Study on the precautionary principle in EU environmental policies
Final report

[November 2017

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Study on the precautionary principle in EU environmental policies

Final Report

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 The authors of this report are, Harriet Bradley, Leonie Reins, Nicola Crook, Nienke van der Burgt and Virginie Rouas. We acknowledge Professor Alberto Alemanno, David Gee and Gretta Goldenman for their input to this study.

Milieu Ltd (Belgium), Chaussée de Charleroi 112, B-1060 Brussels, tel.: +32 2 506 1000; e-mail: nienke.vanderburgt@milieu.be; web address: www.milieu.be.

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ABSTRACT

This study, prepared for the European Commission's DG Environment, reviews the *actual use and implementation of the precautionary principle in EU environmental legislation*. The precautionary principle provides a basis for public authorities to take actions aimed at preventing or reducing uncertain risks, i.e., those risks for which scientific data on the likelihood of a hazard and the nature or the importance of the hazard are insufficient or impossible to identify. The study analyses the use of the precautionary principle in 15 EU legislative instruments. For eight of these acts, including the Habitats Directive, REACH and the Water Framework Directive, it looks at how the use of the precautionary principle evolved during the legislative process. It also considers relevant rulings by the Court of Justice of the European Union (CJEU).

In general, the study finds that the key elements in the Commission's Communication on the precautionary principle (2000) are being implemented in the environmental legislation. However, differences in application were identified. For example, certain aspects such as methodologies for assessing risk and when precautionary action needs to be taken vary across the different sectors, reflecting content-specific approaches and allowing the principle to stay flexible and adaptable to the needs of a particular environmental policy area. While this flexibility is an advantage, it also presents the challenge of how to ensure that the principle is applied when needed to achieve a high level of protection for people and the environment.

EXECUTIVE SUMMARY

The general objective of this study is to provide an overview of the *actual use and implementation of the precautionary principle in EU environmental legislation*[1]. The precautionary principle acknowledges the limits of scientific understanding, and the difficulties of decision-making when conclusive evidence cannot be produced. It provides a basis for public authorities to take actions aimed at preventing or reducing uncertain risks, i.e., those risks for which scientific data on the likelihood of a hazard and the nature or the importance of the hazard are insufficient or impossible to identify.

At EU level, the precautionary principle was introduced by the Treaty of Maastricht in Article 130r(2) (today's Article 191(2) of the Treaty on the Functioning of the European Union) as one of the guiding principles of EU environment policy. In 2000, the European Commission presented a Communication on the precautionary principle, which operationalised for the first time this Treaty reference by providing common guidelines on its application by both the EU and the Member States. The Communication provides that the precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty.

According to the Communication, recourse to the principle belongs to the general framework of risk analysis (which includes risk assessment, risk management and risk communication), and more particularly in the context of risk management, which corresponds to the decision-making phase. It may only be invoked in the event of a potential risk and can never justify arbitrary decisions. Three preliminary conditions must be met, namely (1) identification of potentially adverse effects; (2) evaluation of the scientific data available; and (3) extent of scientific uncertainty.

The Court of Justice of the European Union (hereinafter 'CJEU' or 'the Court') has also played an important role in the development of the precautionary principle in the EU, and on its application by EU institutions and Member States. In addition, the 7th Environment Action Programme, which guides EU environmental policy up to 2020, invokes the precautionary principle, in particular for chemicals that have endocrine-disrupting properties and nanomaterials that may cause adverse effects on health and the environment.

This study focuses on those areas of EU law and policy under the remit of the Commission's Directorate-General for the Environment. However, the precautionary principle - as a general principle of law - has also been shaped by other policy areas, including food safety and public health where it has importance equivalent to that in the environmental area, and these different policy areas influence each other.

Against this background, the general objective of this project is to provide an overview of the actual use and implementation of the precautionary principle in EU environmental legislation. Because the study focuses on legislation that falls under the competence of DG Environment, other areas in which the precautionary principle is highly relevant – such as biocides, plant protection products, climate

[1] Prepared for DG Environment of the European Commission under Contract No ENV.A.3./ETU/2016/741681.

change, pollutant emission standards for cars, etc. – are not included. The study provides an analysis of the use of the precautionary principle in 15 EU legislative documents (such as directives and regulations). For eight of these 15 acts, it looks at how the use of the precautionary principle evolved during the legislative process (in italics and boldface in the overview table below). It also considers relevant CJEU rulings.

	Area of EU environmental legislation	**Legislative acts (*legislative process also reviewed)***
1	Nature and biodiversity	***Birds and Habitats Directives*** (2009; 1992)
2		Invasive Alien Species Regulation (2014)
3	Chemicals	***REACH*** (2006)
4		POPs Regulation (2004)
5	*Water*	***Water Framework Directive*** (2000)
6		***Floods Directive*** (2007)
7	Environmental assessment	***Environmental Impact Assessment Directive*** (2003)
8	Waste	Sewage Sludge Directive (1986)
9		***Waste Framework Directive*** (2008)
10		RoHS 2 Directive (2011, as amended in 2014)
11	Soil	Soil Thematic Strategy and withdrawn proposal for a Soil Framework Directive (2004)
12	Industry	***Seveso III Directive*** (2012)
13		Industrial Emissions Directive (2010)
14	Air	Air Quality Directive (2008)
15	Marine & Coast	***Marine Strategy Framework Directive*** (2008)

Several challenges arise in applying the precautionary principle in the context of EU environmental policy and legislation. One challenge is the differentiated use of the precautionary principle in EU environmental policy and legislation. Few pieces of EU environmental legislation refer explicitly to the precautionary principle or operationalise it, and the only definition of the precautionary principle in EU secondary legislation is found in EU food law. As a result, the features of the precautionary principle differ across the various sectoral policies dealing with environmental risks.

For instance, the concept of risk in EU environmental legislation is interpreted differently depending on the sector in question, e.g., chemicals regulation, water quality or nature conservation. Ultimately, the practice of Member States and interpretation of the CJEU play an important role in forming how the precautionary principle is applied when implementing EU environmental legislation.

While none of the EU environmental legislation reviewed provides a definition of the precautionary principle as such, some instruments do refer to the application or use of the precautionary principle in their Recitals. Others discuss the precautionary principle in their main articles. Still other instruments refer to the precautionary principle via indirect reference, e.g., by relying on concepts such as risk assessment or uncertainty (see table below for overview).

Legislative document	Reference to precautionary principle	Reference to uncertainty	Risk assessment	Burden of proof - General rule on allocation
Air Quality Directive	No direct reference	Identification of uncertainty in available data	Sets limit values for a range of pollutants.	Member States
Birds and Habitats Directives	No direct reference	Harm- and safety related reference	Appropriate assessment must consider the characteristics & specific environmental conditions of the site or project - MS not obliged to examine alternative solutions to the plan or project concerned	Member States (Birds), Proponents of plan or project (Habitats)
Environmental Impact Assessment Directive (EIA)	Reference in Recital	Harm-related reference, identification of uncertainty in available data	Projects likely to have significant impact on the environment must undergo an EIA and be subject to authorization before going ahead; authorised projects likely to have significant effects subject to monitoring and mitigation measures for significant adverse environmental effects.	Developers
Floods Directive	No direct reference	Harm-related reference	Implemented in iterative cycles which incorporate the precautionary approach to risk assessment.	Member States
Industrial Emission Directive (IED)	No direct reference	N/A	Sets emission limit values for pollutants from large combustion plants, waste incineration plants and activities using organic solvents, and implemented for other major industrial activities via Commission decisions laying down Best Available Techniques and associated emission levels	Operators
Invasive Alien Species Regulation	Addressed in main body	Harm-related reference	List of invasive alien species of Union concern.	Member States
Marine Strategy Framework Directive (MSFD)	Reference in Recital	Harm-related reference	Each marine region or sub-region concerned to identify the measures needed to achieve or	Member States

Legislative document	Reference to precautionary principle	Reference to uncertainty	Risk assessment	Burden of proof - General rule on allocation
			maintain good environmental status in their marine waters.	
POPs Regulation	Addressed in main body	Harm- and safety related reference	N/A	Member States and Commission
REACH	Addressed in main body	Harm & safety concerns referenced, identification of uncertainty in available data	All EU manufacturers and importers of substances obliged to register information on the hazard and risk of their substances with ECHA; public authorities (national or ECHA) develop dossiers for unacceptable risks requiring restrictions.	Manufacturers, importers and downstream users of substances or preparations; for restrictions the burden of developing dossiers is on public authorities (national/ECHA).
Restriction of Hazardous Substances Directive (RoHS 2)	Addressed in main body	Safety-related reference, identification of uncertainty in available data	N/A	Manufacturers, importers and distributors of EEE
Seveso III	Addressed in main body (precautionary action)	Harm- and safety related reference	MS competent authority to identify all lower-tier & upper-tier establishments or establishment groups where risk or consequences of a major accident may be increased because of the geographical position and proximity of such establishments, and their inventories of dangerous substances.	Operators
Sewage Sludge Directive	No direct reference	Safety-related reference	Stipulates the need for regular monitoring of soil and sludge based on a risk assessment methodology.	N/A
Soil Thematic Strategy and withdrawn proposal for a Soil Framework Directive	Addressed in main body	Harm-related reference	Identification of risk areas must be based on empirical evidence or modelling; threats of unknown proportions can also be dealt with.	Owner of site to be sold or prospective buyer
Waste Framework	Addressed in main body	Safety-related reference	Requires those carrying out waste treatment to	Member States

Legislative document	Reference to precautionary principle	Reference to uncertainty	Risk assessment	Burden of proof - General rule on allocation
Directive			obtain a permit; MS must keep a register of establishments not subject to permit requirements.	
Water Framework Directive	Reference in Recital	Safety-related reference	Substances prioritised for action on basis of risk to, or via the aquatic environment as identified by a simplified risk-based assessment procedure based on scientific principles.	Commission

Those directives or regulations that lack explicit reference to the precautionary principle may nonetheless integrate a precautionary approach in practice. For instance, the CJEU has confirmed the underlying precautionary approach of Article 6(3) of the Habitats Directive. Thus, whether or not the term 'precautionary principle' is explicitly referred to, as well as the location of the references (Recital or main body), does not accurately portray the actual application of the precautionary principle.

Several trends can be observed in terms of the evolution of the precautionary principle in the legislation under review. Since the adoption of the first legislative act reviewed in this study until the present, references to the precautionary principle have become more prevalent, both in the preamble and the articles of the legislative texts. Therefore, despite a slow take-off, since 2000 there has been an overall increase in the inclusion of the precautionary principle in EU environmental legislation, and also over the course of the legislative process for most of the policy areas reviewed. In several instances the European Parliament's First Reading contained more references to the precautionary principle than the final text, and in several of the pieces of legislation analysed, the final text had dropped some direct references to precaution, such as definitions and references to the 2000 Communication, found in earlier texts.

Risk and risk assessment are intrinsic parts of many of the EU environmental legislative documents under review (e.g. Water Framework Directive, Marine Strategy Framework Directive, Floods Directive and Habitats Directive). This proceeds from an assumption that risks can be assessed probabilistically, employing a combination of statistical evidence and scientific understanding of causal relationships. But not all threats can be assessed probabilistically, and risk assessments need to be supplemented with other decision criteria when managing risk. Thresholds for triggering a risk assessment (where defined) vary, whilst the methodologies for assessing risk range from requirements such as gathering of empirical evidence, modelling of potential effects and establishment of risk reduction targets to the examination of alternative solutions and keeping records of impacts. Hence, risk assessment employs a variety of approaches to risk tailored to the individual requirements of the specific environmental policy area.

Scientific uncertainty, another intrinsic aspect of the precautionary principle, is also not expressly defined in the selected environmental legislation. Nevertheless, a range of implicit definitions of

uncertainty were identified, mostly covering uncertainty of harm and uncertainty over safety. These can be mainly classified into three categories, all of which are covered in the 2000 Communication:

- Requirements for the level and nature of the uncertainty to be documented when carrying out risk assessments (although guidance on what action should ensue as a result of the uncertainty was generally lacking),
- Measures to reduce uncertainty, included in most of the legislation under review, and
- Measures to address a potential threat even when uncertainty remains (it is worth mentioning that further research, whilst often reducing some uncertainties, may increase others as well as sometimes expanding awareness of what is not known).

According to the 2000 Communication, the starting point for implementing a precautionary approach should be *a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty'*. This principle has been implemented by the Habitats Directive, with the CJEU also indicating in the case of *Afton Chemical* that a scientific evaluation should be conducted prior to implementing an approach based on the precautionary principle .[2]

In terms of the general principles of application of the precautionary principle set out in the 2000 Communication, cost-benefit analysis and the revision of measures in line with scientific and technical progress receive the greatest coverage and are the elements most explicitly linked to the precautionary principle itself. However, provisions for adaptation to scientific and technical progress relate more to the ability to introduce additional environmental protection measures in light of additional scientific evidence, rather than the maintenance of precautionary measures for as long as uncertainty remains, as set out in the 2000 Communication. Other important general principles of application included in the 2000 Communication, in particular proportionality, also receive scant reference in the environmental legislation reviewed.

Responsibility for the burden of proof is another key element in implementation of the precautionary principle in EU environmental policies. A precautionary approach implies that the burden of proof to demonstrate the absence of harm of a risk-generating activity should be on the proponent of that activity, as opposed to national authorities or members of the public as has historically been the case. Nonetheless, in general Member States remain the main bearers of the burden of proof, even where the legal instruments endorse a precautionary approach (e.g. POPs Regulation; Invasive Alien Species Regulation).

Few pieces of EU environmental legislation refer explicitly to, or operationalise, the precautionary principle. For instance, the concept of risk assessment in EU environmental legislation is interpreted differently depending on the sector in question. As a result, the requirements of the precautionary principle vary across the various sectoral policies dealing with environmental risks. This reflects the content-specific approach of the principle which is needed in order to make it implementable to the different subject areas and has left the precautionary principle open to interpretation.

This approach has had the advantage of keeping the principle flexible and adaptable to the individual needs of a particular environmental policy area. However, this has led to different approaches related

[2] C-343/09, 8 July 2010, *Afton Chemical,* para 60.

to the context and case specific application of the precautionary principle. What is important is that the general procedures are similar and predictable, e.g. 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.

Overall, in the environmental sector, the precautionary principle is more rarely applied in policy areas related to chemicals or industrial pollution than in nature related cases. This could arguably be linked to the issue of how risk is assessed by those who bear the responsibility for determining extent of risk. In the case of the nature protection directives, for example, proponents of an activity that would depart from the general prohibition of harmful activities in Natura 2000 areas have to prove that there are no alternatives, that the proposed activity does not cause harm and it is needed because of overarching public interests – a generally stricter precautionary principle approach.

Differences in application could be linked to the allocation of the burden of proof for determining the extent of risk as well as to the political aspects of applying the precautionary principle in certain environmental policy areas where stakeholder input is significant. In the area of REACH, for example, the working methods for determining what is an unacceptable risk in the context of proposals for restrictions of certain substances are considered by some to have narrowed the scope for application of the precautionary principle[3].

In conclusion, the precautionary principle is a general principle of EU environmental law which has not been defined by the legislator. This has provided the flexibility needed to adapt it to a range of policy areas, not only in environmental legislation and policy, and prevented it from being a static principle. While this flexibility is an advantage, it also presents the challenge of how to ensure that the principle is applied when needed, in those cases where an occurrence or substance may have a dangerous effect, but where scientific evaluation does not allow the risk to be determined with sufficient certainty

[3] KEMI 2015. *Developing REACH and improving its efficiency*, available at " KEMI 2015 http://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf , e.g. section 4.4, p. 91.

LIST OF ABBREVIATIONS

CJEU	Court of Justice of the European Union
CoRAP	Community Rolling Action Plan
DG	Directorate General
EEA	European Environment Agency
EAP	Environment Action Programme
ECHA	European Chemicals Agency
EIA	Environmental Impact Assessment
EU	European Union
GES	Good Environmental Status
GMO	genetically modified organisms
IED	Industrial Emissions Directive
MSFD	Marine Strategy Framework Directive
PBDE	Polybrominated diphenyl ethers
POPs	Persistent organic pollutants
RAC	Committee on Risk Assessment (REACH)
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SVHC	substance of very high concern
TFEU	Treaty on the Functioning of the European Union
WFD	Water Framework Directive

1. INTRODUCTION

1.1 CONTEXT AND OBJECTIVE OF THE STUDY

The idea underpinning the precautionary principle must be traced back to the mounting public concern associated with decision-making in the face of scientific uncertainty. As a result of the technological revolution, the need has been felt to develop a principle capable of restoring public confidence by requiring public authorities to take action or adopt measures to reduce risk, even in the absence of strong scientific evidence. It is the acknowledgement of the limitations of scientific understanding in providing conclusive evidence in time to avoid or minimise harm that has led to the development of this principle. To the extent that this deficit in predictive capability is unacceptable to society, the precautionary principle permits actions aimed at preventing uncertain risks. Uncertain risks are those for which scientific data on the likelihood of the beginning of a hazard and the nature or the importance of the hazard are insufficient or impossible to identify.

Historically, the precautionary principle emerged in the environmental sphere. Its origins can be traced back to German environmental law, notably the *Vorsorgeprinzip.*[4] At the international level, the precautionary principle gained momentum with the 1992 Rio Declaration on Environment and Development which provided that, *'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'*.[5] The precautionary principle also underpins a number of multilateral environmental agreements, to which the European Union (hereinafter 'EU') is a party, such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity,[6] the Convention for the Protection of the Marine Environment of the North-East Atlantic[7] and the Stockholm Convention on Persistent Organic Pollutants.[8]

At EU level, the precautionary principle was introduced by the Treaty of Maastricht in 1993. Article 130r(2) of the then Treaty establishing the European Community (hereinafter 'TEC') provided that the Community policy on the environment shall aim at a high level of protection and shall be based on various principles, including the precautionary principle. The scope of this principle seemed to be originally limited to environmental policy. However, as anticipated by some commentators,[9] the precautionary principle has been invoked beyond the environmental field as a result of the horizontal nature of Article 6 of the TEC.[10]

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[4] Nollkaemper, A. (1992). The Precautionary Principle in International Environmental Law: What's New under the Sun? *Marine Pollution Bulletin*, 22(3), 107-110, 107.

[5] UN (1992) *Rio Declaration on Environment and Development*, UN Doc A/CONF.151/26 (Vol. I), Principle 15.

[6] UN (2000) *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2226 U.N.T.S. 208, Article 1.

[7] UN (1992) *OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic*, 2354 UNTS 67.

[8] UN (2004) *Stockholm Convention on Persistent Organic Pollutants*, 2256 UNTS 119, Article 1.

[9] See Vaque, L. G., Ehring, L., & Jacquet, C. (1999). Le principe de précaution dans la législation communautaire et nationale relative à la protection de la santé. *Revue du Marché Unique Européen*, *1*, 90; Alemanno, A. (2001). Le principe de précaution en droit communautaire: stratégie de gestion des risques ou risque d'atteinte au marché intérieur?. *Revue du Droit de l'Union Européenne*, *4*, 917-953.

[10] The possibility to invoke the principle outside of the environmental field has been first recognised by the then European Court of Justice. It follows from the Court' case-law that 'the precautionary principle may also apply in policy on the

At present, Article 191(2) of the Treaty on the Functioning of the European Union (hereinafter TFEU) provides that '*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*.' The precautionary principle is therefore one of the guiding principles of EU environmental policy.

Furthermore, Article 114(3) of the TFEU specifies that *'[t]he Commission, in its proposals envisaged in [Article 114(1)] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective*. Article 114(3) explicitly refers to one of the elements of the precautionary principle in providing that proposals must be based on new scientific developments.

This study provides an overview of the use of the precautionary principle in EU environmental legislation. The need for this review arises from the work of the European Commission (hereinafter 'Commission') towards a systematic approach to risk management under the 7th Environment Action Programme (hereinafter '7th EAP').[11] In particular, Priority Objective 5 of the 7th EAP explicitly aims *to improve the knowledge and evidence base for Union environmental policy*. Furthermore, academics and researchers have extensively debated the precautionary principle in recent decades.[12]

protection of human health which, according to Article 152 of the EC Treaty likewise aims at a high level of protection'. See, to that effect, Case C-157/96, Judgment of 12 July 1996, *National Farmers' Union and Others*, ECLI:EU:C:1998:191, para 63 & 64; Case T-13/99, Judgment of 11 September 2002, *Pfizer Animal Health v Council*, ECLI:EU:T:2002:209, para 139-140; Case T-70/99, Judgment of 11 September 2002, *Alpharma v Council*, ECLI:EU:T:2002:210, para 152 and 153; Case C-236/01, Judgment of 9 September 2003, *Monsanto Agricoltura Italie and Others*, ECLI:EU:C:2003:431, para 128 & 133; Case T-177/02, Judgment of 10 March 2004, *Malagutti-Vezinhet v Commission*, ECLI:EU:T:2004:72, para 54.

[11] 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', OJ L 354, 28.12.2013, 171–200, Article 2. The 7th EAP guides EU environmental policy up to 2020 and is based on various principles of environmental law, including the precautionary principle. For instance, precautionary action should be considered for chemicals that have endocrine-disrupting properties and nanomaterials that may cause adverse effects on health and the environment.

[12] For a wide-ranging review of the precautionary principle in EU and international law, see Fisher, E. (2002). Precaution, Precaution Everywhere: Developing a Common Understanding of the Precautionary Principle in the European Community. *Maastricht Journal of European and Comparative Law*, 9(1), 7-28; De Sadeleer, N. (2002). *Environmental principles: from political slogans to legal rules*. Oxford University Press; Christoforou, T. (2002). The origins, content and role of the precautionary principle in European Community law. The Role of Precaution in Chemicals Policy. In Leben, C. & Verhoeven, J. *Le principe de précaution: Aspects de droit international et communautaire*. Ed. Panthéon-Assas; Wiener, J. B. (2003). Whose Precaution after All-A Comment on the Comparison and Evolution of Risk Regulatory Systems. *Duke J. Comp. & Int'l L., 13*, 207; Löfstedt, R. (2004). The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis. *The Journal of Risk and Uncertainty*, 28(3), 237-260; Christoforou, T. (2004). The precautionary principle, risk assessment, and the comparative role of science in the European Community and the US legal systems. *Green giants*, 17-52; Sunstein, C. R. (2005); *Laws of Fear: Beyond the Precautionary Principle*. Cambridge University Press; Alemanno, A. (2007). The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty. In L. Cuocolo, & L. Luparia, *Valori costituzionali e nuove politiche del diritto.* Halley; Wiener, J. B., & and others. (2011). *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. RFF Press ; Vogel, D. (2012). *The politics of precaution: regulating health, safety, and environmental risks in Europe and the United States*. Princeton University Press.

In the context of EU policies, scholarship has tended to focus on the interpretation and use of the precautionary principle in health and food safety policies.[13] As a result, a systematic overview focusing on its use in EU environmental policies does not currently exist.

The study exclusively focuses on subjects that fall under the competence of the Directorate-General for Environment (hereinafter 'DG Environment').[14] This means that other areas in which the precautionary principle might play an important role – such as genetically modified organisms (hereinafter 'GMOs'), climate change, pollutant emission standards for cars, etc. – are not subject to review.

The study reviews key literature addressing the use of the precautionary principle in EU environmental policies, including guidance documents on the application of the precautionary principle. Moreover, it provides an analysis of the use of the precautionary principle in 15 EU legislative documents (such as directives and regulations), considering the legislative history for eight of these 15 documents. Finally, relevant rulings by the CJEU, where it has significantly referred to the use of the precautionary principle in environmental law and, where necessary, in health and food safety law, are also considered.

1.2 METHODOLOGY

This study is based on a four-phase research and analysis:

- **Phase 1** defined the scope of the research and resulted in the identification of the EU environmental directives and regulations under review. A literature review was conducted to identify the areas of environmental policy where the use of the precautionary principle is relevant. Error! Reference source not found. below provides an overview of the criteria used to select the relevant EU environmental instruments.

[13] See Raffensperger, C. (1999). *Protecting public health and the environment: implementing the precautionary principle*. Island Press; Victor, M. (2001). Precaution or Protectionism--The Precautionary Principle, Genetically Modified Organsims, and Allowing Unfounded Fear to Undermine Free Trade. *Transnat'l Law.*, *14*, 295; Cazala, J. (2004). Food safety and the precautionary principle: The legitimate moderation of community courts. *European Law Journal*, *10*(5), 539-554; Grandjean, P. (2004). Implications of the precautionary principle for primary prevention and research. *Annual Reviews Public Health*, 25, 199-223; Sadeleer (de), N. (2006). The precautionary principle in EC health and environmental law. *European Law Journal*, *12*(2), 139-172; Forrester, I., & Hanekamp 1, J. C. (2006). Precaution, science and jurisprudence: a test case. *Journal of Risk Research*, *9*(4), 297-311.

[14] DG ENV shares the responsibility for some chemicals related regulations (REACH and CLP) with DG GROW. Further, there are other pieces of chemicals legislation like plant protection products (pesticides) and biocides, where the precautionary principle is highly relevant, while for which DG ENV is not responsible (but DG SANTE in these cases).

Box 1: Criteria for selecting the EU environmental instruments under review

- The EU instrument under review must belong to an EU policy falling under the competence of DG Environment;
- Existence of literature on the precautionary principle, or relevant concepts, pertaining to the instrument under review;
- The EU instrument must present a link with an environmental issue where the use of the precautionary principle is relevant, or it must contribute to the development of the precautionary principle;[15]
- A balanced selection of environmental topics. The selection includes diverse environmental fields and various types of environmental risks. This approach aims to provide an overall view of the different applications of the precautionary principle.

- **Phase 2** consisted in assessing references to, and the use of, the precautionary principle in documents pertaining to the whole policy-making cycle for eight environmental directives and regulations. This assessment covered, for example, stakeholders' consultations and Commission impact assessments, as well as key documents of the European Parliament and the Council. **Table 1** below presents the eight environmental instruments assessed during Phase 2.

Table 1: Assessment of eight EU environmental instruments throughout the whole policy-making cycle.

No.	Area of EU environmental policy	Legislative instrument
1	Nature and biodiversity	Birds (2009) and Habitats Directives (1992)
2	Chemicals	REACH Regulation (2006)
3	Water	Floods Directive (2007)
		Water Framework Directive (2000)
4	Environmental assessment	Environmental Impact Assessment Directive (2014)
5	Waste	Waste Framework Directive (2008)
7	Industry	Seveso III Directive (2012)
8	Marine & Coast	Marine Strategy Framework Directive (2008)

- **Phase 3** consisted in assessing references to, and the use of, the precautionary principle in 15 environmental directives and regulations (these 15 instruments included the eight instruments assessed during Phase 2). This assessment considered if, and how, the precautionary principle had inspired the legislation as well as how it had been considered and/or used during the implementation of the legislation. **Table 2** below presents the 15 environmental instruments assessed during Phase 3.

[15] It needs to be acknowledged that environmental and health are usually intertwined such that environmental laws and actions by DG ENV and the Member States often have substantial secondary benefits for health as demonstrated by actions on PCBs (banned for wildlife reasons initially but bringing health gains later); climate change (environmental impacts first but actions on fossil fuel burning bringing health gains); floods (risk assessment for floods "may also include adverse consequences for health, cultural heritage, and economic activity"). In addition, chemicals legislation usually aims to protect both health and the environment. These aspects are often closely linked and overlapping (e.g. many substances classified as hazardous to the environment are also hazardous to human health and vice versa). However, there are also differences, where other sensitivities, effects and endpoints are more relevant for environment than for health.

Table 2: Assessment of 15 EU environmental legislative instruments (overlaps with table 1 in italics).

No.	Area of EU environmental policy	Legislative instrument
1	Nature and biodiversity	*Birds (2009) and Habitats Directives (1992)*
2		Invasive Alien Species Regulation (2014)
3	Chemicals	*REACH (2006)*
4		POPs Regulation (2004)
5	*Water*	*Water Framework Directive (2000)*
6		*Floods Directive (2007)*
7	Environmental assessment	*Environmental Impact Assessment Directive (2014)*
8	Waste	Sewage Sludge Directive (1986)
9		*Waste Framework Directive (2008)*
10		RoHS 2 Directive (2011)
11	Soil	*Soil Thematic Strategy and withdrawn proposal for a Soil Framework Directive (2006)*
12	Industry	*Seveso III Directive (2012)*
13		Industrial Emissions Directive (2010)
14	Air	Air Quality Directive (2008)
15	Marine & Coast	*Marine Strategy Framework Directive (2008)*

- **Phase 4** looked at the most relevant cases of the Court of Justice of the European Union (hereinafter 'CJEU' or 'the Court') in which the Court made specific or significant references to the precautionary principle in the context of the directives and regulations under review. This phase aimed to demonstrate how the Court has interpreted the precautionary principle or contributed to its development. Where relevant, case-law in health and food safety was cited in this study.[16]

Various challenges arose during the conduct of this study. First, the precautionary principle is not a homogeneous concept which applies equally to all environmental sectors. Its features tend to differ across the sectoral policies dealing with environmental risks, such as nature protection, persistent organic pollutants (hereinafter 'POPs'), or marine pollution. For instance, the concept of risk in EU environmental legislation is interpreted differently depending on the sector in question (chemicals regulation, biodiversity or nature conservation). It was therefore crucial to approach the use of the precautionary principle flexibly and to understand each associated concept (i.e., risk, uncertainty, etc.) in a broad manner.

Second, invocation of the precautionary principle may justify the enactment of a multitude of different measures,[17] rendering the application of the principle complex and often unclear. Therefore, the

[16] This study presents CJEU's case-law relevant to the understanding of the precautionary principle in EU environmental legislation. During the research, pertinent case-law was, however, unavailable for a number of the directives and regulations under study (e.g. Floods Directive, Invasive Alien Species Regulation or MSFD). Such unavailability is explained by either the general absence of case-law or the inexistence of reference to the precautionary principle, or interrelated concepts, in existing case-law. In order to present an overview of the use of the precautionary principle in EU environmental legislation as complete as possible, and where necessary, references are made to cases concerned with EU environmental legislation outside of the scope of this study.

[17] Sadeleer (de), N. (2010). The Precautionary Principle in EU Law. *AV&S*, 5(October), 173-184, 184.

practice of Member States and the CJEU's interpretations play an important role in forming how the precautionary principle is applied in EU environmental legislation. Third, measuring the impacts of reliance on the precautionary principle in EU environmental legislation is challenging from a methodological perspective. It is particularly difficult for EU and national institutions to determine the ex-ante and ex-post impact of precautionary approaches in environmental protection, since most directives and regulations lack specific guidance for evaluating positive and negative impacts.[18]

1.3 CONTENT OF THE STUDY

Section 1 of this study introduced the context, objective and methodology of the study.

Section 2 provides the core analysis of the precautionary principle in EU environmental legislation. It describes how the precautionary principle is defined and/or referred to in a number of selected directives and regulations. It identifies the constituent elements of the principle, focusing on risk assessments, scientific evaluation and uncertainty. **Section 2** also provides an overview of the implementation of the precautionary principle, looking at the triggering factor for action, the burden of proof and the general principles of application. Finally, it gives an account of the evolution of the precautionary principle during the procedures leading to the adoption of legal acts.

