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## Introduction

The aim of this book is to discuss the role played by the precautionary principle when deciding on regulatory action in relation to risks posed to modern society, and the effects that such action may have for European and international trade. Primarily, this discussion aims to address the issue of how the European Union (EU) currently makes use of the principle, and what lessons the EU institutions and Member States should draw from the use of precautionary considerations in a number of national and international regulatory regimes.

The last 30 years have brought a new awareness of the hidden costs of industrialisation and the welfare state. Suddenly, societies experience the realisation of risks which they did not know that they had created. Such risks include the highly publicised and potentially catastrophic, such as climate change, but also more hidden risks, such as the long-term effects of exposure to chemicals and low-frequency radiation from, for example, mobile phones and electricity networks. Other potential risks are possibly created through the development of new technologies such as gene modification. At the same time, the emergence of highly integrated regional and global markets for trade in goods and services has limited the possibilities for individual states to successfully enact national risk regulatory strategies.

What connects many of the risks that societies are faced with today is the uncertainty which surrounds them. In many cases, the link between an activity and a risk has not been scientifically established. Furthermore, the extent of a risk may be difficult or impossible to ascertain. So far, there has been deep disagreement on how to approach uncertain risks in different practical situations.

Among academic commentators, some claim that uncertain risks are a reasonable price to pay for the advances of society as manifested in the increased quality of life for the individual. The advantages of modern society outweigh its inherent risks. Others resort to pessimism and hold that the state of the world at this moment indeed is so dire that radical

measures need to be considered. The German sociologist Ulrich Beck famously wrote in his *World Risk Society*:

I know of no greater security and no deeper source of creativity than a pessimism which cannot be outbid. Where everything is at stake, everything can and must be re-thought and re-examined.<sup>1</sup>

It is out of this awareness that the notion of precaution in relation to the environment and health has sprung.

One instrument for dealing with uncertain environmental and health risks to society is the precautionary principle, which has been developing as a legal concept in national legal systems since the late 1960s. The precautionary principle affords the decision-maker an opportunity to act before risks have materialised, when only the contours of what might be risks are visible. As the awareness of both perceived and real risks has increased over the years, the importance of ‘the precautionary principle’ has also increased. It should, however, be pointed out that, in practice, governmental intervention before the emergence of scientific certainty is far from a modern concept. What is unique about the precautionary principle is that it appears to treat precautionary action in a more conceptual fashion, and, in some cases, it aims to elevate precautionary action to the status of legal principle.

Different states make different judgements as to what constitutes risks, and as a consequence the precautionary principle has been applied differently in different states and regions, as well as in different areas of policy within the same state. At the same time, it has remained a loosely defined concept with unclear borders in regional and international legal systems. This makes the precautionary principle controversial in today’s world of globalised markets, where states no longer are entirely free to pursue their own risk policies.

At EU level, the application of the precautionary principle takes place primarily at two different levels. First, the European institutions apply it when drafting legislation and deciding on the correct implementation of EU rules by the Member States. Second, the EU Member States often seek to make use of the precautionary principle when issuing national policies by using it as a justification in order to obtain derogations from EU rules. Sometimes, it appears to be used as ‘a magic wand’, the invocation of which can justify virtually any policy choice. In order to safeguard the consistent and foreseeable development of EU law, it is necessary to

<sup>1</sup> U. Beck, *World Risk Society* (Blackwell Publishers Ltd, 1999), p. 88.

investigate more closely what is required by the entity wishing to rely on this principle.

Furthermore, the precautionary principle plays a role in international trade law. In a number of cases, World Trade Organisation (WTO) Panels and the Appellate Body have elaborated on its role under the WTO Agreements.

When considering international trade issues, it is often argued that the EU is a strong proponent of precautionary action and that the USA is an opponent of it. The EU suggests that it employs one specific precautionary principle, the application of which is guided by certain defined requirements.<sup>2</sup> The USA prefers to use the term precautionary approach, rather than principle, in order to signify that it affords it less legal weight.

