





## **Arbitrary and Capricious**



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## **The Precautionary Principle in the European Union Courts**

Gary E. Marchant and  
Kenneth L. Mossman

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# Foreword

One of the definitions of the word shibboleth is “a catchword or formula adopted by a party or sect, by which their adherents or followers may be discerned, or those not their followers may be excluded”.

The enthusiasm with which many have adopted the poorly defined – indeed nebulous – Precautionary Principle suggests that it has acquired shibboleth status. It has no agreed definition, there is dispute about whether it should be applied with one eye on proportionality of response or not, there is no agreement on what level of risk is acceptable in any particular situation – no-one has yet suggested that zero risk is attainable for any aspect of human activity – and its use has varied in different jurisdictions in a way which greatly impedes regulation and trade.

The authors explore the background of the development of adherence to the Principle, consider its history in European courts and describe a number of case studies. The legal background of one of the authors has been directed toward the type of study that enables informed criticism; the other has worked in a field where risk assessment and management are critical. This text will be of value to those who wish to be excluded.

*Professor Sir Colin Berry*  
London, UK  
September 2005



# 1 Introduction

The precautionary principle may well be the most innovative, pervasive, and significant new concept in environmental policy over the past quarter century. It may also be the most reckless, arbitrary, and ill-advised. The precautionary principle is based on the common-sense notion that it is better to be safe than sorry in regulating health and environmental risks under conditions of inherent uncertainty. Some precaution is prudent and necessary in risk management, given that complete scientific certainty is unattainable for virtually any risk.<sup>1</sup>

The precautionary principle goes beyond the usual application of precaution that traditionally underlies all health, safety, and environmental regulation to give a more formal and prominent role to precaution in regulatory decision making. While initially characterized as a general policy or guideline, the precautionary principle has evolved into a binding legal rule in every jurisdiction in which it has been adopted.<sup>2</sup>

The precautionary principle has been criticized on a number of grounds including its potential for overregulation of insignificant or even nonexistent risks, its disregard for scientific evidence, and its failure to adequately consider the economic costs and risk-risk trade-offs inherent in risk regulation.<sup>3</sup> Perhaps the most common criticism of the precautionary principle, however, is that it is inherently ambiguous and arbitrary. There is no consensus definition or formulation of the precautionary principle or agreed-on guidelines or criteria for its application.

There is also ambiguity within and between different formulations of the precautionary principle as to when it applies and what it requires when it does apply. For example, is the principle triggered by the magnitude of a risk, the uncertainty associated with that risk, or some combination of both magnitude and uncertainty? How much of each is necessary to trigger the principle? If the principle applies only to “serious” or “irreversible” risks, how are such risks

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defined? If it applies to any risk, how can any product ever be approved? What types of “precautionary measures” should be taken when a sufficient threat exists? If the precautionary principle requires postponing development of a product until sufficient safety data on that product are available, what type of evidence is required before the product is permitted to move forward? What factors can be considered in determining whether the product should or should not go forward? For example, can the economic benefits of the product be considered? Are the health and safety benefits of products weighed against their risks of harm?

There is no consensus on the answers to any of these fundamental questions, nor are they answered by any of the many different formulations of the precautionary principle. Critics are justifiably concerned that the undefined and open-ended nature of the precautionary “principle” would give regulators almost unlimited discretion to impose restrictions on products and technologies that could otherwise not be justified, whether it be for innocent or improper (e.g. protectionist) motives.

This book examines empirically the prediction that the precautionary principle will be applied in an arbitrary and unprincipled manner. The precautionary principle *qua nomine* has been applied in various jurisdictions around the world for several years, but the most emphatic supporter and adopter of the precautionary principle is unquestionably the European Union (EU). In applying the precautionary principle in its regulatory decisions, the EU regulatory authorities generally fail to define or articulate the requirements of the principle. Accordingly, the most informative and revealing insights into the application of the precautionary principle are provided in the courts of the EU, where the basis of regulatory decisions are challenged and must be justified. The EU courts have now had to grapple with the precautionary principle for close to a decade, providing a unique data set of reported decisions for meaningful empirical analysis of how the precautionary principle is being applied and construed.

Chapter 2 provides additional background on the precautionary

principle, explaining its genesis, intent, and shortcomings. The adoption and application of the precautionary principle in the EU are then briefly summarized in chapter 3. Chapter 4 describes the courts of the EU and analyzes how they have treated the precautionary principle in their reported decisions. Chapter 5 provides three legal case studies of EU cases in which the precautionary principle has figured prominently. The conclusions of this empirical analysis are briefly set forth in chapter 6.

Empirical analysis of the application of the precautionary principle should enable a more-informed view of the practicality and wisdom of the principle. As we shall see, the precautionary principle, as feared by many, indeed has been applied in an inconsistent and ad-hoc manner, producing a growing tangle of inconsistent and irreconcilable decisions. Each time the principle is used to prohibit or restrict a product with little or no evidence of significant risk, a precedent is set that can be used to likewise ban any other product in the future. And each time decision makers allow products with some risk, an unavoidable result in today's world, the arbitrariness and political manipulability of the precautionary principle become more obvious. The real-life experience that has accumulated to date in applying the precautionary principle in the EU courts therefore suggests that the principle in its current ambiguous form is indeed imprudent and untenable.

## 2 The Precautionary Principle: Background

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“There is always an easy solution to every human problem – neat, plausible, and wrong.”

H. L. Mencken

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This chapter summarizes the justification, adoption, and evolving nature of the precautionary principle, as well as the objections levied against the principle. Precaution is not a new concept for health and environment regulatory decision making. Management of risks to public health and the environment has always had to grapple with making decisions under conditions of uncertainty.<sup>1</sup> Risk managers have often accounted for this uncertainty by applying, either explicitly or implicitly, some degree of precaution.<sup>2</sup> For example, in setting national ambient air quality standards, the U.S. Environmental Protection Agency (EPA) incorporates an additional margin of safety to account for health effects that science has not yet discovered.<sup>3</sup> Regulatory agencies conducting health risk assessments usually also apply “conservative” (i.e., plausible upper-bound) assumptions to err on the side of safety in calculating uncertain risks.<sup>4</sup> Some commentators refer to this implicit application of precaution within the traditional risk management framework in U.S. and other regulatory systems as the “precautionary approach” in contrast to the more explicit and stronger “precautionary principle.”<sup>5</sup>

In recent years, a new concept, known as the *precautionary principle*, has been proposed to give greater and more explicit emphasis to precaution in regulating health and environmental risks. Proponents of the precautionary principle believe that the current regu-



latory system is systematically underprotective and the precautionary principle is necessary to better protect against otherwise underestimated or overlooked risks.<sup>6</sup> The precautionary principle is often summarized by the phrase *'better safe than sorry'*. It requires forgoing, postponing, or otherwise limiting a product or activity until uncertainty about its potential risks has been resolved in favor of safety. As demonstrated next, while the precautionary principle has proliferated across the planet in the past decade or so, it remains largely undefined and unconstrained by any consistent decision-making criteria.

### **The Extraordinary Rise and Spread of the Precautionary Principle**

In recent years, the precautionary principle has been incorporated into a growing number of international environmental agreements and national legislative enactments and regulatory programs. The rapid proliferation of the precautionary principle is due in large part to the rhetorical appeal of the principle.<sup>7</sup> After all, we all take precautions in our daily lives against the risks inherent in life.<sup>8</sup> Accordingly, once the precautionary principle has been proposed for adoption, government lawmakers, regulators, and negotiators have a difficult time resisting its adoption.

The precautionary principle originated in German domestic law in the 1970s and 1980s. It was subsequently incorporated into a number of regional environmental agreements in Europe. Over the past two decades, it has been incorporated into approximately twenty international environmental treaties and agreements.<sup>9</sup> Perhaps most notably, the 1992 United Nations Rio Declaration on Environment and Development incorporates one version of the precautionary principle, stating, "Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."<sup>10</sup> Slightly different formulations of the precautionary principle have also been incorporated into other

recent international environmental agreements, including the United Nations Framework Convention on Climate Change, the Convention on Biological Diversity, the Montreal Protocol on Substances That Deplete the Ozone Layer, the Cartagena Protocol on Biosafety, and the Stockholm Convention on Persistent Organic Pollutants (POPs). Indeed, it may well be impossible as a pragmatic matter to negotiate an international environmental agreement in today's political climate without including the precautionary principle in some form.

Europe has been at the forefront of adopting the precautionary principle, and the European Union/European Communities formally committed to implementing environmental policy in conformity with the precautionary principle in the 1992 Maastricht amendments to the EU treaty. Individual European nations, most notably Germany, France, and the Scandinavian nations, are implementing the precautionary principle in their national regulatory programs, as are various non-European nations, such as Australia, Japan, India, and New Zealand. The precautionary principle has also begun to infiltrate North America in recent years. In 1999, Canada incorporated the precautionary principle in its revised Canadian Environmental Protection Act. In the United States, various public interest organizations and regulatory agencies have expressed growing interest in the precautionary principle in the last few years. In 2003, San Francisco became the first U.S. city to formally adopt the precautionary principle as a binding requirement for all its environmental and health decisions.<sup>11</sup>

### **Evolution of the Precautionary Principle**

Coincident with its geographical proliferation, the legal significance of the precautionary principle has also been evolving. From the beginning, there have been confusion and disagreement about whether the precautionary principle should be viewed as a statement of general philosophy, a policy prescription, or a legal decision rule. Some proponents argue that the precautionary principle is not

an “algorithm” dictating particular decisions but rather more akin to the general “legal principle” in criminal law that a defendant is innocent until proven guilty beyond reasonable doubt.<sup>12</sup> Others claim that the precautionary principle reflects simply a “broad approach”<sup>13</sup> or a “mere policy guidance”<sup>14</sup> rather than providing a specific decision rule.<sup>15</sup> For example, one proponent wrote that “we should remember that the precautionary principle is only a principle. If viewed as a rule or a standard, it is hopelessly vague, doing nothing to define the policies that should flow from it.”<sup>16</sup> Other proponents of the precautionary principle argue, however, that it will achieve its purpose only if it is applied as a legally binding rule.<sup>17</sup>

Notwithstanding these conflicting views of the status of the precautionary principle, in every jurisdiction in which it has been adopted to date, the precautionary principle has evolved from policy guidance to a binding legal rule.<sup>18</sup> For example, in the Cartagena Protocol on Biosafety, finalized in January 2000, the precautionary principle, for the first time, was inserted as an operational, binding requirement of an international environmental agreement rather than as a general objective in the preamble of a treaty. Shortly thereafter, in the Stockholm Convention on Persistent Organic Pollutants, concluded in December 2000, the precautionary principle was incorporated into both the treaty preamble and its operational provisions, where it has legal effect on decision making under the treaty. Some international legal theorists argue that the precautionary principle has “crystallized” into a binding norm of customary international law as a result of its frequent inclusion in international environmental agreements and national regulatory decisions.<sup>19</sup> Indeed, the European Commission asserts that the precautionary principle is a “full-fledged and general principle of international law.”<sup>20</sup> Moreover, courts in several nations have begun applying the precautionary principle as a legal rule that directs or at least influences the outcome of environmental disputes.<sup>21</sup>

The precautionary principle has thus morphed from soft law into hard law.<sup>22</sup> A few courts have expressed reservations about applying the vague precautionary principle as a rule of law. In the words of

one Australian court, for example, “The precautionary principle, while it may be framed appropriately for the purpose of a political aspiration, its implementation as a legal standard could have the potential to create interminable forensic argument. Taken literally in practice it might prove to be unworkable.”<sup>23</sup> Such cautionary reservations, however, have been trampled underfoot by the steady pressure to exploit fully the precautionary principle once it is “on the books,” leading to an apparently inevitable metamorphosis from general policy to legal rule.