Section 3 provides an overview of the relationship of the precautionary principle with other key principles of EU environmental legislation, namely the principles of prevention, polluter pays, and rectifying pollution at source.

Finally, **Section 4** presents the overall findings of this study.

2. THE PRECAUTIONARY PRINCIPLE IN EU ENVIRONMENTAL LEGISLATION

Section 2 describes the use of the precautionary principle in EU environmental legislation. It identifies references to the principle in the directives and regulations under review. It also provides an overview of the constituent elements of the precautionary principle in EU environmental law and assesses their implementation.

2.1 NATURE AND DEFINITION OF THE PRECAUTIONARY PRINCIPLE

As mentioned in **Section 1.1**, the precautionary principle was officially introduced in EU law by the Treaty of Maastricht in 1993. Given that there was little guidance as to the meaning and content of this principle at the time, the European institutions have played a key role in developing the precautionary principle in EU law.

Notably, in 2000, the Commission presented a Communication on the precautionary principle (hereinafter 'Communication on the precautionary principle' or 'Communication'), which

[18] Saterson, K. (2013). 'Biodiversity Conservation'. In J. B. Wiener, & others, *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. RFF Press, 215.

operationalized, for the first time, the precautionary principle by providing common guidelines on its application by both the EU and the Member States.[19] The principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty.[20] According to the Communication, recourse to the principle belongs to the general framework of risk analysis (which includes risk assessment, risk management and risk communication), and more particularly in the context of risk management, which corresponds to the decision-making phase.[21] It may only be invoked in the event of a potential risk and can never justify arbitrary decisions. Three preliminary conditions must be met, namely identification of potentially adverse effects; evaluation of the scientific data available; and extent of scientific uncertainty.

The CJEU has also played a major role in shaping the precautionary principle as a general principle of EU law, in both environmental and non-environmental cases.[22] In particular, it asserted the importance of this principle in protecting health and the environment. In *Dow AgroSciences and Others v Commission*,[23] a case concerned with plant-protection products, the CJEU held that the precautionary principle constitutes a general principle of Community (now Union) law requiring the authorities 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 interests.[24]

In some instances, the Court has used the precautionary principle as a guiding principle to interpret key elements of EU environmental directives. This has been visible in the CJEU's case-law on the definition of 'waste' under the former Waste Directive. In *Van de Walle and Others*,[25] the Court held that the verb 'to discard', which determines the scope of 'waste', must be interpreted in the light of the aim of the former Waste Directive (i.e. Directive 75/442), which is the protection of human health and the environment against harmful effects caused by the collection, transport, treatment, storage and tipping of waste, along with that of Article 174(2) EC, which states that Community policy on the environment is to aim at a high level of protection and is to be based, in particular, on the precautionary principle and the principle that preventive action should be taken. Therefore, the verb

[19] European Commission, COM(2000) 0001 final, Communication from the Commission on the precautionary principle.

[20] Communication on the precautionary principle, 3.

[21] As this study demonstrates below, the question whether the precautionary principle may also play a role within risk assessment is particularly controversial. See Ladeur, K. H. (2003). Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental and Public Health Law-Decision-Making under Conditions of Complexity in Multi-Level Political Systems, The. *Common Market L. Rev.*, *40*, 1455.

[22] See, for instance, Case 174/82, Judgment of 14 July 1983, *Sandoz*, ECLI:EU:C:1983:213; T-13/99, *Pfizer Animal Health v Council*; Case T-74/00, Judgment of 26 November 2002, *Artegodan and Others v Commission*, ECLI:EU:T:2002:283; Case C-343/09, Judgment of 8 July 2010, *Afton Chemical*, ECLI:EU:C:2010:419. For a detailed assessment of the case law of the CJEU on the precautionary principle, see Alemanno, A. (2009). The shaping of European risk regulation by community courts. *Jean Monnet Working Paper*. *18/2008*. The role of the CJEU was anticipated in the Communication on the precautionary principle. See Stokes (2005).

[23] Case T-475/07, Judgment of 9 September 2011, *Dow AgroSciences and Others v Commission*, ECLI:EU:T:2011:445.

[24] ibid, para 144. See also T-74/00, *Artegodan*, para 183 and 184; Case T‑392/02, Judgment of 21 October 2003, *Solvay Pharmaceuticals v Council*, ECLI:EU:T:2003:277, para 121.

[25] Case C-1/03, Judgment of 7 September 2004, *Van de Walle and Others*, ECLI:EU:C:2004:490.

'to discard' cannot be interpreted restrictively.[26]

In *Lirussi and Others*, the CJEU provided that, '*In so far as waste, even waste which is stored temporarily, can cause serious harm to the environment, the provisions of Article 4 of Directive 75/442, which are intended to implement the principle of precaution, also apply to temporary storage*'.[27] Similarly, in *Parliament v Commission*,[28] the CJEU used the precautionary principle '*as an interpretative principle supporting a strict interpretation of the basic safety requirements laid down by the EU lawmake*r'[29] on the restriction of the use of certain hazardous substances in electrical and electronic equipment (see **Box** in **Section 2.4.1The triggering factor for action**).

Despite the momentum gained by the precautionary principle in EU law and case-law, a general – as opposed to sectoral – definition of the principle is nonetheless currently lacking.[30] The TFEU refers directly to the precautionary principle as a basis for EU environmental policy but omits to define it. This has left the definition of the principle open to interpretation. The 2002 Communication on the precautionary principle also does not provide a general definition of the principle. Scholars have argued that this lack of definition of the precautionary principle at EU level is justified on the grounds that the implementation of this principle varies across a wide range of policies and is contextually determined.[31]

The CJEU has endorsed a broad definition of the precautionary principle, which allows it to cover a large array of environmental and non-environmental issues. Nonetheless, some scholars have argued that the CJEU's approach to the precautionary principle varies depending on whether the case deals with health and food safety or with environmental issues.[32] According to De Sadeleer, the CJEU has endorsed a stricter approach with respect to health and food safety cases, in which scientific knowledge is far more advanced than it is in the environmental sector. One reason for this is that those cases mainly deal with the placement of products on the market where the principle of free movement of goods is at stake.[33]

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[26] ibid, para 45. See also Joined Cases C-418/97 and C-419/97, Judgment of 15 June 2000, *ARCO Chemie Nederland and Others*, ECLI:EU:C:2000:318, para 36-40; Case C-252/05, Judgment of 10 May 2007, *Thames Water Utilities*, ECLI:EU:C:2007:276, para 27.

[27] Joined Cases C-175/98 &C-177/98, Judgment of 5 October 1999, *Lirussi and Others*, ECLI:EU:C:1999:486, para 53. See also Case C-387/07, Judgment of 11 December 2008, *MI.VER and Antonelli*, ECLI:EU:C:2008:712, para 24.

[28] Joined Cases C-14/06 and C-295/06, Judgment of 1 April 2008, *Parliament and Denmark v Commission*, ECLI:EU:C:2008:176.

[29] Sadeleer (de), N. (2014). *EU Environmental Law and the Internal Market*. Oxford University Press, 84.

[30] Nonetheless, the case law of the court has embraced the definition of Regulation 178/2002 laying down the general principles and requirements of food law, as a result of its general character. See for instance Case C-77/09, Judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços*, ECLI:EU:C:2010:803. For a discussion of this case, see Alemanno, A. (2011). Case C-79/09, Gowan Comercio Internacional e Servicos Lda v. Ministero della Salute. *Common Market L. Rev.*, *48*, 1329.

[31] Sadeleer (de) (2010), 174. See also, Stokes E. (2005). Liberalising the Threshold of Precaution: Cockle Fishing, the Habitats Directive, and Evidence of a New Understanding of Scientific Uncertainty. *Environmental Law Review*, 7(3), 206-214; McIntyre, O. (2013). The Appropriate Assessment Process and the Concept of Ecological 'Integrity' in EU Nature Conservation Law. *Environmental Liability*, 6, 203-215.

[32] Garnett & Parsons (2016), 12.

[33] De Sadeleer points out that the precautionary principle is more explicitly defined in regulations on food safety, in contrast to environmental legislation where it is rarely mentioned in the operative provisions. See Sadeleer (de), N. (2009). The Precautionary Principle as a Device for Greater Environmental Protection: Lessons from EC Courts. *RECIEL*, 18(1), 3-10.

The only EU instrument that expressly defines the principle is found in EU food safety legislation[34], i.e., Regulation 178/2002 laying down the general principles and requirements of food law.. In contrast, few environmental regulations and directives specifically mention and/or define the precautionary principle in their operative provisions.[35] This situation seems to be changing, since an increasing number of recently enacted environmental regulations and directives refer explicitly to the precautionary principle, either in their Recitals or in their operational provisions (e.g. the REACH Regulation;[36] the Invasive Alien Species Regulation;[37] etc.), while other acts operationalise it.[38] Nonetheless, in the context of this study, none of the selected legislation provides a definition of the precautionary principle as such.

2.2 REFERENCES TO THE PRECAUTIONARY PRINCIPLE IN ENVIRONMENTAL LEGISLATION

Section 2.2 describes how references to the application or use of the principle may be found in the Recitals of certain acts whereas in other legislation the precautionary principle may be discussed in the main text.

2.2.1 Direct reference

Some EU environmental legislation are explicitly underpinned by the precautionary principle. For example, the Recital of the EIA Directive[39] states that *'Pursuant to Article 191 of the Treaty on the Functioning of the European Union, Union policy on the environment is based on the precautionary*

[34] Article 7(1) of Regulation (EC) No 178/2002 defines the precautionary principle as follows: '*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.'* Furthermore, Article 7(2) provides that, *'Measures adopted on the basis of para 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.*' For a discussion on the definition of the precautionary principle in EU food law, see Szajkowska, A. (2010). Impact of the Definition of the Precautionary Principle in EU Food Law, *Common Market L. Rev.*, *47*, 173.

[35] Sadeleer (de) (2010), 178.

[36] 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, OJ L 396, 30.12.2006, 1 (hereinafter 'REACH' or 'REACH Regulation').

[37] 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, OJ L 317, 4.11.2014, 35–55 (hereinafter 'Invasive Alien Species Regulation').

[38] Garnett, K., & Parsons, D. (2016). Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. *Risk Analysis*, 37(3), 502-516, 12. See also Løkke, S. (2006). The Precautionary Principle and Chemicals Regulation: Past Achievements and Future Possibilities. *Environmental Science and Pollution Research*, 13(5), 342-349.

[39] Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, OJ L 124, 25.4.2014, 1–18 (hereinafter 'EIA Directive').

principle and on the principle that preventive action should be taken'.[40] Additionally, the Waste Framework Directive[41] directly refers to the principle twice, initially as a general principle of environmental protection that should be taken into account by Member States,[42] and again to specify the need for precautionary measures to be outlined in any permit obtained to carry out waste treatment.[43]

Similarly, Recital 9 to the REACH Regulation states that analysis of existing chemicals legislation reveals *'the need to do more to protect public health and the environment in accordance with the precautionary principle'*.[44] Accordingly, Article 1(3) of REACH states that the provisions of the regulation are underpinned by the precautionary principle, namely that manufacturers, importers and downstream users must *'ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment'*.

In addition, Recital 69of REACH states that for the protection of human health and potentially vulnerable groups, along with the environment, substances of very high concern should be *'subject to careful attention'*, in line with the precautionary principle.[45] This implies that authorisation will only be granted for substances when applicants can prove that the associated risks can be adequately controlled. However, uses may still be authorised if socioeconomic benefits can be shown to outweigh the risks and there are no appropriate alternatives.

In the legislative process accompanying the adoption of REACH (co-decision procedure: first reading), the precautionary principle was explicitly mentioned as the principle underpinning the Section on Authorisation Requirements. The aim was to ensure '*that substances of very high concern are replaced by safer alternative substances or technologies, where available. Where no such alternatives are available, and where the benefits to society outweigh the risks connected with the use of such substances, the aim of this Title is to ensure that the use of substances of very high concern is properly controlled and that alternatives are encouraged. Its provisions are underpinned by the precautionary principle'*.[46] Moreover, the title on the granting of authorisations included a specific reference to the precautionary principle – requiring that it shall apply when such decisions are taken by the Commission.[47] These references are now covered by the general reference in Article 1(3), as noted above.

A similar approach and interpretation is provided by the Recital to the POPs Regulation,[48] which

[40] ibid, Recital 2.

[41] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, 3–30 (hereinafter 'Waste Framework Directive').

[42] Waste Framework Directive, Article 4(2).

[43] ibid, Article 23.

[44] REACH, Recital 9.

[45] Ibid, Recital 69.

[46] European Parliament legislative resolution of 14 March 2017 on the proposal for a regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008, Article 60.

[47] ibid, Article 66.

[48] 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, OJ L 158, 30.4.2004, 7–49 (hereinafter 'POPs Regulation').

states that the provisions of the Regulation are underpinned by the precautionary principle 'as set forth in the Treaty' and also by Principle 15 of the 1992 Rio Declaration on Environment and Development.[49] In view of this, the aim is the elimination of the environmental release of POPs (where feasible). In certain cases, this may warrant control measures stricter than those under the Stockholm Convention on Persistent Organic Pollutants. Article 1(1) of the POPs Regulation confirms that the aim of the Regulation is to protect human health and the environment from POPs, *'with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances'*.

Recital 3 of the 2011 Restriction of Hazardous Substances Directive (RoHS 2)[50] also contains a direct reference to the precautionary principle. Moreover, Article 6 of RoHS 2 requires that the Commission review and amend the Annex II list of already restricted substances on the basis of a thorough assessment, taking the precautionary principle into account. It furthers the precautionary element by indicating that particular attention shall be given to impacts on the environment and human health of other hazardous substances and materials used in electrical and electronic equipment, and whether such substances could be replaced by substitutes or alternative technologies with less negative impacts.[51]

The precautionary principle is also linked to cases where an 'emergency situation' threatens to appear. According to the Invasive Alien Species Regulation, there may be *'cases where alien species not yet recognised as invasive alien species of Union concern appear at the Union borders or are detected in the territory of the Union. Member States should therefore be granted the possibility to adopt certain emergency measures on the basis of available scientific evidence'*. Furthermore, *'emergency measures at Union level would equip the Union with a mechanism to act swiftly in case of presence or imminent danger of entry of a new invasive alien species in accordance with the precautionary principle'*.[52] Article 10 of the Regulation regulates emergency measures, without a further explicit mentioning of the precautionary principle.

Additionally, both the Marine Strategy Framework Directive (MFSD)[53] and the Water Framework Directive (WFD)[54] include in their Recitals general references to the principles of prevention, polluter pays, rectifying pollution at source, and the precautionary principle.[55] The Recital of the MSFD states

[49] ibid, Recital 7.

[50] 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, OJ L 174, 1.7.2011, 88–110 (hereinafter 'RoHS 2 Directive').

[51] ibid, Article 6.

[52] Invasive Alien Species Regulation, Recital 20.

[53] 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), OJ L 164, 25.6.2008, 19–40 (hereinafter 'Marine Strategy Framework Directive' or 'MSFD').

[54] 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, OJ L 327, 22.12.2000, 1–73 (hereinafter 'Water Framework Directive' or 'WFD').

[55] Recital 11 of the WFD states that '*As set out in Article 174 of the Treaty, the Community policy on the environment is to contribute to pursuit of the objectives of preserving, protecting and improving the quality of the environment, in prudent and rational utilisation of natural resources, and to be based on the precautionary principle and on the principles that preventive action should be taken, environmental damage should, as a priority, be rectified at source and that the polluter should pay*.'

that *'Member States should then establish and implement programmes of measures which are designed to achieve or maintain good environmental status in the waters concerned, while accommodating existing Community and international requirements and the needs of the marine region or subregion concerned. Those measures should be devised on the basis of the precautionary principle and 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'*.[56]

2.2.2 General reference to precaution

Other legislative documents reviewed for this study do not include an explicit reference to the precautionary principle but contain language recognising the need for precautionary action. This is the case of the Floods Directive,[57] which is based on the need to develop policies relating to water and land use that *'focus on prevention, protection and preparedness. With a view to giving rivers more space, Member States need to consider the maintenance and/or restoration of floodplains, as well as measures to prevent and reduce damage to human health, the environment, cultural heritage and economic activity.'*[58]

The Industrial Emissions Directive[59] also does not explicitly define the precautionary principle, but the need for precaution is mentioned several times throughout the main body of the text. Article 59 states that *'All appropriate precautions shall be taken to minimise emissions of volatile organic compounds during start up and shut down operations'*. It is also integral to the overall objectives of the Industrial Emissions Directive, which are to prevent, to reduce and, as far as possible, eliminate pollution arising from industrial activities based on the 'polluter pays' and the precautionary principle, whilst taking into account, when necessary, specific local circumstances. The Industrial Emissions Directive applies an integrated environmental approach to the regulation of certain industrial activities, meaning that emissions to air, water, including discharges to sewers, and land, and a range of other environmental aspects must be considered together. Following a precautionary approach, regulators must set permit conditions to achieve a high level of protection for the environment as a whole based on the use of best-available technology, which balances the costs to the operator against the benefits to the environment. Similarly, the Seveso III Directive[60] refers to the need of Member States to provide *'immediate precautions necessary to prevent recurrence*' to the Commission following a major incident.

[56] Marine Strategy Framework Directive, Recital 27.

[57] Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks, OJ L 288, 6.11.2007, 27–34 (hereinafter 'Floods Directive').

[58] ibid, Recital 14.

[59] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), OJ L 334, 17.12.2010, 17–119 (hereinafter 'Industrial Emissions Directive' or 'IED').

[60] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, OJ L 197, 24.7.2012, p. 1–37 (hereinafter 'Seveso III Directive' or 'Seveso III').

The explanatory memorandum to the withdrawn proposal for a Soil Framework Directive[61] stated that the aim of the proposed legislation – *'protecting soil and the preservation of the capacity of soil to perform its environmental, economic, social and cultural functions'* – was based on the precautionary principle, along with other principles of preventive action, rectifying environmental problems at source and the polluter pays, as per Article 174 of the EC Treaty, now Article 192 of the TFEU.[62] The proposed legislation was also based on analysis of the potential costs and benefits of action or lack of action.

2.2.3 Indirect reference through scientific uncertainty and adverse effects on the environment

As well as explicit references to the precautionary principle, or precaution, in EU legislative documents, the use of key features of the principle – such as scientific uncertainty and adverse effects on the environment – also signal the applicability of the principle. Relevant for the interpretation of the precautionary principle is, for example, the definition of *'invasive alien species of Member State concern'* which are *'invasive alien species other than an invasive alien species of Union concern, for which a Member State considers on the basis of scientific evidence that the adverse impact of its release and spread, even where not fully ascertained is of significance for its territory, or part of it, and requires action at the level of that Member State'*.[63] In addition**,** Article 8 on permits of the Invasive Species Regulation regulates that Member States shall empower their competent authorities to issue permits for activities – in relation to which Article 8(5) provides that *'Member States shall empower their competent authorities to withdraw the permit at any point in time, temporarily or permanently, if unforeseen events with an adverse impact on biodiversity or related ecosystem services occur'*. It is further specified that *'Any withdrawal of a permit shall be justified on scientific grounds and, where scientific information is insufficient, on the grounds of the precautionary principle and having due regard to national administrative rules.'*

The relevance of the precautionary principle for dealing with invasive alien species was highlighted in the 2011 Commission Staff Working Paper on the *'Relationship between the initial assessment of marine waters and the criteria for Good Environmental Status'*. Invasive non-indigenous species do not respond in the same way as a chemical pollution or eutrophication which may be diminished provided that appropriate measures are taken. Their impact is not mitigated, but rather potentially aggravated, by water circulation processes. Instead, the risk of new biological invasions can be most effectively reduced by precautionary measures (e.g. ballast water management). Control or eradication of existing invasive non-indigenous species is particularly challenging.[64]

Similar reference to adverse effects is made in the Water Framework Directive: *'In identifying priority hazardous substances, account should be taken of the precautionary principle, relying in*

[61] European Commission, COM(2006) 0232 final, Proposal for a Directive of the European Parliament and of the Council establishing a framework for the protection of soil and amending Directive 2004/35/EC (hereinafter 'withdrawn proposal for a Soil Framework Directive').

[62] ibid.

[63] Invasive Alien Species Regulation, Article 3.

[64] European Commission, SEC(2011) 1255 final, Staff Working Paper, Relationship between the initial assessment of marine waters and the criteria for good environmental status, 33.

particular on the determination of any potentially adverse effects of the product and on a scientific assessment of the risk.'[65] It recognises and applies the precautionary principle to the control of chemicals, by declaring hazard-based assessments (i.e. evaluation of chemicals by their intrinsic properties) a valid instrument for prioritising substances for action.

Elements of adverse effects and significant impacts to the marine environment are important in the MSFD's 'integration' of a precautionary approach. Article 1(2) of the MSFD provides that Member States must develop marine strategies to '(*a) protect and preserve the marine environment, prevent its deterioration or, where practicable, restore marine ecosystems in areas where they have been adversely affected; (b) prevent and reduce inputs in the marine environment, with a view to phasing out pollution, so as to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea.'* Marine strategies should therefore integrate a risk approach to guarantee that no harm is done to the marine environment.

The precautionary principle in the MSFD relates in general to the protection of the marine environment where current knowledge is insufficient to make good environmental status (GES) descriptors operational. The precautionary principle can be applied to develop tools and mechanisms to issue early warnings and undertake risk analyses. Importantly, pursuant to Article 1(3), *'marine strategies shall apply an ecosystem-based approach to the management of human activities, ensuring that the collective pressure of such activities is kept within levels compatible with the achievement of good environmental status and that the capacity of marine ecosystems to respond to human-induced changes is not compromised, while enabling the sustainable use of marine goods and services by present and future generations.'* This provision must be read in the light of Recital 44, which provides that *'[p]rogrammes of measures and subsequent action by Member States should be based on an ecosystem-based approach to the management of human activities and on the principles referred to in Article 174 of the Treaty, in particular the precautionary principle.'*

A strong emphasis on adverse effects can also be identified in the withdrawn proposal for a Soil Framework Directive. In the explanatory memorandum, the legal elements of the proposal include the *'requirement for land users to take precautionary measures when their use of the soil can be expected to significantly hamper soil functions.'* Furthermore, it refers to soil as a '*natural resource of common interest that has to be protected for future generations'.* Article 4 on 'Precautionary Measures' regulates that landowners are obliged to take precautions to prevent or minimise adverse effects on soil functions.

These key elements are also prominent in the definition of the precautionary principle in the Commission's White Paper on a Strategy for a future Chemicals Policy. Fundamental to achieving a high level of protection of human health and the environment – the main objectives of the EU chemicals legislation – is the precautionary principle[66]. Whenever *'reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage,*

[65] WFD, Recital 44.

[66] European Commission, COM(2001) 0088 final, White Paper - Strategy for a future Chemicals Policy, 5.

decision-making must be based on precaution in order to prevent damage to human health and the environment.'[67]

It is important to highlight that approaches to uncertainty may also change when legal instruments are amended, or new instruments adopted. This has been the case for legislation on waste management. The current Waste Framework Directive provides that *'Member States shall take the necessary measures to ensure that waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals; without causing a nuisance through noise or odours; and without adversely affecting the countryside or places of special interest'*.[68] There is a slight departure in the wording of this obligation from the former Waste Directive.[69] Article 13 of the current Waste Framework Directive provides that waste management should be carried out '*without harming the environment*' whereas Article 4 of the former Waste Directive provided that waste should be recovered or disposed of without using processes or methods '*which could harm the environment'*. The current Waste Framework Directive does not refer to uncertainty in waste management, therefore departing from the more clearly worded precautionary approach found in the former Waste Directive.

Table 3: Overview of references to the precautionary principle in selected EU environmental instrumentsTable 3 below summarizes the overview of references to the precautionary principle in the EU environmental instruments under review.

Table 3: Overview of references to the precautionary principle in selected EU environmental instruments

	No reference	Reference only in Recital	Precautionary principle addressed in main body (and Recital)
Air Quality Directive	✓		
Birds Directive	✓		
Environmental Impact Assessment Directive	✓		
Floods Directive	✓		
Habitats Directive	✓		
Industrial Emissions Directive	✓		
Invasive Alien Species Regulation[70]			✓
Marine Strategy Framework Directive		✓	
POPs Regulation			✓
REACH Regulation[71]			✓
RoHS 2 Directive			✓

[67] ibid.

[68] Waste Framework Directive, Article 13.

[69] Council Directive 75/442/EEC of 15 July 1975 on waste, OJ L 194, 25.7.1975, 47–49 (hereinafter 'former Waste Directive').

[70] Invasive Alien Species Regulation, Articles 8 and 10.

[71] REACH, Article 1(3).

	No reference	Reference only in Recital	Precautionary principle addressed in main body (and Recital)
Seveso III[72]		✓	
Sewage Sludge Directive	✓		
Waste Framework Directive			✓
Water Framework Directive		✓	
Withdrawn proposal for a Soil Framework Directive			✓

The explicit inclusion of the term precautionary principle, as well as the location of the references (Recital or main body), does not necessarily provide an accurate portrayal of the actual use of the precautionary principle within a EU environmental sector. For example, the Habitats Directive[73] has no specific reference to the term 'precautionary principle.' Nonetheless, the CJEU has confirmed on several occasions that Article 6(3) of the Habitats Directive integrates the precautionary principle[74] and has provided extensive guidance on the matter.

2.3 CONSTITUENT ELEMENTS OF THE PRECAUTIONARY PRINCIPLE IN ENVIRONMENTAL LEGISLATION

Section 2.3 discusses the components of the precautionary principle. More precisely, it looks at how the EU environmental legislation under review deals with risk and risk assessment, scientific information and uncertainty. This section outlines any definitions identified in the relevant context and then proceeds with the analysis of the different components of the precautionary principle.

2.3.1 Identification of potentially negative effects

Risk is typically interpreted as the product of the probability and consequences (e.g. mortality, morbidity, ecological damage) of an adverse event.[75] In other words it refers to the possibility, with a certain degree of probability, of damage to health and the environment, in combination with the nature

[72] The Seveso III Directive refers to precautionary action.

[73] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, 7–50 (hereinafter 'Habitats Directive').

[74] Case C-127/02, Judgment of 7 September 2004, *Waddenvereniging and Vogelbeschermingsvereniging*, ECLI:EU:C:2004:482, para 44 (hereinafter '*Waddenzee* case'). In particular, the CJEU held that '*Article 6(3) of the Habitats Directive also integrates the precautionary principle and makes it possible to prevent in an effective manner adverse effects on the integrity of protected sites as a result of the plans or projects being considered. A less stringent authorisation criterion than that set out in that provision could not ensure as effectively the fulfilment of the objective of site protection intended under that provision'*. See also Joined Cases C-387/15 and C-388/15, Judgment of 21 July 2016, *Orleans and Others*, ECLI:EU:C:2016:583, para 53.

[75] See for instance Hadden, S. G. (1984). Introduction: Risk policy in American institutions. *Risk analysis, institutions, and public policy*, 3-17; Wiener, J. B., & Rogers, M. D. (2002). Comparing precaution in the United States and Europe. *Journal of risk research*, *5*(4), 317-349.

and magnitude of the damage.[76] Risk assessment involves making an evaluation of the effects of positive and negative outcomes and their probabilities, resulting in actions which aim to mitigate harm and offset losses. Environmental risk assessment is recognised as quite difficult.[77]

Risk assessment is often viewed as the 'sound science' approach to decision-making, on which decisions are made on the basis of what can be quantified, without considering what is unknown or cannot be measured.[78] Consequently, risk assessment tends to work on the assumption that risks can be '*assessed probabilistically, employing a combination of statistical evidence and scientific understanding of causal relationships*.'[79] However, situations which require the application of the precautionary principle have a tendency to involve risks which are multi-causal and include uncertainty, resulting in ambiguity regarding the chain of causality that links the hazard to the final effects or their probability.[80] Therefore, the precautionary principle proceeds from an assumption that probabilistic assessments of risk are not sufficient in certain cases and must be supplemented or replaced by other criteria.[81] Lengthy debates have nevertheless taken place about the level of environmental risk required to trigger the precautionary principle.

Moreover, this rational conceptualisation of risk, due to its objective character, excludes explicit consideration of affect or value-based reactions to risk. In particular, it rejects the so-called 'subjective' or perceived risks that are considered unqualified psychological dimensions of risk experienced by individuals and social groups.[82] Since perceived risks cannot be captured and substantiated by technical calculations, they do not exist. As such they may not appear on regulators' radar, even though these incalculable threats represent a real source of concern.

The Communication indicates that the precautionary principle should be applied when potentially dangerous effects stemming from a phenomenon, product or process have been ascertained, and scientific evaluation fails to establish the level of risk involved with adequate certainty. In such instances, the implementation of an approach which incorporates the precautionary principle should be based on a scientific evaluation which, where possible, identifies the degree of scientific uncertainty present at each individual stage. Consequently, while the Communication does not provide a specific definition of the precautionary principle, it does set out some guidance to apply to all risk management actions, including precautionary actions. For example, risk assessment cannot be used to establish 'safe' levels of exposure, when it is not possible to know what safe levels are, as may be the case in respect of certain endocrine disruptors. However, the procedure can be used to better understand the hazards of an activity and to compare options for prevention.

[76] See Tickner, J., & and others. (1999). *The Precautionary Principle in Action: A Handbook*. Science and Environmental Health Network.

[77] European Commission, *Thematic Issue: Integrating Environmental Risk Assessment*, Science for Environmental Policy, 2015.

[78] Beauchamp, D. E. (2007). *Public health ethics: theory, policy, and practice*. Oxford University Press, 320.

[79] ibid.

[80] Sadeleer (de), N. (2010). The principles of prevention and precaution in international law: two heads of the same coin?. *Research Handbook on International Environmental Law*, 182, 184.

[81] Morris, J. (2002). The relationship between risk analysis and the precautionary principle. *Toxicology, 181*, 127-130.

[82] Alemanno, A. (2007). *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*. Cameron May.

The following section identifies and discusses risk in the context of the application of the precautionary principle in various EU environmental sectors. The analysis is divided into the individual components of the process, more precisely, the definition of risks, thresholds for risk management, the risk assessment methodology and risk management. It takes into account the relevant case-law of the CJEU where available.

2.3.1.1 Definition of risk

Amongst the directives and regulations under study, only a small number explicitly define the concept of risk. For instance, the Seveso III Directive defines risk as *'the likelihood of a specific effect occurring within a specified period or in specified circumstances'*.[83] In the Floods Directive, risk is defined in terms of 'flood risk' which means the combination of the probability of a flood event and of the potential adverse consequences for human health, the environment, cultural heritage and economic activity associated with it.

However, while the concept of risk is prevalent in the majority of EU environmental legislation, it is rarely so explicitly defined. One such example is the withdrawn proposal for a Soil Framework Directive, which states the need to prevent and limit risk to human health and the environment from contaminated sites. Specific examples of risks to soil are given in the explanatory memorandum and Article 6, which identifies 'risk areas' and states that these areas should be subject to revision at least every 10 years; implying some desire to deal with new and evolving risks, but not necessarily immediately as they emerge.

