure to <i>endosulfan</i> for human health and for the environment  <b>[§126-128 and §228]</b>	  Court considers ban a proportionate measure – despite various safe alternative measures suggested by applicants  <b>[§31 and §237]</b>		No proper risk assessment performed on <i>endosulfan</i> – Court approves measure based on data relating to analogical products, i.e. endosulfan sulfate and/or other metabolites of endosulfan  <b>[§247 and §257]</b>	No mention of it	No mention of it	Ban on the use of <i>endosulfan</i> upheld  <b>[§259]</b>	
<b>Case C-77/09</b>  <b>Gowan</b> ‘Fenarimol’ (2010)	Health	Uncertainty regarding risk posed by <i>fenarimol</i> to human and animal health in reason of the product’s potential endocrine disrupting properties  <b>[§34, 38 and 62]</b>  Court relies on the existence of differing scientific opinions to conclude to uncertainty (// Pfizer)  <b>[§76]</b>	  Court considers limitations of the authorization period to 18 months and the restrictions on the authorized		No proper risk assessment - Court approves measure based on data relating to analogical products.  <b>[§79]</b>	No mention of it	The Commission must take the risk assessment performed by the MS rapporteur into account but it is not bound by it.  <b>[§60]</b>	No mention of it  Restrictions on the uses of <i>fenarimol</i> upheld  <b>[§88]</b>	

Case	Subject of protection	Justification of the use of the precautionary principle  Severity of potential harm and level of uncertainty	Application of the criteria in the Communication of 2000					Review of measure foreseen	Responsibility assigned for producing scientific evidence	Nature of regulation (precautionary action)
			Proportionality	Non-discrimination	Consistent	Based on examination of costs and benefits				
			number of uses of the substance proportionate measures [§§62-64]							
<b>Case C-343/09 Afton</b> 'MMT' (2010)	Health & Environment	Uncertainty regarding the risk posed by <i>MMT</i> to human health and to the environment [§3] Court relies on the existence of differing scientific opinions to conclude to uncertainty (// Pfizer) [§§58-59]	<p>✓</p> <p>Court considers limitations potentially leading to a ban a proportionate measure [§68]</p>	<p>✓</p> <p>✓</p>	No proper risk assessment at the time of the case – full risk assessment of potential threat presented to health & environment by <i>MMT</i> to be performed after Commission established test methodologies to that end	<p>✓</p> <p>Court considers the proportionate character of restrictions demonstrate that the Commission made a careful balance between the interests of the consumer and a high level of protection of health &amp; environment, and the traders' interests (costs/benefits analysis subsumed within proportionality test, // Pfizer). [§56 and §64]</p>	Court confirms Commission's discretion to accept new scientific data during the proceedings [§41]	No mention of it	Restrictions on the use of and labelling requirements on <i>MMT</i> upheld [§§95-97]	

Case	Subject of protection	Justification of the use of the precautionary principle  Severity of potential harm and level of uncertainty	Application of the criteria in the Communication of 2000						Nature of regulation (precautionary action)
			Proportionality	Non-discrimination	Consistent	Based on examination of costs and benefits	Review of measure foreseen	Responsibility assigned for producing scientific evidence	
<b>Case C-558/07 S.P.C.M.</b>  ‘Reacted monomer substances’ (2009)	Health & Environment	Registration obligations regarding monomer substances for both importers and manufacturers of such substances within the EU in order to guarantee a high level of protection of human health & the environment and to ensure innovation and fair competition within the internal market <b>[\$19, §36]</b>	✓	✓	✓	No mention of it	No mention of it	No mention of it	Article 6(3) of Regulation 1907/2006 (REACH) is valid <b>[\$81]</b>
<b>Joined cases T-429/13 and T-451/13 Bayer CropScience &amp; Syngenta</b>	Health	Uncertainty regarding the risk posed by three neonicotinoids substances, <i>clothianidin</i> , <i>imidacloprid</i> and <i>thiamethoxam</i> to colonies of bees <b>[\$15]</b>	✓	✓	✓	Balance of potential costs and benefits of the proposed precautionary measure suffices – no need to proceed to a complex economic analysis	No (the measure was already the result of a review procedure) – Court states that ‘new	No mention of it	Restriction on the uses of <i>clothianidin</i> , <i>imidacloprid</i> and <i>thiamethoxam</i> upheld