### **The Rationale behind the Precautionary Principle**

Precaution has always played a central role in regulating health and environmental risks. Given that every risk involves some uncertainties, any decision to reduce an uncertain risk necessarily involves some degree of precaution. Health, safety, and environmental regulators in the United States and elsewhere always applied some degree of precaution, even though it is usually applied implicitly rather than explicitly. The need for some precaution is therefore not controversial. What is controversial is the extent and nature of precaution that should be applied in any particular regulatory context.<sup>24</sup>

The precautionary principle is based on the assumption that “existing environmental regulations and other decisions, particularly those based on risk assessment, have failed to protect adequately human health and the environment.”<sup>25</sup> Therefore, the precautionary principle is premised on the belief that the application of precaution needs not only to be formalized and made explicit, but to be made stronger. To support this position, proponents of the precautionary principle cite a litany of well-known examples of products and technologies with tragic unexpected consequences. The list includes asbestos, chlorofluorocarbons, thalidomide, leaded gasoline, “mad cow” disease, the drug diethylstilbestrol (DES), and methyl-tert-butyl ether (MTBE) in gasoline.<sup>26</sup> Of course, other examples could also be cited where, in

retrospect, perhaps too much precaution was applied to what turned out to be insignificant or nonexistent risks. Examples of excessive precaution include saccharin, silicone breast implants, electromagnetic fields, Bendectin, “ice minus” bacteria, the MMR (measles, mumps, and rubella) vaccine, and the effect of genetically modified Bt corn on the monarch butterfly.<sup>27</sup>

The precautionary principle is directed at trying to avoid repeating tragic mistakes of the past, such as asbestos. It puts the emphasis on prevention, rather than after-the-fact mitigation, of risks.<sup>28</sup> While prevention of harm has always been a central goal of regulatory programs, the precautionary principle calls for renewed emphasis on finding better ways to anticipate and prevent future harm. Because *ex ante* prevention of unreasonable health risks generally is more cost-effective and equitable than attempting to remediate or compensate harms *ex post*, it is in the interest of all affected interests – regulators, regulated parties, nongovernment organizations, and the general public – to anticipate and prevent unreasonable risks.

The precautionary principle can further be credited with emphasizing that risk decisions must be undertaken in the face of irreducible uncertainties.<sup>29</sup> While the precautionary principle is by no means unique in recognizing the inherent uncertainties of risks, it advances the challenge of how to make effective and legitimate environmental decisions under conditions of high uncertainty. Thus, the precautionary principle forthrightly queues the fundamental question of health and environmental regulation: How can we prevent unreasonable risks to human health and the environment *before* they occur, while recognizing the inherent uncertainty in predicting risks?

Of course, it is possible to apply too much precaution. There is always a trade-off between overregulation (false positives) and underregulation (false negatives) in *ex ante* regulation of uncertain risks.<sup>30</sup> The more precaution applied, the more false negatives we avoid but also the more often it turns out that we acted excessively by either regulating nonexistent risks or expending disproportionate resources to reduce small risks (that is, false positives).<sup>31</sup>

Excessive precaution can also have the perverse effect of increasing net risks, due to the risk-risk trade-offs inherent in regulation.<sup>32</sup> A classic example of such trade-offs is the delay in approving life-saving drugs based on potential safety concerns, which in at least some cases may have an overall detrimental impact on public health.

The fundamental question of health and environmental regulation identified in the previous paragraph should therefore be rephrased as follows: How can we prevent unreasonable risks to human health and the environment before they occur, while recognizing the inherent uncertainty in predicting risks and the potentially unduly burdensome economic, social, and health trade-offs of overregulating nonexistent or insignificant risks? In other words, the objective of the precautionary principle should be to seek an optimal balance between false positives and false negatives.<sup>33</sup> As discussed in the next section, this is where the precautionary principle begins to falter.

### **The Inherent Ambiguity of the Precautionary Principle**

“The” precautionary principle is a misnomer.<sup>34</sup> There is no standard or authoritative formulation of the precautionary principle, as it has been adopted or advocated in many different and inconsistent versions. Each formulation of the precautionary principle shares the common prescription that scientific certainty is not required before taking preventive measures. In addition, most versions of the precautionary principle involve some degree of shifting the burden to the proponent of an activity or product to demonstrate the safety of its product. These various definitions of the precautionary principle are often similar in form and substance, yet they contain seemingly minor wording differences with potentially major policy implications.

Swedish philosopher Per Sandin collected nineteen versions of the precautionary principle, finding substantial variation along each of four different dimensions, which he defined as threat, uncer-

tainty, action, and command.<sup>35</sup> For example, different versions of the precautionary principle vary along the threat dimension, which defines the degree of threat necessary to trigger the principle, from “threats of serious or irreversible damage” to “possible risks.”<sup>36</sup> The precautionary principle would obviously apply to a much greater range of products, technologies, and activities under the latter formulation than the former.

Another important difference in the numerous versions of the precautionary principle is whether and how costs are to be considered in making regulatory decisions. Perhaps the most-cited version of the precautionary principle is that included as Principle 15 of the 1992 Rio Declaration on Environment and Development, which provides, “Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”<sup>37</sup> This formulation expressly indicates that costs should be considered to ensure that any precautionary actions are “cost-effective.”

In contrast, the formulation of the precautionary principle favored by many U.S. public-interest proponents, the Wingspread Statement – makes no mention of economic considerations. This version of the precautionary principle states – “When an activity raises threats of harms to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”<sup>38</sup>

The Commission has offered yet a third variation with respect to consideration of costs under the precautionary principle. In its communication explaining the precautionary principle, the Commission stated that the precautionary principle incorporates the principle of proportionality, in that “[m]easures based on the precautionary principle must not be disproportionate to the desired level of protection and must not aim at zero risk, something which rarely exists.”<sup>39</sup> Implementation of this proportionality requirement in applying the precautionary principle “should include an economic cost-benefit analysis where this is appropriate and

possible,” as well as a wider consideration of noneconomic factors.<sup>40</sup>

Other significant differences exist between different versions of the precautionary principle. For example, the Rio Declaration applies by its terms only to actions that would result in “environmental degradation,” whereas the Wingspread Statement is broader, applying to actions that would harm either the environment or human health. The Rio Declaration imposes no affirmative duty to act but simply states that uncertainty shall not preclude the possibility of regulation, while the Wingspread version is phrased in terms of a positive obligation to act. The combined effect of these differences could easily result in inconsistent regulatory outcomes in many cases.

The inconsistencies among different versions of the precautionary principle are compounded by the ambiguity in any specific formulation of the precautionary principle. No version of the precautionary principle is clear on when the precautionary principle applies and, just as important, when the principle does not apply.<sup>41</sup> Moreover, every version of the precautionary principle is ambiguous as to what it requires when it does apply.<sup>42</sup> As U.S. law professor Cass Sunstein recently commented, the biggest problem with the precautionary principle is not that “it leads in bad directions, but [rather], read for all it is worth, it leads in no direction at all.”<sup>43</sup> And as one British judge remarked, “In the absence of any definition of the precautionary principle, ... I find quite remarkable the proposition that each state should be obliged to act alone on the basis of so general a statement of objectives and considerations.”<sup>44</sup>

Consider, for example, the version of the precautionary principle offered by the Wingspread Statement cited previously.<sup>45</sup> Even though this formulation was intended to “clarify” and “operationalize” the precautionary principle,<sup>46</sup> it raises more questions than it answers. For example, under this definition, the precautionary principle is triggered “when an activity raises threats of harms to human health or the environment.”<sup>47</sup> Is any threat sufficient? What weight, if any, is given to the severity of the threat, how wide-



spread it is, or the uncertainty associated with the threat? How much evidence is required to establish a sufficient “threat”? Is a preponderance of the scientific evidence required? Or, is a single study enough? How are the quality and relevance of the evidence evaluated before the determination of a threat is made? Does the principle apply to known risks, or is it reserved solely for uncertain risks?<sup>48</sup>

Once a sufficient threat is established and the precautionary principle is triggered, the Wingspread version of the precautionary principle specifies that “precautionary measures should be taken.” This decree is also rife with ambiguity. What type of “precautionary measures” should be taken? Does it depend on the nature of the threat, and if so, how? Should the precautionary measures be proportional to the seriousness of the threat?

A related set of questions concerns what level of risk is acceptable under the precautionary principle. If the precautionary principle blocks development of a product until sufficient safety data on that product are available, how much data are required before the product is permitted to move forward? If the available evidence indicates the potential existence of some risk, what level of risk, if any, is acceptable to allow the product to proceed?

Some proponents of the precautionary principle reject in principle the concept of “acceptable risk.”<sup>49</sup> Proponents therefore argue that “[a]n inherent potential for harm is sufficient basis on which to take action to reduce, prevent or avoid hazards.”<sup>50</sup> Greenpeace likewise argues that “[c]hemical policies should be based on the precautionary principle: when there is reason to believe a substance or class of substances may cause harm to health or the environment, it should not be used or produced.”<sup>51</sup> Prohibiting any substance that “may” cause harm is in fact a “zero risk” standard. Other proponents of the precautionary principle disclaim a zero risk policy as obviously unrealistic.<sup>52</sup> Yet, these supporters offer no criteria or targets for determining when a risk would be “acceptable” under the precautionary principle.<sup>53</sup>

Another important area of disagreement is the relationship of

the precautionary principle to the traditional risk assessment/risk management framework, in which risk assessment is first used to estimate the risk, followed by risk management to decide whether and how much to reduce the risk.<sup>54</sup> Many activist supporters of the precautionary principle view it as inconsistent with, and an alternative to, the traditional risk assessment/risk management framework.<sup>55</sup>

Other proponents of the precautionary principle, including many governments that support the principle, maintain that the precautionary principle applies exclusively within the traditional risk assessment/risk management framework. Even among adherents of this position, however, there is an additional level of disagreement about where in the traditional framework the precautionary principle should be placed.

The Commission, for example, takes the position that the precautionary principle applies only in the risk management stage of risk decision-making.<sup>56</sup> Other proponents take a different position – that the precautionary principle can apply at either the risk assessment or risk management stage. For example, some take the position that the use of conservative assumptions in risk assessment is an application of the precautionary principle. Others reject this view.

Other risk decision-making criteria or principles also involve substantial uncertainty. For example, the criteria of “cost-benefit analysis” or “acceptable risk” leave many details unanswered and can result in dramatically different outcomes depending on how the ambiguities are resolved.

The precautionary principle is different, however, with respect to both the extent of its ambiguity and the imperviousness of that ambiguity to resolution. While other risk decision-making concepts can be, and indeed have been, subject to more precise refinements, the precautionary principle not only has not been further clarified but, by its very nature, cannot be made more precise. The many questions the precautionary principle avoids answering are the central but unresolved questions at issue in all risk management

decisions. For at least thirty years, interested parties, regulators, and academic commentators have debated these issues, with no resolution or consensus. For example, disputes regularly still rage on whether and how economic costs should be considered in health, safety, and environmental regulatory decisions and what level of risk is acceptable. While these differences may be papered over in the decision to adopt the precautionary principle, they likely will come home to roost when the precautionary principle is applied to specific problems, because in applying the principle, the questions just listed must indeed be answered.

In short, the precautionary principle has not been fully specified because the proponents of the principle recognize that the power of the principle lies in its ambiguity.<sup>57</sup> If the precautionary principle is better defined to simply state that regulators must apply some degree of precaution, while also considering countervailing factors, such as economic costs and risk-risk trade-offs, the principle would represent little change from existing practice and disappoint many of those who seek more fundamental changes from the status quo. Alternatively, if the precautionary principle is construed much more absolutely, as its most ardent proponents would likely prefer, few if any governments could credibly maintain even symbolic adherence to such an extreme measure.

Accordingly, the precautionary principle is necessarily ambiguous, because if it were to be made more specific, it would become enmeshed in the existing regulatory controversies and lose much of its superficial appeal. Some proponents of the precautionary principle recognize that the precautionary principle thrives precisely because it is ambiguous:

Paradoxically, we conclude that the application of precaution will remain politically potent so long as it continues to be tantalizingly ill-defined and imperfectly translatable into codes of conduct, while capturing the emotions of misgiving and guilt... [I]t is neither a well-defined nor a stable concept. Rather, it has become the repository for a

jumble of adventurous beliefs that challenge the status quo of political power, ideology, and environmental rights.<sup>58</sup>

It is therefore not simply a matter of time for the precautionary principle to be better defined and specified. The precautionary principle can remain politically viable only as long as it remains nebulous. The ambiguity of the principle may not impede its adoption, but it is certain to result in major problems as the principle is implemented.

### **An Invitation to Arbitrariness**

The inherent ambiguity of the precautionary principle invites its arbitrary application. This arbitrariness can be of two forms. First, the selection of the target risks to which the precautionary principle is applied may be arbitrary. Second, the specific outcome mandated by the precautionary principle for any particular risk may likewise be arbitrary.

The sweeping potential for arbitrariness in the application of the precautionary principle results not only from the ambiguity of the principle but also because of its premises. One such premise, unobjectionable on its face, is that absence of evidence of risk is not evidence of absence of risk. Combined with the corollary premise of the precautionary principle that the burden of proof is on the proponent of a product or technology to prove its safety, the potential subject matter of the precautionary principle is nearly unlimited.

It is impossible to prove the negative of the absence of risk;<sup>59</sup> moreover, every action or substance has the potential to create some risk in at least some context.<sup>60</sup> As the political scientist Aaron Wildavsky once remarked, "One could well ask whether any technology, including the most benign, would ever have been established if it had first been forced to demonstrate that it would do no harm."<sup>61</sup>

Moreover, the costs of conducting full toxicological testing for

all potential human health and ecological hazards for every substance would approach infinity and clearly are not feasible. Any product or technology is therefore potentially subject to the precautionary principle, because the existence of some risk cannot be precluded and some residual uncertainty about risk remains regardless of how many safety studies have been conducted.