Risk is also not specifically defined in the POPs Regulation. However, risk is referred to in the Recital, which identifies POPs as posing a risk to human health and the environment.[84] The Recital also specifically refers to HCH,[85] which is restricted but not totally prohibited under the Stockholm Convention on Persistent Organic Pollutants. However, due to the possible risks related to its release into the environment, the Regulation stipulates that its production and uses should be minimised and phased out by 2007. Risk is also referred to in relation to the requirement to share information on the risks related to alternatives to POPs, along with their economic and social costs,[86] indicating that risk will be balanced against other factors.

The MSFD establishes a framework for community action in the field of marine environmental policy. Risk is not explicitly defined by the Directive, but is referred to in the Recital, which states that Member States should not be required to take specific steps where there is no significant risk to the marine environment.[87] Risk is also referred to in Article 1(2)(b), which refers to marine strategies being developed to prevent and reduce inputs into the marine environment, with a view to phasing out pollution, so as to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea. Article 13(8) ensures that Member States shall consider the implications of their programmes of measures on waters beyond their marine

[83] Seveso III Directive, Article 3(15).

[84] POPs Regulation, Recital 3.

[85] Hexachlorocyclohexane, listed as substance for prohibition (Annex I). ibid, Recital 11.

[86] ibid, Article 10.

[87] ibid, Recital 11.

waters in order to minimise the risk of damage to, and if possible have a positive impact on, those waters.

This review shows that although the concept of risk is prevalent in much of the legislation analysed, it is often present without a precise definition to support its implementation. This may be related to the particular challenges posed in assessing environmental risks, e.g., the complexity of the physical and ecological systems that must be taken into consideration, as well as the range of events that may occur, including natural disasters, the spread of dangerous substances, and health and security issues.

2.3.1.2 Threshold for risk assessment

EU environmental legislation defines various thresholds which must be reached to trigger a duty to conduct a risk assessment. These triggers can either be low, as assessed by the CJEU for the Habitats Directive for example, or conversely quite high, as is the case for an EIA.

Article 6(3) of the Habitats Directive states the need for an appropriate assessment. Thus, '*any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives […]*'. Consequently, the threshold for triggering a risk assessment is broadly encompassing. Furthermore, the CJEU has upheld and expanded on the low threshold set by the Directive by indicating that the obligation to carry out an appropriate assessment of the impact of a plan or project on a protected site is conditional on the likelihood of the plan or project in question having a significant effect on that site.[88]Additionally, the Court has highlighted its support of the low trigger by stating that '*the trigger for an appropriate assessment is a very light one, and that the mere probability or risk that a plan or project might have a significant effect is sufficient to make an 'appropriate assessment necessary*'.[89]

Similarly, Article 5 of the Invasive Alien Species Regulation establishes a relatively low threshold, with a risk assessment required to be undertaken in relation to the current and potential range of invasive alien species; including a thorough assessment of the risk of introduction, establishment and spread in relevant biogeographical regions in current conditions and in foreseeable climate change conditions. However, rather than the extremely low threshold set by the Habitats Directive, the Regulation appears to slightly increase the level needed to trigger a risk assessment by stating that alien species shall only be included on the Union list if a risk assessment demonstrates that concerted action at Union level is required to prevent their introduction, establishment or spread (Article 4(3).

It is also useful to note that the Industrial Emissions Directive sets a rather low threshold by requiring that an environmental risk assessment must be undertaken to cover potential risks of installations on the environment and human health. Specifically, the use of the phrase *potential* risks is not seen in the other pieces of legislation reviewed in this report.

The EU chemicals legislation does not set a threshold for assessing the risk of a chemical. Rather, it is

[88] C-127/02, *Waddenzee*, para 40. See also Case C‑179/06, Judgment of 4 October 2007, *Commission v Italy*, ECLI:EU:C:2007:578, para 33.

[89] C-127/02, *Waddenzee*, para 41-45.

an integral part of the regulatory control process applied to chemicals. REACH requires all EU manufacturers and importers of substances over certain annual tonnages to register information on the hazards and risks of their substances with the European Chemicals Agency (ECHA). This information is then evaluated by ECHA.

REACH's restriction processes are '*used in cases where it is considered that a substance poses an unacceptable risk to human health or the environment that is not adequately controlled.*'[90] REACH sets forth two types of control procedures – authorisation and restriction, and risk assessment is important for both. Opinions on the risks of substances are prepared for ECHA by the Committee for Risk Assessment (RAC)[91].

Under the authorisation procedure, substances meeting the Article 57 criteria and included in REACH Annex XIV as Substances of Very High Concern (SVHC) can only be placed on the market for those uses that have been specifically authorised. Applications for authorisation of a specific use of an SVHC are subject to an assessment of the risk to human health and/or the environment arising from that use, including the appropriateness and effectiveness of the risk management measures described in the application (Article 64(4)(a)).

The restriction procedure is to be applied '*[w]hen there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances'* (Article 68). REACH does not define the specific term "unacceptable risk".

A study from the Swedish Chemicals Agency (KEMI) has expressed concern that the current interpretation of "unacceptable risk" results in a cautious approach to restrictions which is tending to reduce the scope for application of the precautionary principle in practice[92]. The KEMI study explains that REACH Annex I, paragraph 6.4 states that the risk can be deemed "adequately" controlled if the exposure level does not exceed the maximum dose that is not considered to cause an effect. The Committee for Risk Assessment (RAC) applies this reasoning when determining the need for restriction measures at EU level, an interpretation which follows from ECHA's guidance concerning risk assessment, i.e., that an unacceptable risk is deemed to exist if the so-called "risk quotient" is greater than 1. KEMI notes that before REACH, scope was available for supplementary deliberations as regards what should be deemed an unacceptable risk and for imposing broad restrictions on a particular substance. However, while the RAC process of approving proposals for REACH restrictions enables restriction of those uses that involve the greatest and most obvious risks, uses with a low risk quotient are frequently identified, and this appears to have reduced considerably the scope for a complete restriction (ban) on the use of a substance based on its intrinsic properties.

The KEMI study states that this interpretation of "unacceptable risk" makes it difficult to adopt a preventive approach in the restriction procedure, e.g., to intervene before the use of a problematic substance becomes widespread or before new applications are developed which in the long term, or by the time they become sufficiently widespread, would result in an unacceptable risk. It notes that

[90] European Commission, SWD (2013) 025 final, Staff Working Document, General Report on REACH.

[91] https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment.

[92] KEMI 2015. *Developing REACH and improving its efficiency*, available at " KEMI 2015 http://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf , e.g. section 4.4, p. 91.

similar interpretations of "unacceptable risk" are also constraining the phase-out of substances of very high concern (SVHC) through the REACH authorisation procedure.

In contrast to the low thresholds set by the previously mentioned Directives, the EIA Directive screening process, which aims to determine whether an EIA is required for projects listed in Annex II of the EIA Directive, sets a more stringent requirement level for risk assessment by asserting that an EIA is only requisite if significant environmental effects exist.[93] Additionally, the CJEU supports the view that a decision on screening needs to be duly justified.[94] Consequently, the obligation to subject projects which are likely to have significant effects on the environment, by virtue of their nature, size or location, to an impact assessment, limits the discretion of Member States.[95]

It is therefore evident that the thresholds set by EU environmental legislation to trigger a duty to conduct a risk assessment operate on a sliding scale depending on the policy area covered by the legislation in question. Of the specific legislation reviewed for this report, the majority tend to lean towards a lower threshold. However, it is also evident that certain pieces of legislation, specifically the EIA Directive, set a high threshold for the need for a risk assessment to be triggered. Consequently, although EU legislation provides thresholds that must be attained in order for a risk assessment to be undertaken, these are set differently across the environmental legislation reviewed in this study.

2.3.1.3 Risk assessment methodology

The methods used to conduct a risk assessment vary depending on the EU legislation in question.[96] This is also the case within the environmental sector. For example, Article 7 of the withdrawn proposal for a Soil Framework Directive stipulates that identification of risk areas must be based on empirical evidence or modelling, and indicates that threats of unknown proportions can also be dealt with. The Recital also asserts that Member States must establish risk reduction targets and measures, and that these measures should consider their social and economic impacts. In contrast, the Invasive Alien Species Regulation is a list of invasive alien species of Union concern, which has been drawn up based on strict criteria and scientifically robust risk assessments, and approved by the Committee of Member State representatives.

Additionally, the Sewage Sludge Directive[97], despite not defining or referring to risk specifically, requires Member States to keep records of various aspects of the use of sludge. Annex II A gives guidance on sludge analysis, which must be carried out at least every six months, and more frequently if the characteristics of the waste changes. Annex II B, on soil analysis, outlines the rules for testing

[93] Member States may also set thresholds or criteria to determine when projects need not undergo the obligations of Annex II-projects or the obligation of screening or EIA (Article 4(3)).

[94] Case C-75/08, Judgment of 30 April 2009, *Mellor*, ECLI:EU:C:2009:279, para 59.

[95] Case C-141/14, Judgment of 14 January 2016, *European Commission v Republic of Bulgaria*, ECLI:EU:C:2016:8, para 92. See also Case C-244/12, Judgment of 21 March 2013, *Salzburger Flughafen*, ECLI:EU:C:2013:203, para 29; Case C‑531/13, Judgment of 11 February 2015, *Marktgemeinde Straßwalchen and Others*, ECLI:EU:C:2015:79C-531/13, para 40.

[96] Alemanno (2009).

[97] Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, OJ L 181, 4.7.1986, 6–12 (hereinafter 'Sewage Sludge Directive').

soils on which sludge is to be applied, including ensuring that limit values for heavy metals are not exceeded. Consequently, it would appear that despite not specifying it as such, the Directive requires regular monitoring of soil and sludge based on a risk assessment methodology.

Furthermore, the methods adopted by the various pieces of legislation incorporate the precautionary principle to differing degrees. Article 6(4) of the Habitats Directive specifies that, when carrying out an appropriate assessment, Member States are not obliged to examine alternative solutions to the plan or project concerned. This distinction is *'essential in terms of decision-making and represents a clear application of the precautionary principle'*.[98] The assessment of the risk under Article 6(3) of the Habitats Directive must take into consideration the characteristics and specific environmental conditions of the site or project. Additionally, it is possible to override an appropriate assessment indicating sufficient risk of resultant negative impacts, to authorise the project in the public interest.[99] However, although no explicit reference to the precautionary principle is included in the Habitats Directive, in the landmark *Waddenzee* judgment, the CJEU confirmed that *'the Habitats Directive must be interpreted by reference to the precautionary principle'*.[100]

A key provision of the Habitats Directive triggering the application of the precautionary principle is Article 6(3), which requires an assessment of the implications of a project or a plan before it is approved, in view of its conservation objectives for the site and, in particular, the potential effects on the particular habitats or species for which the site was designated. Such plans or projects can only be approved once it has been determined that they will not adversely affect the integrity of the site and, if appropriate, after public consultation (Article 6(3) and (4) of the Habitats Directive).

In *Waldensee*, the CJEU argued that '*As regards the conditions under which a particular activity may be authorised, it lies with the competent national authorities, in the light of the conclusions of the assessment of the implications of a plan or project for the site concerned, to approve the plan or project only after having made sure that it will not adversely affect the integrity of that site….Where doubt remains as to the absence of adverse effects on the integrity of the site linked to the plan or project being considered, the competent authority will have to refuse authorisation*'.[101] The Court further provided that '*in this respect, it is clear that the authorisation criterion laid down in the second sentence of Article 6(3) integrates the precautionary principle […] and makes it possible effectively to prevent adverse effects on the integrity of protected sites as the result of the plans or projects being considered. A less stringent authorisation criterion than that in question could not as effectively ensure the fulfilment of the objective of site protection intended under that provision*'.[102] Thus under Article 6(3) an appropriate assessment of the implications for the site concerned by the plan or project '*implies that, prior to its approval, all the aspects of the plan or project which can, by themselves or in combination with other plans or projects, affect the site's conservation objectives must be identified in the light of the best scientific knowledge in the field*'.[103]

[98] Truilhé-Marengo (2015), 338.

[99] ibid.

[100] C-127/02, *Waddenzee*, para 44. See also Case C-521/12, Judgment of 15 May 2014, *Briels and Others*, ECLI:EU:C:2014:330, para 26; Joined Cases C-387/15 and C-388/15, *Orleans and Others*, para 53.

[101] C-127/02, *Waddenzee*, para 55-57.

[102] ibid, para 58.

[103] ibid, para 61.

In *Briels and Others*, the CJEU argued in this context that the authorisation criterion laid down in the second sentence of Article 6(3) of the Habitats Directive '*integrates the precautionary principle and makes it possible to prevent in an effective manner adverse effects on the integrity of protected sites as a result of the plans or projects being considered' and that 'a less stringent authorisation criterion than that in question could not ensure as effectively the fulfilment of the objective of site protection intended under that provision*.'[104] In *Sweetman and Others*,[105] the Advocate General argued that '*the precautionary principle is a procedural principle, in that it describes the approach to be adopted by the decision-maker and does not demand a particular result*.'[106]

Similar to an appropriate assessment under the Habitats Directive, the Water Framework Directive includes in Article 4(7) of WFD a practical application of the precautionary principle. Article 4(7) establishes exemptions under which deteriorations from the aims of the Directive are allowed. Accordingly, the Article establishes a three-step screening process consisting of screening, assessment/mitigation and the application of tests.[107] As it has been concluded in the guidance document for the Water Framework Directive that, "*the application of the precautionary principle can help to avoid situations where ex-post evaluations provide evidence that deterioration actually occurred without applying an Article 4(7) assessment. Such situations should be avoided by applying 4(7) assessments also in cases where deterioration is uncertain. This can also be relevant in terms of transparency and documenting evidence which supports decisions by competent authorities whether an Article 4(7) assessment needs to be undertaken*.".[108]

In contrast, the Air Quality Directive[109] does not include such a clear-cut application of the precautionary principle in the measures it lays down for assessing the ambient air quality in member states based on common methods and criteria, and for setting measures for achieving air quality objectives. The key criteria for air quality includes whether there is a *risk* that environmental standards will be breached and the *probability* of the effect occurring. The Directive sets health-based limit values for particulate matter, sulphur dioxide, nitrogen dioxide, lead, benzene and carbon monoxide and imposes a duty on the Member State to achieve them by a given deadline, regardless of the cost. For the purposes of monitoring and assessing air quality, Member States designate 'zones and agglomerations'. Ultimately, member states must ensure that 'throughout their zones and

[104] C-521/12, *Briels and Others*, para 26.

[105] Case C-258/11, Judgment of 11 April 2013, *Sweetman and Others*, ECLI:EU:C:2013:220.

[106] Case C-258/11, Opinion of Advocate General Sharpston, 22 November 2012, *Sweetman and Others* (AG opinion), ECLI:EU:C:2012:743, para 78. However, McIntyre argues that this statement is difficult to reconcile with the court's conclusion that '*a less stringent authorisation criterion*' than that based on the precautionary principle '*could not ensure as effectively the fulfilment of the objective of site protection intended under that provision*.' The Court clearly appears, therefore, to have regarded the precautionary principle as capable of informing the substantive standard of protection afforded to a protected site under Article 6(3). See McIntyre (2013), 211.

[107] Dworak et al., Exemptions under Article 4(7) of the Water Framework Directive, Common Implementation Strategy Workshop, 13-14 December 2016, Brussels, Key Issues Paper, 17.

[108] Common Implementation Strategy for the Water Framework Directive, Guidance Document No. 35 8 - Exemptions to the Environmental Objectives according to Article 4(7), available at http://www.vannportalen.no/globalassets/nasjonalt/dokumenter/organisering/europeisk--eus-rammedirektiv/felles-europeisk-gjennomforing/norsk-deltakelse-i-de-ulike-cis-gruppene/temagruppe-for-gjennomforing-av-art.-4.7-under-vanndirektivet/referater/2017/draft-no-35-article-4-7.pdf p. 31

[109] Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe, OJ L 152, 11.6.2008, 1–44 (hereinafter 'Air Quality Directive').

agglomerations', levels of these pollutants do not exceed the limit values by the relevant deadlines. However, Member States have considerable discretion in setting 'zones and agglomerations, and in the types of measures they put in place for complying with the limit values for covered pollutants.

Additionally, the development of risk management within the EIA Directive is useful to demonstrate how the precautionary principle has evolved within EU legislation. The EIA Directive specifies that projects that are likely to have a significant impact on the environment must undergo an environment report and be subject to authorisation for the development to go ahead, whilst authorised projects likely to have significant effects must be subject to monitoring and mitigation measures for significant adverse environmental effects.

A 2012 Commission proposal to amend the EIA Directive was adopted by the EU Council in 2014, with i.a. the aim to improve the quality of the environmental impact assessment. Recital 7 of the amending legislation states that, '*Over the last decade, environmental issues, such as resource efficiency and sustainability, biodiversity protection, climate change, and risks of accidents and disasters, have become more important in policy making. They should therefore also constitute important elements in assessment and decision-making processes*'. In addition to acknowledging the importance of risk assessment in environmental decision-making and planning, it extends the competent authority's obligation to be informed about the environmental impact of a project not only before it is undertaken, but to also include monitoring after a project is carried out.

Article 8a, paragraph 4, now states that Member States need to '*determine the procedures regarding the monitoring of significant adverse effects on the environment'*. This provision is to be read in conjunction with Annex IV, paragraph 7, which now states that the EIA must contain, '*A description of the measures envisaged to avoid, prevent, reduce or, if possible, offset any identified significant adverse effects on the environment and, where appropriate, of any proposed monitoring arrangements (for example the preparation of a post-project analysis). That description should explain the extent, to which significant adverse effects on the environment are avoided, prevented, reduced or offset, and should cover both the construction and operational phases*.' This obligation to verify the effective implementation of any measures foreseen as necessary to avoid or prevent significant adverse effects, both during the construction and after the completion of the project makes the EIA Directive a more powerful instrument and shifts it towards a more precautionary approach to assessment of adverse effects.

It is therefore evident that risk assessment methodologies vary depending on the individual legislation and range from empirical evidence, modelling, the establishment of risk reduction targets and record keeping, to the examination of alternative solutions. Additionally, the variance in the methods employed has also resulted in the precautionary principle being implemented to varying degrees across the legislation analysed for this report. Specifically, the Habitats Directive and Water Framework Directive directly incorporate the principle into their risk assessment methodology, whilst the Air Quality Directive focuses on a probability approach rather than specifically identifying the need for precaution. Furthermore, it appears that the amended EIA Directive has shifted towards a precautionary approach. However, this development may be specific to this particular Directive and therefore not demonstrative of EU environmental policy in general.

2.3.1.4 Risk management

Risk management is the process of deciding what appropriate actions should be taken in order to avoid or eliminate a perceived risk,[110] and is crucial to numerous environmental policies. Both the EU and its Member States are called upon to manage environmental risks by establishing the risk threshold which may be acceptable for the whole of society. The discretion of competent authorities is not limited to the evaluation of the significance of a risk, which leads to a determination of the acceptable level of protection, but also extends to the choice of action to be taken to achieve that protection threshold. As a result, a risk management decision does not consist solely of a selection of both the facts and the methods of assessment, but also requires a complex decision on whether to accept the risks in question or not (risk choice). As de Sadeleer explains, contrary to risk assessment, risk management is '*the public process of deciding how safe is safe'*.[111]

Risk management is intrinsic to the Water Framework Directive, which establishes a framework for sustainable water management through the development of River Basin Management Plans and Programmes of Measures with the objective of preventing deterioration of the aquatic environment and of achieving good status of all water bodies. The Directive requires the Commission to submit a proposal setting out a list of priority substances which present a significant risk to, or via, the aquatic environment. Substances are prioritised for action on the basis of risk and identified by a risk assessment or a targeted risk-based assessment. The precautionary approach to risk is particularly applied to a number of 'Specific Pollutants' because of their inherent toxicity, persistence etc. The standards set for these chemicals are more rigorous than those required to support Good Environmental Status, reflecting the fact that they pose a significant long-term risk to aquatic ecosystems and human health.

Similarly, assessment of marine waters forms a key element under the MSFD. In order to prepare their marine strategies, Member States shall make an initial assessment of their marine waters for each marine region or subregion (Article 8(1)). Then, on the basis of this initial assessment, they must:

- determine, for the marine waters of each marine region or subregion, a set of characteristics for good environmental status on the basis of qualitative descriptors (Article 9(1));
- establish a comprehensive set of environmental targets and associated indicators for their marine waters so as to guide progress towards achieving good environmental status in the marine environment, taking into account indicative lists of pressures and impacts (Article 10(1)); and
- implement coordinated monitoring programmes for the ongoing assessment of the environmental status of their marine waters on the basis of indicative lists of elements and by reference to the environmental targets established (Article 11(1)).

Once Member States have carried out these compulsory tasks, pursuant to Article 13, they must, in respect of each marine region or subregion concerned, identify the measures which need to be taken to achieve, or maintain, good environmental status in their marine waters. Importantly, according to Recital 27, *'[t]hose measures should be devised on the basis of the precautionary principle and the principles that preventive action should be taken, that environmental damage should, as a priority, be*

[110] Chanley, G., & Rogers, M. (2011). Frameworks for Risk Assessment, Uncertainty, and Precaution. In J. Wiener, *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. Earthscan, 364.

[111] De Sadeleer, N. (2006), 147.

rectified at source and that the polluter should pay', therefore quoting directly Article 191(2) of the TFEU. Furthermore, Article 13(8) requires Member States to consider the implications of their programmes of measures on waters beyond their marine waters in order to minimise the risk of damage to, and if possible have a positive impact on, those waters.

Recital 14 of the EIA Directive establishes a link to disaster risk prevention and management, whilst Recital 15 states that '*In order to ensure a high level of protection of the environment, precautionary actions need to be taken for certain projects which, because of their vulnerability to major accidents, and/or natural disasters (such as flooding, sea level rise, or earthquakes) are likely to have significant adverse effects on the environment*.' Hence it identifies risk management as a means to ensure a high level of environmental protection. '

Within REACH, risk management of the substances is based on the information provided by the risk assessment. The manufacturers, importers or those who place on the market or use relevant substances are legally obliged to identify the measures necessary to manage the risk of those substances and to communicate those measures to downstream users.[112] This responsibility for the safe management of the risks from chemicals is intended to '*encourage enterprises to apply risk reduction measures from an early point in the life cycle of the substance concerned and thereby to avoid any negative impact on downstream users and customers*.'[113]

For a substance of very high concern (SVHC), slightly more guidance is provided, with risks related to any authorised use needing to be adequately controlled through *'appropriate risk management measures'*, including ensuring that exposure is *'below the threshold level beyond which adverse effects may occur'*.[114] Additionally, risk management measures should include *'a view to progressively substituting these substances with a suitable safer substance.'*[115] For other substances, risk reduction under REACH is defined in its Recital which states that '*for any other substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects*.'[116]

The precautionary principle is also relevant to the assessment in the Floods Directive. Flood risk assessments should consider many factors '*including all sources of flood water, the potential for failure of any raised flood defences, the control of increased runoff from the developments, mitigation of residual risks and make precautionary allowances for the potential increase in rainfall or sea level arising from climate change*'.[117] The Floods Directive is implemented in iterative cycles which incorporate the precautionary approach to risk assessment. At the end of each six-year cycle, flood risk management plans are prepared. The first steps in the risk management process established by the

[112] Cunningham, R. (2012). *Glass half full or half empty? Why 2009 Water Framework Directive classification results are over-optimistic about the state of rivers despite the One-Out, All-Out rule*. Royal Society for the Protection of Birds.

[113] Commission Staff Working Document, General Report on Reach (2013).

[114] European Commission, SWD(2013) 25 final, 70.

[115] ibid.

[116] ibid.

[117] Klijn, F., & Others. (2008). Towards flood risk management in the EU: State of affairs with examples from various European countries. *International Journal of River Basin Management*, 6(4), 307-321, 311.

Floods Directive were the preparation of preliminary flood risk assessments by the end of 2011 and the identification of areas of potential significant flood risks, which enabled Member States to focus implementation on areas where this risk is significant. Preliminary assessments were largely based on available information about past significant floods and on forecasts of potential significant floods in the future.

Additionally, the Recital to the withdrawn proposal for a Soil Framework Directive states that Member States must establish risk reduction targets and measures,[118] and that these measures should consider their social and economic impacts.[119] The Directive also stipulates that measures should be put in place to ensure that methods of identifying risk areas can be rapidly adapted, suggesting a link to a proactive and potentially precautionary, rather than a reactive, approach.

Consequently, it is evident that risk management is fundamentally established within most of the environmental legislation analysed in this report. However, the form that said management takes differs greatly depending on the policy issue that is being covered; including the establishment of programmes of measures and the creation of specific risk reduction targets. Despite a lack of direct reference to the precautionary principle, many of the risk management actions nonetheless adopt measures which tend to be proactive in nature.

Table 4: The use of risk and risk management in the selected legislation

Legislative document	Threshold	Risk assessment	Risk management
Air Quality Directive	Member States shall assess ambient air quality with respect to the pollutants referred to in all their zones and agglomerations.	Sets limit values for a range of pollutants.	Where, in given zones or agglomerations, the levels of pollutants in ambient air exceed any limit value or target value, plus any relevant margin of tolerance in each case, Member States shall ensure that air quality plans are established for those zones and agglomerations to achieve the related limit value or target value.
Birds and Habitats Directives	If there is any doubt in relation to the effects a project may cause, an appropriate assessment should be undertaken.	Must take into consideration the characteristics and specific environmental conditions of the site or project - when carrying out an appropriate assessment, Member States are not obliged to examine alternative solutions to the plan or project concerned.	Requires an assessment of the implications of a project or a plan before it is approved, in view of its conservation objectives for the site and, in particular, the potential effects on the particular habitats or species for which the site was designated.
Environmental Impact Assessment	An EIA is only a requisite if significant environmental effects can exist.	Projects that are likely to have a significant impact on the environment must	N/A

[118] Withdrawn proposal for a Soil Framework Directive, Recital 17.

[119] ibid, Recital 18 and Article 8(2).

Legislative document	Threshold	Risk assessment	Risk management
Directive		undergo an environment report and be subject to authorisation for the development to go ahead, whilst authorised projects likely to have significant effects must be subject to monitoring and mitigation measures for significant adverse environmental effects.	
Floods Directive	Member States shall, for each river basin district, or unit of management, or the portion of an international river basin district lying within their territory, undertake a preliminary flood risk assessment.	Must include maps of river basin district, description of past floods and an assessment of potential consequences of future floods.	Implemented in iterative cycles which incorporate the precautionary approach to risk assessment.
Industrial Emissions Directive	Requires environmental risk assessment to cover *potential* risks of installations on the environment and human health.	Sets emission limit values for a range of pollutants from large combustion plants and waste incineration plants and activities using organic solvents, and grants Commission the power to adopt implementing decisions laying down Best Available Techniques to be applied by the activities covered and ranges of associated emission levels to be respected	To ensure the prevention and control of pollution, each installation should operate only if it holds a permit which should include emission limit values for pollutants emitted to air, water and soil (in case of activities using organic solvents, permit can be replaced with a registration).
Invasive Alien Species Regulation	Required to be undertaken in relation to the current and potential range of invasive alien species.	List of invasive alien species of Union concern.	Management measures shall be prioritised based on the risk evaluation and their cost-effectiveness
Marine Strategy Framework Directive	In respect of each marine region or subregion, MS must make an initial assessment of their marine waters.	In respect of each marine region or subregion concerned, identify the measures which need to be taken to achieve, or maintain, good environmental status in their marine waters.	Shall establish and implement coordinated monitoring programmes for the ongoing assessment of the environmental status of their marine waters based on indicative lists of elements and by reference to the environmental targets established.

Legislative document	Threshold	Risk assessment	Risk management
REACH	All substances manufactured, produced or imported in quantities of over 1 tonne/year must be registered with ECHA. Chemical safety assessment must be conducted for substances imported or manufactured in quantities of 10 tonnes/year or more.	Screening of all registered substances. Chemical safety assessment covers human health, physiochemical environmental and PBT/vPvB hazards. Chemicals displaying vPvB properties, an exposure assessment must also be carried out Priority for risk assessment by ECHA is given to certain substances, including SVHCs.	Based on the information provided by the risk assessment, the obligation to introduce measures that manage the risk of substances is placed on manufacturers, importers or those who place on the market or use relevant substances. They must demonstrate how to use their products safely and inform users of any risk management measures they should take to ensure safe use throughout the supply chain. National authorities may restrict the manufacture or use of certain substances if they consider that the risks are not adequately managed. Risk management measures should aim to substituted SVHCs with safer alternatives. Exposure must also be "below the threshold level beyond which adverse effects may occur."
Seveso III	Two thresholds in terms of quantities of dangerous substances present in an establishment; first one to determine its application and a second, higher one, to determine stricter obligations of operators (the more substances present, the more likely the accident, the more precautionary measures to be taken)	Member States shall ensure that the competent authority identifies all lower-tier and upper-tier establishments or groups of establishments where the risk or consequences of a major accident may be increased because of the geographical position and the proximity of such establishments, and their inventories of dangerous substances.	Operators must set up a major accident prevention policy (including safety management measures), a safety report, an internal emergency plan; competent authorities have to set up external emergency plans, carry out risk assessment when decisions on siting (land use planning are taken)
Sewage Sludge Directive	Establishes limit values for 7 heavy metals in sewage sludge and soil	Stipulates the need for regular monitoring of soil and sludge based on a risk assessment methodology.	Member States must keep records of various aspects of the use of sludge. Sludge analysis must be carried out at least every 6 months, and more often if characteristics of the waste changes. Use of sludge that exceeds the concentration limits is banned
Soil Thematic Strategy and	Areas where soil is threatened by any of a range	Member States are obliged to identify areas at risk of	Member States must establish risk reduction

Legislative document	Threshold	Risk assessment	Risk management
withdrawn proposal for a Soil Framework Directive	of soil degradation processes, hampering its ability to fulfil its functions. Risk to health and the environment from contaminated sites must also be prevented and limited	erosion, organic matter decline, compaction, salinisation and landslides, or where the degradation process is already underway. This would be done based on criteria set out in the proposal. Identification of risk areas must be based on empirical evidence or modelling, and indicates that threats of unknown proportions can also be dealt with. A common risk assessment methodology should be established for contaminated sites, by exchanging information and by developing and improving methodologies on eco-toxicological risk assessment.	targets and programmes of measures, which consider both social and economic impacts. Risk areas must be reviewed every 10 years. Measures should be put in place to ensure that methods of identification of risk areas can be rapidly adapted.
Waste Framework Directive	Waste management must be carried out without any risk to water, air, soil, plants or animals, without causing a nuisance through noise or smells, or harming the countryside or places of special interest. 'Technical minimum standards' must be established for treatment activities subject to permits, 'where there is evidence that a benefit in terms of the protection of human health and the environment would be gained from such minimum standards,' and also for activities subject to registration, where there is evidence of benefit to human health or the environment or avoiding disruption to the internal market. Establishes concentration limits for hazardous substances	Requires those carrying out waste treatment to obtain a permit and to keep a register of establishments not subject to permit requirements	MS must establish waste management plans including the measures to be taken to improve environmentally sound preparation for re-use, recycling, recovery and disposal of waste Those producing or dealing with hazardous wastes must keep a record of aspects relating to the waste and its origin and destination
Water	Member States shall ensure	Substances shall be	Obligates the Commission

Legislative document	Threshold	Risk assessment	Risk management
Framework Directive	that a river basin management plan is produced for each river basin district lying entirely within their territory.	prioritised for action on the basis of risk to, or via the aquatic environment identified by a simplified risk-based assessment procedure based on scientific principles.	to submit a proposal setting out a list of priority substances which present a significant risk to or via the aquatic environment. Substances are prioritised for action on the basis of risk and identified by a risk assessment or a targeted risk-based assessment.