Case	Subject of protection	Justification of the use of the precautionary principle  Severity of potential harm and level of uncertainty	Application of the criteria in the Communication of 2000						Nature of regulation (precautionary action)
			Proportionality	Non-discrimination	Consistent	Based on examination of costs and benefits	Review of measure foreseen	Responsibility assigned for producing scientific evidence	
'Neonicotinoids' (2018)						No requirement of a formal written impact assessment  [§460]	available scientific data' can be 'new' under both substantial and temporal aspects  [§§178-179]		
<b>Case C-528/16</b> <b>Confédération paysanne &amp; Others</b> 'Novel directed mutagenesis technique' (2018)	Health & Environment	Question whether novel direct mutagenesis technique should be exempted from the requirements of Directive 2001/18						Organisms modified through novel directed mutagenesis technique are 'GMOs' falling within the scope of the GMO Directive and are subjected to all its provisions and principles	

## 9.2 Legal analysis: lists

### List of all legal acts<sup>697</sup>

Regulations
Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 on a revised Community eco-label award scheme
Council Regulation (EC) No 1407/2002 of 23 July 2002 on State aid to the coal industry
Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy
Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)
Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (Text with EEA relevance)
Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships
Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999
Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. (Text with EEA relevance)
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

<sup>697</sup> The legal acts regarding the specific country studies are explicitly mentioned in their sections

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Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture

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Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)

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Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (Text with EEA relevance)

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Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance)

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Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (Text with EEA relevance)

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Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions

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Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Text with EEA relevance)

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Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

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Commission Regulation (EU) No 756/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes IV and V. Text with EEA relevance

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Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (Text with EEA relevance)

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Regulation (EU) No 1255/2011 of the European Parliament and of the Council of 30 November 2011 establishing a Programme to support the further development of an Integrated Maritime Policy. Text with EEA relevance

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Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. Text with EEA relevance

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Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006

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Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC

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Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change and repealing Decision No 280/2004/EC Text with EEA relevance

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Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. Text with EEA relevance

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Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species

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Commission Delegated Regulation (EU) 2015/1576 of 6 July 2015 amending Regulation (EC) No 606/2009 as regards certain oenological practices and Regulation (EC) No 436/2009 as regards the registering of those practices in the wine sector registers

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Commission Implementing Regulation (EU) 2015/207 of 20 January 2015 laying down detailed rules implementing Regulation (EU) No 1303/2013 of the European Parliament and of the Council as regards the models for the progress report, submission of the information on a major project, the joint action plan, the implementation reports for the Investment for growth and jobs goal, the management declaration, the audit strategy, the audit opinion and the annual control report and the methodology for carrying out the cost-benefit analysis and pursuant to Regulation (EU) No 1299/2013 of the European Parliament and of the Council as regards the model for the implementation reports for the European territorial cooperation goal

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Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance)

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Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (Text with EEA relevance)

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Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (Text with EEA relevance)

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Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour (Text with EEA relevance)

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Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104

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Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC

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Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)

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Regulation (EU) 2017/1004 of the European Parliament and of the Council of 17 May 2017 on the establishment of a Union framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the common fisheries policy and repealing Council Regulation (EC) No 199/2008

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Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers (Text with EEA relevance. )

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Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Text with EEA relevance. )

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Regulation (EU) 2018/975 of the European Parliament and of the Council of 4 July 2018 laying down management, conservation and control measures applicable in the South Pacific Regional Fisheries Management Organisation (SPRFMO) Convention Area

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Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (Text with EEA relevance.)

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Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (Text with EEA relevance.)

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Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

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## **Directives**

Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residues - Commission declaration

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Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

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Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to limit values for benzene and carbon monoxide in ambient air

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Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste

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Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Text with EEA relevance.)

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Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration

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Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment

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Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants

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Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance)

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Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement

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Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) - Joint declaration of the European Parliament, the Council and the Commission relating to Article 9

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Commission Directive 2003/2/EC of 6 January 2003 relating to restrictions on the marketing and use of arsenic (tenth adaptation to technical progress to Council Directive 76/769/EEC) (Text with EEA relevance)

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Commission Directive 2004/1/EC of 6 January 2004 amending Directive 2002/72/EC as regards the suspension of the use of azodicarbonamide as blowing agent (Text with EEA relevance)

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Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance)

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Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 amending for the 22nd time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles)

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Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version). (Text with EEA relevance)

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Commission Directive 2006/132/EC of 11 December 2006 amending Council Directive 91/414/EEC to include procymidone as active substance. (Text with EEA relevance)

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Commission Directive 2006/133/EC of 11 December 2006 amending Council Directive 91/414/EEC to include flusilazole as active substance. (Text with EEA relevance)

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Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as active substance Text with EEA relevance

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Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Text with EEA relevance

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Directive 2008/101/EC of the European Parliament and of the Council of 19 November 2008 amending Directive 2003/87/EC so as to include aviation activities in the scheme for greenhouse gas emission allowance trading within the Community (Text with EEA relevance)