Despite its broad sweep that could potentially encompass every product and technology, the precautionary principle fails to specify any principles or criteria for limiting which risks should be included within the ambit of the precautionary principle. In the absence of such limiting criteria, the application of the precautionary principle becomes entirely arbitrary, subject only to political pressure and whim.<sup>62</sup>

For example, the EU and many environmental groups advocate application of the precautionary principle to genetically modified (GM) foods. But environmentalists do not apply the precautionary principle to organic food or natural dietary supplements, which unlike GM foods are responsible for many documented cases of illness and death.<sup>63</sup> And European countries, such as France and Italy, which have adopted restrictive policies for GM foods based on the precautionary principle, do not apply the precautionary principle to restrict economically important activities such as tourism, even though tourism likely inflicts far greater damage to the natural environments of those countries than GM foods.

Other examples of the arbitrary application of the precautionary principle are beginning to accumulate. The government of Norway recently invoked the precautionary principle to ban Kellogg's Corn Flakes fortified with vitamins because "the fortification in question might be a health hazard when eaten in uncontrollable and unforeseen amounts," although that restriction was subsequently overturned by the European Free Trade Association Court as an unjustified restraint of trade.<sup>64</sup>

France recently employed the precautionary principle to ban the caffeinated energy drink Red Bull based on a paternalistic concern that its citizens, in particular pregnant women, would consume too

much caffeine.<sup>65</sup> Denmark invoked the precautionary principle to prohibit the marketing of Ocean Spray Cranberry drink on the grounds that the vitamin C added to the beverage could conceivably harm some individuals.<sup>66</sup> In an application going in the opposite direction, the EU invoked the precautionary principle to justify state aid to the coal-producing industry, an unlikely beneficiary of the precautionary principle for most of its advocates.<sup>67</sup>

The president of Zambia expressly cited the precautionary principle as the basis for his recent decision to reject food aid from the United States that contained some genetically modified corn kernels, even though the United Nations Food and Agriculture Organization concluded that the decision would leave 2.9 million citizens at risk of starvation.<sup>68</sup> Hungry citizens rioted and broke into the locked sheds containing the embargoed food aid to help feed their starving families.<sup>69</sup> Many Western advocates of the precautionary principle praised the Zambian president's invocation of the precautionary principle to deny U.S. food aid,<sup>70</sup> apparently disregarding the frequently asserted view of many proponents that the precautionary principle must be applied democratically with full consultation with affected citizens,<sup>71</sup> which obviously did not happen in Zambia.

Courts, too, can use the precautionary principle to reach questionable results. One such example is the decision of an Australian court to prohibit, based on the precautionary principle, a town from building a much-needed bridge because of its potential effect on the endangered giant burrowing frog.<sup>72</sup> The problem was that the giant burrowing frog had never been seen anywhere near the proposed bridge, having been observed several kilometres away on only two occasions some twenty years earlier and on another occasion allegedly heard near the bridge site.<sup>73</sup>

The selective application of the precautionary principle to a small subset of the almost infinite range of risks potentially subject to the principle based on ad-hoc political judgments unconstrained by objective criteria or decision rules predictably creates at least the strong appearance, if not the reality, of arbitrariness. Such arbitrariness in the application of the precautionary principle has

already been the basis of charges that the principle is being used for protectionist measures.<sup>74</sup> For example, the retroactive application of the precautionary principle by the EU to justify its previous decision to exclude North American beef treated with hormones “debases” the precautionary principle by using it “for what appears solely as a trade barrier to protect [EU] farmers against cheaper imported beef.”<sup>75</sup> The appellate body of the World Trade Organization (WTO) sustained this allegation in concluding that the EU ban was unjustified and “result[ed] in discrimination or a disguised restriction on international trade.”<sup>76</sup>

The potential for arbitrariness also is present in selecting the appropriate policy measures for those risks to which the precautionary principle is applied. The precautionary principle is generally silent on the types of actions that are appropriate to prevent potential risks. Most versions of the principle refer simply to the need to take some vague “precautionary action.”

One version of the precautionary principle, adopted in the 1982 World Charter for Nature, appears to mandate prohibitions or bans in nearly all circumstances by requiring that “where potential adverse effects are not fully understood, the activities should not proceed.”<sup>77</sup>

According to other proponents of the precautionary principle, precautionary action might mean a ban or prohibition of the activity or technology in question, but it could also require something less stringent, such as a standard or a warning.

The Commission acknowledges, for example, that “[t]here is a whole range of actions available to decision-makers under the head of the precautionary principle.”<sup>78</sup> Yet, nothing in the text or justifications for the precautionary principle provides any criteria for choosing among the many possible precautionary actions or sets forth any stopping point against yet more precautionary action. Any action taken short of an absolute ban or prohibition leaves some residual uncertainty and risk, seemingly compelling further restrictions pursuant to the precautionary principle.

Without objective criteria limiting when it applies and what it

requires, the potential reach and force of the precautionary principle are boundless, restrained only by arbitrary political vagaries. The use of the precautionary principle by the EU, and in particular by the EU courts that review the community's regulatory decisions, provides empirical support of such arbitrariness, and it is to that inquiry that we now turn.



### **3 The Precautionary Principle in the European Union**

The European Union has been at the forefront of adopting, implementing, and proselytizing for the precautionary principle. The EU's official position and actions on the precautionary principle are summarized here, following a brief overview of the key players within the EU governmental structure.

#### **Brief Overview of the EU's Institutions**

The EU is a unique political association that involves sovereign nations joining together in a political federation that is less formal and centralized than the U.S. federal system but nevertheless involves the sacrifice of significant national sovereignty to a European level supranational government entity known formerly as the European Community (EC) and now as the European Union. The EU describes itself using a model of "pooled sovereignty," under which "the member states delegate some of their decision-making powers to shared institutions they have created, so that decisions on specific matters of joint interest can be made democratically at [the] European level."<sup>1</sup>

The six original nations in the predecessor of the EU (Belgium, Germany, France, Italy, Luxembourg, and the Netherlands) signed the Treaty of Rome in 1957 to create the initial institutional structure of the European Community. The powers and membership of the EU have steadily expanded since then, with the number of member nations growing to fifteen by 1995 and to twenty-five in 2004 with the integration of the former Eastern European nations. The 1992 Treaty of Maastricht amended the Treaty of Rome to create the European Union to replace the European Community, and, among many other changes, to incorporate the precautionary principle into EU law.

The stated purpose of the EU is the economic and political integration of the member states, while at the same time seeking to preserve the diverse traditions and languages of its members. The EU increasingly expanded its power to make binding legislative and regulatory decisions on behalf of its member states in subject areas ranging from agriculture to culture, from consumer affairs to competition, and from the environment and energy to transport and trade. In addition, the EU increasingly represented its member nations in negotiations on international treaties and agreements in subjects such as environmental protection trade, security, and foreign aid.

The decision-making authority for promulgating laws and policies in the EU involves three primary institutions: (1) the European Commission, (2) the Council of the European Union, and (3) the European Parliament. In general, the Commission develops and proposes new laws and regulations, while the Council and Parliament adopt them. For some subject areas, such as environmental protection, new regulations proposed by the Commission must be approved by both the Council and the Parliament (via a procedure known as codecision). For other subject areas, such as agricultural policy, the Council alone approves the Commission's proposal, after consulting the Parliament for its opinion.

The Commission carries out the major bureaucratic workload of the EU. It is composed of twenty individual commissioners appointed by the member states and the European Parliament, supported by over 24,000 European civil servants. The functions of the Commission include developing and proposing new legislation to the Council and parliament, managing and implementing EU policies, administering the EU budget, enforcing EU law, and representing the EU in international forums.

The Council of the European Union is the main decision-making body of the EU. The Council represents the governments of the member states, with each Council meeting attended by one minister from each member state, which can vary depending on the subject matter of the meeting (for example, a meeting on environmental

issues generally is attended by the environmental ministers of each member state). The ministers attending a Council meeting have the authority to bind their governments to Council decisions. The Council's responsibilities include adopting EU legislation (in some subject areas with the coapproval of the parliament), approving the EU budget, concluding international agreements on behalf of the EU, and coordinating the economic policies of member states.

The European Parliament is directly elected by the citizens of the EU. Elections occur every five years, and a set number of seats are allocated to each member state. However, the members of the European Parliament (MEPs) are organized not by national blocs but rather by European-wide political groups, such as the European People's Party (Christian Democrats) or the European Liberal, Democrat and Reformist Party. The European Parliament shares authority with the Council for approving new legislation and the EU budget and provides "democratic supervision" of the other EU institutions.

The EU also includes a number of other institutions with advisory or management responsibilities. For example, the European Economic and Social Committee (EESC) expresses the opinions of organized "civil society" on economic and social issues of relevance to the EU. The EESC currently consists of over 220 individuals, representing employers, trade unions, farmers, consumers, and other interest groups. The EESC must be consulted before decisions are taken by the EU on any issue relating to economic and social policy, and the Committee may also offer opinions on other matters at its own initiative. Another advisory body is the Committee of the Regions, composed of several hundred representatives of Europe's regional and local authorities, such as regional presidents, regional parliamentarians, town councilors, and mayors of large cities. The Committee must be consulted on matters that concern local and regional government, such as regional policy, the environment, education, and transport.

The other major institution of the EU is its court system. In particular, the European Court of Justice, established in 1951, has the

power to settle legal disputes between member nations, the EU institutions and one or more member states, and EU institutions and businesses or individuals. The European Court of Justice is composed of one judge per member state, which prior to enlargement in 2004 consisted of fifteen judges, each appointed to a six-year term. Depending on the case, the European Court of Justice can sit in plenary session or in smaller chambers consisting of three, five, or seven judges. Decisions are made by the majority of judges sitting on a case; dissenting opinions are not made public.

The types of cases before the European Court of Justice include: (1) requests by the national court of a member nation seeking clarification on the interpretation of an EU law, known as the preliminary ruling procedure; (2) proceedings instituted by the Commission against a member state for failing to fulfill its obligations under EU law; (3) challenges to the legality of EU laws by member states or private parties, known as proceedings for annulment; and (4) actions alleging that a community institution has failed to act in accordance with EU law.

In 1989, the EU created a lower court, the Court of First Instance, to reduce some of the growing caseload of the Court of Justice. Certain types of cases, such as those brought by private individuals or companies concerning commercial issues, are assigned to the Court of First Instance for an initial decision. The losing party before the Court of First Instance has the right to appeal the decision to the European Court of Justice.

The European Court of Justice and the Court of First Instance are each assisted by eight advocate generals. The advocate generals are highly regarded lawyers or former judges appointed for six-year terms by agreement of the member states. Their role is to present “reasoned opinions” on cases brought before the court in a public and impartial manner. The advocate general appointed to a case issues his or her opinion in advance of the Court of Justice or Court of First Instance hearing the case and provides an influential recommendation for the court, but one that is not always followed.

## The EU's Adoption and Implementation of the Precautionary Principle

The EU adopted the precautionary principle into community law in the 1992 Maastricht Amendments to the European Treaty (Treaty of Rome), which incorporated the principle in a new Article 130r(2) (subsequently renumbered Article 174[2]).<sup>2</sup> This provision in relevant part states that “[t]he community policy on the environment ... shall be based on the *precautionary principle* and on the principles that preventive actions should be taken” (emphasis added).<sup>3</sup> The treaty itself does not define or otherwise articulate the requirements of the precautionary principle, nor was any official explanation or definition of the precautionary principle provided during the process of its enactment into the European Treaty. It has therefore been left to the community institutions to define and apply the precautionary principle.

In particular, the Commission has taken the lead in trying to better define and explain the precautionary principle, most notably in a twenty-eight-page “communication” on the precautionary principle issued in February 2000.<sup>4</sup> This communication represents the most detailed description of the precautionary principle by any official government body anywhere in the world to date.

Yet, while providing useful insight into the meaning and application of the precautionary principle, the Commission’s communication has two serious limitations. First, it fails to answer many central questions about the meaning of the precautionary principle. Second, the interpretation of the precautionary principle provided by the communication is not in accord with the views of many other precautionary principle proponents, resulting in even more confusion and uncertainty about the actual meaning of the precautionary principle.