2.3.2 Scientific evaluation

The Communication on the precautionary principle stipulates that the '*implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty'*.[120]

The Commission's guidance document on the Habitats Directive states that if *'no reasonable scientific doubt remains as to the absence of effects in the site, the competent authorities can give their consent on the plan or project. In case of doubt, or negative conclusions, the precautionary and preventive principles should be applied and procedures under art. 6(4) followed'*.[121] This requires conducting a scientific evaluation prior to a project going ahead. If this evaluation reveals uncertainty over the project's absence of effects for the Natura 2000 site, the precautionary and preventative principles should be applied.[122] This implies that there must be no doubt as to the safety of a project for it to be authorised, which in effect reverses the burden of proof, and goes beyond the guidance in the Communication.

The CJEU has also indicated that a scientific evaluation should be conducted prior to implementing an approach based on the precautionary principle. A notable example is *Afton Chemical*[123], where the CJEU provided detailed guidance on the application of the precautionary principle in the area of scientific evaluation. The CJEU held that a correct application of the precautionary principle in that context presupposes, first, the identification of the potentially negative consequences for health of the proposed use of MMT [a specific metallic additive], and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research[124].

[120] ibid, 16.

[121] European Commission (2007), Guidance document on the strict protection of animal species of Community interest under the Habitats Directive 92/43/EEC, 3.

[122] However, Article 6(4) of the Habitats Directive provides exceptions where there is an overriding public interest as discussed in this study.

[123] C-343/09, 8 July 2010, *Afton Chemical*, para 60.

[124] C-343/09, *Afton Chemical*, para 60. See also Case C‑333/08, Judgment of 28 January 2010, *Commission v France*, ECLI:EU:C:2010:44, para 92.

2.3.3 Scientific uncertainty

Section 2.3.3 explores how scientific uncertainty is dealt with in the context of applying the precautionary principle. It first outlines the general definitions of uncertainty relevant to this analysis, before looking at how scientific uncertainty is dealt with in the legislation reviewed.

2.3.3.1 Definitions

Because it focuses on situations with significant scientific uncertainty, the precautionary principle should be distinguished from the preventive principle, which requires authorities to prevent risks when their existence has been proven. According to de Sadeleer: 'The distinction between the preventive principle and the precautionary principle rests *on a difference of degree in the understanding of risk*. Prevention is based on *certainties*: it rests on cumulative experience concerning the degree of risk posed by an activity (Russian roulette, for example, involves a predictable one-in-six chance of death) […] Preventive measures are thus intended to avert risks for which the cause-and-effect relationship is already known […] Precaution, in contrast, comes into play when the probability of a suspected risk or its potential impacts cannot be irrefutably demonstrated. The distinction between the two principles is thus *the degree of uncertainty surrounding the probability of risk.* The lower the margin of uncertainty, the greater the justification for intervention as a means of prevention, rather than in the name of precaution. By contrast, precaution is used when scientific research has not yet reached a stage that allows the veil of uncertainty to be lifted'[125].

It follows, therefore, that recourse to the precautionary principle presupposes that scientific evaluation does not allow the risk to be determined with sufficient certainty. The problem of understanding, conceiving and defining uncertainty within the framework of risk assessment is extremely difficult, but it is the logical precondition to a viable use of the principle.[126]

Uncertainty can be defined broadly as an inherent feature of all risks, even when probabilities are known.[127] It is possible to distinguish between several types of situations giving rise to scientific uncertainty by looking, in particular, at how uncertainty manifests itself in the risk assessment process.

One should first distinguish scientific uncertainty deriving from conflicting scientific results, from that stemming from situations of ignorance. The former situation can be labelled as 'genuine uncertainty', as opposed to all other categories of scientific uncertainty attributable to ignorance. 'Genuine uncertainty' encompasses all those scenarios where scientific studies are available, but the resulting science may not establish a direct causal link between an activity, process or substance and an identified adverse effect.[128]

[125] De Sadeleer (2002), 74-75.

[126] For a taxonomy, Alemanno (2007).

[127] See Smith, C. (2000). The Precautionary Principle and Environmental Policy: Science, Uncertainty, and Sustainability. *International Journal of Occupational & Environmental Health*, 6(3), 263-330; Sadeleer (de) (2009), 3-10.

[128] See Christoforou, T. (2003). The precautionary principle and democratizing expertise: a European legal perspective. *Science & Public Policy (SPP)*, *30*(3), 207. According to the Commission, such a situation corresponds to 'absence of proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure'. See Communication on the precautionary principle.

Within the broad category of scientific uncertainty attributable to ignorance, it is crucial to differentiate between situations where the impossibility of achieving certainty is merely material, e.g., when the costs involved in conducting scientific research are too high, and those where such an impossibility is due to the unavailability of definitive scientific data. This in turn can be ascribed to the novelty of the product concerned and to the consequent lack of sufficiently developed assessment techniques. Alemanno suggests that while the former can be labelled 'unjustifiable uncertainty', the latter can be qualified as 'justifiable uncertainty'.

The Communication on the Precautionary Principle outlines that the principle applies *'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 environment, human, animal or plant health may be inconsistent with the chosen level of protection'.*[129] Another definition used in the Communication refers to situations where a scientific evaluation of the risk does not yield conclusive results; when *'a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question'.*

The Communication identifies that uncertainty can arise from controversy over existing data, or lack of relevant data.[130] This maps onto the categories identified in Janssen & Rosenstock (see below). The Communication also outlines different ways of categorising uncertainty: in some instances, it has been separated into three categories—bias, randomness and true variability. In others, it has been defined as uncertainty over the severity of the hazard's impact and the confidence interval attached to the probability of occurrence.[131] The Communication also refers to four reports by the European Scientific Technology Observatory, which give a 'comprehensive description of scientific uncertainty'.[132] Finally, it asserts that deciding what is an acceptable level of risk for society is ultimately a 'political responsibility'.

Other key policy documents on the precautionary principle mention but do not define uncertainty. For example, Principle 15 of the 1992 Rio Declaration on Environment and Development, which is referenced in some of the policy documents reviewed here[133], states that '*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 environment degradation*'. The Wingspread Statement on the Precautionary Principle[134] refers to uncertainty over cause and effect relationships: '*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*'[135].

[129] Communication on the precautionary principle, 9-10.

[130] ibid, 14.

[131] ibid.

[132] ibid.

[133] POPs Regulation, Recital 7.

[134] The Wingspread Statement on the Precautionary Principle was written by a group of scholars, scientists, lawyers, policy-makers and environmentalists, who attended a 3-day meeting at the Wingspread Center in Racine, Wisconsin in mid-January, 1998.

[135] ibid.

The CJEU has also played an active role in developing the definition of the precautionary principle and its relationship to uncertainty. De Sadeleer asserts that the jurisprudential definition of the principle is: '*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*'. This stems from various judgments across different fields of law, including environment, food safety and health.[136]

Finally, various ways of defining scientific uncertainty appear in the literature on the precautionary principle. Overall, most studies recognise more than one definition or type of scientific uncertainty.[137] A recent study identified three categories of scientific uncertainty employed in case-law concerning the precautionary principle: 1) a lack of sufficient information to prove safety, 2) a lack of sufficient information to prove harm and 3) where information is available but there are conflicting scientific opinions over the conclusions.[138] Scholars have also noted that uncertainty in the context of the precautionary principle can apply both to uncertainty over cause and effect relationships, not just over the severity of consequences.[139]

The final distinction relevant to this study is between scientific uncertainty over the probabilities of an event occurring (which distinguishes uncertainty from risk, where probabilities are known), and gross ignorance, where the relationship between cause and effect is not established.[140] All these various levels or types of uncertainty remind us that there are different ways of dealing with uncertainty corresponding to the type of uncertainty in question. The elaborations in the literature therefore provide a useful lens onto how uncertainty is dealt with in the policies under review. Based on this, the following section reviews how scientific uncertainty is dealt with in the selected EU environmental legislation.

2.3.3.2 Uncertainty in EU environmental legislation

Section 2.3.3.2 looks at how scientific uncertainty is referred to, and dealt with, in EU environmental legislation. None of the instruments reviewed for this study define scientific uncertainty, and explicit references to uncertainty are rare. The only text (indirectly) referring to uncertainty in the context of the precautionary principle is Recital 7 of the POPs Regulation, which refers to Principle 15 of 1992 Rio Declaration on Environment and Development.[141] Furthermore, various provisions dealing with issues of uncertainty cover different readings of the term. As with the definitions, these are mainly

[136] De Sadeleer lists the following cases as important for the jurisprudential definition of uncertainty: Case C-157/96, *National Farmers' Union and Others*, para 63; Case C-180/96, Judgment of 12 July 1996, *United Kingdom v. Commission*, ECLI:EU:C:1998:192, para 111. See also T-13/99, *Pfizer*, para 139. Sadeleer (de) (2009).

[137] See, for example, Weale, A. (2007). The Precautionary Principle in Environmental Policies. In J. Pretty, & Others, *The Sage Handbook of Environment and Society* (pp. 590-600). Sage Publications.

[138] Janssen, A., & Rosenstock, N. (2016). 'Handling Uncertain Risks: An Inconsistent Application of Standards?: The Precautionary Principle in Court Revisited. *European Journal of Risk Regulation*, 7(1), 144-154.

[139] Weale (2007).

[140] Randall, A. (2011). *Risk and Precaution*. Cambridge University Press.

[141] The 1992 Rio Declaration on Environment and Development defines the precautionary principle as: '*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*.'

implicit rather than explicit.

Insufficient information concerning harm

The EU environmental legislation under review refers to different levels of uncertainty over hazards as triggering a regulatory response. Some of the instruments under review set the threshold of uncertainty at *potential* threats to human health or the environment, which as such may be subject to legal interpretation. For example, Article 4 of the Invasive Alien Species Regulation charges the Commission with adopting a list of invasive alien species of Union concern on the basis of certain criteria, and in light of a risk assessment concerning the current and potential range of the species, including potential pathways of introduction and the potential costs of damages. It sets a series of restrictions aimed at preventing the unintentional introduction or spread of invasive alien species of EU concern. In addition, it allows emergency measures to be taken 'on the basis of 'preliminary scientific evidence' concerning the presence in, or imminent risk of introduction into its territory of an alien invasive species not included on the Union list but likely to meet the criteria for inclusion. It also provides for permits allowing establishments to carry out research on, or ex-situ conservation of, invasive alien species of Union concern to be withdrawn '*where scientific information is insufficient, on the grounds of the precautionary principle*' (Article 8(5)).

Referring to a similar threshold of uncertainty, the withdrawn proposal for a Soil Framework Directive would have required Member States to establish a list of *'potentially soil polluting activities'* and to identify areas where *'there is decisive evidence or* ***legitimate grounds for suspicion****, that one or more of the […] degradation processes has occurred or is likely to occur in the near future'* (emphasis added).

Article 7 of the Floods Directive also requires that flood risk management measures should focus 'on the reduction of *potential adverse consequences* of flooding for human health, the environment, cultural heritage and economic activity'. Annex I (0.3) of REACH also provides that the chemical safety assessment shall be based on a comparison of *'potential adverse effects'* with the *'known or reasonably foreseeable exposure.'* Finally, in the area of industry regulation, the Seveso III Directive defines a hazard according to '*a potential for creating damage to human health or the environment'* (Article 3(4)), while the Industrial Emissions Directive includes potential impacts of installations on human health and the environment as one of the elements to appraise the environmental risk, in view of deciding on the frequency of inspections (Article 23(4)).

These references to *potential* threats allow for decisions to be made under uncertainty over the precise impacts or their probability. Such provisions appear to be related to measures which are not very restrictive (as with the gathering of information), or when the threat is large (as with the invasive alien species emergency measures).

Other directives refer to *likely* rather than *potential* harm as being the threshold needed to prompt action. Again, what constitutes *likely* harm is not explicitly defined within the Directives and may therefore also be subject to legal interpretation. Article 6(3) of the Habitats Directive provides that any plan or project '*likely* to have a *significant effect*' (emphasis added) on a Natura 2000 site, shall have to complete an assessment of its implications for the site. The same approach is taken under Article 13(5) of the Marine Strategy Framework Directive which requires Member States to propose

measures to address any activity that 'is likely to have a significant impact on the marine environment'.

Similarly, the Environmental Impact Assessment Directive, requires developers to identify and assess factors relating to human health and the environment that are likely to be significantly affected, and identify projects with *'potentially hazardous or irreversible effects'*, as examples of those that should be subject to an EIA. The Industrial Emissions Directive also requires environmental risk assessment to cover *potential* risks of installations on the environment and human health. On the other hand, Article 57(f) of REACH specifies that where there is scientific evidence of 'probable serious effects to human health or the environment' substances can be subjected to the authorisation process. Therefore, in some policy areas, notably REACH, more restrictive measures appear to require a larger level of threat and greater level of scientific certainty than other measures such as the information gathering on potential threats under the withdrawn proposal for a Soil Framework Directive.

In general, the directives and regulations analysed do not go into detail about different types of uncertainty, such as whether it relates to cause and effect relationships, the severity of the consequences, or the uncertainty of the probability of certain hazards.

Insufficient information concerning safety

It is an implicit assumption that the need for legislative action is prompted by uncertainty over the safety of certain actions, and the desire to make sure that activities not proven to be safe do not cause future harm. For example, the Waste Framework Directive implies that there must be some certainty over environmental safety for authorities to issue permits, as they cannot be issued if they consider that 'the intended method of treatment is unacceptable from the point of view of environmental protection'.

Similarly, under the Restriction of Hazardous Substances Directive (2002/95/EC), covering electrical and electronic products, Member States must ensure that products are not placed on the market where a manufacturer, importer or distributer *'considers or has reasons to believe'* that a product covered by the Directive contains above the maximum limit concentrations for 6 dangerous substances listed in Annex III[142] (see Articles 7, 9 and 10). Also in the field of chemicals, the POPs Regulation requires new POPs to be added to the Regulation as a default to Annex I (prohibited substances), and 'only in exceptional cases and when duly justified' should they be added to Annex II (restricted substances). This implies a default approach of applying the most stringent restrictions until or unless the use of less stringent controls can be justified as safe.

Likewise, according to the Seveso III Directive, for a dangerous substance to be excluded from the scope of the directive, the Commission '*must assess whether it is impossible in practice for a particular dangerous substance to cause a release of matter or energy that could create a major accident under both normal and abnormal conditions which can reasonably be foreseen'* (Article 4(1)). This implies that in the fields of chemicals and industrial regulation there is a greater emphasis on the need to have certainty over the safety of a product or action, than perhaps in other areas (see Error! Reference source not found. below).

[142] These are: lead, cadmium, mercury, chromium, some PBDEs, and some phthalates.

Box 2: The EU ban of penta-brominated diphenyl ether (PDBE)

One of the few times a precautionary approach was applied in the face of scientific uncertainty in the chemicals sphere was on the basis of two risk assessments for certain brominated diphenyl ethers carried out under Council Regulation (EEC) 793/93 on Existing Substances (a predecessor to REACH). The risk assessments of penta-brominated diphenyl ether (PBDE) and octa-brominated diphenyl ether (OBDE), carried out in 2001 and 2003 respectively, reviewed evidence of possible environmental and health impacts. Both RAs identified a need for further information on the extent of the chemicals' excretion into breast milk and cow's milk, and the effects of prolonged (lifetime) exposure. The detection of increasing concentrations of the chemicals in breastmilk in Europe was a particular concern. The risk assessments concluded that further information and/or testing was needed.

However, resolving the uncertainties in current understanding could have taken as long as ten years. In light of the time it would take to reduce the uncertainties over the toxicity of the substances[143], and because of the possible risks presented to infants exposed via breast milk, the European Chemicals Bureau/JRC (predecessor to ECHA) recommended that risk reduction measures be taken immediately, instead of waiting for further research. Based on that recommendation, the European Union banned the use of PBDE and OBDE by 2004.

A third risk assessment for deca-BDE carried out at the same time had concluded that the scientific uncertainties related to that substance in breast milk would take just five years to resolve; in that case it was decided to proceed with the scientific research required to resolve the uncertainty, rather than take a precautionary approach. On the basis of the evidence gathered after the additional testing, it was decided to ban deda-BDE in 2008.[144] These bans were based on human health concerns, but implemented through environmental legislation, backing up the assertion by some that policymakers tend to apply the precautionary principle in the field of human health more readily than in the area of environmental protection.[145]

Article 6(3) of the Habitats Directive states that, for a plan or project to be approved, it must be shown that *'it will not adversely affect the integrity of the site concerned'*, indicating that no doubt as to its safety should remain. This can be derogated from if there are *'imperative reasons of overriding public interest'*, implying that in such cases full certainty of safety is not required. However, in practice, courts have taken a strict interpretation of Article 6(3) implying recourse to the precautionary principle (in terms of not authorising a project) where there is uncertainty over its safety.[146] For example, in *Waddenzee*, the CJEU ruled that an activity can only be authorised where *'no reasonable scientific doubt remains as to the absence of such effects'*.[147] Stokes argues that this represents the Court broadening the scope of precaution or the meaning of 'uncertainty' in relation to which the

[143] European Chemicals Bureau (2001) *Diphenyl Ether, Pentabromo Derivative (Pentabromodiphenyl Ether)*, 169-171; ECHA (2003) *Diphenyl Ether, Octabromo Derivative*, 142. https://echa.europa.eu/documents/10162/781ee1e9-6c90-467e-998b-8910ca2793e5 and https://echa.europa.eu/documents/10162/781ee1e9-6c90-467e-998b-8910ca2793e5.

[144] This followed a ruling by the CJEU to ban the substance, as originally the Commission issued an exception for deca-BDE under the RoHS Directive (Joined Cases C-14/06 and C-295/06, *Parliament and Denmark v Commission*). See also Siddiqi, M.A. (2003), Polybrominated Diphenyl Ethers (PBDEs): New Pollutants-Old Diseases, *Clinical Medicine & Research*, 1(4): 281–290; Petrescu-Mag, I., & Petrescu-Mag, R. (2013). The Role of Prevention and Precautionary Principles in Reducing the Waste Management Problems linked to Heavy Metals: Directive 2002/95/EC. *Metallurgia International*, 18(9), 256-259.

[145] Sadeleer (de) (2009). On the other hand, the Commission's Recommendation of OBDE recommended that 'Marketing and use restrictions should be considered at Community level to protect the environment from the use of octabromodiphenyl ether.' European Commission (2002/755/EC), Commission Recommendation of 16 September 2002 on the results of the risk evaluation and risk reduction strategy for the substance diphenyl ether, octabromo derivative.

[146] Truilhé-Marengo (2015).

[147] C-127/02, *Waddenzee*, para 61.

precautionary principle operates, including to future uncertainties over the impact of a project on the environment.[148] The same ruling also established the ability of authorities, where necessary, to order additional investigations to remove uncertainty.[149]

Uncertainty over available data

The EU environmental legislation under review does not provide guidance as to how uncertainty regarding scientific consensus should be dealt with. Instead, there are some provisions requiring the level of scientific uncertainty in general to be identified.[150] This fits with the Communication on the Precautionary Principle which stipulates that precautionary approach should also identify (where possible) the degree of scientific uncertainty at each stage of the evaluation of a hazard.[151] For example, under REACH, the production of Safety Data Sheets (necessary for all substances meeting a hazard classification criteria) requires the level of uncertainty over certain elements of the risk characterisation of a substance, such as its Desired No Effect Level, to be taken into account. The EIA Directive requires that the main uncertainties regarding impacts are detailed as part of any EIA, and the Air Quality Directive prescribes the maximum level of uncertainty that is permitted concerning assessment information. Lastly, the RoHS 2 Directive provides that the review of a substance must include information on, inter alia, the reliability of possible substitutes and other alternatives, suggesting that the level of uncertainty attached to these will be considered.

However, whilst there is provision for identifying uncertainty in some of the EU environmental legislation reviewed, none stipulate what should happen when uncertainty is identified, or what threshold would prompt a particular action. Particularly in the chemicals policy field, lack of knowledge and lack of data still tends to be interpreted as equivalent to no risk. This is contrary to the precautionary approach.

Reducing uncertainty

One way of implementing the precautionary principle set out in the Communication is to '*facilitate the production of scientific evidence necessary for a more comprehensive risk assessment.*' Various provisions within the selected EU environmental legislation allow for the reduction of scientific uncertainty through information gathering. For example, the EIA Directive can be seen to reflect certain constructions of the precautionary principle because it aims to identify and reduce the uncertainties and negative impacts (including environmental) associated with development.[152] The REACH architecture could also be seen to reflect this application of the precautionary principle given the requirement to register all substances over one tonne, and the provision that uncertainties arising from the Registrant's data gathering/evaluation/gap analysis/risk assessment can be dealt with by a Dossier Evaluation or a substance evaluation by the ECHA. Finally, the Floods Directive provides for

[148] Stokes (2005).

[149] Sadeleer (de) (2009).

[150] The type of uncertainty is not defined, so this could apply not just to the lack of scientific consensus, but also to insufficient data to establish harm or safety.

[151] Communication on the precautionary principle, 16.

[152] Jalava, K., & Others. (2013). The precautionary principle and management of uncertainties in EIAs: Analysis of waste incineration cases in Finland. *Impact Assessment and Project Appraisal*, 31(4), 280-290.

improving information to enable a more comprehensive risk assessment, by mandating flood risk assessments mapping potential risks on the basis of which Member States must '*identify those areas for which they conclude that potential significant flood risks exist or might be considered likely to occur'*.[153]

Various other selected Directives also contain provisions relating to the reduction of uncertainty, notably the Seveso III Directive in its duty on operators to inform the authorities of any activity or change to operations likely to cause or increase the risk of major accidents; the IED Directive in requiring the systematic appraisal of environmental risks to decide upon the frequency of inspections (Article 23(4)); and the Waste Framework Directive due to the need for a permit for waste treatment operations, granted on the basis of, *inter alia*, information provided on environmental risks (Article 23(3)).

Evolution of the provisions relating to uncertainty

In general, in the evolution of the legislative processes of the policies under review, discussions of uncertainty are more overt at the start of the process than in the final documents.

For example, in relation to the reduction of uncertainty, the Commission Proposal for the MSFD refers to the '*substantial need to develop additional scientific understanding for assessing good environmental status'* (Recital 3), and the Staff Working Paper on the MSFD makes explicit reference to scientific uncertainty: '*sometimes there is insufficient scientific understanding so far of the relationships between pressures and impacts, and this can limit the ability to directly link a deterioration in the state of the ecosystem (or its components) to particular pressures,'* which is also the only overt reference to uncertainty over cause and effect in the documents reviewed. The proposed way to deal with this in the Staff Working Paper is through further research on these relationships, rather than specifying more restrictive measures in line with a stronger application of the precautionary principle. Therefore, both documents refer to the need to improve scientific knowledge or understanding, which was not included in the final text of the Directive.

Over the course of the legislative process for REACH, the references to uncertainty also became less frequent.[154] In particular, the REACH 'White Paper' specifically defined the precautionary principle as applying where *'reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty over the precise nature or the magnitude of the potential damage'*.[155] This establishes that uncertainty applies to both nature and magnitude of the harm and that there must be some (reliable) evidence of harm, but does not specify the severity of the adverse impact. This reference did not appear in subsequent policy documents.

[153] Floods Directive, Articles 4 and 5.

[154] This observation is also made by Løkke (2006).

[155] For a discussion of the precautionary principle and the REACH White Paper, see Rogers, M. (2003). The European Commission's White Paper "Strategy for a Future Chemicals Policy": A Review. *Risk Analysis*, 23(2), 381-388.

In terms of waste legislation, some scholars have argued that there has been a shift away from the use of the precautionary principle.[156] On the other hand, the final text of the Waste Framework Directive does mention the principle in its provisions, including in Article 4(2) on 'Waste Hierarchy', but not in terms of the more contested issue of the definition of 'waste'.[157]

On the other hand, over the course of the revision of the EIA Directive, it seems that more measures were put in place to reduce uncertainty or provide scientific evidence, especially regarding the monitoring of impacts and measure to anticipate or address unforeseen significant effects. Specifically, the 2009 Impact Assessment of the EIA Directive concluded that there was no systematic ex-post monitoring of adverse significant effects of a project, whereas the revised Directive introduced mandatory ex-post monitoring, including measures to '*identify any unforeseen significant adverse effects*'[158]. However, whilst this monitoring can be anticipatory (involving measures to avoid or prevent these effects) it is not clear from the text what the threshold of certainty is for taking such action.

Table 5 below summarises the key findings regarding scientific uncertainty.

Table 5: Summary of findings dealing with scientific uncertainty

	Harm-related reference	Safety-related reference	Identification of uncertainty in available data
Air Quality Directive			✓
Environmental Impact Assessment Directive	✓		✓
Floods Directive	✓		
Habitats Directive	✓	✓	
Invasive Alien Species Directive	✓		
Marine Strategy Framework Directive	✓		
POPs Regulation	✓	✓	
REACH	✓	✓	✓
RoHS 2 Directive		✓	✓
Seveso III Directive	✓	✓	
Sewage Sludge Directive		✓	
Waste Framework Directive		✓	
Withdrawn proposal for a Soil Framework Directive	✓		

[156] Cheyne, I. (2007). Taming the Precautionary Principle in EC Law: Lessons from Waste and GMO Regulation. *Journal for European Environmental & Planning Law*, 4(6), 468-483.

[157] ibid.

[158] European Commission, SWD(2012) 355, Impact Assessment accompanying the Proposal for a Directive amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, 14.

2.4 IMPLEMENTING THE PRECAUTIONARY PRINCIPLE IN ENVIRONMENTAL POLICIES

The Communication on the precautionary principle provides guidelines for applying the precautionary principle. It states that, *'when decision-makers become aware of a risk to the environment or human, animal or plant health that in the event of non-action may have serious consequences, the question of appropriate protective measures arise'*[159]. In such cases, the application of the precautionary principle should follow a specific order and respect general principles.

Section 2.4 looks at how the precautionary principle as found in EU environmental legislation has been dealt with in practice. More precisely, it looks at the triggering factor for action, the burden of proof and the general principles of application, as established in the Communication on the precautionary principle. It draws on guidance documents and case-law at EU level where relevant. The CJEU has particularly played a major role in providing guidance on the application of the precautionary principles in both environmental and non-environmental cases.

2.4.1 The triggering factor for action

The Communication provides that, once the scientific evaluation has been performed as best as possible, it may provide a basis for triggering a decision to invoke the precautionary principle. The conclusions of this evaluation should show if the desired level of protection for the environment or a population group (this is generally referred to as Appropriate Level of Protection) could be jeopardised, and therefore require an assessment of the scientific uncertainties and a description of the hypotheses used to compensate for the lack of the scientific or statistical data. Furthermore, an assessment of the potential consequences of inaction and of the uncertainties of the scientific evaluation should be considered by decision-makers.[160]

In some instances, guidance documents provide useful information. Some of the REACH guidance documents in general, such as on Chemical Safety Assessment, Authorisation and Annex XV dossiers on SVHCs, refer to the fact that risk calculations involve a scientific assessment of potential adverse effects, but most do not discuss the role and implications of uncertainty in this evaluation. One exception is the chapter on the analysis of uncertainty in the guidance document on information requirements and chemical safety assessment. This specifies that uncertainty, both in terms of causal relation of the effect and magnitude, must be incorporated into most stages of the chemical safety assessments. This appears to be in line with the Communication. In terms of decision-making, the REACH guidance document on information requirements and chemical safety assessment states that *'ultimately, the importance of uncertainty analysis to each individual chemical safety report will depend on the specific circumstances and will be a matter of judgment for the reports [sic] author(s).'* This leaves more room for manoeuvre on how to deal with uncertainty within the scientific evaluation compared to the implementation of the Habitats Directive.

A recent study by the Swedish Chemicals Agency (KEMI) highlights major uncertainties in the risk assessment process under REACH. It notes that ultimately the decision on what is a 'safe' exposure

[159] Communication on the precautionary principle, 15.

[160] Communication on the precautionary principle,16.

scenario is 'impossible to justify scientifically', and is thus more of a policy decision[161]. The study recommends that due to pervasive uncertainty 'it may in the individual case be required to apply the precautionary principle to improve the protection of human health and the environment'[162]. In line with this, the ongoing REACH review/fitness recommends that in relation to the Community Rolling Action Plan (CoRAP), uncertainties should be clearly communicated to decision-makers so that they can take their decision on whether to apply the PP or not on a more informed basis.

Discussion on when precautionary action should be triggered can also be found in the context of the Marine Strategy Framework Directive. In 2010 the Commission published a Decision setting out guidelines on the criteria and methodological standards on good environmental status of marine waters.[163] This is relevant to the role of the precautionary principle in improving the scientific evidence base as set out in the 2000 Communication and discussed in Section 2.3 of this study. The Decision specifies that the standards should be reviewed and adapted to reflect changes in the determination of good environmental status, implying ongoing scientific evaluation.[164] However, the Decision does not elaborate on the uncertainties involved in the criteria for the establishment of good environmental status, or on how to deal with them. This has led one analyst to argue that the Decision *'does not indicate how the precautionary principle will be implemented for the establishment and application of criteria and methodological standards'*.[165]

State practice might also be useful to understand how scientific evaluation may provide a basis for triggering precautionary action. For instance, Finland has followed Articles 6(3) and 6(4) quite literally in its transposition of the Habitats Directive.[166] An appropriate assessment' must be carried out for any project likely to have significant negative impacts on a Natura 2000 site(s), and must provide evidence to show that no significant adverse effects will harm the integrity of the site in question. The Finnish transposing act also requires that an official opinion be given by the regional environment centre on the adequacy of the appropriate assessment. However, a survey of 73 appropriate assessments and 70 official opinions found that: screening practices and guidance for carrying out appropriate assessments vary between different Finnish regions, and that the information basis in the appropriate assessments for the impact assessments was weak, especially with regards to cumulative impacts. The study also asserted that these data problems were experienced across Europe.[167] Authorities responded variously to these appropriate assessments , including: giving the choice between a one fixed alternative or a new more complete assessment, changes to plans or project and additional mitigation measures. This implies that the information requirements are taken seriously in the implementation of the Habitats Directive in Finland, but that issues regarding the quality of the scientific evaluation remain, and apply across Europe. Jalava argues that the Finnish

[161] Swedish Chemicals Agency (2015), *Developing REACH and improving its efficiency – an action plan*, 20.

[162] ibid, 21.

[163] Commission Decision, (2010/477/EU) of 1 September 2010 on criteria and methodological standards on good environmental status of marine waters, OJ L 232, 2.9.2010, 14-24.

[164] ibid, Recital 4.

[165] Markus, T. (2013). Changing the Base: Legal Implications of Scientific Criteria and Methodological Standards on what Constitutes Good Marine Environmental Status. *Transnational Environmental Law*, 2(1), 145-165, 164.

[166] Söderman, T. (2009), Natura 2000 appropriate assessment: Shortcomings and improvements in Finnish practice, *Environmental Impact Assessment Review*, 29(2), 79-86.