When looking at the policies of individual Member States of the EU as well as the national policies of the USA, the picture becomes somewhat more complicated. In certain areas, it appears that there is great disagreement among the Member States of the EU as to what actually constitutes precaution.<sup>3</sup> Some Member States, such as Sweden, take pride in being 'precautionary' in general, with a firm, legally binding precautionary principle in effect in national legislation. It is investigated below whether such a 'strong' reliance on the precautionary principle is, indeed, equally applicable in all policy areas and what the basis for such an approach is. Conversely, Member States such as the United Kingdom that do not have a tradition of precautionary action may apply a stricter precautionary approach in certain defined areas than in others. Here, too, the issue of how and when the precautionary principle actually comes into play arises.

When considering the differences in the application of the precautionary principle, the question arises as to whether it is possible to talk about one single precautionary principle. This book aims to investigate if it is indeed the case that the 'precautionary principle' is defined differently depending upon the area in which it is being applied, and by whom. In this context, how the precautionary principle has been applied in EU and WTO law and in the national legal orders of Sweden, the UK and the USA is discussed and analysed.

<sup>2</sup> Communication from the Commission of 2 February 2002 on the Precautionary Principle, COM (2001) 1.

<sup>3</sup> See, for example, J. Scott and E. Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO', in Ch. Joerges and R. Dehousse (eds.), *Good Governance in Europe's Integrated Market* (Oxford University Press, 2002).

It is investigated whether precautionary considerations are applied differently in relation to comparable risks in different policy areas within the same state, and between different states. Since the refusal to accept one single, all-encompassing precautionary principle does not, in itself, mean that precautionary action is not taken in certain individual cases, this book uses the term ‘precautionary approach’ to indicate a vague and open application of precaution, which is not necessarily based on a conceptual precautionary principle. The term ‘precautionary principle’ is used to describe an institutionalised and systematic use of precaution in one or more policy areas.

This book is based on the presumption that all responsible governments will act out of precaution in certain situations, regardless of whether they are subscribing to ‘a precautionary principle’ or not. Below, the issue of whether it is possible to identify a common precautionary principle, or common principles for precautionary action, which are applicable in all policy areas and in relation to different states, is analysed.

The aim of this analysis is to examine if a common foundation for treating the precautionary principle as a legal principle exists. Whether such a common conceptual framework is, indeed, necessary, or whether it can be concluded that the application of precautionary measures is better left up to the discretion of the individual states in each case, is also discussed. The primary target for this discussion is the EU, and of particular importance in this regard is the interrelationship between the EU institutions and the Member States.

The first part of this book deals with the reasons for the increased recourse to precaution in environmental and health protection, as well as the legal status of the precautionary principle in European and international trade law. The second part is devoted to the study of two different policy areas in three different countries.

The research builds on the excellent work already carried by several authors with regard to the current legal status of the precautionary principle in international, as well as European, law.<sup>4</sup> This book aims to take the

<sup>4</sup> See, for example, A. Trouwborst, ‘Prevention, Precaution, Logic and Law: The Relationship Between the Precautionary Principle and the Preventative Principle in International Law and Associated Questions’, *Erasmus Law Review*, 2:2 (2009), 105; M. Fitzmaurice, *Contemporary Issues in International Environmental Law*, (Edward Elgar Publishing, 2009), pp. 1–67; N. de Sadeleer, *Implementing the Precautionary Principle: Approaches from the Nordic Countries, the EU and the USA* (Earthscan, 2007); J. Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*, (Oxford University Press, 2007); E. Fisher et al., *Implementing the Precautionary Principle*, (Edward Elgar Publishing, 2006); A. Trouwborst, ‘The Precautionary Principle in General International Law: Combating

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matter a step further and look beyond the inclusion of the precautionary principle as a concept in legal acts and policy documents at international and European levels. Instead, the primary focus is on the practical application of the concept. Of importance in this regard is the study of the relevant case law in the legal systems investigated. Furthermore, the focus is on the concrete application of the principle by a number of states in their national policies. These case studies aim to discuss whether there are differences between how precautionary considerations are applied in comparable situations in certain areas and in certain countries.

The areas investigated are chemicals (pesticides) and mobile phone systems (base stations). These areas have been chosen because they are examples of areas surrounded by varying, but comparable, amounts of uncertainty as to the risks associated with them. At the same time, they are areas in which different states have chosen to apply different approaches to these risks. The areas surveyed include risks to human health posed by food and technology, and risks to the environment. They share the basic trait that they are, to varying extents, involuntary risks: risks that are difficult or impossible to avoid even through vigilant behaviour on the part of the subjects to the risk.