The Commission’s communication does not offer a specific definition of the precautionary principle, but it does make some progress in clarifying the principle. The communication explains that implementation of the precautionary principle involves two distinct steps: “(i) the political decision to act or not to act as such,

which is linked to the factors triggering recourse to the precautionary principle; [and] (ii) in the affirmative, how to act, i.e. the measures resulting from application of the precautionary principle.”<sup>5</sup> The guidance provided on the first question of when to trigger the precautionary principle provides little more than the following: “An assessment of the potential consequences of inaction and of the uncertainties of the scientific evaluation should be considered by decision-makers when determining whether to trigger action based on the precautionary principle.”<sup>6</sup> This vague instruction provides no specific direction on when the precautionary principle should apply, nor much assurance “that the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions.”<sup>7</sup>

The communication also fails to articulate clear, usable factors or criteria to determine when the precautionary principle applies and when it does not. At one point, the communication states that the precautionary principle applies only when it is “impossible to determine with sufficient certainty the risk in question.”<sup>8</sup> But, given that every risk involves some uncertainty, it is not clear when risk is “sufficiently” uncertain to justify application of the precautionary principle.

The communication also states that a political decision is necessary to determine when a risk is “acceptable” but gives little guidance on how such acceptability is to be determined. While the communication emphasizes the need to avoid misuse of the precautionary principle for arbitrary or protectionist purposes, it is not apparent how this is to be accomplished, given the continuing vagueness of the precautionary principle. The U.S. government criticized the communication for, among other things, failing to ensure that the precautionary principle will not be applied in an arbitrary or discriminatory fashion, given that “a clear definition has not been provided and ... political decisions will determine its use.”<sup>9</sup>

The communication also specifies that the precautionary principle applies only to risk management and not risk assessment<sup>10</sup> and is triggered only by risks identified by scientific risk assessment.<sup>11</sup>

Moreover, according to the communication, the precautionary principle incorporates the principle of proportionality and “should include an economic cost-benefit analysis where this is appropriate and possible.”

Many precautionary principle proponents criticized the EU’s communication, especially its incorporation of cost-benefit analysis and scientific risk assessment, which is contrary to the position of many precautionary principle supporters.<sup>12</sup> This disagreement between the EU, the strongest government proponent of the precautionary principle, and many leading nongovernment precautionary principle supporters further confirms the unsettled meaning of the precautionary principle.

Other EU institutions have been even less helpful in clarifying the precautionary principle. The Economic and Social Committee advocated, in one pronouncement, that the application of the precautionary principle should be ad hoc, advising EU regulators to “evaluat[e], on a case by case basis, the costs and benefits of the application of the ‘precautionary principle.’”<sup>13</sup>

Yet, in a subsequent opinion, the same Economic and Social Committee seemed to offer a quite different recommendation: “The difficulty is that [the precautionary principle] must be recognised in the same way by the entire international community, and be applied uniformly at [the] international level. This is clearly not the present picture. The EU should propose an international conference to consolidate application.”<sup>14</sup>

Other EU institutions have expressed frustration over the ambiguity of the precautionary principle and the failure of community regulators to articulate why and how they apply the precautionary principle in specific cases. For example, the Committee of the Regions (CoR), responding to the Commission’s proposal to adopt a new fisheries conservation framework “based on the precautionary principle,” stated, “As there are different definitions of the precautionary principle, the CoR calls on the European Commission to state clearly what exactly is meant by this.”<sup>15</sup>

Although the EU treaty refers to the precautionary principle only

in the context of environmental protection, the EU institutions have applied the principle more broadly in a wide range of environmental and public health contexts. As one judicial decision expressly acknowledged, “Although the precautionary principle is mentioned in the Treaty only in connection with environmental policy, it is broader in scope. It is intended to be applied in order to ensure a high level of protection of health, consumer safety and the environment in all of the Community’s spheres of activities.”<sup>16</sup>

The EU has applied the precautionary principle in hundreds of regulatory decisions, opinions, resolutions, and reports, ranging from severe restrictions on genetically modified foods and bans on various chemical products, to a proposed fundamentally new chemical testing regime (REACH). In these decisions, the determination of whether or not to apply the precautionary principle appears to be completely arbitrary. For example, the Commission rejected suggested amendments from the European Parliament and the Council to its traceability and labeling regulations for genetically modified organisms because they made reference to the precautionary principle.<sup>17</sup> The Commission gave this rather cryptic rationale for why the precautionary principle does not apply to traceability and labeling regulations:

The precautionary principle relates to the risk analysis of products and is accounted for as part of the approval process under the authorizing legislation... Any safety measures to protect human health and the environment arise directly from this authorising legislation. Traceability is not a “safety measure” per se but can be used to “facilitate” the application of other measures, such as product withdrawals and monitoring, as a means to ensure safety. The precautionary principle cannot, therefore, be taken into account when implementing traceability requirements.<sup>18</sup>

Of course, the precautionary principle could be invoked to require product warnings or labels if the relevant authority were so



inclined. This type of regulatory doublespeak is used whenever the EU chooses not to apply the precautionary principle.

When the EU elects to apply the precautionary principle to a particular problem or risk, the EU institutions generally provide no explanation or insight as to why the precautionary principle applies in that case and what it specifically requires. A regulatory decision routinely includes a phrase to the effect of “[T]aking into account the precautionary principle,” in the list of justifications for a regulatory decision. The public has no idea what role or importance, if any, the precautionary principle actually played in the regulatory outcome. Therefore, little can be gained from scrutinizing the large number of regulatory decisions citing the precautionary principle as a justification, because almost no information or insight is provided on the principle’s meaning and significance in those decisions. Further elucidation must wait until a regulatory decision is challenged in the courts of the EU, when the EU regulators will be forced to explain and justify their decision, including any reliance on the precautionary principle.

## 4 **The European Union Courts and the Precautionary Principle: Overview**

Judicial decisions involving the precautionary principle are likely to provide the most informative insight into the meaning and effect of the precautionary principle. While a regulatory agency can simply cite the precautionary principle in support of its regulatory decision with no explanation of how or why the principle applies, courts cannot so easily escape confronting the meaning of the precautionary principle. When a regulatory action invoking the precautionary principle (or that failed to appropriately apply the principle) is challenged in court, a judicial decision on the merits of that challenge must address the underlying justification for the regulation, including, where relevant, the applicability and meaning of the precautionary principle.

Through February 2004, the precautionary principle has been cited in sixty decisions of the European Union courts.<sup>1</sup> A table listing these decisions is provided in the Appendix. The role the precautionary principle played in these decisions varied considerably, from insignificant in some cases to central to the outcome in others. As shown in the Appendix, the precautionary principle played a major role in fourteen cases, playing only a minor role in forty-six cases. In those cases in which the precautionary principle played a major role, the court decided the case in favor of the party relying on the precautionary principle in half of those cases (7 of 14). In contrast, in the cases where the precautionary principle played a minor role and the court issued a decision on the merits of the issue for which the precautionary principle was invoked, approximately 75 percent (25 of 34) of the decisions favored the side asserting the precautionary principle.<sup>2</sup>

These summary statistics suggest that the precautionary principle received very mixed and inconsistent treatment by the EU courts. For example, the courts are much more likely to decide in favor of precaution where the precautionary principle plays a minor role than where it plays a major role. As discussed later, some of the most stringent applications of precaution are found in cases where the precautionary principle plays a minor role, and yet some of the least stringent (or most permissible) applications of precaution are found in other decisions where the precautionary principle played a major role. The findings described here suggest that the precautionary principle is not being applied to produce a consistent, uniform increase in precaution but rather is being used selectively to produce extreme results in certain cases in an arbitrary and unprincipled manner.

### **Definition of the Precautionary Principle**

Perhaps the most noteworthy and extraordinary observation about the more than sixty EU judicial opinions mentioning – and in many cases extensively discussing and applying – the precautionary principle is that, with perhaps a single exception, none of the opinions attempts to define the precautionary principle. The EU courts are well aware that the precautionary principle is not defined in the EU legislation, in specific regulatory enactments, or by the EU courts themselves.<sup>3</sup>

Given the resulting uncertainty and controversy about both the definition and meaning of the precautionary principle, it would seem reasonable to assume that a court would need to define the principle before applying it. The observation that only one in more than sixty judicial decisions attempted to define the principle suggests that the precautionary principle is being applied in the EU from legislation to regulation to judicial review as some type of amorphous concept that the relevant authorities are either incapable of defining or unwilling to define.

This absence of a clear definition of the precautionary principle

while it is being applied to decide important cases indicates that the objectivity, transparency, and accountability of applying the precautionary principle are suspect.

The one exception in which an EU court attempts to define the precautionary principle is the decision of the Court of First Instance in *Artegodan GmbH v. Commission*, which at least devotes a few paragraphs to defining the precautionary principle.<sup>4</sup> According to this decision, “the precautionary principle implies that where there is uncertainty as to the existence or extent of risks to human health, the institutions may take precautionary measures without having to wait until the reality and seriousness of those risks become fully apparent.”<sup>5</sup>

This definition gives enormous discretion and flexibility to regulators, because there always is some uncertainty about the “existence or extent” of risks associated with any product or technology, which under the court’s definition would trigger application of the precautionary principle. Of course, because the precautionary principle, in practice, is not applied to every product and activity, the key issue is this: Under what criteria or according to what factors should regulators invoke the precautionary principle?

The *Artegodan* court attempts to answer this question by stating that “[w]here scientific evaluation does not make it possible to determine the existence of a risk with sufficient certainty, whether to have recourse to the precautionary principle depends as a general rule on the level of protection chosen by the competent authority in the exercise of its discretion... That choice must, however, comply with the principle that the protection of public health, safety and the environment is to take precedence over economic interests.”<sup>6</sup>

This articulation of the precautionary principle is problematic in several respects. First, it appears to give regulators almost carte blanche discretion on when to deploy and when to disregard the precautionary principle. It is left to the competent authority to determine what level of protection is warranted against a particular risk, then to decide whether the precautionary principle is necessary to achieve the desired level of risk. The only constraint on the

authority's discretion is that it must give greater weight to health risks than to economic impacts.

Second, the court's condition that protecting against health, safety, and environmental risks is to take precedence over economic interests is problematic. There must be some point at which risk prevention becomes economically (and politically) infeasible. The court's formulation would suggest absurd results such as spending near infinite resources to reduce the smallest health risk. By failing to recognize that there must be a balance between risk reduction and economic costs, the court's definition of the precautionary principle paves the way for unreasonable regulatory decisions. Moreover, excessive attempts at risk reduction can have the perverse result of increasing net health risks due to risk-risk and health-wealth trade-offs.<sup>7</sup>

A final problem with the *Artegodan* court's definition of the precautionary principle is that neither the EU regulators nor EU courts consistently follow the dictate that regulation must err on the side of protecting human health and the environment at the expense of economic interests.

The *Artegodan* decision itself provides a good illustration of this double standard. In that case, the Commission decided to rescind the regulatory approval of certain obesity drugs, consistent with the recommendation of the relevant scientific advisory committee that the marketing approvals for such drugs should be withdrawn based on an unfavorable risk-benefit balance.<sup>8</sup>

The advisory committee concluded that the drugs in question provided little or no effective therapy for obesity and presented potential serious health risks.<sup>9</sup> Notwithstanding the decisions of the Commission and its expert advisory committee that the drugs should be taken off the market and despite acknowledging a new consensus in the medical community that the drugs should no longer be prescribed,<sup>10</sup> the court overturned the Commission's decision because it was not substantiated by "new objective scientific and/or medical data or information."<sup>11</sup> It is difficult to reconcile this application (or perhaps better described as nonapplication) of

the precautionary principle in terms of what the court decided with the very broad and protective definition of the precautionary principle offered in the same judicial opinion.

The closest other judicial decisions have come to defining the precautionary principle are vague statements, such as, under the precautionary principle, “institutions may adopt protective measures without having to wait until the reality and seriousness of those risks have become fully apparent.”<sup>12</sup> Of course, no regulatory agency is required to wait until the “reality and seriousness” of risks from a product become “fully apparent” before taking regulatory action. Such a position would, for example, preclude any pre-marketing regulatory authority. The vague definitions of the precautionary principle offered by the EU courts thus contribute nothing toward better elucidation and understanding of the meaning of the precautionary principle, and raise serious doubts about the consistency and transparency of applying such an undefined concept in a legal setting.

### **Requirements of the Precautionary Principle**

The EU courts have not been consistent in construing the requirements of the precautionary principle. For example, judicial decisions differ as to the types of risks subject to the precautionary principle. In one opinion, the advocate general of the court held that, “[u]nder the precautionary principle, ... the Community must take action even in cases where there is not an existing, but a potential risk to the environment.”<sup>13</sup> In a second opinion, the advocate general stated that the precautionary principle applies “when no concrete threat to [the environment or human, animal, or plant life] has yet been demonstrated but initial scientific findings indicate a possible risk.”<sup>14</sup>

The European Court of Justice appeared to apply a different standard in another case, when it held that the precautionary principle requires regulators “to prevent, reduce, and so far as is possible, eliminate from the outset, the sources of pollution or

nuisance by adopting measures of a nature such as to eliminate recognised risks.”<sup>15</sup> So, in the first two opinions, the precautionary principle applies only to “potential” or “possible” risks but not “existing” or “concrete” risks, whereas in the second opinion the principle applies only to “recognized” risks, which seems closer to existing risks than potential risks.