[167] ibid.

transposition of the EIA legislation goes beyond the EU EIA Directive in terms of precautionary action,[168] and in requiring information related to uncertainty factors, whereas the content requirements under the EU level legislation for environmental impact assessments do not refer to considerations of uncertainties and risk assessments as such.[169]

Also relating to the environmental impact assessment, but in the context of the French transposition of the Marine Strategy Framework Directive, scholars have asserted that defining what a significant effect is has, in practice, been difficult and highly variable.[170] According to them, this is the reason why offsetting actions have been generally been preferred to precautionary measures, on the grounds of socio-economic benefits.

The CJEU has also played an important role in providing guidance as to the understanding of uncertainty in the context of scientific evaluation and the definition of the triggering factor. In *Afton Chemical*, the Court held that, 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 persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.[171]

Nonetheless, measures based on the precautionary principle must be based on a thorough scientific evaluation of the risks, given that the precautionary principle cannot render the adoption of arbitrary measures legitimate in any circumstances. In *Bayer Crop Science and Others v Commission*,[172] the CJEU recalled that, under the precautionary principle, the EU institutions are entitled in the interest of human health to adopt, on the basis of as yet incomplete scientific knowledge, protective measures which may '*seriously harm legally protected positions*,'[173] and they enjoy a broad discretion in that regard. However, in such circumstances, the guarantees conferred by the Community (now Union) legal order in administrative proceedings, such as the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case, are of even more fundamental importance. Therefore, '*a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures'*.[174]

Similarly, in *ICdA and others v Commission*,[175] a case concerned with the implementation of REACH, the Court held that '*where experts carry out a scientific evaluation of the risks, the Commission must*

[168] Jalava, K. and others (2013).

[169] ibid.

[170] Jacob, C. and others (2016) The effectiveness of the mitigation hierarchy in environmental impact studies on marine ecosystems: A case study in France, *Environmental Impact Assessment Review*, Vol 60, 2016, 83-98. See also Lawrence, D.P. (2007) 'Impact significance determination—back to basics, *Environmental Impact Assessment Review*, 27(8), 755–769.

[171] C-343/09, *Afton Chemical*, para 61. See also C-333/08, *Commission v France*, para 93.

[172] Case T-75/06, Judgment of 9 September 2008, *Bayer CropScience and Others v Commission*, ECLI:EU:T:2008:317. See also T-13/99 *Pfizer*, para 172.

[173] Ibid.

[174] ibid, para 250.

[175] Case T-456/11, Judgment of 14 November 2013, *ICdA and Others v Commission*, ECLI:EU:T:2013:594.

be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. Consequently, if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the Commission must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific evaluation of the risks as possible, account being taken of the particular circumstances of the case at issue'.[176]

In certain cases, the 2000 Communication points out that an incomplete assessment of the risk may considerably limit the number of options available to risk managers. The CJEU has accepted that, in these situations, the precautionary principle justifies the adoption of restrictive measures for the protection of the environment. This is the case *'[w]here it proves impossible to determine with certainty the existence or extent of the risk envisaged because of the insufficiency, inconclusiveness or imprecision of the results of the studies conducted, but the likelihood of real harm to human or animal health or to the environment persists should the risk materialise*'.[177] Furthermore, Member States' obligations to protect exist even before the risk has materialised. The CJEU has, for instance, formulated this principle in the context of the implementation of the Birds Directive. The obligations of Member States to protect exist even before any reduction in the number of birds has been observed or before the risk of a protected species becoming extinct has materialised.[178] This principle seems to apply also to non-environmental policies, such as in food law, as well.[179]

Box 2: C-374/98 - Commission v France[180]

The Commission lodged an application for legal action against France for failure to respect Article 4 of the Birds Directive. The Commission maintained that the Basses Corbières site in France should have been classified as a Special Protection Area having regard to its importance for the conservation of wild birds, particularly the Bonelli's eagle, and that the opening and working of limestone quarries on that site had caused its deterioration without the required conditions being met.

In this case, the parties' arguments were based on scientific uncertainty and precautionary measures. For instance, France claimed that the Commission did not present any scientific or other evidence to demonstrate that the quarries create significant disturbance for Bonelli's eagles or for other species. Furthermore, it argued that operation of the quarries had been preceded by a detailed impact study which concluded that the project had no significant effect on the environment, and that important precautionary measures designed to avoid potential negative effects of the project on the environment had been put into operation.[181]

Ultimately, the Court declared that, by not classifying the Basses Corbières site as a SPA and by not adopting special conservation measures for that site sufficient in their geographical extent, France had failed to fulfil its obligations under Article 4(1) of the Birds Directive.

[176] ibid, para 52.

[177] Case C-219/07, Judgment of 19 June 2008, *Nationale Raad van Dierenkwekers en Liefhebbers and Andibeln*, ECLI:EU:C:2008:353, para 38. This case related to the implementation of Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein.

[178] Case C-355/90, Judgment of 2 August 1993, *Commission v Spain*, ECLI:EU:C:1993:331, para 15; C-141/14, *Commission* v *Bulgaria*, para 76; Case C‑461/14, Judgment of 24 November 2016, *Commission v Spain*, ECLI:EU:C:2016:895-461/14, para 83.

[179] T-13/99, *Pfizer*, para 141; T-70/99 - *Alpharma v Council*, para 151.

[180] Case C-374/98, Judgment of 7 December 2000, *Commission v France*, ECLI:EU:C:2000:670.

[181] ibid, para 38.

In the context of its large body of case-law on Articles 6(3) and 6(4) of the Habitats Directive,[182] the CJEU has also applied a strict interpretation of the precautionary principle with regards to scientific evaluation and, in particular, uncertainty.[183] For example, in *Waddenzee*, the Court ruled that an activity can only be authorised where *'no reasonable scientific doubt remains as to the absence of such effects*'.[184] Stokes argues that this represents the Court liberalising the threshold of precaution– meaning that they are broadening its scope or the meaning of 'uncertainty' in relation to which the precautionary principle operates, including to future uncertainties over the impact of a project on the environment.[185] The same ruling also established the ability of authorities, where necessary, to order additional investigations to remove uncertainty.[186] The Court passed the same judgment in other cases,[187] although it specified that a project can go ahead where reasonable doubt remains if Article 6(4) is applied.[188] The Fitness Check of the Nature Directives highlighted that the provisions of Article 6(3) were leading to risk-adverse approaches to development projects by authorities and raised the difficulties of providing sufficient information to remove all reasonable scientific doubt over a potential impact.[189]

2.4.2 Burden of proof

The burden of proof, a term familiar in legal courtrooms[190] and in science, is a core component of the precautionary principle.[191] The burden of proof generally refers to *'the obligation to prove one's assertion'*[192] or *'the responsibility for proving something'*.[193] The Communication on the precautionary principle refers to the burden of proof as the *'assignment of responsibility for producing scientific evidence'*. [194] It also provides that *'[m]easures based on the precautionary principle may*

[182] This has received a large amount of attention in the academic literature. See for example Stokes (2005); Sadeleer (de) (2009); McIntyre (2013); Truilhé-Marengo (2015).

[183] Truilhé-Marengo (2015).

[184] C-127/02, *Waddenzee*, para 61.

[185] Stokes (2005).

[186] Sadeleer (de) (2009).

[187] C-258/11, *Sweetman and Others;* Case C-139/04, 12 January 2006, *Commission v Italy*, ECLI:EU:C:2006:19.

[188] Truilhé-Marengo (2015).

[189] European Commission, SWD(2016) 472 final, Staff Working Document, Fitness Check of the EU Nature Legislation (Birds and Habitats Directives) Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds and Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, 296.

[190] It should be pointed out that the concept of burden of proof varies from one jurisdiction to another and depending on the nature of the legal proceedings at stake (civil/criminal/administrative). Our study aims to provide a general analogy; it does not reflect the specificities of the burden of proof in the various situations it is encountered.

[191] Jones, J., & Bronitt, S. (2006). The Burden and Standard of Proof in Environmental Regulation: The Precautionary Principle in an Australian Administrative Context. In E. Fisher, & Others, *Implementing the Precautionary Principle: Perspectives and Prospects*. ElgarOnline, 137.

[192] Oxford University. (n.d.). Burden of proof. Retrieved from Oxford Dictionaries: https://en.oxforddictionaries.com/definition/us/burden_of_proof

[193] Cambridge University. (n.d.). Burden of Proof. Retrieved from Cambridge Dictionaries. http://dictionary.cambridge.org/dictionary/english/burden-of-proof

[194] Communication on the precautionary principle, 4.

assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation'.[195] In most EU environmental legislation under review, there are no explicit mentions of the burden of proof.

In a broad sense, the burden of proof generally asks the question of who is responsible for doing something. In environmental matters, the responsibility is generally on either the authorities or the proponent of a risk-generating activity. Furthermore, the obligation to do something may differ depending on the nature of the activity or of the environmental risk at stake, and the actor carrying the responsibility. For instance, the holder of the burden of proof may be required to communicate information, sometimes through the production of an impact assessment, to demonstrate that an activity will not be harmful to the environment or human health. Sometimes, the authorities may be obliged to justify political action (or inaction). Importantly, the burden of proof in the context of a precautionary approach means that it usually imposes an obligation before the risk-generating activity occurs.

An analogy with evidence law provides an interesting insight into the procedural nature of the burden of proof and its potential purposes.[196] Generally, two forms of burden of proof can be identified. The first one is an evidential or subjective form, also called the burden of production. It refers to the *'burden of going forward with the evidence by producing evidence'.*[197] The second form is a legal or objective one, also called the burden of persuasion. It means *'the burden of persuading the fact-finder that the allegations made are true'*.[198] This distinction is relevant in the context of this study. In some instances, EU environmental directives or regulations may formulate a burden of production, which is less stringent. This is the case when the proponent of a risk-generating project must provide information on the potential risks linked to the project. This obligation to produce information can move back and forth between various parties. In other situations, EU environmental legislation may formulate a burden of persuasion, which imposes a stringent obligation upon one main actor. For instance, a Member State might be obliged to justify action or inaction in the face of potential risks.

This part identifies and discusses various aspects of the burden of proof in EU environmental legislation. It focuses on the allocation of the burden of proof, the threshold and the strength of evidence of proof. This analysis considers relevant case-law of the CJEU where it is available.

2.4.2.1 Allocation

The allocation of the burden of proof is central to the application of the precautionary principle. Who should bear the onus of proving that an activity or a product will or will not be harmful: the proponent of the risk-generating activity or product, the national authorities, or the public? The allocation of the burden of proof has been the subject of intense debate, since it has far-reaching consequences for the outcomes of a decision-making process or of a dispute settlement.[199]

[195] ibid.

[196] This analysis is based on Ambrus, M. (2012). The Precautionary Principle and a Fair Allocation of the Burden of Proof in International Environmental Law. *RECIEL*, 21(3), 259-270, 262-263.

[197] ibid, 263.

[198] ibid.

[199] ibid, 259.

The Communication on the precautionary principle distinguishes between two main situations: the situation of prior approval for *'substances deemed 'a priori' hazardous or which are potentially hazardous at a certain level of absorption*' and other cases. In the first situation, *'the principle of prior approval (positive list) before the placing on the market of certain products, such as drugs, pesticides or food additives […] is one way of applying the precautionary principle, by shifting responsibility for producing scientific evidence'*.[200] The Communication further provides that *'[i]n this case the legislator, by way of precaution, has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven otherwise. Hence it is up to the business community to carry out the scientific work needed to evaluate the risk'*.[201]

In other cases, where such a prior approval procedure does not exist, '*it may be for the user, a private individual, a consumer association, citizens or the public authorities to demonstrate the nature of a danger and the level of risk posed by a product or process'*.[202] Nonetheless, *'[a]ction taken under the head of the precautionary principle must in certain cases include a clause reversing the burden of proof and placing it on the producer, manufacturer or importer, but such an obligation cannot be systematically entertained as a general principle. This possibility should be examined on a case-by-case basis when a measure is adopted under the precautionary principle, pending supplementary scientific data, so as to give professionals who have an economic interest in the production and/or marketing of the procedure or product in question the opportunity to finance the necessary research on a voluntary basis*.'[203]

Traditional approach

In various areas of law, including tort law, international law or multilateral environmental agreements, the burden of proof has traditionally been allocated *'to those questioning whether a risk-generating activity should proceed'*.[204] Some authors consider that such an approach may have unsatisfactory outcomes from an environmental perspective. Environmental degradation or a health hazard is likely to occur or continue when opponents to a risk-generating activity, be it a product, a process, a plan or a project, fail to demonstrate the risk or the detrimental effect of that activity. In most cases, demonstrating the existence of risk is likely to be challenging; access to scientific evidence may be limited or in the hands of the proponent of the risk-generating activity, and collecting relevant scientific evidence may be expensive.[205]

In a number of EU environmental directives or regulations, public authorities carry the burden of producing evidence to justify action (or inaction) or inform relevant stakeholders, even where the legislator explicitly endorses the precautionary principle.

[200] Communication on the precautionary principle.

[201] ibid, 20.

[202] ibid.

[203] ibid, 20-21.

[204] Nollkaemper, A. (1996). What you risk reveals what you value. In D. Freestone, & E. Hey, *The Precautionary Principle and International Law: The Challenge of Implementation*. Kluwer Law International, 85.

[205] Ambrus (2012), 259.

Under the Invasive Alien Species Regulation, Member States must establish a permit system allowing establishments to carry out research on, or ex-situ conservation of, invasive alien species of Union concern.[206] However, national competent authorities can be allowed to withdraw a permit *'at any point in time, temporarily or permanently, if unforeseen events with an adverse impact on biodiversity or related ecosystem services occur'*.[207] In such a case, the national competent authority carries the burden of proof, as *'[a]ny withdrawal of a permit shall be justified on scientific grounds and, where scientific information is insufficient, on the grounds of the precautionary principle and having due regard to national administrative rules'*.[208]

The European legislator may also have the burden of demonstrating the potential toxicity of specific substances. For example, under Article 16 of the Water Framework Directive, the Commission must submit a proposal setting out a list of priority substances which present a significant risk to, or via, the aquatic environment. These substances shall be prioritised for action based on risk to or via the aquatic environment, identified by a risk assessment or a targeted risk-based assessment focusing solely on aquatic ecotoxicity and on human toxicity via the aquatic environment. The Commission's proposal must also identify priority hazardous substances.

Precautionary approach

In contrast to the traditional approach, some authors state that the precautionary principle would imply that the burden of proof is allocated to those proposing to undertake a risk-generating activity, meaning the proponents of a product, a process, a plan or a project.[209] This is also called the 'reverse onus'. For instance, the 1998 Wingspread Statement on the Precautionary Principle states that, '*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. In this context, the proponent of an activity, rather than the public, should bear the burden of proof*'.[210] Some commentators have suggested that *'[r]eversing the burden of proof can induce prevention in cases where thresholds are not crossed and shift the balance between risks and benefits'*.[211] Others have justified shifting the allocation of the burden of proof based on 'fairness', since harm, especially to the environment, is difficult to reverse or falls unequally on those affected. At the same time, reversing the burden of proof should not necessarily exclude all balancing interests.[212]

The REACH Regulation provides a striking example of a general precautionary allocation of the burden of proof. Traditionally, governments had to demonstrate the impacts of chemicals before acting to protect human health and the environment. However, the REACH Regulation introduced a

[206] Invasive Alien Species Regulation, Article 8(1). Member States may also include scientific production and subsequent medicinal use within their permit system where the use of products derived from invasive alien species of Union concern is unavoidable to advance human health.

[207] Invasive Alien Species Regulation, Article 8(5).

[208] Invasive Alien Species Regulation, Article 8(5).

[209] Trouwborst, A. (2006). *Precautionary rights and duties of states.* Brill, 193.

[210] The Wingspread Statement on the Precautionary Principle.

[211] Nollkaemper (1996), 85.

[212] ibid.

general shift of responsibility for the registration and authorisation of chemicals onto companies.[213] It *'is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment'*.[214] Substances on their own, in mixtures or in articles, shall not be manufactured or placed on the market unless they have been registered. REACH therefore introduced a shift from post-market testing to pre-market testing. In practice, to register a substance, companies are responsible for collecting information on the properties and uses of the substances they manufacture or import above one tonne a year. For many observers, the 'no data, no market' set up under the REACH Regulation reverses the burden of proof in line with the precautionary principle.[215]

However, in specific circumstances, the REACH Regulation shifts the burden of proof to both European and national regulators. This is the case for the introduction of new restrictions and the amendment of current restrictions under Article 68 of REACH, which requires regulatory authorities, including Member States and the European Commission, to conduct the risk assessment themselves. Such exceptions to the 'reverse onus' have led commentators to question the precautionary approach of the REACH Regulation. Furthermore, some commentators have argued that the shift of the burden of proof did not occur adequately for lower volume chemicals.[216]

Other pieces of EU environmental legislation also generally place a burden of proof on the proponent of a risk-generating activity. The Industrial Emissions Directive obliges operators of an industrial installation to describe measures to comply with the application of best available techniques when applying for a permit.[217] Under the RoHS 2 Directive, manufacturers of electrical and electronic equipment must ensure that their equipment has been designed and manufactured in a preventive way when placing it on the market. They must also draw up required technical document and carry out the internal production control procedure to ensure that their equipment does not harm the environment.[218] Importers and distributors of electrical and electronic equipment must also check or ensure that equipment is in line with legal requirements and does not contain substances found in Annex II of the RohS 2 Directive.[219]

EU legislation may occasionally place the burden of proof on the proponent of the risk-generating activity under specific circumstances. This is the case under the PoPs Regulation which imposes on the holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or Annex II and the use of which is permitted, to provide competent authorities with information concerning the nature and size of that stockpile.[220] In such a case, the onus of providing information is

[213] Foss Hansen, S., & Others. (2007). Chemicals regulation and precaution: does REACH really incorporate the precautionary principle? *Environmental Science and Policy*, 10(5), 395-404, 399; Christensen, F., & Others. (2011). European Experience in Chemicals Management: Integrating Science into Policy. *Environmental Science & Technology*, 45(1), 80–89. See also Crawford-Brown, D., & Crawford-Brown, S. (2011). The precautionary principle in environmental regulations for drinking water. *Environmental Science and Policy*, 14(4), 379-387.

[214] REACH, Article 1(3).

[215] Karlsson, M. (2015). TTIP and the environment: the case of chemicals policy. *Global Affairs*, 1(1), 21-31, 23.

[216] Hansen & Others (2007), 399.

[217] REACH, Article 12(1).

[218] ibid, Article 7.

[219] ibid, Art 9 and 10.

[220] POPs Regulation, Article 5(2).

on the holder of the stockpile. This is important since the Member State has the obligation to monitor the use and management of notified stockpiles. Furthermore, the holder shall manage the stockpile in a safe, efficient and environmentally sound manner.

The withdrawn proposal for a Soil Framework Directive also provided for a precautionary approach of the burden of proof where a site was to be sold on which a potentially polluting activity was taking place or had taken place. In such a case, the owner of that site or the prospective buyer should have made a soil status report[221] available to the competent authority responsible for the identification of contaminated sites and to the other party in the transaction.[222] Putting the burden of proof equally onto the owner of the site and the prospective buyer reflects a precautionary approach by prioritising the need for information on risk and transparency.

One way to implement a precautionary approach is to oblige the proponent of a project to assess potential risks or impacts of the project on the environment to be granted authorization. As discussed previously, this is the case under Article 6(3) of the Habitats Directive. Accordingly, any plan or project not directly connected with or necessary to the management of a Natura 2000 site but likely to have a significant effect thereon shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives. If Article 6(3) does not explicitly mention who is responsible for the conduct of this assessment, in practice, the management of this assessment is entrusted to the proponent of the project.[223] Under the EIA Directive, the developer of a public or private project must also assess the likely significant environmental effects of the project before development consent is granted.[224] It is worth noting that the obligations of the developer have become more stringent over time. While the developer had to supply in an appropriate form specific information required under Annex IV under the former EIA Directive,[225] he/she must now prepare and submit an environmental impact assessment report.[226]

However, the completion of a risk assessment says nothing about the subsequent decision to implement risk reduction measures.[227] For instance, under Article 6(3) of the Habitats Directive, competent national authorities shall agree to the plan or project in light of the conclusions of the assessment of the implications for the site only after having ascertained that the plan or project will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the public. In *Solvay and others*, the CJEU has confirmed that '*Article 6(3) of the Habitats Directive must be interpreted as not allowing a national authority, even if it is a legislative authority,*

[221] This soil status report should have included minimum required information, including the concentration levels at which there are sufficient reasons to believe that the dangerous substances concerned pose a significant risk to human health or to the environment. See withdrawn proposal for a Soil Framework Directive, Article 12(2)(c).

[222] ibid, Article 12(1).

[223] Mauerhofer, V. (2014). Ignorance, Uncertainty and Biodiversity: Decision Making by the Court of Justice of the European Union. *Jean Monnet Working Paper Series - Environment and Internal Market, 2014/8*, 8; Truilhé-Marengo (2015), 341.

[224] EIA Directive, Recital 7.

[225] Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC, OJ L 156, 25.6.2003, 17–25 (hereinafter 'former EIA Directive'), Article 5.

[226] EIA Directive, Article 5.

[227] Hansen & Others (2007), 399.

to authorise a plan or project without having ascertained that it will not adversely affect the integrity of the site concerned'.[228] This obligation is incumbent on the Member States under the Habitats Directive regardless of the nature of the national authority with competence to authorise the plan or project concerned.[229] When Member States fail to fulfil their obligations under Article 6(3) of the Habitats Directive, '*it is for the Commission to furnish the proof that, in the light of the characteristics and the specific environmental conditions of the site affected by a plan or project, that plan or project is likely to have a significant effect on that site, in the light of the conservation objectives fixed for the site'*.[230]

Shifting the burden of proof may nonetheless be insufficient to ensure environmental and health protection. Scholars have questioned the quality and reliability of risk assessments conducted by proponents of risk-generating activities. Proponents might be tempted to minimise the impacts that their activity may have on the environment.[231] A precautionary approach may therefore require that the information provided by the proponent be assessed by competent authorities or independent third parties, or supplemented with information from other sources. This is the case under the EIA Directive, which provides that national authorities should examine the substance of the information provided by the developer and complement it with supplementary information received through consultation or other appropriate channels.[232] When such a control does not exist, the 'fear of judicial action' may however be the only guaranty of the quality of the assessment.[233]

2.4.2.2 Threshold of safety and strength of evidence

Another important element of the burden of proof is the demonstration of a threshold of safety. In the case of a risk-generating product, what is the minimum level of safety that must be demonstrated by the person who carries the burden of proof to allow or forbid the marketing of that product? For instance, a product or an activity might be banned until proof of harmlessness is delivered.

The strength of evidence is another central component of the burden of proof. In a court of law, this would refer to the standard of proof, meaning the level of evidence and certainty necessary to establish a fact. Both in criminal and civil proceedings, there are various standards of proof, such as 'beyond reasonable doubt', 'prima facie', or 'preponderance of the evidence'.[234] Under a precautionary approach, the strength of evidence may be particularly important to justify action (or inaction).

Most directives and regulations set a threshold that should not be crossed for a risk-generating activity to be authorised. However, the same cannot be said for the strength of evidence. Under most EU

[228] Case C-182/10, Judgment of 16 February 2012, *Solvay and Others*, ECLI:EU:C:2012:82,para 70. See also C-127/02, *Waddenzee*, para. 49-44 and 52 – 61.

[229] C-182/10, *Solvay and Others*, para 69.

[230] C‑ 179/06, *Commission v Italy*, para 39. The CJEU further stated that, 'Nor has the Commission provided data on the technical nature of the works in question or provided explanations as to what extent those works, in the light of the characteristics and specific environmental conditions of the site, are likely to have a significant effect on it'. See para 44.

[231] Truilhé-Marengo (2015), 341.

[232] EIA Directive, Recital 23.

[233] For the Habitats Directive, see Truilhé-Marengo (2015), 341. For REACH, see Foss Hansen, S., & Others. (2007), 399.

[234] For a discussion on the standard of proof, see Jones, J., & Bronitt, S. (2006), 140-141.

environmental legislation, there is a general lack of explicit provisions concerning the strength of evidence required to demonstrate safety, or the precautions to be taken on this basis.

Pursuant to the Invasive Alien Species Regulation, a Member State may take emergency restriction measures when it has evidence concerning the presence in, or imminent risk of introduction into, its territory of an invasive alien species not included on the Union list. In such cases, the competent authorities must demonstrate that the invasive alien species is likely to meet the criteria set out in Article 4(3) based on preliminary scientific evidence.[235] They must carry out a risk assessment for the invasive alien species subject to the emergency measures, given the available technical and scientific information.[236] Member States must immediately notify the Commission and all other Member States of the measures taken and the evidence justifying those measures.[237]

Member States must produce information that describes potential adverse consequences of future floods under the Floods Directive. For instance, they should undertake a preliminary flood risk assessment that includes a description of past significant floods *'where significant adverse consequences of similar future events might be envisaged'*.[238] This preliminary flood risk assessment may also include an assessment of the potential adverse consequences of future floods for human health, the environment, cultural heritage and economic activity. Furthermore, Member States must prepare flood hazard maps and flood risk maps[239] for areas *'for which they conclude that potential significant flood risks exist or might be considered likely to occur'*.[240] The flood risk maps must show the potential adverse consequences associated with different flood scenarios.[241]

Under Article 16(2) of the Water Framework Directive, the European Commission must demonstrate that priority substances present a significant risk to or via the aquatic environment. It must also prioritise substances for action based on risk to or via the aquatic environment identified by a simplified risk-based assessment procedure. This procedure must be based on scientific principles taking particular account of *'evidence regarding the intrinsic hazard of the substance concerned, and in particular its aquatic ecotoxicity and human toxicity via aquatic exposure routes, and evidence from monitoring of widespread environmental contamination, and other proven factors which may indicate the possibility of widespread environmental contamination, such as production or use volume of the substance concerned, and use patterns.'*[242]

Under the MSFD, Member States are not required to take specific steps for the implementation of marine strategies[243] where there is no significant risk to the marine environment, or where the costs would be disproportionate taking account of the risks to the marine environment, and if there is no

[235] Invasive Alien Species Regulation, Article 10(1).

[236] ibid, Article 10(3).

[237] ibid, Article 10(2).

[238] Floods Directive, Article 4.

[239] Floods Directive, Article 6(1).

[240] ibid, Article 5(1).

[241] ibid, Article 6(5).

[242] ibid, Article 16(2).

[243] Except in respect of the initial assessment described in Article 8.

further deterioration.[244] This means that, conversely, Member States should act when there is significant risk to the marine environment. Furthermore, they should not be required to take specific steps if any decision not to take action is properly justified.[245] Member States have a burden of persuasion, as they must justify their decision not to take action. However, it is unclear which threshold must be demonstrated and which strength of evidence is required. Ultimately, this approach seems to offer flexibility to Member States when they articulate national policy in the face of potential environmental risk.

The CJEU has also played a significant role in defining thresholds and standards of proof in the context of the implementation of EU environmental directives, in particular the Habitats and the Birds Directives. The CJEU has provided that the assessment carried out under Article 6(3) of the Habitats Directive cannot present lacunae and must contain complete, precise and definitive findings and conclusions capable of removing all reasonable scientific doubt as to the effects of the works proposed on the protected site concerned. Furthermore, the CJEU has specified that a plan or project may be authorised only on the condition that the competent national authorities are certain that it will not have adverse effects on the integrity of the site concerned.[246] That is so where '*no reasonable scientific doubt remains as to the absence of such effects at the time of adoption of the decision authorising implementation of the project'*.[247] Moreover, the competent national authority must assess the implications of the project for the site concerned in view of the site's conservation objectives and taking into account the protective measures forming part of that project aimed at avoiding or reducing any direct adverse effects on the site.[248]

Under Article 4 of the Birds Directive, Member States must classify specific territories as special protection areas (SPAs) in order to conserve particularly threatened wild bird species. They must also take appropriate steps to avoid pollution or deterioration of habitats or any disturbances affecting the birds, in so far as these would be significant having regard to the objectives of Article 4. The CJEU clarified that Member States should not wait for adverse effects to materialize to take preventive action. The obligations on Member States under Article 4 of the Birds Directive exist before any reduction is observed in the number of birds or any risk of a protected species becoming extinct has materialized.[249] Furthermore, breach of these obligations is to deemed to exist where the Commission establishes that there is a probability or risk that a project will cause deterioration to the habitats of protected species of birds or cause significant disturbance to those species.[250] As such, it is sufficient to prove that a project is likely to cause significant disturbances and deterioration to the habitats of protected species of birds.[251]

[244] MSFD, Article 14(4).

[245] MSFD, Recital 11.

[246] C-182/10, *Solvay and Others.*

[247] ibid, para 67.

[248] Joined Cases C-387/15 & C-388/15, *Orleans and Others*, para 54.

[249] C-355/90, *Commission v Kingdom of Spain*, para 15. See also C‑461/14, *Commission v Spain*, para 83. This reasoning also applies to risks to health, see T-13/99, *Pfizer*, para 141; T-70/99, *Alpharma v Council*, para 154.

[250] C-141/14, *European Commission v Republic of Bulgaria*, para 70. See also C‑461/14, *Commission v Spain*, para 77.

[251] C‑461/14, *Commission v Spain*, para 79-81.

Table 6: Summary of findings regarding the burden of proof

Legal instrument	General rule on allocation	Obligation	Risk/Threshold
Air Quality Directive	Member States	Monitoring and management of fine particulate matter	Target and limit values set in Annex XIV
Birds Directive	Member States	Take appropriate steps to avoid pollution, deterioration of habitats or any disturbances affecting protected birds	Pollution, deterioration of habitats or any disturbances affecting the birds would be significant having regard to the conservation objectives of Article 4
EIA Directive	Developers	Prepare and submit an environmental impact assessment report	Projects likely to have significant effects on the environment by virtue, inter alia, of their nature, size or location
Floods Directive	Member States	Produce a flood hazard maps and flood risk maps, and flood risk management plans	Potential adverse consequences of future floods for human health, the environment, cultural heritage and economic activity
Habitats Directive	Proponents of plan or project	Appropriate assessment of implications for the site in view of the site's conservation objectives	No adverse effect on the integrity of the site concerned
Industrial Emissions Directive	Operators	When site closure: -assess state of soil and groundwater contamination - take necessary measures to remove, control, contain or reduce relevant hazardous substances	Where the contamination of soil and groundwater at the site poses a significant risk to human health or the environment as a result of the permitted activities
Invasive Species Regulation	National competent authorities	Withdraw permits allowing establishments to carry out research on, or ex-situ conservation of, invasive alien species of Union concern	Unforeseen events with an adverse impact on biodiversity or related ecosystem services occur
MSFD	Member States	Adopt marine strategies and take measures to achieve or maintain good environmental status of the marine environment	No significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea
POPs Regulation	Member States and Commission	Draw up an implementation plan	Substances subject to the Stockholm Convention on Persistent Organic Pollutants
REACH	Manufacturers, importers	■ Collection of information	No adverse effect on

Legal instrument	General rule on allocation	Obligation	Risk/Threshold
	and downstream users of substances or preparations	■ Risk and hazards assessment	human health or the environment
RoHS 2 Directive	Manufacturers, importers and distributors of electrical and electronic equipment	Design and produce EEE, or check or ensure that EEE are in line with legal requirements	EEE should not contain substances in Annex II
Seveso III	Operators	■ Provide information on the establishment, the dangerous substances present and the potential dangers ■ Draw up a major-accident prevention policy and a safety report	Ensure a high level of protection of human health and the environment, be proportionate to the major-accident hazards
Withdrawn proposal for a Soil Framework	Owner of site to be sold or prospective buyer	Production of a soil status report	A significant risk to human health or to the environment
Waste Framework Directive	Member States	Justifying the reclassification of hazardous waste as non-hazardous waste	No display of properties as listed in Annex III
Water Framework Directive	European Commission	Risk assessment or a targeted risk-based assessment Establishment of list of priority substances for action	A significant risk to, or via, the aquatic environment

2.4.3 General principles of application of the precautionary principle

On the basis of the conclusions of the scientific evaluation, decision-makers may decide to act on the basis of the precautionary principle. When this is the case, the Communication on the precautionary principle encourages them to respect a number of general principles of EU law when invoking the precautionary principle. The Communication stresses that these principles apply to all risk management measures.