Throughout this book the precautionary principle is treated by breaking it down to a number of constituent parts. This means that in every legal system and in each case study the same topics are evaluated and compared. This includes, in all cases, an assessment of the definition and status of the precautionary principle in the relevant legal system; the type

the Babylonian Confusion', *RECIEL*, 16:2 (2007), 185; M. B. A. van Asselt and E. Vos, 'The Precautionary Principle and the Uncertainty Paradox', *Journal of Risk Research*, 9, (2006), 4; P. van den Bossche and D. Prevost, 'The Agreement on the Application of Sanitary and Phyto-sanitary Measures', in P. McRory, A. Appleton and M. Plummer (eds.), *The World Trade Organisation: Legal, Economic and Political Analysis*, (Springer, 2005), pp. 231–70; K.-H. Ladeur, 'The 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', *CMLR*, 40:6 (2003), 1455; Scott and Vos, 'The Juridification of Uncertainty', 253–86; J. Cameron, 'The Precautionary Principle in International Law', in T. O'Riordan, J. Cameron and A. Jordan (eds.), *Re-interpreting the Precautionary Principle*, (Cameron May, 2001); W. Douma, 'The Precautionary Principle; Its Application in International, European and Dutch Law', Proefschrift Rijksuniversiteit Groningen, 6 January 2003; D. Grimeaud, Hoofdstuk II, 'The Precautionary Principle in International Environmental and Trade Law', in M. Faure and E. Vos (eds.), *Juridische afpakening van het voorzorgbeginsel: mogelijkheden en grenzen, Achtergrondstudie voor de Nederlandse Gezondheidsraad*, No. A03/03 2003. A. Trouwborst: *Evolution and Status of the Precautionary Principle in International Law*, (Aspen Publishers, 2002); D. Freestone and E. Hey (eds.), *The Precautionary Principle in International Law: The Challenge of Implementation*, (Kluwer Law International, 1996).

and scope of judicial review applied by courts; if a separation of risk assessment and risk management is upheld; an analysis of the burden and level of proof in place for the issuing of precautionary measures; if costs and benefits are considered; if risks are targeted rationally; and if trade-offs are considered. All of the above issues necessarily come into play when issuing precautionary measures, whether they are explicitly considered in a decision or not.

The first question to be answered in this book is if it is possible to find an objectively justifiable precautionary principle which is generally agreed upon by the states and organisations investigated below. If the answer to this question is yes, then this principle will be outlined and analysed. If the answer to this question is no, then the discrepancies will be identified and considered. Furthermore, the issue of whether it is necessary or even desirable, to establish such a system is also considered. Finally, the future role to be played by the precautionary principle is discussed. The main focus of this discussion is the EU and how the Member States and the EU institutions can, and should, make use of the precautionary principle in order to safeguard an efficient and reliable risk reduction strategy.

Pesticides regulation is, to a large extent, regulated at EU level. Below it is discussed that, regardless of this, EU Member States might, in some cases, attempt to use the precautionary principle in order to apply their own risk levels. Two Member States of the EU, Sweden and the United Kingdom, have been especially chosen in order to illustrate the different approaches assumed by Member States to the precautionary principle within the EU. These two states are then compared with the policies adopted by the United States in the same areas.

The reason for choosing to compare Sweden and the UK is that they traditionally represent different European approaches to precaution when it comes to the environment and health protection. Sweden has a long tradition of far-reaching precautionary thinking when it comes to, for example, chemicals, pollution and public health protection.<sup>5</sup> The UK, on the other hand has traditionally applied a less stringent approach. However, recent ‘food scares’, for example, the BSE (bovine spongiform encephalopathy) crisis, has put a new emphasis on environmental and health concerns.

<sup>5</sup> See, for example, the preparatory works to the original Swedish Chemicals Code of 1973 in Proposition 1973:17, pp. 96 *et seq.*

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The United States, on the other hand, has a tradition of precaution when it comes to environmental and health protection in domestic policies,<sup>6</sup> but is today perceived – at least by the EU – as not accepting the precautionary principle within the international arena. Here, the current use of precautionary considerations by the USA is investigated and compared with the approach assumed by Sweden, the UK and the EU.