A third view is offered by the Court of First Instance, which opined that the precautionary principle can “apply only in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated.”<sup>16</sup> This statement suggests that the precautionary principle applies to only a narrow range of cases in which a risk has been “scientifically confirmed” but not “fully demonstrated.”

Yet another decision by the advocate general held that “a plausible public-health risk is enough, according to the precautionary principle,” for an EU member nation to ban a substance.<sup>17</sup> Applying this “plausible” risk standard, the advocate general upheld Denmark’s decision to ban Ocean Spray Cranberry drink under the precautionary principle on the grounds that it was plausible that the vitamin C in the beverage could be harmful to some individuals.<sup>18</sup> The European Court of Justice reached the opposite conclusion and overturned Denmark’s ban, holding that a member state that seeks to ban the import of a food product must demonstrate, notwithstanding the precautionary principle, that the product presents a “real risk” that is “sufficiently established on the basis of the latest scientific data.”<sup>19</sup>

Further confusion is sowed by two back-to-back statements in a single opinion by the advocate general. He first stated that, “[a]ccording to the precautionary principle, ... conclusive scientific evidence of the reality of risk is not required. Action is therefore appropriate even where cause for concern is based on preliminary scientific findings.”<sup>20</sup> In the very next paragraph, the opinion continues, “On the other hand, ... not every claim or scientifically unfounded presumption of potential risk to human health or the

environment can justify the adoption of national protective measures. Rather, the risk must be adequately substantiated by scientific evidence.”<sup>21</sup>

To begin with, the structure of this statement suggests that some “scientifically unfounded presumptions” might be sufficient to trigger national protective measures pursuant to the precautionary principle. More fundamentally, the juxtaposition of these two statements suggests that the precautionary principle applies when “preliminary scientific findings” have been “adequately substantiated by scientific evidence.” This may be a null set, since findings that have been “adequately substantiated” likely no longer qualify as “preliminary.”

Notwithstanding this problematic description of when the precautionary principle should apply, the advocate general proceeded to uphold Italy’s temporary suspension of the sale of food products containing minute traces of genetically modified corn where, by the advocate general’s own admission, there was no shred of scientific evidence that the affected products presented any risk whatsoever.<sup>22</sup>

The EU case law is also inconsistent about the outcome required when the precautionary principle is applied. One decision of the European Court of Justice explained that “whilst it is undisputed that Article 130r(2) of the treaty requires Community policy in environmental matters to aim for a high level of protection, such a level of protection, to be compatible with that provision, does not necessarily have to be at the highest that is technically possible.”<sup>23</sup>

This decision suggests a rather lenient construction of the precautionary principle, which does not even require installation of the best available technology to control risks that are otherwise sufficient to trigger application of the precautionary principle.

In another case involving the precautionary principle, the Court of First Instance concurred that the precautionary principle does not require reducing risks to as close to zero as possible, especially given that “it is not possible to prove scientifically that there is no current or future risk associated with” a given product.<sup>24</sup>



Another decision by the advocate general stated that the “precautionary principle has a future only to the extent that, far from opening the door wide to irrationality, it establishes itself as an aspect of the rational management of risks, designed not to achieve zero risk, which everything suggests does not exist.”<sup>25</sup> These decisions seem to reject a “zero risk” construction of the precautionary principle.

In other cases, however, the courts suggest that a zero emissions or zero risk standard was in fact favored by the precautionary principle. In one case, the advocate general held that, “[i]n accordance with the precautionary principle, any discharge should, broadly speaking, ... thus be avoided.”<sup>26</sup> In another decision denying interim relief against regulations banning certain antibiotics in animal feed, the president of the Court of First Instance cited approvingly the Commission’s decision “to withdraw the products until it can be conclusively demonstrated that they pose no present or future risk to human health,” which the court endorsed as acting “in a precautionary manner” pursuant to the precautionary principle.<sup>27</sup> In another decision, the advocate general suggested that the precautionary principle compels reducing risks “to the lowest level reasonably imaginable.”<sup>28</sup> These opinions seem to indicate that the precautionary principle requires reducing, or at least striving to reduce, risks to the zero level.

### **Significance of the Precautionary Principle**

The decisions of the EU courts leave no doubt that the precautionary principle is a binding rule of law in the EU.<sup>29</sup> Notwithstanding this legally binding status, judicial decisions vary greatly on the importance and significance of the precautionary principle. Some EU judicial decisions appear to treat the precautionary principle as a fundamental shift in the paradigm by which the EU manages risks, while other decisions seem to treat the precautionary principle as “business as usual.”

For example, the Court of First Instance upheld the Council’s

decision to ban the use of four antibiotics used in animal feed even though they had been used in such applications without any adverse effects for decades and the EU's own scientific advisory committee had not supported the termination of such antibiotic use. This decision was based primarily on the precautionary principle, which the court cast as imposing a rigid new emphasis on preventing risk and required upholding the product bans because the mere potential of a risk could not be excluded.<sup>30</sup> In another decision applying the precautionary principle, the advocate general upheld Italy's suspension of the sale of food products containing trace levels of genetically modified corn, even though the EU had approved sale of such products and three separate scientific expert committees (including Italy's) had found no evidence of any human health or environmental risk.<sup>31</sup>

Yet another decision indicating that the precautionary principle brought about a fundamental shift in the EU's approach to risk management involved a criminal proceeding against directors of a company selling health juices in France that had been fortified with nutrients and vitamins that had not received regulatory approval in the EU.<sup>32</sup>

The defendants argued that France lacked authority to prohibit the nutrients in the absence of any proven health risks and, accordingly, France could not criminally prosecute the defendants for selling adulterated food products, since such prosecution had the equivalent effect of a prohibition.<sup>33</sup>

The European Court of Justice described the legal standard for prohibiting such products under EU law as follows: "A decision to prohibit the marketing of a fortified foodstuff, which is in fact the most restrictive obstacle to trade in products lawfully manufactured and marketed in other Member States, can be adopted only if the alleged real risk for public health appears to be sufficiently established on the basis of the latest scientific data available at the date of the adoption of such decision."<sup>34</sup>

However, if "scientific uncertainty persists as regards the existence or extent of real risks to human health"<sup>35</sup> (which surely will

always be the case), “it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the existence and gravity of those risks are fully demonstrated.”<sup>36</sup> Specifically, “[w]here 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.”<sup>37</sup> This standard would appear to require (or at least permit) banning a product where there is an “alleged risk,” not substantiated by scientific evidence, that would cause “real harm” if the alleged risk should turn out to be true, a truly radical departure from past risk management practices. It could conceivably result in the banning of any product for which a significant risk could be alleged without any proof, which could encompass almost any product. In this particular case, the European Court of Justice remanded the case back to the French national court to make appropriate factual findings pursuant to the EU court’s newly announced standard.

Other decisions likewise attach great significance to the precautionary principle by, for example, holding that the principle trumps traditional legal rules and principles, thereby giving it special supralegal status. In one case, the European Court of Justice cautioned that judicial decisions must be guided by the realization that the precautionary principle “would be undermined if the national legislature were to use modes of proof such as statutory presumptions which had the effect of restricting the scope” of the applicable regulations.<sup>38</sup>

In another decision, the court’s advocate general held that, in light of the precautionary principle and preventive principles set out in the EU treaty, “the protection of public health is a matter of public interest which the legislature must be able to protect in full. The value of this public interest is so great that, in the legislature’s assessment other matters of interest, such as the freedom of market

participants, must be made subsidiary to it.”<sup>39</sup> These judicial statements suggest that the precautionary principle and its requirement for protecting public health and the environment take precedence over all other considerations in making regulatory decisions.

A very different approach to the precautionary principle is seen, however, in other decisions by the same courts. For example, the Court of First Instance rejected an appeal by a prominent scientist to suspend the approval of the drug deferoxamine, used for thalassemia treatment, because of its alleged inefficacy and toxicity.<sup>40</sup> The complainant scientist, Dr. Nancy Olivieri, was described by the court itself as “an internationally recognised specialist” in thalassemia,<sup>41</sup> and indeed she was the primary investigator for two of the three primary studies relied on for the regulatory approval of deferoxamine.<sup>42</sup>

As summarized by the court, Dr. Olivieri argued that “the precautionary principle has been infringed” by the EU’s approval of deferoxamine given that “the conclusions of the ad hoc working group note that the data which she provided reinforce the already existing doubts” about the drug.<sup>43</sup> The EU, in defense of its action, argued that “the precautionary principle is incorporated into the concepts of safety and efficacy which have to be taken into account” by the existing regulatory approval process. In other words, the precautionary principle added nothing new to the existing regulatory criteria. The court sided with the EU, in effect giving no weight at all to the precautionary principle.

Another case in which the Court of Justice treated the precautionary principle as essentially meaningless involved a challenge by Greenpeace to France’s approval of a genetically modified corn product.<sup>44</sup>

Under the EU regulatory scheme for genetically modified organisms (GMO) in effect at the time (the late 1990s), approval of the deliberate release of GMOs followed a two-step process. First, the company proposing to market a new GMO must apply to the competent authority in one of the EU’s member states for written approval.<sup>45</sup> The competent authority must carry out a risk assess-

ment of the new GMO and ensure that the product fulfills the conditions specified in the EU directive.<sup>46</sup> If it makes such a favorable opinion, the national authority must forward the dossier to the Commission, which then must consult with all other member states and make its own determination on whether the GMO shall be approved.<sup>47</sup> If the Commission issues a favorable decision, the competent authority that received the original notification shall give consent in writing to marketing of the product, and this approval shall be effective in all EU member nations.<sup>48</sup>

In the case at hand, France was the competent authority that received the initial application for a strain of GM corn, and after conducting the inquiry required by the EU directive, forwarded the dossier with a favorable decision to the Commission. The Commission, over the objections of some member nations, approved the GM corn, based in part on the conclusions of three different expert scientific advisory committees that there was no reason to believe that the product would have an adverse effect on human health or the environment.<sup>49</sup>

In the meantime, however, Greenpeace brought a legal action within the French legal system challenging France's approval of the same product based on the precautionary principle.<sup>50</sup> The French court (the Conseil d'Etat) found that the Greenpeace argument had "considerable force" and suspended the French government's regulatory approval of the GM corn product. It then requested the European Court of Justice to give an opinion on whether a member country could exercise its discretion to deny approval of a GM product after both it and the Commission had initially approved the same product under the procedures specified by the relevant EU directive.

The European Court of Justice found the legal issue relatively straightforward, as the EU Directive specified that the initial member state that had approved a GM product (in this case, France) shall give final regulatory approval to the product once it has forwarded its favorable opinion to the Commission and the Commission had itself issued a favorable opinion. The European Court of

Justice therefore found that France did not have discretion to second-guess its initial approval once the community had given its approval, unless new information justified a reexamination of the product's safety by the Commission.<sup>51</sup>

Greenpeace argued that this straightforward reading of the language of the directive was contrary to the precautionary principle.<sup>52</sup> The Court of Justice flatly rejected this argument. It claimed that the procedures provided by the EU Directive – specifically, the requirement for a case-by-case risk assessment prior to release, the opportunity for review of that assessment by the Commission and other member states, and the obligation for a member state to notify the Commission if new risk information becomes available – all adequately reflect observance of the precautionary principle. In other words, the precautionary principle requires only a premarket risk assessment and an obligation to consider further measures if new risk information becomes available. This construction of the precautionary principle is very much consistent with the traditional risk assessment model, which relies on an assessment of the existing scientific evidence of risk in making regulatory decisions, that many proponents of the precautionary principle claim it was intended to supersede.

Another decision diminishing the importance of the precautionary principle is a case brought by Germany against the Commission for refusing to allow Germany to adopt more stringent standards for certain mineral wool products.<sup>53</sup> Under the applicable law, the Commission was responsible for adopting community-wide measures for such products, but an individual member state could petition the Commission for more stringent national standards if it deemed it necessary “based on new scientific evidence relating to the protection of the environment or the working environment.”<sup>54</sup>

Germany adopted more stringent carcinogen classifications for some types of mineral wool, but the Commission rejected those measures.<sup>55</sup> One argument Germany advanced in challenging the Commission's decision was that it was entitled to adopt more stringent measures pursuant to the precautionary principle.<sup>56</sup> The

advocate general's opinion upheld the Commission, which argued that "where there is doubt the precautionary principle can lead to the adoption of higher protective measures" by member states, but only "if it is scientifically proven that they are necessary and better able than the [Commission's] directive to protect" health and the environment.<sup>57</sup> The Commission successfully argued that where, as here, "that proof has not been provided because the scientific position cannot yet be assessed definitively, it is necessary to hold to the general application of the Community legislation."<sup>58</sup> Under this construction of the precautionary principle, it can lead to more stringent measures only when it has been "scientifically proven" that such measures are necessary, which seems to be antithetical to the precautionary principle described by its supporters.