The general principles listed in the Communication are:

- proportionality,
- non-discrimination,
- consistency,
- examination of the benefits and costs of action or lack of action,
- examination of scientific developments.[252]

The following sections discuss the inclusion of these general principles in the policy areas under review. This analysis covers both legislative documents and implementation through guidance

[252] Communication on the precautionary principle, 17.

documents and case-law.

2.4.3.1 Proportionality

According to the Communication, measures based on the precautionary principle should be proportional to the desired level of protection[253]. This means that these measures must not be disproportionate to the desired level of protection and must not aim at zero risk, something which rarely exists. The precautionary principle and the principle of proportionality are not only closely interlinked, but the role that the precautionary principle plays in proportionality is one of the key issues surrounding the relevance of the precautionary principle under EU Law.[254]

There are various references to proportionality in the legislation under review. For example, Article 19 of the Invasive Alien Species Regulation specifies that '*management measures shall be proportionate to the impact on the environment and appropriate to the specific circumstances of the Member States'*. Likewise, the Seveso III Directive stipulates that operators must draw up a major accident prevention policy, which shall be proportionate to the major-accident hazards (Article 8(1)). The Thematic Strategy on waste specifies that the end-of-life criteria and compliance system for recycled aggregates *'should be proportionate to the environmental issues'*. Furthermore, the Water Framework Directive allows an extension to the deadline to achieve objectives, or the application of less stringent objectives where these can be justified on the grounds of disproportionately expensive measures (Articles 4(4) and 4(5)). However, uncertainty and the precautionary principle are not mentioned in the context of proportionality, which could imply more of a focus on prevention rather than precaution. This is also seen in the withdrawn proposal for a Soil Framework Directive which laid down that Member States must take *'appropriate and proportionate'* measures to *prevent* soil contamination (Article 9).

In practice, in some policy areas, stakeholders have raised concerns over the proportionality of precautionary measures. Specifically, the Fitness Check of the Birds and Habitats Directives reported that there is a perception amongst some operators that local authorities have acted disproportionately, in particular relating to requests for additional information for the assessment of impacts under Article 6(3).[255] The same report also highlighted that in some cases local authorities have systematically prohibited certain types of activities affecting Natura 2000 sites, even when these activities could be carried out in accordance with conservation objectives.[256] However, the courts have taken a different stance. For example, the *Waddenzee* case[257] established the ability of authorities, where necessary, to order additional investigations to remove uncertainty.[258]

A number of complaints raising infringement of the principle of proportionality in environmental provisions based on the precautionary principle have found their way to the CJEU. In *S.P.C.M. and*

[253] ibid, 18.

[254] Alemanno (2011).

[255] European Commission, SWD(2016) 472 final, 177.

[256] ibid.

[257] C-127/02, *Waddenzee*.

[258] Sadeleer (de) (2009).

others,[259] the CJEU examined whether the obligation to register monomer substances under Article 6(3) of the REACH Regulation constituted a proportionate means to achieve the objectives of that regulation. It first clarified that, according to settled case-law, '*the principle of proportionality, which is one of the general principles of Community law, requires that measures implemented through Community provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it'*.[260] Then, it held that '*taking account of the limited number of potential monomer substances, the 12-year period of validity for a previous registration of substances, as provided for in Article 27 of the REACH Regulation, and the possibility of sharing information in order to reduce costs, the burden deriving from the obligation to register reacted monomer substances in polymers does not appear to be manifestly disproportionate in the light of the free movement of goods on the internal market open to fair competition*'.[261] Ultimately, the Court concluded that Article 6(3) did not infringe the principle of proportionality. In *Parliament and Denmark v Commission*, the CJEU also provided guidance as to the understanding of proportionality in the context of a Commission's amendment to the former RoHS Directive (See **Box** below).

Box 4: Joined Cases C-14/06 and C-295/06, Parliament and Denmark v Commission

Joined Cases C‑14/06 and C‑295/06 were related to Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (former RoHS Directive)[262]. Article 4(1) prohibited new electrical and electronic equipment from being put on the market from 1st July 2006 as they contained specific hazardous substances, including polybrominated diphenyl ethers (PBDE).[263] Nonetheless, derogations to this rule were possible for applications listed in the Annex to Directive 2002/95/EC. In 2005, the Commission amended the Annex to Directive 2002/95/EC to grant a general exemption for the use of decaBDE, a hazardous chemical substance used as a flame retardant in electrical and electronic equipment and belonging to the PBDE category.[264]

This decision was challenged by the European Parliament and Denmark. They argued that the Commission's decision ran counter to the objective pursued by the legislature of establishing the principle of the prohibition of the components referred to in Directive 2002/95/EC. The applicants also claimed that the Commission had breached the precautionary principle and the principle of proportionality in that the contested decision exempted all the polymeric applications of decaBDE.

The CJEU held that, as regards the objectives of Directive 2002/95, it was clear that the intention of the legislator was to prohibit products referred to in the directive and to grant exemptions only in accordance with carefully defined conditions. Such an objective, in compliance with Article 152 EC, according to which a high level of human health protection is to be ensured in the definition and implementation of all Community policies

[259] Case C-558/07, Judgment of 7 July 2009, *S.P.C.M. and Others*, ECLI:EU:C:2009:430.

[260] ibid, para 41.

[261] ibid, para 71-72.

[262] 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, OJ L 37, 13.2.2003, 19–23. This Directive was repealed from 3 January 2013 by the RoHS 2 Directive.

[263] The substances included lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE).

[264] Commission Decision 2005/717/EC of 13 October 2005 amending for the purposes of adapting to technical progress the Annex to Directive 2002/95/EC of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (notified under document number C(2005) 3754), OJ L 271, 15.10.2005, 48–50.

and activities, and in compliance with Article 174(2) EC, according to which Community policy on the environment is to aim at a high level of protection and is based on the principles of precaution and preventive action, justifies the strict interpretation of the conditions for exemption. In the present case, it is sufficient to state that the contested decision, which is equivalent to a general exemption for the use of DecaBDE in electrical and electronic equipment, runs counter to the objective pursued by that legislation of establishing the principle of the prohibition of the components referred to in Directive 2002/95/EC.[265]

2.4.3.2 Non-discrimination

The Communication states that measures on the precautionary principle should not be discriminatory in their application.[266] Further, it provides that the '*principle of non-discrimination means that comparable situations should not be treated differently and that different situations should not be treated in the same way, unless there are objective grounds for doing so. Measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner*'.[267]

In the legislation under review there are some provisions relating to non-discrimination in the context of measures aimed at environmental protection. Although not explicitly referring to precautionary measures, Recital 3 of REACH states that '*legislation should ensure a high level of protection of human health and the environment and be applied in a non-discriminatory manner'*. This clearly reflects the wording of the Communication. Similarly, Article 10(7) of the Invasive Alien Species Regulation provides that Member States must repeal any emergency measures that concern a species not included on the Commission's list. This implies a desire to harmonise measures aimed at environmental protection across the EU, and limits the exercising of precautionary action by individual Member States, implying that such action must be non-discriminatory. In the other policy areas under review, non-discrimination did not figure in the context of applying the precautionary principle.

The CJEU has also adopted the approach of the Communication on the non-discriminatory nature of measures based on the precautionary principle. On several occasions, the Court has held that '*the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified*'.[268]

This was the case in *S.P.C.M. and others.* The Court found that the registration of polymers manufactured in, and imported into, the Community presented advantages to address potential risks and to protect human health and the environment. The existence of a registration obligation for both manufacturers and importers satisfied the precautionary principle as referred to in Article 1(3) of the REACH Regulation. Importantly, *'[t]he registration obligation imposed on importers leads to a more equitable attribution of the costs of registration between Community manufacturers and importers.*

[265] C-14/06 and C-295/06, *Parliament and Denmark v Commission*, para 74-76.

[266] Communication on the precautionary principle, 18

[267] ibid.

[268] C-558/07, *S.P.C.M. and others*, para 74; Case C-344/04, Judgment of 10 January 2006, *IATA and ELFAA*, ECLI:EU:C:2006:10, para 95

Such equality of treatment prevents distortions of competition and thereby guarantees fair competition within the Community."[269]

In *Afton Chemical*,[270] the CJEU had to assess whether limiting the use of MMT (Methylcyclopentadienyl manganese tricarbonyl) in fuel was in violation of the precautionary principle and contrary to the principle of equal treatment. The Court held that, '*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 persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective. In those circumstances, it must be acknowledged that the European Union legislature may, under the precautionary principle, take protective measures without having to wait for the reality and the seriousness of those risks to be fully demonstrated'*.[271] In this case, the limit for the MMT content of fuel was not discriminatory, since it applied to the whole of the EU and to all producers and importers of MMT.[272] The Court also found that the principle of equal treatment had not been infringed since MMT is not in a situation which is comparable to that of other manganese-based metallic additives and the European Union legislature was therefore not required to set limits for those other additives.[273]

2.4.3.3 Consistency

As per the Communication, measures based on the precautionary principle should be consistent with the measures already adopted in similar circumstances or using similar approaches.[274] The Communication specifies that, if the absence of certain scientific data makes it impossible to characterise the risk, taking into account the uncertainties inherent to the evaluation, these measures should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.[275]

The 'consistency principle' also has a prominent place in EU law, being enshrined in Article 7 of the TFEU. It requires that all EU policies be consistent and coherent with one another. Article 7 provides that '*the Union shall ensure consistency between its policies and activities, taking all of its objectives into account and in accordance with the principle of conferral of powers*'.[276]

This analysis did not identify any measures in the policy areas under review that deal with consistency of methods with previous approaches in situations where scientific data are insufficient, compared to the other aspects of implementation of the precautionary principle set out in the Communication.

[269] C-558/07, *S.P.C.M. and Others*, para 52-56.

[270] C-343/09, *Afton Chemical.*

[271] C-343/09, *Afton Chemical*, para 61-62. See also C-333/08, *Commission v France*, para 91, 93.

[272] ibid, para 63.

[273] ibid, para 76.

[274] Communication on the precautionary principle, 18.

[275] ibid.

[276] Herlin-Karnell, E., & Konstadinides, T. (2013). The rise and expressions of consistency in EU law: legal and strategic implications for European integration. *Cambridge yearbook of European legal studies*, *15*, 139-167.

However, there are some examples in the policies' background documents on the need for consistent approaches to environmental assessment methods. For example, the Staff Working Paper on assessment and criteria for good environmental status (GES) relating to the Marine Strategy Framework Directive sets out that Member States are subject to regional cooperation in the interests of coherence and consistency, which is needed not only '*between the Marine Directive and Conventions, but also with other relevant EU legislation'*. In particular, they should '*endeavour to follow a common approach for their initial assessment, determination of GES, targets, indicators, monitoring and measures*',[277] which would therefore theoretically encompass any precautionary measures involved in these assessments and criteria. However, as with the Commission Decision on criteria and methodological standards for good environmental status, the Staff Working Paper did not identify how the precautionary principle will be implemented in terms of establishing and applying these criteria and methodological standards.[278]

Finally, the Seveso II Directive drew on previous hazard classifications set out in the Directive 67/548/EEC, which were superseded by REACH and the CLP Regulation.[279] As a consequence, the Seveso III Directive has been adopted in view of making the classification of dangerous substances coherent with that in the CLP Regulation. This implies consistency of approaches in hazard classification across legislation relating to dangerous substances. Although this does not directly relate to the absence of sufficient scientific data, it implies an established protocol for testing even when data is insufficient.

2.4.3.4 Examination of the benefits and costs of action or lack of action

An examination of the benefits and costs of action and lack of action is another general principle of application for measures adopted on the basis of the precautionary principle in the Communication. This is generally referred to as proportionality *stricto sensu*, mentioned for the first time in the *Pfizer* judgment.[280] This examination should include an economic cost/benefit analysis when this is appropriate and feasible and should include non-economic considerations[281]. This also clearly relates to proportionality, but the two are separate in the 2000 Communication.

Most of the policies under review contain provisions requiring an analysis of the costs and benefits of various measures, notably Article 60(4) of REACH concerning authorisation, and Recital 73 of REACH concerning substitution; Article 8(3) of the Waste Framework Directive concerning extended produced responsibility; Recital 12 of the Water Framework Directive referring to the need for Community environmental policy to take account of the potential benefits and costs of action or lack of action (as per Article 174 of the Treaty); Article 19 of the Invasive Alien Species Regulation with regards to management measures; the POPs Regulation concerning the analysis of alternatives; the RoHS 2 Directive regarding substitution; and the withdrawn proposal for a Soil Framework Directive in relation to measures to combat risks to soil functions. In addition, Recital 24 of the Marine Strategy

[277] European Commission, SEC(2011) 1255 final, 70-71.

[278] Markus (2013), 164.

[279] European Commission, SEC(2010) 1590 final, Staff Working Paper, Impact Assessment Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances COM(2010) 781 final SEC(2010) 1591 final.

[280] T-13/99, *Pfizer Animal Health v Council*.

[281] Communication on the precautionary principle, 18.

Framework Directive includes a reference to an economic and social analysis regarding programmes of measures. Even though the Directive includes a complex mix of economic assessment obligations, only new measures are subjected explicitly to a cost-benefit assessment (Art.13(3)), not the programmes as a whole. Further, in the Common Implementation Strategy the Member States and the Commission have agreed to interpret this requirement in such a way that only new measures that are germane to the Directive are covered by the requirement of a CBA; new measures under other policies, which are relevant for the ocean environment and therefore part of the programmes of measures, are not.

In terms of actual implementation, the 2015 report on progress on implementation of the Water Framework Directive found that 8 out of the 23 Members States assessed had performed a cost-effectiveness analysis in developing their programmes of measures for all significant pressures, and another 8 for some but not all significant pressures.[282] The report also highlighted the issue of uncertainty in the analysis on costs and effectiveness, and stressed the importance of this uncertainty being '*clearly spelt out and reported alongside the results of the analysis*', in line with the Communication guidelines on the precautionary principle.[283]

In some instances, derogations to applying precautionary measures may occur when the socioeconomic benefits can be shown to outweigh the risks. A prime example is REACH, which sets in place the authorisation procedure aimed at ensuring that risks from substances of very high concern (SVHC) are adequately controlled. An SVHC may be used only if that use has been specifically authorised. Applications for authorisation of a specific use are subject to risk assessment to ascertain the risk to human health and/or the environment arising from that use as well as the appropriateness and effectiveness of the risk management measures[284]. Socio-economic factors are also assessed, including the availability and technical feasibility of alternatives associated with the use(s) of the substance. Some uses of substances – even if not shown to be safe – may eventually be allowed when the socioeconomic benefits can be shown to outweigh the risks[285].

2.4.3.5 Examination of scientific developments

The Communication on the precautionary principle specifies that measures based on the precautionary principle, although provisional, *'should be maintained so long as scientific information is incomplete or inconclusive, and the risk is still considered too high to be imposed on society, in view of the chosen level of protection'*. Maintenance of the measures depends on the development of scientific knowledge, in the light of which they should be re-evaluated. This means that scientific research shall be continued with a view to obtaining more complete data. Measures based on the precautionary principle shall be re-examined and, if necessary, modified depending on the results of the scientific research and the follow up of their impact.[286]

[282] European Commission, SWD(2015) 50 final, Staff Working Paper, Report on the progress in implementation of the Water Framework Directive Programmes of Measures, 24.

[283] ibid, 23.

[284] REACH, Article 60.

[285] Butti, L. (2009). Hazardous waste management and the precautionary principle. *Waste Management*, 209(9), 2415-2416.

[286] Communication on the precautionary principle, 20.

A related obligation exists under Article 114[287] of the TFEU, which allows Member States to depart from EU harmonisation (by introducing national measures) in light of new scientific evidence 'relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State'. However, this relates more to the ability to introduce environmental protection measures in light of scientific evidence, which is distinct from the monitoring of the evidence base for precautionary measures.

In most of the pieces of legislation under consideration, there are provisions for review in light of scientific progress, although these are not normally explicitly related to the maintenance of precautionary measures, as set out in the 2000 Communication. For example, adaptation to scientific and technical progress is a requirement of:

- the flood risk management plans under the Floods Directive (Article 11(2));
- the Annexes III to V[288] of the MSFD;
- the Annexes listing POPs under the POPs Regulation;
- certain Annexes of the Birds Directive (see Recital 17); the Sewage Sludge Directive; the Air Quality Directive; and
- and the Restriction of Hazardous Substances Directive.

On the other hand, as just mentioned, most of these refer to the general review of scientific information, rather than to a review of precautionary measures.

The only explicit reference to review in the context of the precautionary principle within the selected legislation is in the RoHS 2 Directive. Article 6 states that '*with a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter*'. The case of the banning of PBDEs (discussed in more detail in Section 2.3.3) illustrates that this has been implemented even where some uncertainty over the exact effects of a substance or group of substances still exists, in line with the precautionary principle.

Other provisions relating to the review or monitoring of scientific evidence include the proposed Soil Directive, which required provisions to be made *'to allow the rapid adaptation of methods of identification of risk areas'*, (Recital 33) and envisaged revision of risk areas at least every 10 years. Also, under REACH, when new knowledge of the risks of a substance to human health or the environment emerges, the registrant is responsible for updating their registration. Further, the REACH authorisation process can be subject to a time-limited review (Article 61). Article 14(1)(e) of the Industrial Emissions Directive also requires the 'regular maintenance and surveillance of measures taken to prevent emissions to soil and groundwater', and 'periodic monitoring of soil and groundwater in relation to relevant hazardous substances likely to be found on site'. Under the Waste Framework Directive permits are time-limited and subject to renewal, which would involve submission of up-to-date information on their environmental impacts (Article 23(2)); waste management plans and

[287] In particular Article 114(4) and (6).

[288] They cover environmental characteristics, pressures and impacts, environmental target setting and monitoring programmes.

prevention programmes need to be evaluated and revised as appropriate every 6 years (Article 30); and the European Environment Agency is invited to review progress on waste prevention programmes in its annual report (Article 30).

Therefore, whilst provisions exist for adapting the EU environmental legislation under review to new information, and hence reflect an element of the precautionary principle, this appears to apply to information more generally, not specifically to the review of precautionary measures (with the exception of the RoHS 2 Directive).

2.5 EVOLUTION OF THE PRECAUTIONARY PRINCIPLE IN ENVIRONMENTAL LEGISLATION

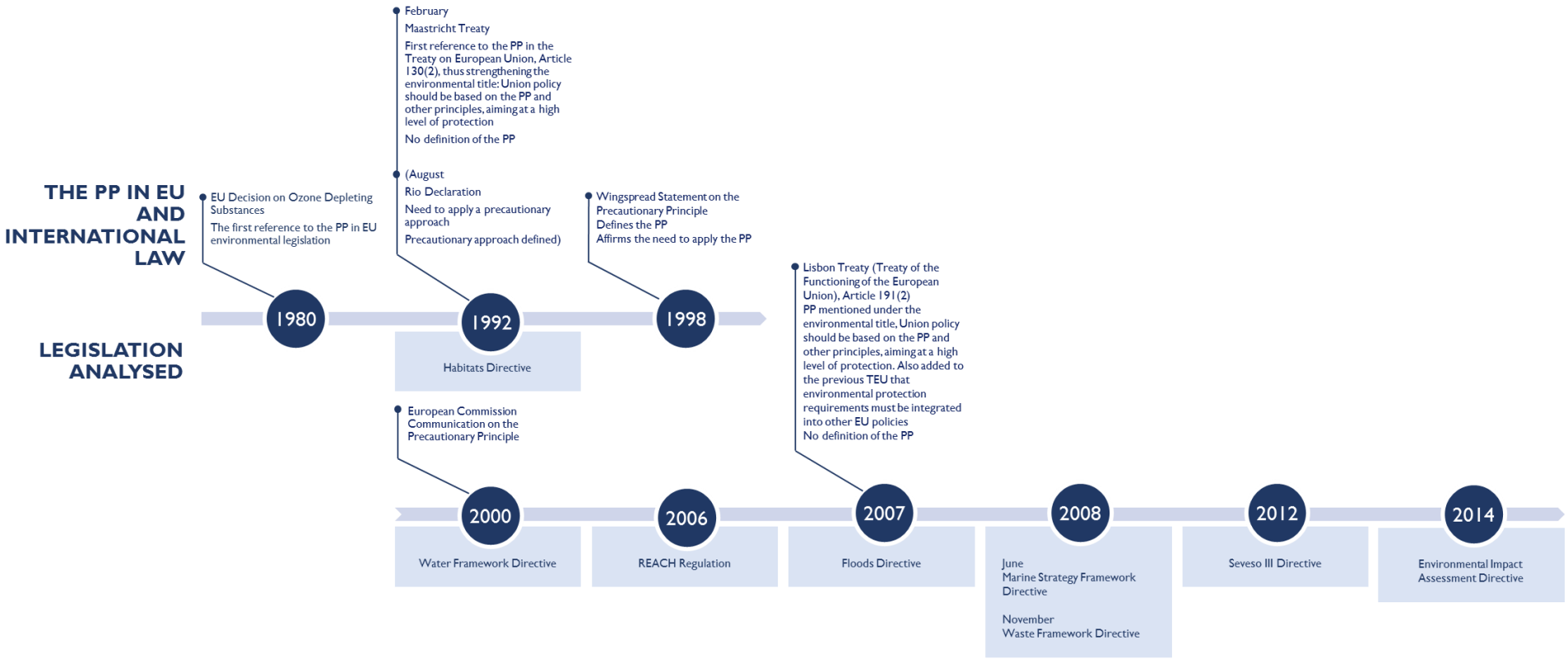
The general evolution of the precautionary principle with EU and international environmental law is illustrated in the Figure 1 timeline below. The first mention of the precautionary principle in EU environmental law was the European Commission's 1980 Decision on ozone-depleting substances.[289] However, it was not until 1992 that the precautionary principle was first introduced into EU primary law via Article 130(2) of the Treaty of Maastricht as one of the guiding principles of EU environment policy. This was augmented by Article 191(2) of the TFEU in 2007 (the Lisbon Treaty), which maintained the same wording on precaution as the Maastricht Treaty, but added that the environmental policy of the EU should also be integrated into all policy areas. Additionally, Article 114 of the Lisbon Treaty indicates that this includes '*taking account in particular of any new development based on scientific facts*', hence referring explicitly to one of the elements of the precautionary principle.

Since then, the principle has been furthered by the Commission Communication of 2000, which provides common guidelines on its application by both the EU and the Member States:[290] the precautionary principle can be incited when a phenomenon, product or process may have a dangerous effect, identified by scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty. This section reviews the eight pieces of environmental legislation selected for in-depth analysis, to examine and compare the general development of the precautionary principle to its progression within EU environmental policy.

The Annex to this report also provides timelines for each of the eight pieces of environmental legislation analysed in depth. The first mentions of the precautionary principle are found by reference to the Treaty on the European Union (TEU)—initially in the Water Framework Directive (see Figure 2 in Annex) which came into force in 2000 (the same year as the publication of the Commission Communication on the Precautionary Principle) and secondly in the Floods Directive in 2007 (see Figure 3 in Annex).

[289] Council Decision 80/372 of 26 March 1980 concerning chlorofluorocarbons in the environment, OJ L 90, 3.4.1980, p. 45–45. The amending Decision of 1982 (Decision 82/795) is entitled 'Decision on the consolidation of precautionary measures concerning chlorofluorocarbons in the environment' and hence contains a reference to "precaution" in its title. Council Decision 82/795 of 15 November 1982 on the consolidation of precautionary measures concerning chlorofluorocarbons in the environment, OJ L 329, 25.11.1982, p. 29–30.
[290] European Commission, COM(2000) 0001 final, Communication from the Commission on the precautionary principle.

Figure 1 - General evolution of the Precautionary Principle in EU and International Environmental Law



However, the principle has been applied prior to these references. For example, although the Habitats Directive does not explicitly mention the precautionary principle, according to the Commission guidance on its Article 6(3) and (4), its application has been implicit in the Directive (see Annex Figure 4) since it came into force in 1992, and its application has evolved through the case law of the CJEU, as discussed in Section 2.4.1 of this study[291].

The progression of the principle within EU legislation was given momentum with the publication of the Commission Communication in 2000, which had a direct effect on its inclusion in legislative documents, with the REACH White Paper of 2001 (see Annex Figure 5) explicitly referring to the precautionary principle for the first time. Although no definition of the principle appears in the 2000 Communication or in the environmental legislation analysed for this report, the REACH White Paper offers a definition both in the text and the glossary. The White Paper definition is that:

> *whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment.*

Similarly, the definition in the glossary of the White Paper is as follows:

> *This principle is contained in Article 174 of the Treaty and the subject of a Commission Communication of 2 February 2000. It applies when there is a preliminary objective scientific evaluation indicating reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community.*

In the legislation reviewed, references to the precautionary principle become more prevalent over time. For example, the analysis of the progression of legislative documents found instances where no reference to the precautionary principle appeared in the original proposal. However, by the time of adoption of the actual legislative act, the principle had been worked into the body of the text to varying degrees. For example, the proposal, the COMM Thematic Strategy and the Staff Working Paper for the MSFD (all of which were published in 2005) contain no reference to the precautionary principle (see Annex Figure 6). However, the principle is mentioned twice in the preamble of the adopted Directive—measures implemented by the MS must be based on the precautionary principle, as well and subsequent actions.

References to the precautionary principle also become stronger over time in the development of the EIA Directive (see Annex Figure 7). Whereas the original EIA Directive adopted in 1985 made no reference to the principle, 25 years later, the Parliament added a reference in the articles in its first reading of the updated and amended Directive, bringing the total number of references to two. Concerning the Seveso Directives, precaution was included for the first time in the context of Seveso III (see Annex Figure 8), with the first mention in the Impact Assessment in 2010 and then in the Directive itself which came into force in 2012.

[291] European Commission (November 2001), Assessment of plans and projects significantly affecting Natura 2000 sites. Methodological guidance on the provisions of Article 6(3) and (4) of the Habitats Directive 92/43/EEC, p. 11/12. Available at: 2001http://ec.europa.eu/environment/nature/natura2000/management/docs/art6/natura_2000_assess_en.pdf.

In some cases, the references to the precautionary principle appear to have been introduced during the first parliamentary reading. For example, the proposal for the Waste Directive of 2005 (see Annex Figure 9) does not mention the precautionary principle. However, the Council Common Position issued after the first parliamentary reading in 2007 contains three references to precaution; with the final Waste Framework Directive containing two direct references to the precautionary principle in the context of other environmental law principles.

However, despite the general increase in references to precaution, in some of the same pieces of legislation the principle was eventually not referred to in their final text. In particular, despite the gradual inclusion of a more precautionary approach throughout the development of the Seveso Directives, the Impact Assessment also discarded an option to have a precautionary alignment of Annex I on substances to the Globally Harmonised System (GHS), on the basis that it was too 'far away from the current scope' of the Directive.

In contrast, REACH provides an example of the precautionary principle becoming less prevalent throughout the legislative process, as can be seen from Figure 5. Despite being the only piece of legislation out of those reviewed to provide a precise definition of the principle in the initial REACH White Paper of 2001 (as discussed above), this was removed in the original legislative proposal of 2003 and not reinstated. The definition was then removed by the Parliament's First Reading, whilst the number of references to the principle gradually lessened. It is also interesting to note the references to the 2000 Communication in the Parliament's First Reading, which were removed by Council Common Position and not re-introduced in the final Directive.

Additionally, it would appear that the significant dates of progression of the principle within EU environmental legislation coincide with general developments within the EU community. For instance, the Floods Directive directly refers to TFEU, which came into force the same year that the Directive was published. Those pieces of legislation that came into force closer to the publication of the 2000 Communication are more likely to include references to both the Communication and the precautionary principle, for example, REACH and the Water Framework Directive. However, this is not a blanket policy, as demonstrated by the EIA Directive, which, despite being in force since 1985, was only revised in 2011 to include a reference to the precautionary principle; 11 years since the Communication, and 4 years since the Treaty of Lisbon added that protection should be integrated into all policy areas (Article 190(2)). Consequently, although it is clear that the general progress of the precautionary principle within the EU influences the development of the principle in environmental policy to a certain extent, it cannot be said to obviously effect all legislation immediately.

Overall, several trends can be observed in terms of the evolution of the precautionary principle in the legislation under review, including in the context of the general evolution of the principle in EU environmental law. Firstly, at it took a long time since the first inclusion of the principle in 1980 in the legislation on ozone-depleting substances for the principle to be enshrined in the European Treaty (in 1992). Similarly, a substantial gap occurred between its inclusion in the treaty and its first mention in the environmental legislation reviewed (in 2000, via the Water Framework Directive). This no doubt reflects the impact of the 2000 Communication. Interestingly references to the Communication tended to be clustered nearer to its year of publication in 2000, with none of the later directives reviewed referring to the Communication.

For most environmental legislation analysed, references to the precautionary principle become more frequent over the course of the legislative process, both in the preamble and the articles of the legislative texts. This is also the case for REACH, which is the only piece of legislation where the references to the precautionary principle became less prevalent over the course of the legislative process, in both their frequency and also their nature (in particular, with definitions of the principle taken out).

The general trend was for the principle to be mentioned in the preamble of legislation in the context of the need for a high level of protection (in accordance with TFEU Article 191(2)). However, stronger references to the precautionary principle in early versions of Seveso III (in relation to the classification system of substances) and REACH (the definition of the principle in the REACH White Paper) were not adopted in the final legislation. Similarly, references to the 2000 Communication also dropped away over the course of the legislative process in the legislation reviewed.

Therefore, despite a slow take-off, since 2000 an overall increase in the inclusion of the precautionary principle in EU environmental legislation can be noted for most of the policy areas reviewed. On the other hand, many of the arguably stronger references to precaution, such as references to the 2000 Communication and inclusion of definitions, disappeared from the final text in the pieces of legislation analysed.