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Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council

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Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (Text with EEA relevance)

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Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Text with EEA relevance)

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Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (Text with EEA relevance)

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Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (Text with EEA relevance)

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Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance)

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Directive 2010/78/EU of the European Parliament and of the Council of 24 November 2010 amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC and 2009/65/EC in respect of the powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority) Text with EEA relevance

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Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles. Text with EEA relevance

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Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Text with EEA relevance

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Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment. Text with EEA relevance

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Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE). Text with EEA relevance

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Directive 2013/30/EU of the European Parliament and of the Council of 12 June 2013 on safety of offshore oil and gas operations and amending Directive 2004/35/EC. Text with EEA relevance

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Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. Text with EEA relevance

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Directive 2014/51/EU of the European Parliament and of the Council of 16 April 2014 amending Directives 2003/71/EC and 2009/138/EC and Regulations (EC) No 1060/2009, (EU) No 1094/2010 and (EU) No 1095/2010 in respect of the powers of the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority)

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Directive 2014/89/EU of the European Parliament and of the Council of 23 July 2014 establishing a framework for maritime spatial planning

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Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. Text with EEA relevance

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Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance)

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Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance.)

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Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance)

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## Decisions

2000/325/EC: Commission Decision of 11 May 2000 authorising Member States to take measures provisionally against the introduction into, and the spread within the Community of Pepino mosaic virus as regards tomato plants, intended for planting, other than seeds (notified under document number C(2000) 1312)

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2002/628/EC: Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety

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2002/628/EC: Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety

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Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme

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2002/835/EC: Council decision of 30 September 2002 adopting a specific programme for research, technological development and demonstration: "structuring the European Research Area" (2002–2006)

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Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006)

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2002/623/EC: Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (Text with EEA relevance) (notified under document number C(2002) 2715)

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2002/836/EC: Council Decision of 30 September 2002 adopting a specific programme of research, technological development and demonstration to be carried out by means of direct actions by the Joint Research Centre (2002–2006)

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2003/1/EC: Commission Decision of 18 December 2002 relating to national provisions on limiting the importation and placement on the market of certain NK fertilisers of high nitrogen content and containing chlorine notified by France pursuant to Article 95(5) of the EC Treaty (Text with EEA relevance) (notified under document number C(2002) 5113)

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2003/653/EC: Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty (Text with EEA relevance) (notified under document number C(2003) 3117)

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2003/549/EC: Commission Decision of 17 July 2003 extending the period referred to in Article 95(6) of the EC Treaty in relation to the national provisions on the use of short-chain chlorinated paraffins notified by the Netherlands under Article 95(4) (Text with EEA relevance) (notified under document number C(2003) 2539)

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2004/1/EC: Commission Decision of 16 December 2003 concerning national provisions on the use of short-chain chlorinated paraffins notified by the Kingdom of the Netherlands under Article 95(4) of the EC Treaty (Text with EEA relevance) (notified under document number C(2003) 4749)

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2005/317/EC: Commission Decision of 18 April 2005 on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products (notified under document number C(2005) 1257) (Text with EEA relevance)

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2006/372/EC: Commission Decision of 3 May 2006 concerning draft national provisions notified by the Kingdom of the Netherlands under Article 95(5) of the EC Treaty laying down limits on the emissions of particulate matter by diesel powered vehicles. (notified under document number C(2006) 1791)

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2006/871/EC: Council Decision of 18 July 2005 on the conclusion on behalf of the European Community of the Agreement on the Conservation of African-Eurasian Migratory Waterbirds

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2006/507/EC: Council Decision of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants

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2006/871/EC: Council Decision of 18 July 2005 on the conclusion on behalf of the European Community of the Agreement on the Conservation of African-Eurasian Migratory Waterbirds#Agreement on the Conservation of African-Eurasian Migratory Waterbirds

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2006/507/EC: Council Decision of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants#Stockholm Convention on Persistent Organic Pollutants

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2006/601/EC: Commission Decision of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products (notified under document number C(2006) 3932). (Text with EEA relevance)

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2006/578/EC: Commission Decision of 23 August 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products (notified under document number C(2006) 3863). (Text with EEA relevance)

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2007/395/EC: Commission Decision of 7 June 2007 concerning national provisions on the use of short-chain chlorinated paraffins notified by the Kingdom of the Netherlands under Article 95(4) of the EC Treaty (notified under document number C(2007) 2361). (Text with EEA relevance)

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2007/799/EC: Council Decision of 12 October 2006 on the signature, on behalf of the Community, of the Protocol on the Implementation of the Alpine Convention in the field of transport (Transport Protocol)