The discussion on how and when to use precautionary measures is likely to continue for the foreseeable future, especially as the public becomes increasingly aware of the risks to health and the environment. This book aims to contribute to this debate by providing a detailed look at the precautionary principle in a number of areas and states in order to provide some interesting input for the further development of the precautionary principle in the EU and its Member States.

<sup>6</sup> See, for example, D. Vogel, 'Ships Passing in the Night: GMOs and the Politics of Risk Regulation in Europe and the United States', Working Paper No 2001/16, Robert Schuman Centre for Advanced Studies, European University Institute, 2001.

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## Risk and uncertainty: basic concepts and tools for the application of the precautionary principle

### 2.1 Introduction

When Rachel Carson published her hugely influential book *Silent Spring* in 1962, she laid the foundation upon which the then recently conceived environmental movement would rest.<sup>1</sup> With a language which is as dystopian as it is strangely poetic, Carson framed a rhetoric that would come to be much used by the environmental movement. Her fears and predictions with regard to chemicals, in particular dichloro-diphenyl-trichloroethane (DDT), still linger in the public minds of Europeans and Americans alike. Reports published over time maintaining that some of these fears are exaggerated have had nowhere near the same resonance as her original work.

*Silent Spring* was followed by other works in the 1970s which warned of the environmental consequences of industrialisation: *Limits to Growth* was published in 1972 and made the spectacular, and much publicised, claims that, by 1990, the world would have run out of gold, silver, mercury and zinc.<sup>2</sup> In *The End of Affluence*, published in 1974, Paul and Anne Ehrlich predicted the dangers following global cooling and the near end of fish in the seven seas.<sup>3</sup> Fortunately, none of these particular claims have materialised. However, in recent years publications have also emerged with the aim of highlighting the risks to human health and the environment that have actually materialised as a consequence of modernisation.<sup>4</sup>

As a response to the above literature, some authors have also emphasised the lack of development and innovation that would have resulted

<sup>1</sup> R. Carson, *Silent Spring* (Houghton Mifflin, 1962).

<sup>2</sup> D. Meadows *et al.*, *The Limits to Growth: A Report for the Club of Rome's Project on the Predicament of Mankind* (Universe Books, 1974).

<sup>3</sup> P. R. Ehrlich and A. Ehrlich, *The End of Affluence: A Blueprint for your Future* (Ballantine Books, 1974).

<sup>4</sup> The European Environmental Protection Agency, 'Late Lessons From Early Warnings: The Precautionary Principle 1896–2000', Environmental Issue Report No. 22, 2002. Available at: [http://reports.eea.europa.eu/environmental\\_issue\\_report\\_2001\\_22/en](http://reports.eea.europa.eu/environmental_issue_report_2001_22/en) (accessed 1 March 2010).



had a certain amount of risks not been taken.<sup>5</sup> Certainly, there is no lack of either nightmare scenarios or sunshine stories in the history of risk regulation.

At the beginning of the present century, the precautionary principle has emerged in an increasingly risk-averse Europe as a 'miracle cure' of sorts to the problems of dealing with risks. In allowing for regulation in spite of scientific controversy and the lack of clear scientific evidence, it seems to provide the regulator with the ultimate tool to address any risk deemed necessary. Until recently, the strict interpretation of the precautionary principle has been criticised mainly by American authors.<sup>6</sup> In Europe, this critical discourse has been elaborated on to a more limited extent.<sup>7</sup>

This chapter aims to provide the theoretical background to the fundamental concepts of risk regulation in general and the precautionary principle in particular. Critical to this discussion is the definition of risk and risk perception, scientific uncertainty, how risks are analysed and how the instruments for weighing the costs and benefits of regulation are set up, as well as risk trade-off analysis. Furthermore, some attempts at conceptualising the precautionary principle are briefly summarised.

## 2.2 Fundamental concepts

### 2.2.1 Defining risk

Throughout the ages, mankind has been subjected to risks, by chance and as a means of surviving, as well as by choice. No doubt a fundamental part of human existence has been preoccupied with considering which risks

<sup>5</sup> See, for example, A. Wildawsky, 'Trial and Error versus Trial Without Error', in J. Morris, *Rethinking Risk and the Precautionary Principle* (Butterworth-Heinemann, 2000), pp. 22–46.