3. RELATION OF THE PRECAUTIONARY PRINCIPLE TO OTHER KEY ENVIRONMENTAL PRINCIPLES

Section 3 discusses the relationship of the precautionary principle with other key environmental principles. As previously mentioned, the precautionary principle is one of the four basic principles of EU environmental legislation.[292] It is enshrined in the TFEU together with the principles of prevention, polluter pays, and rectifying pollution at source. In various instances, the principles are referred together. For example, in the Recital of the MSFD, it is stated that '*measures to achieve or maintain good environmental status should be devised on the basis of the precautionary principle and 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*'.[293] A similar wording is also used in the Water Framework Directive.[294]

3.1 PREVENTION PRINCIPLE

The prevention principle was introduced by the Single European Act in 1987, whereas the precautionary principle was added by the Treaty of Maastricht in 1993. The fact that they were put side by side – rather than having the precautionary principle replace the prevention principle –

[292] Other important principles of EU law for the environmental area are the Integration principle as codified in Article 11 TFEU, as well as the proportionality principle codified in Article 5 TEU and lastly the innovation principle which is not codified as such but arguably included in Article 3(3) TFEU.

[293] MSFD, Recital 27.

[294] WFD, Recital 11.

indicates that both principles have a different meaning and are conceptually different. This can be derived from their own genesis, not from their textual references.[295]

Both principles allow *'action to be taken to protect the environment at an early stage'* to prevent damage.[296] However, the concept of risk is different for each principle. While the precautionary principle tries to minimise future threats before '*the reality and seriousness of the threats become manifest,*'[297] the prevention principle does not address *potential risk* on ground of *scientific uncertainty* but rather *'risks, which are known and likely to occur while carrying out a certain activity or as result of an inaction.'*[298] In discussing the difference between the two principles, it is important to underline that some risks can be calculated or quantified, while others cannot. Risks which cannot be calculated are called potential risks or probabilities. According to the Communication, the precautionary principle only applies to potential risks, i.e. '*risks that cannot be fully demonstrated or quantified or their effects determined because of the insufficiency or inconclusive nature of the scientific data'*.[299] For instance, precaution could have been used between 1950 and 1964 to minimise future lung cancer from smoking when risks were either unknown or difficult to quantify.[300] By contrast, prevention has been the main approach used for smoking since the damage have been well identified. However, the distinction between the precautionary and the prevention principles might not always be clear-cut.[301] For instance, there is no sharp dividing line regarding sufficiency of evidence when justifying action under the precautionary principle or the prevention principle. Both principles may slide into each other along a continuum of expanding evidence.[302]

Risk managers should use available scientific and technical data, and consider whether risks are quantifiable, to decide whether to adopt measures based on the prevention or precautionary principle. Nonetheless, the precautionary and the prevention principles have in common that their application is subject to two key thresholds, *'namely the actual relationship between the probability and the extent of damage, and a cost-benefit analysis'*.[303] Regarding the precautionary principle, an evaluation should show that the desired high level of protection of the environment or a population group could

[295] Milieu Ltd, T.M.C. Asser Institute & PACE. (2011). *Considerations on the application of the Precautionary Principle in the chemicals sector*. DG Environment, European Commission, 15. Article 191(2) of the TFEU follows up on its predecessors Article 130r of the Treaty establishing the European Economic Community and Article 174(2) of the Treaty establishing the European Community, which already referred to (and therewith distinguish between) the preventive and the precautionary principle.

[296] See Jans, J., & Vedder, H. (2008). *European Environmental law*. European Law Publishing.

[297] C-180/96 United Kingdom v. Commission [1998] ECR I -2265 at 99: When 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 those risks becomes fully apparent

[298] Calster (van), G., & Reins, L. (2017). *EU Environmental Law*. Edward Elgar, 34.

[299] Note that the Communication on the precautionary principle talks of insufficiency or 'inclusive' nature of scientific data (see p. 13). Also looking at other language versions (German: 'nicht eindeutiger'), this should be 'inconclusive'.

[300] The Reports of the Surgeon General, The 1964 Report on Smoking and Health, available at https://profiles.nlm.nih.gov/ps/retrieve/Narrative/NN/p-nid/60 , last accessed 24.07.2017

[301] For a discussion on the distinction between the precautionary and the prevention principles in shale gas extraction, see Fleming, R., & Reins, L. (2016). Shale gas extraction, precaution and prevention: A conversation on regulatory responses. *Energy Research and Social Science*, 20, 131-141.

[302] See for example the ECDC on how to deal with evidence: European Centre for Disease Prevention and Control. Evidence-based methodologies for public health – How to assess the best available evidence when time is limited and there is lack of sound evidence. Stockholm: ECDC; 2011.

[303] Calster & Reins (2016).

be endangered. Absence of an established causal relationship, a quantifiable dose/response relationship or a quantifiable evaluation of the probability that the potential risk would materialise, should not be used as a reason for inaction. The manner in which scientific and technical data are to be gathered, and a risk assessment is to be carried out, is important – without demanding a minimum amount of quantified risks.[304]

On various occasions, the CJEU has referred to the precautionary and the prevention principles together. For instance, in several cases where it interpreted the meaning of 'waste', the Court held that the verb 'to discard' must be interpreted in light of Article 174(2) TEC (now Article 191 (2) of the TFEU), and that the EU's policy on the environment is to aim at a high level of protection and is to be based, in particular, on the precautionary principle and the principle that preventive action should be taken.[305]

3.1.1 Prevention of damage to the environment

The principle of prevention is one of the central principles to the Floods Directive: *'Flood risk management plans should focus on prevention, protection and preparedness'.*[306] It is, moreover, one of the key objectives of the EU Flood Action Programme, based on Article 175(1) of the EU Treaty, now 192 of the TFEU.[307] The Recital to the REACH Regulation discusses the importance of prevention of adverse effects on human health and the environment.[308]

The aim of the Sewage Sludge Directive is to *'prevent harmful effects on soil, vegetation, animals and man' from the application of sewage sludge in agriculture,*[309] and is therefore preventative in nature. Additionally, it establishes limit values to prevent soil contamination by heavy metals present in sewage sludge. Annex 1A (heavy metals in soil) also states that limit values for heavy metals must *'seek to ensure that there is no resulting hazard to human health or the environment'*, whilst Annex 1C (heavy metals in agricultural soil) states that Member States *'must also ensure that there is no resulting hazard to human health or the environment'*.

The prevention principle is also intrinsic to the Air Quality Directive. Specifically, the Directive necessitates the elaboration of short-term action plans when alert thresholds are at risk of being exceeded, as well as Member States to take cost-effective measures by adapting existing programmes and adopting new plans for reaching the target values. Recital 2 states that *'emissions of harmful air pollutants should be avoided, prevented or reduced',* whilst the key objective of the Directive is stated as '*defining and establishing objectives for ambient air quality designed to avoid, prevent or reduce*

[304] Milieu Ltd, T.M.C. Asser Institute and PACE (2011), 15.

[305] Case C-9/00, Judgment of 18 April 2002, *Palin Granit*, ECLI:EU:C:2002:232, para 22 and 23. See also Case C‑457/02, Judgment of 11 November 2004, *Niselli*, ECLI:EU:C:2004:707, para 33; Case C-188/07, Judgment of 24 June 2008, *Commune de Mesquer*, ECLI:EU:C:2008:359, para 38.

[306] Floods Directive, Recital 14.

[307] European Commission, SEC(2006) 0066, Staff Working Document - Annex to the Proposal for a Directive of the European Parliament and of the Council on the assessment and management of floods - Impact Assessment {COM(2006) 15 final}.

[308] REACH, Recital 17.

[309] Sewage Sludge Directive, Article 1.

harmful effects on human health and the environment as a whole'.[310] The limit and target values set by the Directive are also fixed on the basis of scientific knowledge with a preventative focus,[311] whilst Member States are obliged to inform the public about actual or predicted exceedances of alert thresholds, which must include information on preventive action to reduce pollution and/or exposure to it.[312] Nonetheless, the Air Quality Directive adopts a precautionary approach in relation to fine particulate matter. The Directive acknowledges that although fine particulate matter is responsible for significant negative impacts on human health, there is currently no identifiable threshold below which fine particulate matter would not pose a risk. As such, this pollutant should not be regulated in the same way as other air pollutants.[313]

Additionally, the Seveso III Directive is rooted in the principle of prevention, with the purpose of the legislation being to set '*rules for the prevention of major accidents which might result from certain industrial activities and the limitation of their consequences for human health and the environment.*'[314] The Directive deals with establishments where dangerous substances may be present in quantities above a certain threshold. These establishments are categorised into lower and upper tiers based on the amount of dangerous substances present, with those in the latter subject to more stringent requirements. In particular, Article 13 (2) of the Directive is an example of a typical implementation of the preventive principle, stating that:

> '*Member States shall ensure that their land-use or other relevant policies and the procedures for implementing those policies take account of the need, in the long term:*
> *(a) to maintain appropriate safety distances between establishments covered by this Directive and residential areas, buildings and areas of public use, recreational areas, and, as far as possible, major transport routes;*
> *(b) to protect areas of particular natural sensitivity or interest in the vicinity of establishments, where appropriate through appropriate safety distances or other relevant measures;*
> *(c) in the case of existing establishments, to take additional technical measures in accordance with Article 5 so as not to increase the risks to human health and the environment.*'[315]

The Waste Framework Directive incorporates the principle in two distinct ways: prevention of waste and prevention of the harmful effects of waste. By adopting a life-cycle approach, the Directive places waste prevention as the preferred waste option to be applied by Member States' national waste policies, followed by preparing for re-use, recycling, other recovery and disposal. The Directive also affirms that the Member States should launch waste prevention programmes, which describe existing prevention measures, determine appropriate specific qualitative or quantitative benchmarks for waste prevention measures and establish indicators for waste prevention measures.

[310] Air Quality Directive, Article 1(1).

[311] ibid, Article 2(5) and 2(9).

[312] ibid, Annex XVI 4(d).

[313] ibid, Recital 11.

[314] Seveso III Directive, Recital 1.

[315] Seveso III Directive, Article 13(2).

Prevention of damage to the environment also occurs through derogation of key principles – for example species' protection. Under the Habitats Directive, Member States can derogate from certain provisions regulating the protection of species.[316] Derogations are allowed, amongst other reasons, *'to prevent serious damage, in particular to crops, livestock, forests, fisheries and water and other types of property'*.[317] In the MSFD, the Recital relates specifically to prevention and references the principle of subsidiarity as mentioned in the EC treaty. It underlines that the protection and preservation of the marine environment, the prevention of its deterioration and where practicable the restoration of that environment in areas where it has been adversely affected, is the objective of the Directive. Where this cannot be sufficiently achieved by Member States, *'the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty'*.[318]

In line with prevention, there has also been reference to 'avoidance of damage'. An example can be found in the Proposal for the Habitats Directive, which provided that – in respect of special protection areas – Member States should take *'the appropriate steps to avoid pollution or deterioration of habitats or any disturbances affecting fauna and flora, insofar as these would have significant effects 'with regard to the objectives of this Directive'*[319]. This article is not included in the current Directive.

3.1.2 [New] substances or species

The prevention principle is used to prevent the use of new substances or occurrence of new (to the specific environment) species that are considered harmful to the environment. The POPs Regulation, for example, notes in its Recital that the Regulation is inspired by the lack of a framework to *'prevent the production and use of new substances that exhibit persistent organic pollutant characteristics'*[320]. The Recital to the withdrawn proposal for a Soil Framework Directive stated that in line with the prevention principle, the Directive *'should contribute to the prevention and reduction of the introduction of dangerous substances into soil to avoid soil contamination and to preserve soil functions.'*[321] The prevention principle can also apply to the occurrence of alien species: the Invasive Alien Species Regulation regulates early detection and rapid eradication, where it requires Member States to *'establish a surveillance system of invasive alien species of Union concern'*.[322] The collecting of data on the occurrence in the environment of invasive alien species by survey, monitoring or other procedures should help to prevent the spread of invasive alien species.

[316] Article 16(1) of the Habitats Directive allows Member States to derogate from the provisions of Articles 12, 13, 14 and 15 (a) and (b).

[317] Habitats Directive, Article 16(1)(b).

[318] MSFD, Recital 43.

[319] European Commission, COM/88/381Final, Proposal for a council directive on the protection of natural and semi-natural habitats and of wild fauna and flora, OJ C 247, 21.9.1988, Article 7.

[320] Pops Regulation, Recital 4.

[321] European Commission, COM(2006) 0232 final, Proposal for a Directive of the European Parliament and of the Council establishing a framework for the protection of soil and amending Directive 2004/35/EC.

[322] Invasive Alien Species Regulation, Article 14(1).

3.1.3 Use of alternatives

The prevention principle, similar to the precautionary principle is used to promote the use of alternatives –being either substances or activities. The POPs Regulation (Article 6(2)) stipulates that alternative substances should be promoted in order to *'prevent the formation and release of substances listed in Annex III'* (substances for release reduction). In addition to highlighting the need to prevent adverse effects on human health and the environment, the Recital to the REACH Regulation more specifically provides that adverse effects on human health and the environment from substances of very high concern *'should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, with a view to progressively substituting these substances with a suitable safer substance.* '[323]

3.1.4 Listing of risks

Another approach identified in the use of the prevention principle is the 'listing' of risks. An example can be found in the Invasive Alien Species Regulation, which requires that invasive alien species shall be included on the Union list after meeting several criteria, amongst others *'that it is likely that the inclusion on the Union list will effectively prevent, minimise or mitigate their adverse impact.'* Similarly, Article 4 of the RoHS 2 Directive states that Member States must ensure that electrical and electronic equipment products placed on the market do not contain substances listed in Annex II (restricted substances).

3.2 PRINCIPLE OF RECTIFICATION OF POLLUTION AT SOURCE

The principle of rectification of damage at source was included in Article 191(2) at the same time as the inclusion of the environmental legal basis by the Single European Act. This principle and the prevention principle are closely related – both have the objective of combatting damage, at best before it occurs, or, if that is too late, at an early stage. Environmental damage should be rectified at source, *'rather than being prevented by using end-of-pipe technology'*.[324] There is no clarity on the meaning of rectification, however '*EU institutions have a large discretion as to what measures they wish to take, and the time-span and content of these measures'*.[325]A tool often used to implement this principle is the introduction of emission standards for a certain activity.[326]

Limited explicit reference to the rectifying pollution at source principle has been identified in the selected Directives. One example can be found in the Water Framework Directive. With regard to pollution prevention and control, it provides that Union water policy should be based on a combined approach using control of pollution at source through the setting of emission limit values and of

[323] REACH, Recital 70.

[324] Jans and Vedder (2008), 42.

[325] Kramer (2012). P. 25.

[326] Calster and Reins (2017), 35.

environmental quality standards.[327] Additionally, the Recital of the Air Quality Directive states that *'In order to protect human health and the environment as a whole, it is particularly important to combat emissions of pollutants at source and to identify and implement the most effective emission reduction measures at local, national and Community level.'*[328] In more general wording, the withdrawn proposal for a Soil Framework Directive mentioned rectifying pollution/damage at pollution source, stating that '*environmental damage should as a priority be rectified at source'*, as set out in Article 191 of the TFEU.

3.3 POLLUTER PAYS PRINCIPLE

The polluter pays principle, included in the EU Treaties by the 1986 Single European Act and now set out in Article 191(2) of the TFEU, has been one of the cornerstones of European environmental policy. The principle ensures that *'the cost of measures to deal with pollution should be borne by the polluter who caused the pollution'*.[329] It has evolved from *'a principle to avoid distortions of competition to an instrument of pollution control'*. What the rectification of damage at source principle and the polluter pays principle have in common is that *'they step in once the application of the prevention principle has failed and the damage has occurred'*.[330]

Some EU environmental directives and regulations based on the precautionary principle clearly impose obligations based on the polluter pays principle. This is the case in the Invasive Alien Species Regulation, which provides a clear use of the polluter pays principle with the objective of cost recovery of measures. Its Recital sets out that *'the costs of such restoration measures should be recovered in accordance with the polluter pays principle'*.[331] This is further elaborated in Article 21, where it is stated that, in accordance with the polluter pays principle, Member States *'shall aim to recover the costs of the measures needed to prevent, minimise or mitigate the adverse impact of invasive alien species, including environmental and resources costs as well as the restoration cost'*. It is moreover underlined in the Recital that, to guarantee compliance with this Regulation, it is important that the Member States impose effective, proportionate and dissuasive sanctions for infringements, taking into account the nature and gravity of the infringement, the principle of recovery of the costs and the polluter pays principle.[332]

In contrast, the Habitats Directive acknowledges that the *'polluter pays principle can have only limited application in the special case of nature conservation'*.[333] The Preamble states that '*Whereas it is recognized that the adoption of measures intended to promote the conservation of priority natural habitats and priority species of Community interest is a common responsibility of all Member States; whereas this may, however, impose an excessive financial burden on certain Member States given, on the one hand, the uneven distribution of such habitats and species throughout the Community and, on*

[327] WFD, Recital 40.

[328] Air Quality Directive, Recital 2.

[329] Jans and Vedder (2008), 43.

[330] Calster and Reins (2017), 37.

[331] Invasive Alien Species Regulation, Recital 26.

[332] ibid, Recital 33.

[333] Habitats Directive, Preamble.

the other hand, the fact that the "polluter pays" principle can have only limited application in the special case of nature conservation.'

The withdrawn proposal for a Soil Framework Directive included reference to the polluter pays principle, highlighting that the responsibility should first fall on the individual polluter, or, where they cannot be identified, on the competent authority.[334] According to the Water Framework Directive, Member States shall take account of the principle of recovery of the costs of water services, including environmental and resource costs, having regard to the economic analysis conducted according to Annex III, and in accordance with the polluter pays principle (Article 9(1) WFD).[335]

The Industrial Emissions Directive enacts the polluter pays principle by holding that, under certain conditions, operators can be held liable for contamination caused by a previous owner of the company.[336] Specifically, Recital 25 states that *'In accordance with the polluter pays principle, when assessing the level of significance of the pollution of soil and groundwater caused by the operator which would trigger the obligation to return the site to the state described in the baseline report, Member States should take into account the permit conditions that have applied over the lifetime of the activity concerned, the pollution prevention measures adopted for the installation, and the relative increase in pollution compared to the contamination load identified in the baseline report.'* The RoHS 2 Directive places an obligation on manufacturers to ensure any electrical and electronic equipment that they place on the market has been designed and produced in line with the requirements set out in the legislation. Importers must check that equipment has been approved as meeting the required standards, while distributors must also ensure adherence to the rules.

The polluter pays principle has been a part of European waste legislation since 1975, and is intrinsic to the current Waste Framework Directive whose Recital states that *'in accordance with the polluter-pays principle, a requirement that the costs of disposing of waste must be borne by the holder of waste, by previous holders or by the producers of the product from which the waste came.'*[337] Additionally, Article 14 states that *'…the costs of waste management shall be borne by the original waste producer or by the current or previous waste holders.'* The second part of article 14 contains a provision enabling the Member States to put liability on the distributors of the product from which the waste came. The principle allocates liability for costs for waste disposal or waste management to the final holder of the waste, or the previous holders of the waste.

3.4 COMPLEMENTARITY OF KEY ENVIRONMENTAL PRINCIPLES

The precautionary principle relates closely to the other key environmental principles, providing a partly overlapping and complementary approach to limit threats of serious or irreversible damage and to control the damage. Whereas the prevention principle and the precautionary principle have a different meaning and are conceptually different, some authors have argued that '*there seems to be no*

[334] Withdrawn proposal for a Soil Framework Directive, Recital 26 and 28, and Article 23.

[335] Correlje, A., & Others. (2006). Integrating water management and principles of policy: towards an EU framework? *Journal of Cleaner Production*, 15(16), 1-8.

[336] This applies only to contamination discovered after 7 January 2013.

[337] Waste Framework Directive, Recital 1.

EU action which would be possible under the precautionary principle, but not under the prevention principle – and vice versa'.[338] Both principles center mainly on the link between the presumption and the extent of the damage in relation to a cost-benefit analysis.[339] The prevention principle is the principle the most referred to in the EU environmental instruments reviewed in this study.

The principle of rectification of pollution at source and the polluters pays principle are also complementary to the precautionary and prevention principles, as they focus on situations where precaution and prevention have failed, and actual pollution of damage has occurred. Often environmental damage *'cannot really be completely rectified [and it is] up to the legislature to decide how to manage, once it has occurred, can be minimised, how the environmental can be restored – at the same or as a different place – and further damage prevented'*.[340] The other aspect of control lies in the identification of who is responsible for the cost of measures concerning pollution. All key principles deal with environmental risks, without requiring the elaboration of the risks as such. The argument of a lack of general definition of the precautionary principles might also apply to the other key environmental principles. Similarly, the open definition, which is implying what is allowed but does not dictate what is required, can be justified on the same reasoning as for the precautionary principle, namely that the implementation of these principle varies across a wide range of policies and is contextually determined.

4. OVERALL FINDINGS

As already noted, this study aims to provide an overview of the use of the precautionary principle in EU environmental policies. The scope of the study was exclusively on subject matters falling within the competence of DG Environment. The study assessed how the precautionary principle has been implemented in the design and application of 15 EU environmental legislative instruments. It also looked more closely at how the precautionary principle was applied throughout the policy-making cycle for eight of those EU environmental legislative documents.

4.1 SPECIFIC FINDINGS

The legislative documents subject to review were analysed with respect to how the precautionary principle was reflected in the document itself, as well as to how the related concepts of uncertainty and risk were applied. The burden of proof in terms of strength of evidence and responsibility for action was also reviewed. The table below presents an overview of the specific findings per legislative document assessed.

[338] Kramer (2012), p. 24.

[339] Calster & Reins (2016).

[340] Kramer (2012). P. 25.

Table 7: Overview of main findings

Legislative document	Reference to precautionary principle	Reference to uncertainty	Risk assessment	Burden of proof - General rule on allocation
Air Quality Directive	No direct reference	identification of uncertainty in available data	Sets limit values for a range of pollutants.	Member States
Birds and Habitats Directives	No direct reference	Harm- and safety related reference	Appropriate assessment must consider the characteristics & specific environmental conditions of the site or project - MS not obliged to examine alternative solutions to the plan or project concerned	Member States (Birds), Proponents of plan or project (Habitats)
Environmental Impact Assessment Directive (EIA)	Reference in Recital	Harm-related reference, identification of uncertainty in available data	Projects likely to have significant impact on the environment must undergo an EIA and be subject to authorization before going ahead; authorised projects likely to have significant effects subject to monitoring and mitigation measures for significant adverse environmental effects.	Developers
Floods Directive	No direct reference	Harm-related reference	Implemented in iterative cycles which incorporate the precautionary approach to risk assessment.	Member States
Industrial Emission Directive (IED)	No direct reference	N/A	Sets emission limit values for pollutants from large combustion plants, waste incineration plants and activities using organic solvents, and implemented for other major industrial activities via Commission decisions laying down Best Available Techniques and associated emission levels	Operators
Invasive Alien Species Regulation	Addressed in main body	Harm-related reference	List of invasive alien species of Union concern.	Member States
Marine Strategy Framework	Reference in Recital	Harm-related reference	Each marine region or sub-region concerned to	Member States

Legislative document	Reference to precautionary principle	Reference to uncertainty	Risk assessment	Burden of proof - General rule on allocation
Directive (MSFD)			identify the measures needed to achieve or maintain good environmental status in their marine waters.	
POPs Regulation	Addressed in main body	Harm- and safety related reference	N/A	Member States and Commission
REACH	Addressed in main body	Harm & safety concerns referenced, identification of uncertainty in available data	Obliges all EU manufacturers and importers of substances to register information on the hazard and risk of their substances with ECHA. Public authorities (national or ECHA) develop dossiers showing unacceptable risks requiring restrictions.	Manufacturers, importers and downstream users of substances or preparations; for restrictions the burden of developing dossiers is on public authorities (national/ECHA).
RoHS 2	Addressed in main body	Safety-related reference, identification of uncertainty in available data	N/A	Manufacturers, importers and distributors of EEE
Seveso III	Addressed in main body (precautionary action)	Harm- and safety related reference	MS competent authority to identify all lower-tier & upper-tier establishments or establishment groups where risk or consequences of a major accident may be increased because of the geographical position and proximity of such establishments, and their inventories of dangerous substances.	Operators
Sewage Sludge Directive	No direct reference	Safety-related reference	Stipulates the need for regular monitoring of soil and sludge based on a risk assessment methodology.	N/A
Soil Thematic Strategy and withdrawn	Addressed in main body	Harm-related reference	Identification of risk areas must be based on empirical evidence or	Owner of site to be sold or prospective buyer

Legislative document	Reference to precautionary principle	Reference to uncertainty	Risk assessment	Burden of proof - General rule on allocation
proposal for a Soil Framework Directive			modelling; threats of unknown proportions can also be dealt with.	
Waste Framework Directive	Addressed in main body	Safety-related reference	Requires those carrying out waste treatment to obtain a permit; MS must keep a register of establishments not subject to permit requirements.	Member States
Water Framework Directive	Reference in Recital	Safety-related reference	Substances prioritised for action on basis of risk to, or via the aquatic environment as identified by a simplified risk-based assessment procedure based on scientific principles.	Commission

While none of the EU environmental legislation reviewed provides a definition of the precautionary principle as such, some instruments do refer to the application or use of the precautionary principle in their Recitals. Others discuss the precautionary principle in their main articles. Still other instruments refer to the precautionary principle via indirect reference, e.g., by relying on concepts such as risk assessment or uncertainty (see also table 3 of the study).

Those directives or regulations that lack explicit reference to the precautionary principle may nonetheless integrate a precautionary approach in practice. For instance, the CJEU has confirmed the underlying precautionary approach of Article 6(3) of the Habitats Directive.[341] Thus, whether or not the term 'precautionary principle' is explicitly referred to, as well as the location of the references (Recital or main body), does not accurately portray the actual application of the precautionary principle.

The diversity of the application of the principle also becomes apparent in the assessment of the key components of the precautionary principle in the selected EU environmental legislation, namely the various approaches towards risk, risk assessment, uncertainty, and burden of proof. For instance, risk and risk assessment are intrinsic parts of many of the EU environmental legislative documents under review (e.g. Water Framework Directive, Marine Strategy Framework Directive, Floods Directive and Habitats Directive). Risk assessment proceeds from an assumption that risks can be assessed probabilistically, employing a combination of statistical evidence and scientific understanding of causal relationships. However, not all threats can be assessed probabilistically, and it is important to supplement risk assessments with other decision criteria when managing risk. Nevertheless, most legislative documents do not explicitly define the nature of the risk or provide guidance concerning when such an assessment would be triggered, with a few exceptions (e.g. Seveso III and the withdrawn proposal for a Soil Framework Directive).

[341] Case C-127/02, *Waddenzee*, para 44. See also joined Cases C-387/15 and C-388/15, *Orleans and Others*, para 53.

Among the legislation examined, the thresholds for triggering a risk assessment (where defined) also vary. In the context of the Habitats Directive, the CJEU has stated that '*the trigger for an appropriate assessment is a very light one*', [342] whereas under the EIA Directive an EIA must be carried out only if significant environmental effects can exist.[343] This seems to indicate that identifying thresholds for assessing risk in the individual legislative acts could be an operational way to support more consistent application of the precautionary principle. However, it should be noted that ensuring consistency with this application might prove problematic due to the majority of hazardous situations assessed relating to a specific situation.

The methodologies for assessing risk also differ across the legislation under review. They range from requirements such as gathering of empirical evidence, modelling of potential effects and establishment of risk reduction targets to the examination of alternative solutions and keeping records of impacts. It is hence not surprising that the measures to be undertaken during and after the required risk assessment similarly vary throughout the legislation under review. Hence, under the selected EU environmental legislation, risk assessment employs a variety of approaches to risk tailored to the individual requirements of the specific environmental policy area.

Scientific uncertainty, another intrinsic aspect of the precautionary principle, is also not expressly defined in the selected environmental legislation. Nevertheless, a range of implicit definitions of uncertainty were identified, mostly covering uncertainty of harm and uncertainty over safety. These can be mainly classified into three categories, all of which are covered in the 2000 Communication:

- Requirements for the level and nature of the uncertainty to be documented when carrying out risk assessments (although what action should ensue as a result of the uncertainty was generally not specified),
- Measures to reduce uncertainty, included in most of the legislation under review, and
- Measures to address a potential threat even when uncertainty remains. It is worth mentioning that further research, whilst often reducing some uncertainties, may increase others as well as sometimes expands awareness of what is not known.

The legislative review found significant variation in the response levels authorised in the face of uncertainty. These appeared to depend on a number of related factors - to some extent on the severity of the potential consequences and the level of uncertainty, but also related to the subject of the legislation. Note that while the specific legislative acts rarely explicitly mention uncertainty, more open discussions of uncertainty were often found in the background documents to the legislative acts, especially at the start of the policy discussions. The study was not able to identify why aspects related to uncertainty came to be glossed over during the legislative process. However, many scientists prefer to talk about what they know instead of what they do not know, and policymakers and politicians also prefer to deal in certainties.

[342] C-127/02, *Waddenzee*, para 41-45.

[343] Member States may also set thresholds or criteria to determine when projects need not undergo the obligations of Annex II-projects or the obligation of screening or EIA (EIA Directive, Article 4(3)).

Another finding is that in general, the guidelines of the 2000 Communication in terms of carrying out scientific evaluations, and to some extent specifying the uncertainty attached, are being implemented in the legislation reviewed. However, the Commission's guidance for invoking the precautionary principle has not been followed consistently.[344] For example, guidance is generally lacking on how to apply the precautionary principle when uncertainty is revealed by a risk assessment (such as in the guidance documents for REACH). A lack of clarity on other key terms or thresholds, such as what constitutes 'significant effects', has also meant that in certain cases (e.g. the French transposition of the MSFD), socio-economic benefits have been given precedence over precautionary measures towards the environment.[345] Another example is in the area of REACH where the concept of "unacceptable risk" is not defined in the legislation, but where implementation guidance based on evaluating the severity of a risk ("risk quotient") and which enables restriction of high risk uses of a substance may nonetheless impede application of more precautionary approaches, such as a substance ban, by allowing other lower risk uses to continue..

Responsibility for the burden of proof and for acting in cases of uncertainty is another key element in implementation of the precautionary principle in EU environmental policies. Some authors would argue that a precautionary approach implies that the burden of proof to demonstrate the absence of harm of a risk-generating activity should be on the proponent of that activity, as opposed to national authorities or members of the public as has historically been the case. In this regard, in general Member States remain the main bearers of the burden of proof, even where the legal instruments endorse a precautionary approach (e.g. POPs Regulation; Invasive Alien Species Regulation). The nature of the burden of proof may also vary amongst legal instruments. In some instances, Member States may carry responsibility for production of information on risk while in other cases they may carry responsibility for persuasion.

A few directives and regulations (e.g. REACH with respect to regarding registration; RoHS 2) do explicitly place the burden of proof on the proponent of a risk-generating activity. This may also be the case in particular circumstances (e.g. holders of specific stockpiles under the POPs Regulation). However, the research carried out for this study suggests that shifting this responsibility onto the proponent of a risk-generating activity may not be enough to ensure the protection of health or the environment. When the proponent is tasked with conducting a risk or impact assessment, the tendency may be to minimise the potential negative impacts of the proposed product or activity (e.g. Habitats Directive; socio-economic assessment under REACH).