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2007/799/EC: Council Decision of 12 October 2006 on the signature, on behalf of the Community, of the Protocol on the Implementation of the Alpine Convention in the field of transport (Transport Protocol)# Protocol on the implementation of the 1991 Alpine Convention in the field of transport – Transport protocol

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Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (Text with EEA relevance)

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2008/62/EC: Commission Decision of 12 October 2007 relating to Articles 111 and 172 of the Polish Draft Act on Genetically Modified Organisms, notified by the Republic of Poland pursuant to Article 95(5) of the EC Treaty as derogations from the provisions of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (notified under document number C(2007) 4697) (Text with EEA relevance)

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Council Decision 2008/206/JHA of 3 March 2008 on defining 1-benzylpiperazine (BZP) as a new psychoactive substance which is to be made subject to control measures and criminal provisions

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2008/805/EC: Council Decision of 15 July 2008 on the signature and provisional application of the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part#Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part

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2008/289/EC: Commission Decision of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products (notified under document number C(2008) 1208) (Text with EEA relevance)

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2009/726/EC: Commission Decision of 24 September 2009 concerning interim protection measures taken by France as regards the introduction onto its territory of milk and milk products coming from a holding where a classical scrapie case is confirmed (notified under document C(2009) 3580)

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2009/121/EC: Council Decision of 18 December 2008 rejecting the proposal from the Commission for a Council Regulation implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the use of antimicrobial substances to remove surface contamination from poultry carcasses (Text with EEA relevance)

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2009/187/EC,Euratom: Decision of the European Parliament of 22 April 2008 on discharge in respect of the implementation of the European Union general budget for the financial year 2006, section III – Commission#Resolution of the European Parliament of 22 April 2008 with observations forming an integral part of the decision on discharge in respect of the implementation of the European Union general budget for the financial year 2006, section III – Commission

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2009/187/EC,Euratom: Decision of the European Parliament of 22 April 2008 on discharge in respect of the implementation of the European Union general budget for the financial year 2006, section III – Commission

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2009/420/EC: Commission Decision of 28 May 2009 amending Decision 2006/133/EC requiring Member States temporarily to take additional measures against the dissemination of *Bursaphelenchus xylophilus* (Steiner et Buhner) Nickle et al. (the pine wood nematode) as regards areas in Portugal, other than those in which it is known not to occur (notified under document number C(2009) 3868)

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2011/402/EU: Commission Implementing Decision of 6 July 2011 on emergency measures applicable to fenugreek seeds and certain seeds and beans imported from Egypt (notified under document C(2011) 5000).Text with EEA relevance

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Commission Decision of 19 January 2012 on setting up of the European Union Offshore Oil and Gas Authorities Group

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Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' Text with EEA relevance

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Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ( 'Overseas Association Decision' )

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2013/332/EU: Council Decision of 10 June 2013 on the conclusion on behalf of the European Union of the Protocol on the implementation of the 1991 Alpine Convention in the field of transport (Transport protocol)

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2014/274/EU: Commission Decision of 20 March 2013 on State Aid No SA.23420 (11/C, ex NN40/10) implemented by Belgium for SA Ducroire/Delcredere NV (notified under document C(2013) 1497).Text with EEA relevance

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2014/350/EU: Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (notified under document C(2014) 3677).Text with EEA relevance

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2014/312/EU: Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes (notified under document C(2014) 3429).Text with EEA relevance

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Council Decision (EU) 2015/627 of 20 April 2015 on the position to be taken, on behalf of the European Union, at the seventh meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants as regards the proposals for amendments to Annexes A, B and C

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Commission Decision (EU) 2017/848 of 17 May 2017 laying down criteria and methodological standards on good environmental status of marine waters and specifications and standardised methods for monitoring and assessment, and repealing Decision 2010/477/EU (Text with EEA relevance. )

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Decision of the Authority for European political parties and European political foundations of 20 July 2017 to register European Green Party

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Commission Decision (EU) 2017/2112 of 6 March 2017 on the measure/aid scheme/State aid SA.38454 — 2015/C (ex 2015/N) which Hungary is planning to implement for supporting the development of two new nuclear reactors at Paks II nuclear power station (notified under document C(2017) 1486) (Only the English version is authentic)Text with EEA relevance.

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Council Decision (EU) 2017/758 of 25 April 2017 on the position to be adopted, on behalf of the European Union, at the eighth meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants, as regards the proposals for amendments to Annexes A, B and C

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European Parliament decision of 6 February 2018 on setting up a special committee on the Union's authorisation procedure for pesticides, its responsibilities, numerical strength and term of office (2018/2534(RSO))

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