In another case, the court stated that, while the precautionary principle does give the community institutions "broad discretion," "the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental importance," suggesting that the precautionary principle cannot trump existing procedural and substantive standards of administrative procedure.<sup>59</sup> Another opinion cautioned that the precautionary principle must be applied in conjunction with other principles that "are just as fundamental," including the principle of proportionality, "which can be said to be inseparable from the precautionary principle," and the principle of nondiscrimination.<sup>60</sup> The advocate general further noted in that same opinion that while the precautionary principle is "enshrined" in community law, it "must not in any way mark the resurgence of unilateralism" and therefore cannot be invoked by member nations to adopt regulations more protective than the community actions that themselves supposedly observe the precautionary principle.<sup>61</sup>

Similarly, another case rejected Denmark's reliance on the precautionary principle to adopt more stringent restrictions on food additives than the applicable EU legislation, holding that "a Member State cannot unilaterally invoke the precautionary principle in order to maintain derogating national provisions. In an area where

Member State legislation has been harmonised, it is for the Community legislature to apply the precautionary principle.”<sup>62</sup>

In rejecting France’s opposition based on the precautionary principle to the EU’s lifting of the ban on beef and veal from the United Kingdom in response to the outbreak of “mad cow” disease in that nation, the European Court of Justice downplayed the legal and practical significance of the precautionary principle.<sup>63</sup> France argued that, before voting to bring legal action against France for failing to comply with the lifting of the ban, the EU was obligated to notify the commissioners that France was relying expressly on the precautionary principle in refusing to lift the export ban.<sup>64</sup> Noting that the commissioners already were aware that France’s position was based on the remaining uncertainty about the risks of mad cow disease transmission and the importance of protecting public health, the court held that “[t]he addition of the label ‘precautionary principle’ to those arguments added nothing to their content.”<sup>65</sup> Since the debate on any risk likewise involves concerns about the uncertainty of the risk and the need to protect public health, this statement suggests that the precautionary principle is meaningless, “adding nothing” to these standard arguments.

A final example is provided by a legal action brought by citizens of French Polynesia challenging the Commission’s approval of France’s plans to resume underground testing of nuclear weapons on nearby atolls.<sup>66</sup> The citizens claimed that the Commission’s determination that the nuclear testing would not present “a perceptible risk of significant exposure for workers or the general public” was inconsistent with the precautionary principle.<sup>67</sup>

The Court of First Instance dismissed the citizens’ application for interim relief on technical grounds, ruling that the citizens failed to establish standing to bring a suit, because the relevant legislation is concerned only with “the general objective of protecting the health of workers and the general public as a whole,” and hence the Commission “cannot be required to take into consideration the particular situation of each individual resident and worker within the



geographical area concerned by a given experiment unless there are specific grounds for taking such considerations into account.”<sup>68</sup> The court gave no consideration whatsoever to the citizens’ reliance on the precautionary principle.

These examples demonstrate that the European courts are prepared to give great, even decisive, weight to the precautionary principle in some cases, while ignoring it altogether in other cases. There appear to be no obvious criteria or factors that explain this discrepant application of the precautionary principle, nor do the courts offer any explanation in any of the cases why they are strictly enforcing the precautionary principle in some cases but not others.

### **Opportunity for Meaningful Judicial Review of the Precautionary Principle**

The opinions of the EU courts recognize that the ambiguity and tensions in the precautionary principle make judicial review of regulatory actions based on the precautionary principle difficult. In the words of the Court of First Instance, regulators “enjoy a broad discretion” under the precautionary principle to adopt measures “on the basis of as yet incomplete scientific knowledge.”<sup>69</sup> A decision by the advocate general stated that courts must exercise “caution” in reviewing application of the precautionary principle, given “that the courts can, in this field, only exercise minimal review since the political authorities must be granted a broad discretion.”<sup>70</sup>

In another case, the European Court of Justice recognized the tension between the precautionary principle and the other principles and criteria identified in the same section (Article 174, previously Article 130r) of the European treaty, including the “polluter pays” principle and the requirements to “take account” of “available scientific and technical data,” “the potential benefits and costs of action or lack of action,” and the “economic and social development of the Community.”<sup>71</sup> According to the court, “in view of the need to strike a balance between certain of the objectives and principles

mentioned in Article 130r [now Article 174] and of the complexity of the implementation of those criteria, review by the Court must necessarily be limited to the question whether the Council in adopting the regulation, committed a manifest error of appraisal regarding the conditions for the application of Article 130r [now Article 174] of the Treaty.”<sup>72</sup>

These judicial statements essentially give EU regulators *carte blanche* discretion in their application of the precautionary principle. They frustrate any hopes that judicial review will check the otherwise unlimited discretion afforded by the precautionary principle by imposing some limits and criteria on its application.

### **The Precautionary Principle and Science**

The EU judicial opinions are also inconsistent with regard to the relationship of the precautionary principle to scientific evidence and advice. In one case, the European Court of Justice ruled against a challenge by France to the Commission’s decision to lift the ban on British beef and veal that had been imposed based on the risk of “mad cow” disease. A government expert panel in France had issued a scientific opinion that some risk of contamination from British beef remained, even though unquantifiable, and an ad-hoc panel established by the EU could not reach consensus on how serious these remaining risks were.<sup>73</sup>

Notwithstanding this significant expert scientific support from at least two scientific bodies (in one case, the consensus view; in another, at least a minority view) that British beef remained a risk, the court upheld the EU’s decision to reject adopting more protective measures based on that scientific advice. The Commission argued, as paraphrased by the court, that “the precautionary principle ... does not have the effect of obliging it to follow every scientific opinion without any power to carry out its own assessment.”<sup>74</sup> In this case, the court effectively ruled against application of the precautionary principle even where there was credible scientific opinion for the existence of some continued risk. While

this position may have been correct on the merits, given the likely small magnitude and likelihood of residual risk, it is contrary to other EU applications of the precautionary principle.

For example, contrast this decision with the position of the Commission and court with regard to the EU's ban on the continued use of four specific antibiotics in animal feed, where the applicable EU scientific committee concluded that there was no significant risk to human health from continuing this antibiotic use. The Commission concluded, in a decision upheld by the Court of First Instance, that the EU could nevertheless ban the use of the four antibiotics in animal feed pursuant to the precautionary principle.<sup>75</sup> In other words, the EU can ban a product even when the relevant scientific expert advice is that such a ban is not warranted by the scientific evidence.

In a similar holding, the advocate general authorized Italy to temporarily ban products derived from genetically modified corn, at least until the EU institutions had an opportunity to consider the substantive merits of Italy's position.<sup>76</sup> The products in question contained only trace amounts of transgenic protein, estimated to be between 0.04 and 0.30 parts per million.<sup>77</sup>

Both the EU's Scientific Committee for Food and Italy's own advisory committee (the Italian Istituto Superiore di Sanita) excluded any health risk from the products based on the available scientific evidence.<sup>78</sup> The products had been approved for sale in the EU based on a finding by the United Kingdom's Advisory Committee on Novel Foods and Processes that the products were "substantially equivalent" to products derived from non-genetically engineered corn.<sup>79</sup>

Although not disagreeing with the three separate scientific advisory committees that there was no evidence the products presented any risk, the advocate general nevertheless concluded that Italy was permitted to suspend the sales of the relevant food products based on the precautionary principle until the relevant EU institutions reviewed the substantive grounds for Italy's actions.<sup>80</sup> The European Court of Justice subsequently remanded the case to

the Italian national court to determine whether Italy's action was justified, taking into account the precautionary principle.<sup>81</sup>

In another case, the relevant EU scientific advisory committee, the Committee for Veterinary Medicinal Products (CVMP), twice issued opinions that progesterone should be included on a list of approved veterinary medicinal products that do not require regulatory limits to protect public health.<sup>82</sup> Notwithstanding these favorable scientific opinions, the Commission refused to approve the product, arguing (as paraphrased by the court) that "a high level of human health protection may be achieved only if assessments made by committees such as the CVMP are balanced by the competent institutions against all the scientific information available, taking into account scientific uncertainty, consumers' concerns, ethical or moral considerations or other legitimate factors and *the precautionary principle*" (emphasis added).<sup>83</sup> The court gave short shrift to the Commission's attempted reliance on the precautionary principle and other factors to balance against the expert scientific opinions, holding that the Commission acted unlawfully by refusing to list progesterone as recommended by the Commission's own expert scientific committee.<sup>84</sup>

Taken together, these decisions indicate that the EU courts failed to apply a consistent approach to the relationship between scientific advice and the precautionary principle. In some cases, the courts upheld regulatory decisions that fail to apply the precautionary principle in any meaningful manner, even when the relevant scientific advice suggests that there may be a real risk. In other cases, the courts upheld regulatory actions to prohibit substances that the scientific advisors concluded present no significant risks. Yet in still other decisions, the courts rejected the regulators' attempt to use the precautionary principle to take action inconsistent with the relevant scientific advice. In short, there appears to be no coherent relationship in the judiciary's opinions on the appropriate relationship between scientific advice and the precautionary principle.

## 5 **The European Union Courts and the Precautionary Principle: Three Case Studies**

This chapter describes three cases or sets of cases decided by the EU courts that demonstrate in greater depth the potential arbitrariness and unreasonableness of the precautionary principle as applied.

### **Case 1. *Fornasar*: Eliminating Fair Notice**

An important principle of due process in regulatory enforcement is the concept of “fair notice,” in which a party subjected to agency enforcement has the right to prior warning of the government’s nonobvious construction of an applicable regulatory provision.<sup>1</sup>

In the *Fornasar* case, Italian national authorities sought to prosecute a company for violating hazardous waste laws, even though the waste it had in its possession did not meet the definition of hazardous waste in either the relevant EU directive or existing Italian national regulations.<sup>2</sup> EU Directive 91/689 defined hazardous waste as wastes included on an EU list developed according to procedures set forth in Article 18 of Directive 75/442 or wastes that a member state determined to be hazardous on the ground that they displayed any of the properties listed in Annex III to Directive 91/689.

However, if a member state chooses to list a waste not on the EU list, that classification applies only in the territory of the member state, and the member state must provide notification of the listing to the Commission for review in accordance with the procedure laid down in Article 18 of Directive 75/442. This regulatory scheme, by providing prior classification of hazardous wastes, provides advance notice to regulated parties on which wastes will be deemed hazardous, consistent with the principle of fair notice.

In the *Fornasar* case, however, first the advocate general and then the European Court of Justice, in separate opinions, eliminated this fair notice requirement over the objections of the Commission. The advocate general held that limiting enforcement to the text of the existing regulations would be inconsistent with the precautionary principle:

Of particular interest for the resolution of this case is the reference to specific (negative) manifestation of the precautionary principle. It implies that the competence of public authorities to adopt for a particular purpose the measures deemed necessary to avert a risk to the environment cannot be restricted, particularly where this risk has not been ascertained or charged by prior regulation. In other words, determining in advance and in a limitative manner the circumstances requiring the intervention of public authorities to avert a specific risk to the environment, even if it is impossible to define the risk in advance in a concrete manner, would be contrary to the precautionary principle.<sup>3</sup>

Simply put, the long-standing requirement for fair notice is inconsistent with the precautionary principle. Because Directive 91/689 limited enforcement to wastes that had previously been listed by the EU or member states, the advocate general's opinion concluded that the directive infringes the precautionary principle and is therefore invalid.<sup>4</sup>

The European Court of Justice, also citing the precautionary principle, ratified the advocate general's decision, holding that Directive 91/689 does not prevent member states, including the courts of member states in enforcement actions, from classifying new wastes as hazardous, provided that they subsequently notify the EU Commission of such decisions.<sup>5</sup> In other words, the requirement for "prior classification" could be satisfied with retroactive *ex post* classifications. Not only does this remove any requirement for advance notification of hazardous wastes, but it retroactively reverses an

express statutory provision that enforcement would be limited to wastes included in such prior classification.