4.2 GENERAL FINDINGS

The precautionary principle is one of the basic principles of EU environmental legislation, mentioned together with the related principles of prevention, polluter pays, and rectifying pollution at source in Article 191(2) of the TFEU. In the EU environmental legislation selected for review, the principle most often referred to is that of prevention. Whereas both principles can be strictly divided conceptually, it is not always straightforward to separate them as clearly in their application. Some legal instruments based on a general preventive approach nonetheless integrate a precautionary

[344] Garnett & Parsons (2016), 12. See also Löfstedt, R. (2014). The precautionary principle in the EU: Why a formal review is long overdue. *Risk Management*, 16(3), 137-163.

[345] Jacob, C. and others (2016)

approach for specific substances where risks to health and the environment or the thresholds needed to limit hazards are not identifiable (e.g. Air Quality Directive, SEVESO III, IED Directive).

Since its introduction into EU law via the 1992 Maastricht Treaty and its further elaboration in the 2000 Commission Communication, the precautionary principle has also been found useful in other areas of EU policy, such as food safety legislation and policy. Because the different policy sectors influence each other, limiting the focus of the study to EU environmental law and policy has also partially limited a full consideration of certain features and characteristics of the principle, as it has evolved over time in other areas of EU law.

For example, EU food safety legislation has expressly defined the precautionary principle for application in that sector. In contrast, EU secondary environmental legislation 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 approach has had the advantage of keeping the principle flexible and adaptable to the individual needs of a particular environmental policy area. Commentators have generally concurred with this approach, arguing that the lack of general definition of the precautionary principle at EU level is justified on the grounds that the principle's application will differ across the range of policies and must be context-specific.

However, this has obviously led to different approaches related to the context and case specific application of the precautionary principle, a problem only for those who expect the same features of the application of the precautionary principle to apply across very different circumstances. All that can be expected is that the general procedures are similar and predictable, e.g. 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.

As the specific analysis demonstrates, few pieces of EU environmental legislation refer explicitly to, or operationalise, the precautionary principle. For instance, the concept of risk assessment in EU environmental legislation is interpreted differently depending on the sector in question. As a result, the requirements of the precautionary principle vary across the various sectoral policies dealing with environmental risks. This reflects the content-specific approach of the principle which is needed in order to make it implementable to the different subject areas.

It could be noted here that Article 191(2) TFEU does not require scientific assessment of risk as a precondition for taking precautionary action. Rather, such requirements have been introduced via secondary legislation, as part of a general trend towards more evidence-based policies

In terms of the general principles of application of the precautionary principle set out in the 2000 Communication, cost-benefit analysis and the revisions of measures in line with scientific and technical progress receive the greatest coverage and are the elements most explicitly linked to the precautionary principle itself. However, provisions for adaptation to scientific and technical progress relate more to the ability to introduce additional environmental protection measures in light of additional scientific evidence, rather than the maintenance of precautionary measures for as long as

uncertainty remains, as set out in the 2000 Communication. Other important general principles of application included in the 2000 Communication, in particular proportionality, also receive scant reference in the environmental legislation reviewed.

The CJEU's approach to the precautionary principle has varied depending on whether the case deals with health and food safety or with environmental issues. According to De Sadeleer, it has endorsed a stricter approach with respect to health and food safety cases than in the environmental sector[346]. However, the evolution of the case law by the CJEU in the environmental area has picked up in the last years, following the release of the 2000 Communication, and in particular with respect to application of the precautionary principle in the area of nature protection.

Overall in the environment sector, it appears easier to apply the precautionary principle in nature related cases than in policy areas related to chemicals or industrial pollution. In the case of the nature protection directives, for example, proponents of an activity that would depart from the general prohibition of harmful activities in Natura 2000 areas have to prove that there are no alternatives, that the proposed activity does not cause harm and it is needed because of overarching public interests – a generally stricter precautionary approach. In contrast, in the area of REACH, the "risk quotient" approach used to determine what is an "unacceptable risk" has arguably narrowed the scope for taking more precautionary measures in setting restrictions on substances and their uses[347]. Such differences in application could be linked to the allocation of the burden of proof for determining the extent of risk as well as to the political aspects of applying the precautionary principle in certain environmental policy areas where stakeholder input is significant.

In conclusion, the precautionary principle is a general principle of EU environmental law which has not been defined by the legislator. This has provided the flexibility needed to adapt it to a range of policy areas, not only in environmental legislation and policy, and prevented it from being a static principle. While this flexibility is an advantage, it also presents the challenge of how to ensure that the principle is applied when needed to achieve a high level of protection for people and the environment, in those cases where an occurrence or substance may have a dangerous effect, but where scientific evaluation does not allow the risk to be determined with sufficient certainty.

[346] De Sadeleer, N. (2014). *EU Environmental Law and the Internal Market*. Oxford University Press, 84.

[347] KEMI 2015. *Developing REACH and improving its efficiency*, available at " KEMI 2015 http://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf , e.g. section 4.4, p. 91.

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ANNEX: TIMELINES FOR LEGISLATIVE ACTS

Figure 2 Legislative Process of the Water Framework Directive

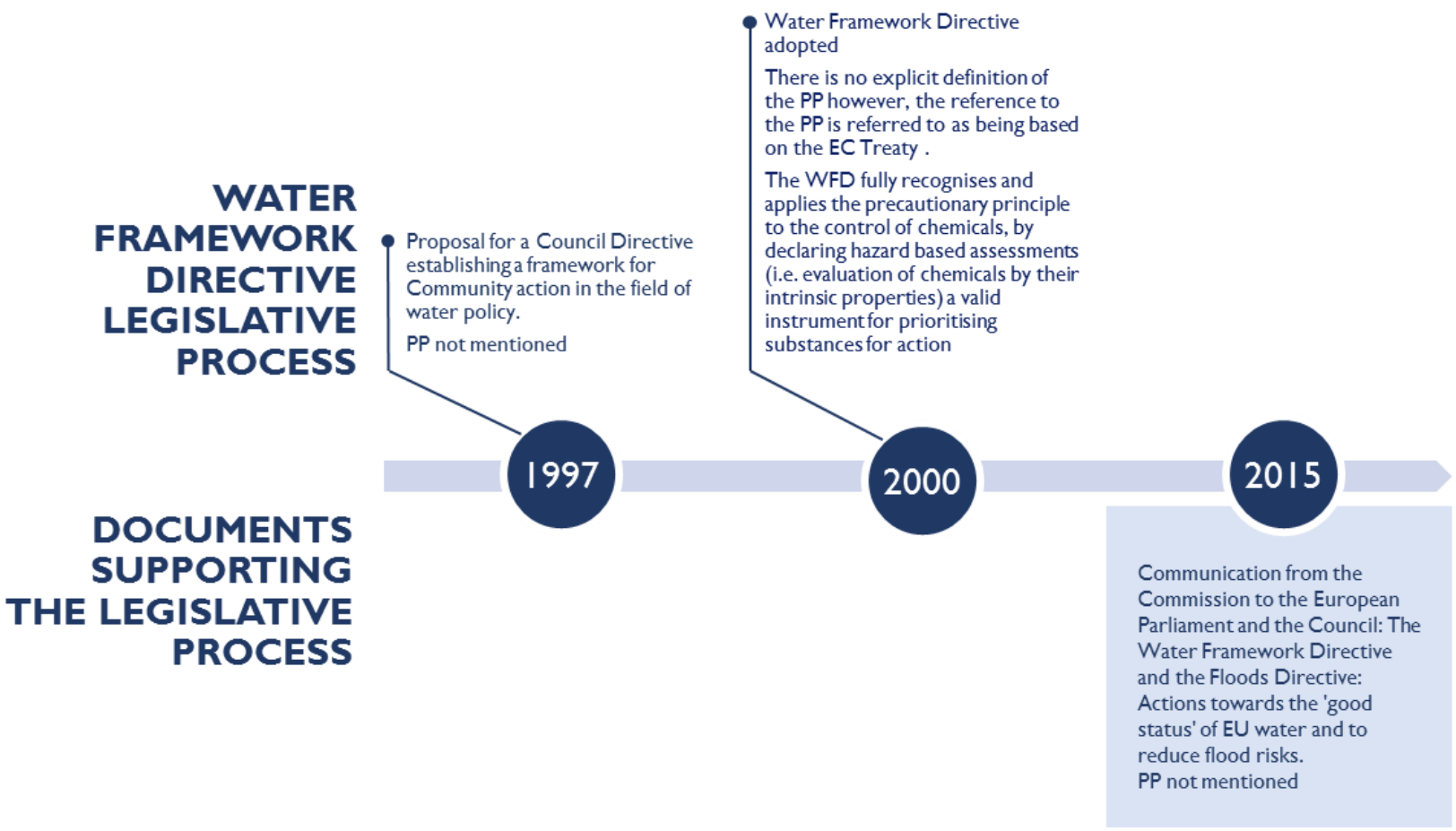


Figure 3 Legislative Process of the Floods Directive

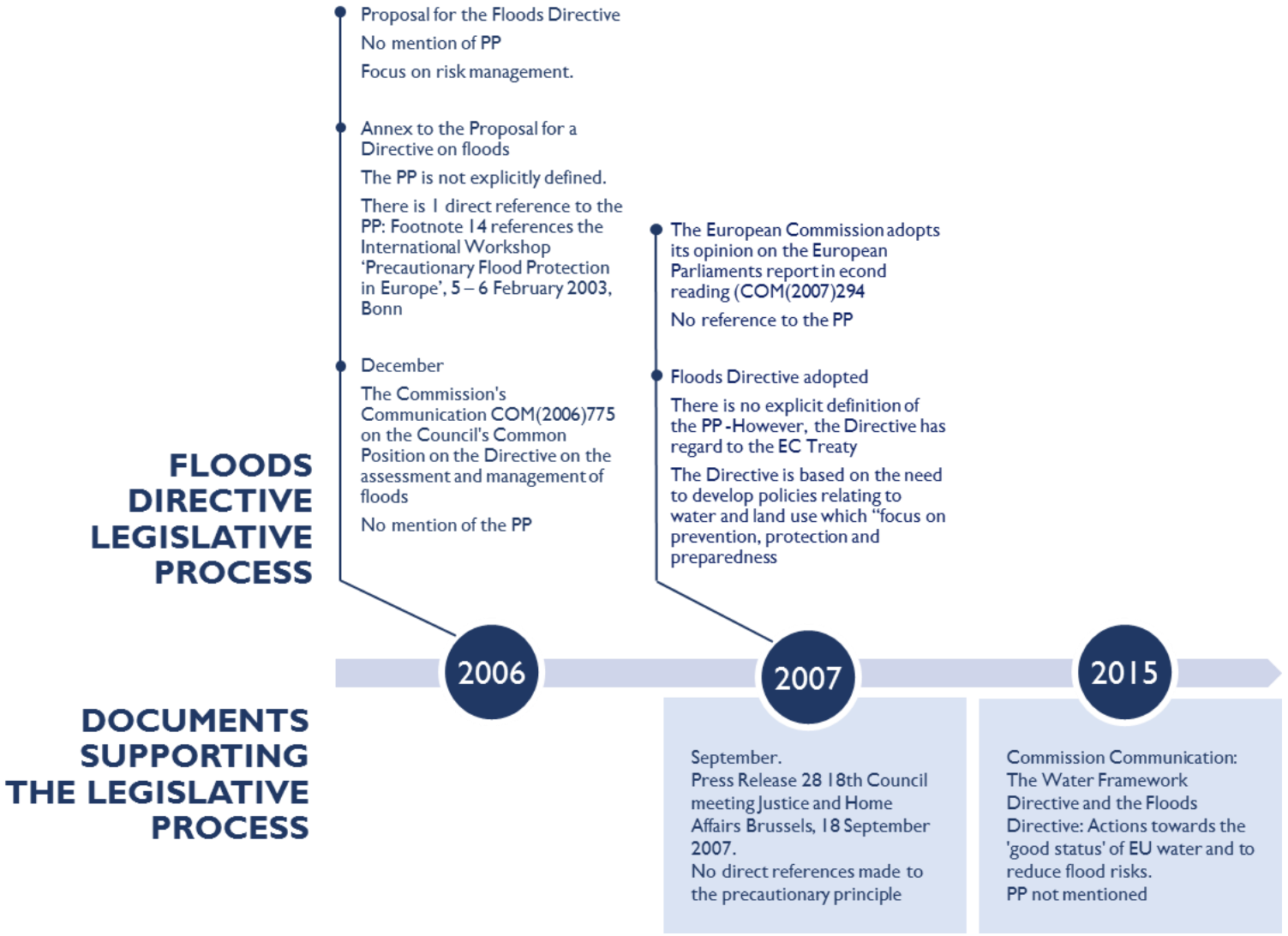


Figure 4 Legislative Process of the Habitats Directive

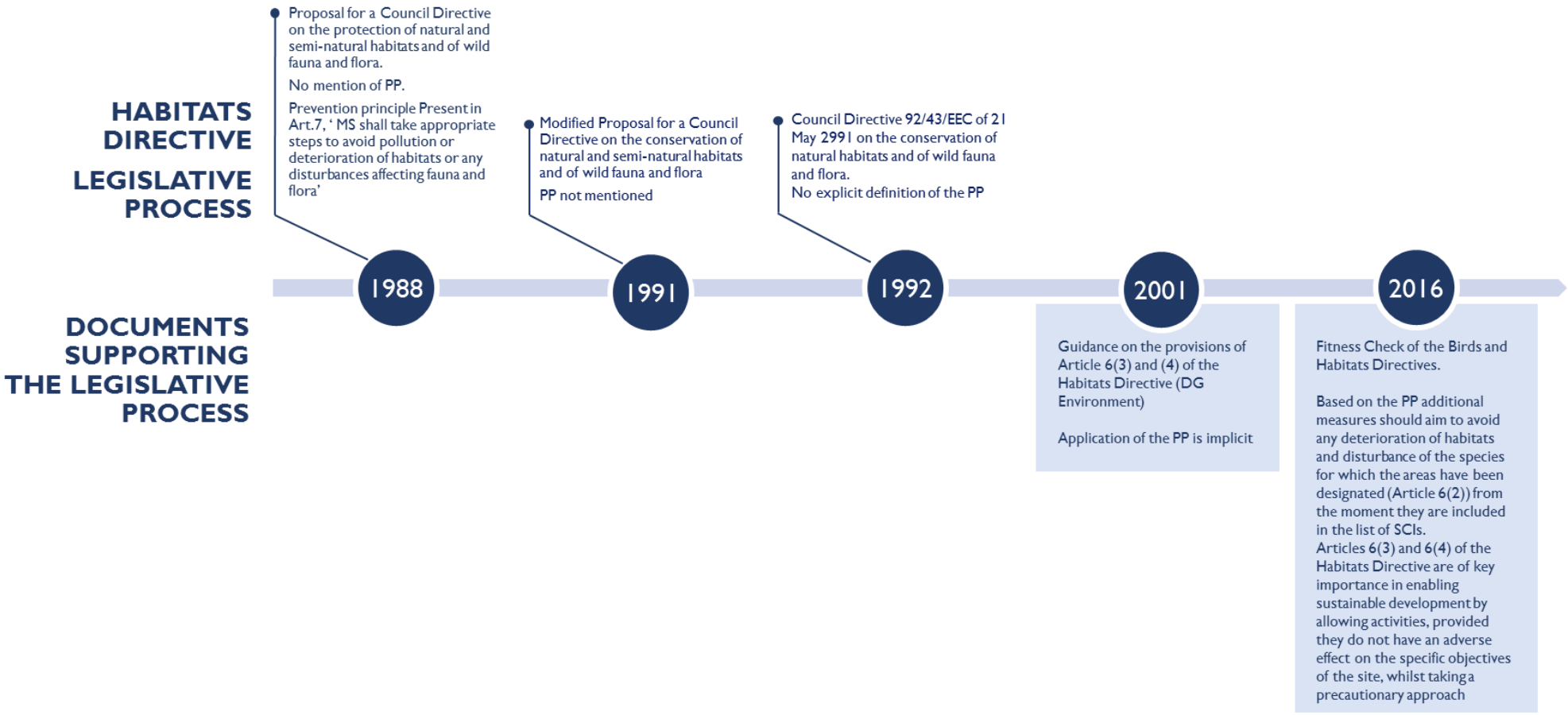


Figure 5 Legislative Process of the REACH Regulation

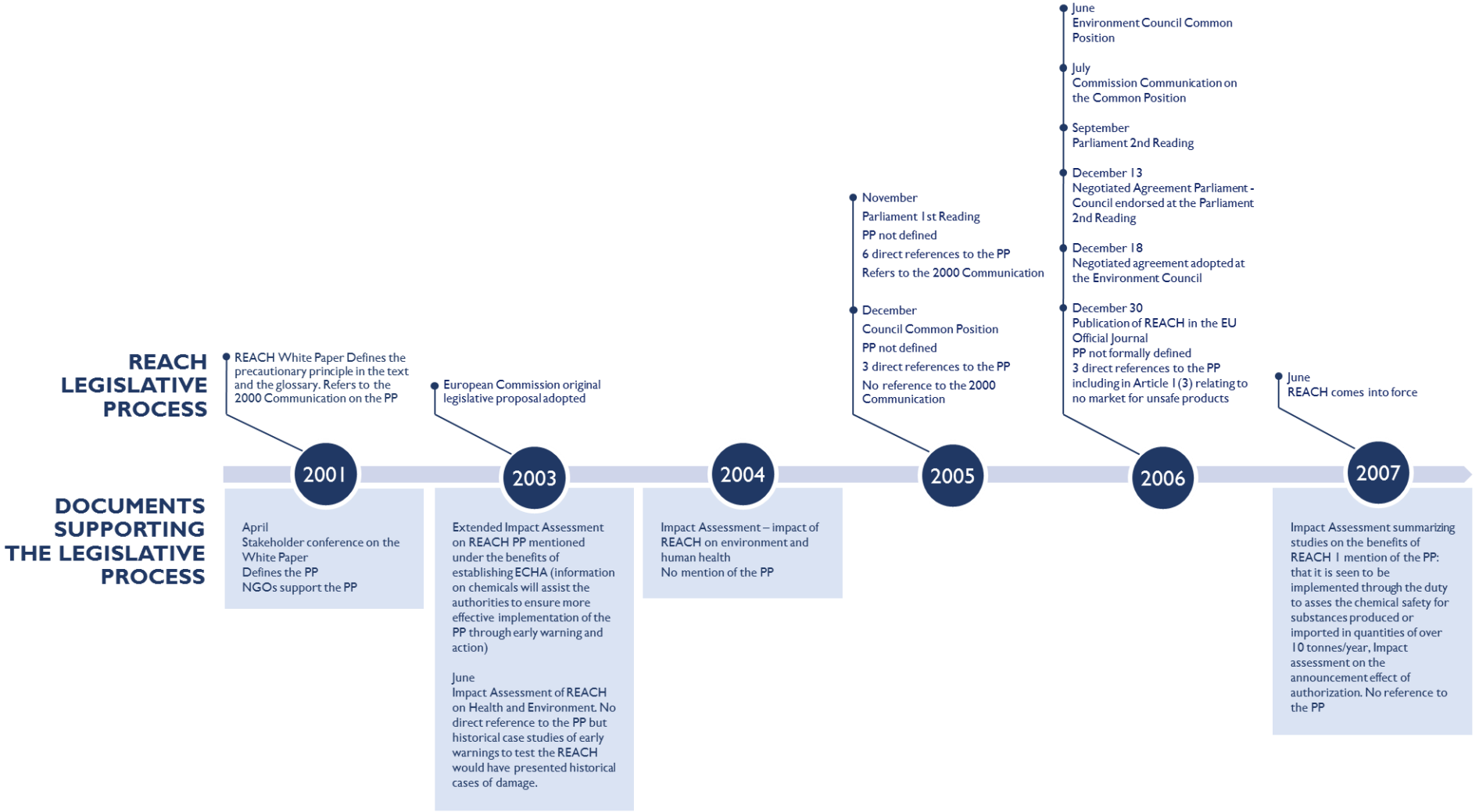


Figure 6 Legislative Process of the MSFD

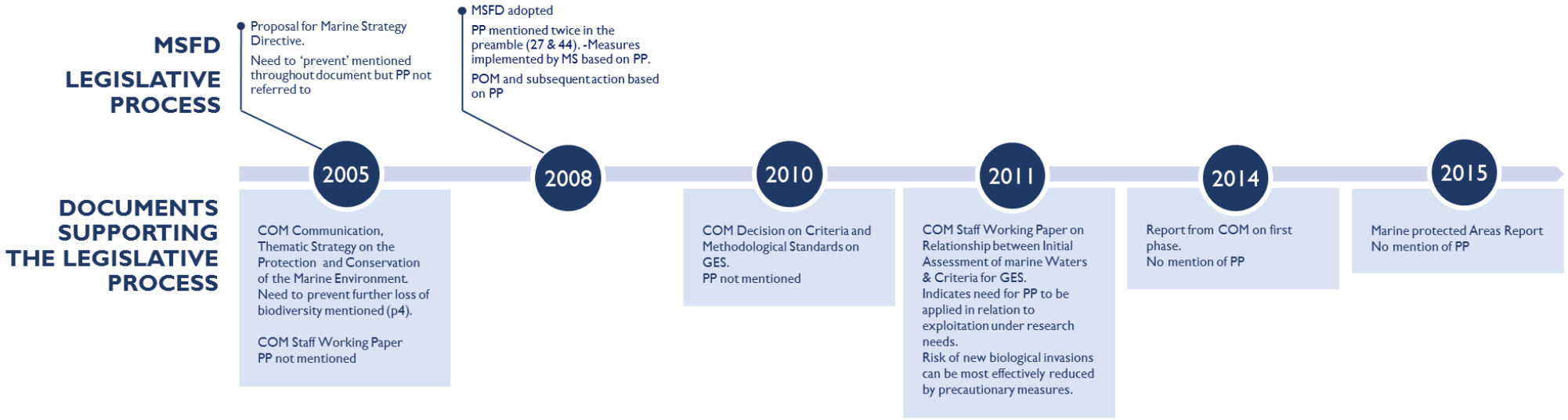


Figure 7 Legislative Process of the EIA Directive

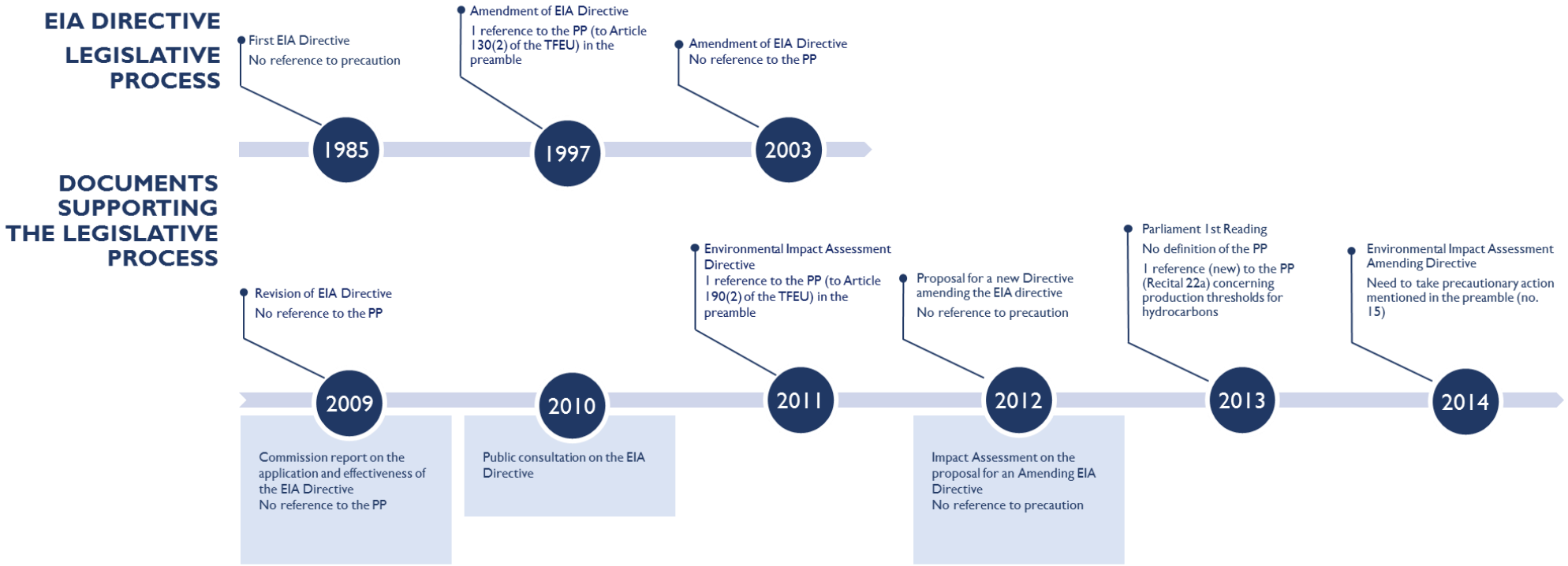


Figure 8 Legislative Process of the Seveso III

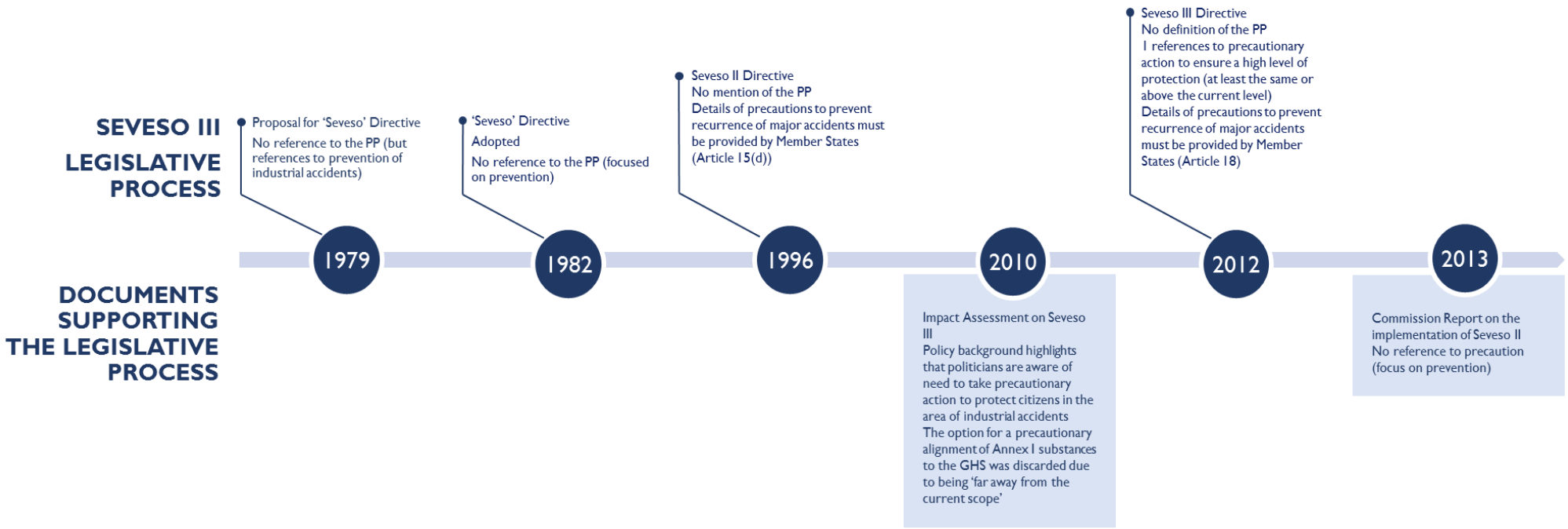
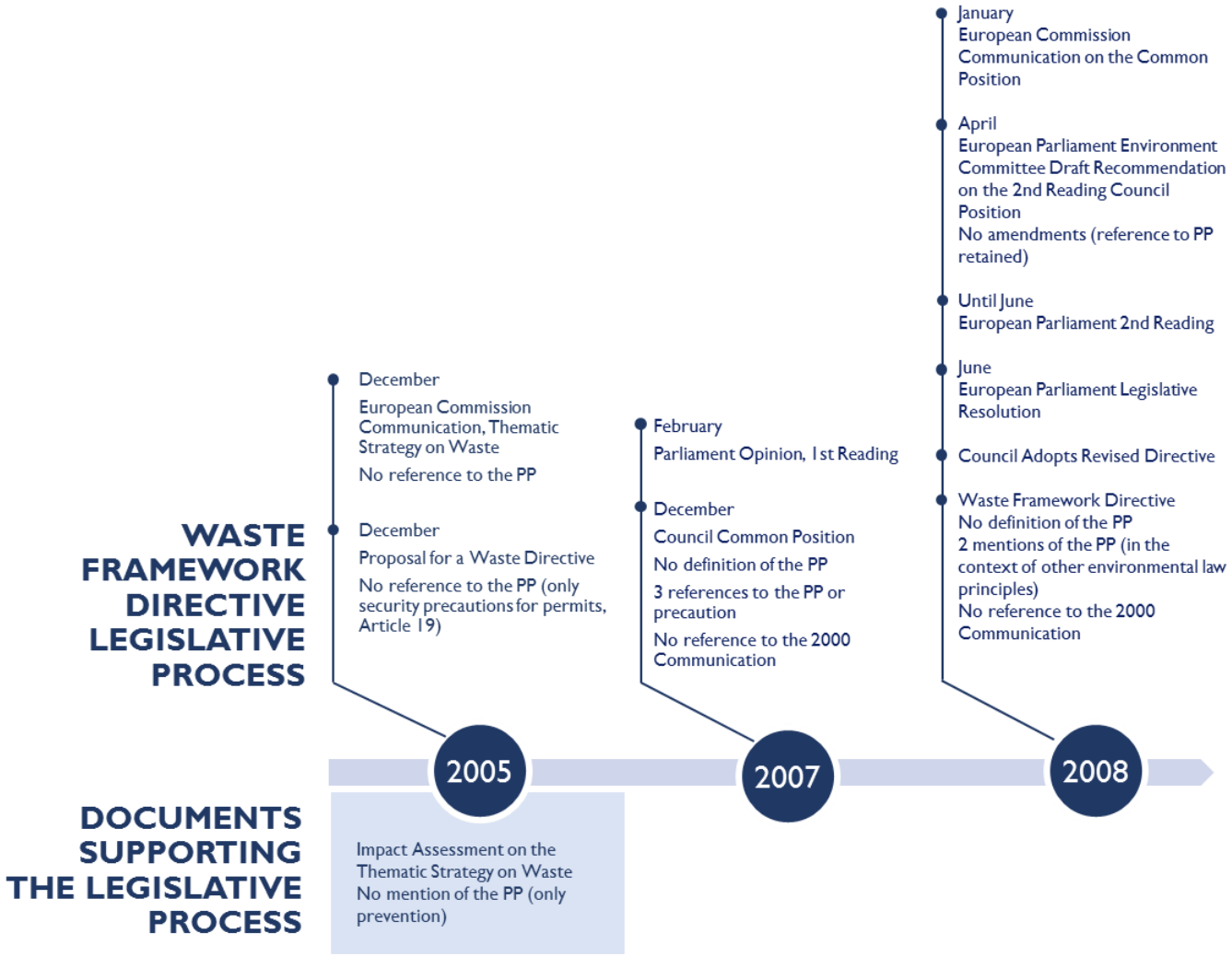


Figure 9 Legislative Process of the Waste Framework Directive



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