<sup>6</sup> See, for example, J. Morris, *Rethinking Risk and the Precautionary Principle* (Butterworth-Heinemann, 2000); C. Sunstein, *Risk and Reason: Safety, Law and the Environment* (Cambridge University Press, 2004); C. Sunstein, *The Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press, 2005); G. E. Marchant and K. L. Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Union Courts* (American Enterprise Institute Press, 2004).

<sup>7</sup> See, for example, F. Furedi, 'Precautionary Culture and the Rise of Possibilistic Risk Assessment', *Erasmus Law Review*, 2:2, (2009), 198; J. C. Hanekamp, 'Neither Acceptable nor Certain – Cold War Antics for 21st Century Precautionary Culture', *Erasmus Law Review*, 2:2 (2009), 221; Ladeur, 'The Introduction of the Precautionary Principle into EU Law', 1455; and L. Bergkamp, 'Understanding the Precautionary Principle (Parts I and II)', *Env. Liability*, 10 (2002), 18–30 and 67–82.

to take and which to avoid, long before this was known as ‘risk regulation’. Despite this, the ‘mastery of risk’, the intention to control or apply one’s behaviour in accordance with risks, is considered a uniquely modern concept.<sup>8</sup> The rational science of risk, as we now know it, originally developed as a mathematical puzzle concerned with optimising gambling results.<sup>9</sup> Later it matured within the framework of economics and finance.<sup>10</sup> During the second half of the twentieth century the influence of risk as a concept had spread to almost all areas of society and life. In fact, at present the ‘mastering’ of risk has become so fundamental for Western societies that influential commentators argue that the age of modernisation has given way to a ‘risk society’, in which the assessment and management of risks are its overriding concerns.<sup>11</sup>

Generally, the term ‘risk’ is understood to express something about the likelihood that a hazard will occur.<sup>12</sup> Definitions usually focus on the possibility of humans altering the chain of events leading to the realisation of a hazard. Thus, the relationship between the actions and the consequences is considered from a non-fatalistic viewpoint.<sup>13</sup> Building on previous literature, Jaeger *et al.* have defined the term risk as:

A situation or event in which something of human value (including humans themselves) has been put at stake and where the outcome is uncertain.<sup>14</sup>

Stirling has formulated it in the following fashion:

[Risk is] a situation under which it is possible to define all possible outcomes and confidently assign a probability to reflect the likelihoods of each outcome.<sup>15</sup>

<sup>8</sup> P. L. Bernstein, *Against the Gods: The Remarkable Story of Risk* (John Wiley & Sons Inc., 1996), p. 11.

<sup>9</sup> D. A. Moss, *When All Else Fails: Government as the Ultimate Risk Manager* (Harvard University Press, 2002), p. 22 *et seq.*

<sup>10</sup> Bernstein, *Against the Gods*, p. 97 *et seq.*

<sup>11</sup> See, for example, U. Beck, *Risk Society: Towards a New Modernity* (Sage Publishers, 1992), and Beck, *World Risk Society*.

<sup>12</sup> See, for example, The Royal Society, *Risk: Analysis, Perception, Management*, The Royal Society, 1992, p. 2; J. Wiener, ‘Precaution in a Multi-Risk World’, Duke Law School Public Law and Legal Theory Working Paper No. 23, December 2001, p. 3.

<sup>13</sup> B. Rohrman and O. Renn, ‘Risk Perception Research – An Introduction’, in O. Renn and B. Rohrman, *Cross-cultural Risk Perception: A Survey of Empirical Studies* (Kluwer, 2000), p. 14.

<sup>14</sup> C. C. Jaeger, O. Renn, E. A. Rosa and T. Webler, *Risk, Uncertainty and Rational Action* (Earthscan, 2001), p. 17.

<sup>15</sup> A. Stirling, ‘On Science and Precaution in the Management of Technological Risk’. An Esto Project, Prepared for the European Commission – JRC Institute Prospective Technological Studies Seville, May 1999 (available from author), p. 40.