## **Case 2. Antibiotics in Animal Feed: Ignoring Scientific Advice**

In December 1998, the European Council adopted a regulation delisting four antibiotics from the list of additives approved for use in animal feed in the EU. This delisting had the practical effect of banning the use of these antibiotics in animal feed in Europe. The four antibiotics were used as growth promoters in animals, which entails adding very low concentrations of the antibiotic to the feed of poultry, pigs, and calves. The antibiotics result in improved growth and weight gain, so that the animal is ready for slaughter sooner, and are also believed to have other beneficial effects, including preventing diseases in animals and reducing the production of waste in livestock farming.

The EU banned the use of the four antibiotics based on a concern that the use of the antibiotics in livestock would select for antibiotic-resistant pathogenic bacteria, which might be transmitted from animals to human beings. While a number of scientific and international reports expressed concern about the potential spread of antibiotic resistance to humans from such feed uses, no such cases have been documented and one recent scientific review (published after the EU and judicial decisions discussed here) concluded that “[w]hereas a theoretical hazard to human health arises from the use of growth-promoting antibiotics, an independent examination of the facts, free from commercial or political influence, shows that the actual risk is extremely small and may be zero in many cases.”<sup>6</sup>

The EU decision led to separate but related judicial challenges to the ban on two of the antibiotics, virginiamycin<sup>7</sup> and bacitracin zinc.<sup>8</sup> The ban on virginiamycin was prompted by an earlier decision by Denmark to ban the antibiotic in its territory, which triggered a duty on the Commission to consider whether the grounds cited by the member state (in this case, Denmark) for its action justified

changes to the community regulations.<sup>9</sup> In considering the Danish action, the Commission requested a scientific advisory committee, known as the Scientific Committee for Animal Nutrition (SCAN), to provide a scientific opinion on the potential human health risks posed by the use of virginiamycin as an animal growth promoter.<sup>10</sup>

Under EU law, the SCAN is an expert advisory committee that “shall be responsible for assisting the Commission, at the latter’s request, on all scientific questions relating to the use of additives in animal nutrition.”<sup>11</sup> As the Court of First Instance itself emphasized, “The Commission set up SCAN specifically with the aim of ensuring that Community legislation is founded on objective and sound scientific findings.”<sup>12</sup> After reviewing the available evidence that Denmark relied on for its decision, the SCAN concluded that the use of virginiamycin as a growth promoter did not constitute an immediate health risk to public health.<sup>13</sup> Specifically, the SCAN report concluded that there would be no risk from continued use of the antibiotic while further data on its safety was being gathered and evaluated:

The SCAN is therefore firmly of the opinion that any risk that might be posed in the future by the use of virginiamycin as a growth promoter will not materialise in the time required to make such an evaluation and most probably not for some years after.<sup>14</sup>

This scientific opinion was important because, as indicated by the SCAN’s conclusion, the EU had studies underway to better evaluate the potential human health risks of the antibiotics. The SCAN report “firmly” concluded that no potential human harm would result from waiting for the results of those pending studies before taking any regulatory action.

The decision to ban bacitracin zinc followed a similar but slightly different pathway. The EU’s decision on bacitracin was prompted by Sweden’s decision to ban the antibiotic in animal feed, based on its own scientific report, which concluded that there were no known risks from the use of bacitracin:



In conclusion, available information is too scarce for an assessment of the possible risks of bacitracin usage to human and animal health. Bacitracin usage does not appear to represent any substantial danger to the environment.<sup>15</sup>

In fact, bacitracin zinc had been used as a growth promoter in animal feed for more than forty years, and no increase in resistance to the antibiotic had been observed.<sup>16</sup> In response to the Commission's request, the SCAN considered the possible risks of bacitracin and, at its April 1998 meeting, agreed to establish a multidisciplinary working group to examine the problem of antibiotic resistance in detail and issue a report by mid-1999.<sup>17</sup>

Notwithstanding the pending SCAN evaluation, the Commission moved forward and recommended, and the Council adopted, the delisting of the four antibiotics in December 1998, before the SCAN could complete its work.<sup>18</sup> The decision to ban the four antibiotics was based primarily on the precautionary principle. As the Court of First Instance stated in reviewing the Commission's decision, "It is common ground between the parties that, at the time when the contested regulation was adopted, neither the reality nor the seriousness of the risk had been scientifically proven," and "that the Council relied on the precautionary principle as justification for adopting the regulation."<sup>19</sup>

Itself relying largely on the precautionary principle, the Court of First Instance upheld the EU's antibiotics ban against challenges by manufacturers of the prohibited antibiotics. The court agreed with the manufacturers that the precautionary principle cannot be construed to require zero risk and preventive measures "cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified."<sup>20</sup> Rather, "a scientific risk assessment must be carried out before any preventive measures are taken."<sup>21</sup> To be sure, "a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to

become a reality.”<sup>22</sup> Nevertheless, “it follows from the community courts’ interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been ‘fully’ demonstrated by conclusive scientific evidence, appears to be adequately backed up by scientific data available at the time when the measure was taken.”<sup>23</sup>

Despite recognizing that a “full” risk assessment may not always be feasible or warranted, the court cautioned that measures based on the precautionary principle must be based on “as thorough a scientific risk assessment as possible” to guard against arbitrary regulation:

[I]f it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. Notwithstanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society... That is the basis on which the authority must decide whether preventive measures are called for.<sup>24</sup>

The court found further support for the requirement to base precautionary measures on the results of scientific risk assessments in the Commission’s 2000 communication on the precautionary principle.<sup>25</sup> The court agreed with the Commission that the communication, even though published after the decision to ban the four antibiotics, was consistent with the approach being applied at the time of the contested decision, and hence “certain aspects of the communication could reflect the law as it stood at the time when the contested regulation was adopted.”<sup>26</sup>

Therefore, according to the court's own analysis of the applicable legal standard, "the Community institutions must show, first, that the contested regulation was adopted following as thorough a scientific risk assessment as possible, which took account of the particular circumstances of the present case, and, second, that they had available, on the basis of that assessment, sufficient scientific indications to conclude, on an objective scientific basis, that the use of [the prohibited antibiotics] as a growth promoter constituted a risk to human health."<sup>27</sup> The court added that "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."<sup>28</sup>

Yet the court nevertheless upheld the EU's ban on the four antibiotics in the absence of supporting scientific evidence by invoking the precautionary principle. In a truly Orwellian twist, both the EU and the Court of First Instance relied primarily on the very SCAN scientific opinion that concluded there is no risk from virginiamycin to supply the necessary scientific evidence that there is in fact an unacceptable risk associated with that antibiotic.<sup>29</sup>

As the court noted, "It is apparent from the preamble to the contested regulation that in reaching its conclusion the Council relied primarily on various aspects of SCAN's own analysis."<sup>30</sup> The court suggested that, while the community institutions are not bound by SCAN's opinion,<sup>31</sup> the SCAN opinion provides the necessary scientific support for the Council's decision, as "[t]here is no doubt that the SCAN opinion meets the criteria of excellence, independence and transparency required of scientific advice."<sup>32</sup> The only problem, of course, is that the SCAN opinion reached a conclusion on virginiamycin that was diametrically opposed to the decision of the Council.

Under the precautionary principle, that did not seem to matter. The court concluded that reliance on the SCAN scientific opinion without accepting its conclusion provided "a proper scientific basis

for taking action under the precautionary principle.”<sup>33</sup> Given the existing scientific uncertainty and the goals of the precautionary principle, the court held that the community was justified “to depart from the SCAN opinion on the ground that it was in the interests of human health protection.”<sup>34</sup>

Therefore, when applying the precautionary principle, it seems that a regulatory decision not only does not need to be supported by an affirmative expert scientific opinion but can even be based on a negative scientific opinion that is directly contrary to the regulatory action. Under this standard, the substance of expert scientific advice becomes irrelevant, because the regulators can take their preferred action regardless of what conclusion the independent scientific experts reach. Yet, if by the court’s own reckoning, the SCAN was established to “ensur[e] that Community legislation is founded on objective and sound scientific findings,”<sup>35</sup> then adopting regulations in direct contradiction to a SCAN expert opinion would seem, by definition, to be arbitrary and scientifically unsound.

Moreover, the court’s application of the precautionary principle to virginiamycin, especially in the preliminary opinion of the president of the Court of First Instance, implicitly imposed a zero risk standard. The Council argued to the court that the SCAN analysis had not definitely excluded any possible risk from virginiamycin, even though it might have concluded that such risks were insignificant.<sup>36</sup> The Council argued, and the court agreed, that once the existence of a risk could not be excluded, there is no need to undertake a quantitative assessment of that risk before taking protective action.<sup>37</sup> As the president of the Court of First Instance stated in his preliminary opinion, the Council properly applied the precautionary principle once it determined that there was a possibility of a risk to require withdrawal of the antibiotic products “until it can be conclusively demonstrated that they pose no present or future risk to human health.”<sup>38</sup>

Of course, it is not possible to “conclusively demonstrate” that any product presents “no present or future risk to human health.” The EU regulators and judiciary are therefore applying a zero risk

construction of the precautionary principle in this case that could be used to justify banning any product in commerce today.

The court's decision in the companion *Alpharma* case involving bacitracin zinc pushes the precautionary principle even further. For this antibiotic, the SCAN had not yet issued a scientific opinion, but had commissioned a special task force to study the issue and report by mid-1999. The Commission and Council nevertheless decided to ban bacitracin in December 1998 without waiting for the SCAN report, even though bacitracin had been used for over forty years with no adverse effects.

The court recognized that the special SCAN committee was in the process of evaluating whether bacitracin had the potential to cause adverse effects and the product manufacturers had undertaken expensive research at the community's request, but ruled that "[i]f the Community institutions were required to await completion of such research before being entitled to take protective measures, the precautionary principle, whose purpose is to prevent such adverse effects from arising, would be rendered nugatory."<sup>39</sup>

The court added that "the Community institutions were entitled to give priority to human health protection over the successful conclusion of research in progress, even though that research had, in part, been initiated by the Community institutions themselves and given rise to considerable expense for the industry concerned."<sup>40</sup> Under this absolute construction of the precautionary principle, it was irrelevant that the product had been on the market for forty years with no adverse effects and that it was only a matter of months before the SCAN would issue its expert report.<sup>41</sup>

Alpharma objected that, by not waiting for the SCAN scientific opinion, the EU violated its own policy articulated in the Commission's communication on the precautionary principle to apply the precautionary principle based on the results of a risk assessment. The court found that the Commission and Council had sufficient scientific support for their decision from two sources – "first, ... the SCAN opinions concerning the other antibiotics whose authorisations were withdrawn by the contested regulation and, second, of

the reports on antimicrobial resistance of the various international, Community and national bodies” cited by the Commission.<sup>42</sup> In the companion *Pfizer* case, the same court acknowledged that these latter sources (i.e., the opinions of the “various international, Community and national bodies”) were only “supplementary” and did not provide the primary justification for a product ban.<sup>43</sup> The only other scientific authority cited by the court to justify the EU’s ban on bacitracin zinc was the SCAN opinions on other antibiotics, which found that those other antibiotics such as virginiamycin did not present an immediate risk.

Under this stretched version of the precautionary principle, therefore, a scientific opinion that one product does not cause a risk is sufficient scientific evidence to justify banning a completely different product with no evidence of an adverse impact.<sup>44</sup> As one European commentator recently concluded, the judicial decisions upholding the antibiotic bans have established a precedent that “effectively grant[s] the legislative institutions license to make arbitrary political decisions in the name of the precautionary principle.”<sup>45</sup>

### Ignoring Risk-Risk Trade-Offs

A major criticism of the precautionary principle is that it will lead to excessive precautions that increase net risk due to risk-risk trade-offs.<sup>46</sup> Such increases in net risks could result from a variety of second-order effects, including undue delays in developing safer or health-promoting technologies or risks from substitute products. In its various decisions applying the precautionary principle, the EU courts systematically fail to address the potential risk-risk trade-offs inherent with excessive precaution.

Indeed, in at least some cases, the courts steadfastly refused to consider the risk-risk trade-offs even when confronted with evidence of such trade-offs. For example, in the animal antibiotics cases just discussed, the manufacturers argued, supported by expert opinions, that the antibiotic bans would have a net adverse effect on animal and human health.<sup>47</sup> Specifically, the manufacturers argued that the use of the contested antibiotics in animal foods has a pro-

phylactic effect against conditions such as necrotic enteritis that require increased use of more powerful new-generation antibiotics such as amoxicillin and ampicillin.<sup>48</sup> Because human use of these antibiotics is much more significant than the banned antibiotics used in animal feed, the manufacturers argued that the increased use of these antibiotics as a direct result of the ban presents a greater overall risk to human health than the banned antibiotic uses.<sup>49</sup> The manufacturers also argued that the ban on bacitracin zinc increases the risk of meat contamination by fecal bacteria from ruptured intestinal walls in processed poultry, since the antibiotic use strengthens the intestinal wall.<sup>50</sup>

These concerns about the increased risks from the antibiotic ban are not frivolous. An independent scientific review published by a panel of experts after the court decisions concluded that the antibiotic ban might indeed increase net risks to animal and human health.<sup>51</sup> Just as the antibiotic manufacturers predicted, the expert review found that “there was a marked increase in the therapeutic use of antibiotics commonly used in veterinary and human medicine” following the ban on antibiotic use in animal feeds.<sup>52</sup>

The experts also expressed concern about more serious consequences from the antibiotic ban:

An even more disturbing conclusion was that, if the banning of [the antibiotics] gave even a modest increase in the variance of microbial loads on chickens leaving the processing plant, it would create far more cases of human infection than cases of resistant infection that it might prevent. Could some such consideration help to explain the increase in human campylobacter infections seen in Europe? ... The possibility is something that advocates of the “precautionary principle” should weigh carefully before recommending bans on animal antimicrobials. The evidence from Europe is that such bans may lead to a reduction of resistant bacteria in animals and perhaps even in some healthy members of the community

who eat those animals, while allowing human illness and food-borne disease burdens to reach new heights.<sup>53</sup>

Focusing specifically on the EU ban on bacitracin zinc, the expert scientific panel concluded that the effect of the ban is “entirely undesirable.”<sup>54</sup>

How did the EU courts respond to the evidence presented before them that the EU bans would likely have these counterproductive effects on animal and human health? The Court of First Instance recognized that such countervailing risks were inevitable but argued that the resulting increased risks to animal and human health could be managed or mitigated “to some extent.”<sup>55</sup> The court also claimed that the argument that the antibiotic feed ban would increase net health risks was not shared by “all the experts,”<sup>56</sup> even though the evidence discussed by the court clearly showed the potential for increased risks. The court ended its discussion of the increased health risks from the antibiotic bans by stating that “in any event” it is the prerogative of the EU regulators and not the responsibility of the courts to weigh the conflicting factors and effects to decide the appropriate policy.

In so deciding, the court is giving a green light for the EU regulators to ignore risk-risk trade-offs when invoking the precautionary principle to ban activities or products involving only hypothetical or even non-existent risks. The outcome of this policy, as demonstrated by the antibiotic feed bans, is that costly regulations will be implemented that may end up producing greater health risks than they seek to prevent.

### **Case 3. Mad Cows and Erratic Courts**

In the 1990s, the EU faced a crisis caused by a disease called bovine spongiform encephalopathy (BSE), or “mad cow” disease. First detected in the United Kingdom in 1986, BSE is one of a group of diseases, the transmissible spongiform encephalopathies, affecting various animal species, including sheep in the form of scrapie and



humans in the form of a new variant of Creutzfeldt-Jakob disease (nvCJD). It is believed that the genesis of the new variant of CJD came from cattle producers who fed the ground-up remains of cattle and sheep infected with BSE to other cattle. The nvCJD results when humans eat meat from certain high-risk tissues (primarily neurological tissue) of a cow infected with BSE. Humans infected with nvCJD experience tremors, loss of memory and balance, hallucinations, weakness, and eventually death.

The first known human victim of nvCJD, a nineteen-year-old Briton, died on May 21, 1995. During the same year, the deaths of three others in the United Kingdom were blamed on nvCJD. On March 20, 1996, the United Kingdom Health Secretary officially announced a "probable link" between nvCJD and BSE and that the cattle disease could be transmittable to humans.

In response, the leaders of the EU enacted several pieces of legislation in an attempt to control this outbreak. The EU demanded that farmers in the United Kingdom destroy millions of cattle and sheep. The Commission also enacted, in 1996, a complete ban on the export of beef and veal products from the United Kingdom. In 1999, the EU believed that the epidemic had passed and it lifted the ban. The Commission set the date of August 1, 1999, to lift the ban on the export of cattle products from the United Kingdom. This decision proved to be the most controversial and most litigated legislative step taken to combat BSE.

The French republic was the member state that expressed the most concern over lifting the ban on UK beef. Even after the decision to lift the ban was made, France continued to enforce the embargo. In response, on November 24, 1999, the French and United Kingdom authorities and the Commission drew up a protocol of understanding.<sup>57</sup> According to that protocol, the French authorities acknowledged that they were satisfied with the clarifications provided by the United Kingdom authorities and the Commission with regard to traceability of products in the United Kingdom and on-the-spot controls in France. Significant for future litigation, a reference to the precautionary principle arises in Annex II to that protocol of under-

standing in the Commission's interpretive declaration worded as follows:

The Commission declares that, in accordance with its obligations as regards traceability and recall, and following Decision 98/256 as amended by Decision 98/626, each member state, in order to guarantee the effectiveness of this measure based on the *precautionary principle*, shall take binding measures with a view to maintaining maximum traceability and ensuring that all meat and all products dispatched from the United Kingdom [are] in accordance with Annex II and Annex III of that Decision. (emphasis added)<sup>58</sup>

In response to these events, five significant cases were litigated in the EU courts. In 2000, the families of two French victims of nvCJD filed suit, claiming that the authorities in France, Britain, and Europe did not act quickly enough to stop the epidemic. Additionally, other lawsuits dealt with BSE in which member states, in particular the French republic, brought actions to fight the 1999 lifting of the EU embargo on the United Kingdom. The EU and beef producers also filed suits to enforce the lifting of the ban.

In all these cases, one of the parties raised the precautionary principle in its arguments. The resulting decisions indicate that the court's application of the precautionary principle has been influenced primarily by result-oriented political considerations, such as the economic benefit of lifting the 1996 ban and restoring open trade within the EU.

One might expect that the community institutions, including the Commission and its courts, would apply the precautionary principle strictly to the BSE problem, given both the actual manifestation of a risk in dozens of known human deaths attributed to nvCJD from eating certain meat products, as well as the public concern about mad cow disease in the EU.

Some decisions are consistent with this expectation. For example, in one case, the European Court of Justice held that

Northern Ireland may impose national emergency measures against the importation of potentially risky meat products in advance of the community measures' taking effect.<sup>59</sup> The court agreed that such interim restrictions may be "necessary" under the precautionary principle and member states might be challenged under the precautionary principle by their own citizens if they failed to impose such restrictions.<sup>60</sup>

Yet, most of the EU jurisprudence on BSE holds in favor of trade rights over the protection of public health based on the precautionary principle. In a series of cases, the plaintiff, most often a member state, sought to annul the EU decision to lift the ban on exports of beef and veal from the United Kingdom. In each case and the subsequent appeal, the EU court decided against the member state and held that the Commission's decision setting the date to lift the ban was appropriate, may commence, and the member state must comply. These decisions to allow the resumption of UK beef exports were decided despite the argument of the contesting party that the precautionary principle required continuation of the export ban until the remaining uncertainty about the potential nvCJD risks from the beef had been addressed.

For example, the French republic brought an action to annul the lifting of the UK ban, claiming that the precautionary principle required that the Commission not lift the ban on UK beef exports given remaining scientific uncertainty about the risks of BSE.<sup>61</sup> France cited the scientific opinion of its French Food Safety Agency, which concluded that there were remaining questions about the safety of UK beef, as well as the transmissible spongiform encephalopathy (TSE)/BSE ad-hoc group of the EU's Scientific Steering Committee, which was unable to agree on the scientific merits of the concerns expressed by the French authorities.<sup>62</sup>

Specifically, the opinion of the French agency and the minority view of the TSE/BSE ad-hoc group was that there was a possible third route of contamination from BSE (i.e., horizontal transmission, or transmission by contact between animals) in addition to the two routes of contamination already known about (i.e., feed and

maternal transmission).<sup>63</sup> The French authorities also cited uncertainties about whether the conditions laid down for the export of UK beef (only tissues that had been boned and the nerves removed from animals between six and thirty months of age) provided “sufficient guarantees to ensure the protection of public health.”<sup>64</sup> France claimed that the Commission violated the precautionary principle by authorizing UK beef exports notwithstanding the remaining uncertainties about the potential risks from such beef.<sup>65</sup>

The Court of Justice dismissed the French suit based on a legal technicality, claiming that the case was “inadmissible” because the Commission had not indicated its position to not reconsider lifting the UK beef export ban with sufficient formality.<sup>66</sup> Yet, there was no real doubt that the EU intended to enforce the lifting of the export ban, and the Court’s rejection of the French appeal was an implicit repudiation of the precautionary principle by refusing to overturn a Commission decision to require France to import British beef despite the remaining uncertainties about the risks from such products.

After France’s continued intransigence to adopt the measures necessary to comply with lifting the ban, the Commission brought a legal action against France in the European Court of Justice.<sup>67</sup> The Court sided with the Commission, holding that, by refusing to allow imports of UK beef, the French republic failed to fulfill its obligations under the EU treaty. This decision rejected France’s argument that the precautionary principle justified France’s actions to continue its ban in light of the fact that some risk of BSE from UK beef and veal remained.

France again based its arguments on a scientific opinion by its own food safety agency, which concluded that the risks of BSE from British beef and veal are “plausible but not currently quantifiable, linked to the absence of certainty, first, as to the distribution of BSE infectivity in the body of bovine animals over time and, secondly, as to all the modes of transmission of the infectious agent in animals.”<sup>68</sup> The French government also argued that the minority opinions of the EU’s own TSE/BSE ad-hoc group justified greater protection under the precautionary principle.

Finally, France pointed to a recent case of BSE in a British cow that developed notwithstanding the safety measures implemented in the United Kingdom, which the French government claimed demonstrated that its concerns about remaining risks were not merely hypothetical.<sup>69</sup>

The European Court of Justice construed the French claims as “a challenge, in the light of the precautionary principle, to the legality of the decision” to lift the export ban.<sup>70</sup> It dismissed these claims on a legal technicality, arguing that a member country cannot challenge the lawfulness of a community decision as a defense to an infringement action brought against that member country for failure to implement the decision.<sup>71</sup>

In so deciding, the Court gave no weight to France’s reliance on the precautionary principle and, elsewhere in the decision, further denigrated the precautionary principle. For example, the Court cited approvingly the Commission argument that “the precautionary principle . . . does not have the effect of obliging it [the Commission] to follow every scientific opinion without any power to carry out its own assessment, be it an opinion issued by a Member State body or by minority members of a Community working party.”<sup>72</sup> While perhaps a sensible policy on the merits, it runs contrary to the Commission’s own position in its communication on the precautionary principle that even minority scientific opinions expressing concerns about potential risks should be credited under the precautionary principle.<sup>73</sup>

The Court also rejected an ancillary argument made by France that the Commission improperly failed to communicate to all the commissioners France’s express reliance on the precautionary principle in opposing the lifting of the ban on UK products. France claimed that the principle of collegiality required the commissioners to have been informed of France’s express reliance on the precautionary principle before the commissioners voted to bring legal action against France.<sup>74</sup> The Court rejected this argument out of hand. It held that France’s arguments against lifting the export ban, including “arguments regarding the obligation to protect public

health, scientific uncertainty in the matter and problems connected with risk management,” were well known to the commissioners, and “[t]he addition of the label ‘precautionary principle’ to those arguments added nothing to their content.”<sup>75</sup>

In another case relating to the same underlying dispute, a private party brought an action against the French republic for its refusal to lift the 1996 ban.<sup>76</sup> The plaintiff, a professional body representing the farmers of England and Wales, brought an action in the Conseil d’Etat (French national court) for annulment of the French government’s failure to allow UK beef imports. The French court referred to the European Court of Justice the question of whether the Commission’s decision, lifting the ban on exports of British beef and veal, was inconsistent with the precautionary principle.<sup>77</sup>

The advocate general chose not to decide the merits of the question, based once again on a legal technicality that the French republic was time barred from contesting the validity of the decision ordering it to lift the ban on beef and veal.<sup>78</sup> France was therefore required to adhere to the Commission’s decision to lift the export ban. Given this ruling, the advocate general held that there was no need to examine the question of whether or not the Commission violated the precautionary principle.<sup>79</sup> The advocate general nevertheless volunteered some “brief comments” on the applicability of the precautionary principle.

First, the advocate general noted that, while “the precautionary principle has been enshrined in the Community legal order, both by primary law and case-law, as well as by the positions adopted by the Commission and the European Council,” it “must not in any way mark the resurgence of unilateralism.”<sup>80</sup> The advocate general continued that, because “observance of the [precautionary] principle forms part of Community action,” an EU member state cannot rely on the precautionary principle to take more protective actions that would “obstruct” the community measure.<sup>81</sup> This holding appears inconsistent with the belief of many proponents of the precautionary principle that governments should be able to adopt more-protective measures consistent with

public opinion by invoking the precautionary principle, as well as the argument of the EU in international forums and negotiations that individual countries should be able to impose more stringent measures based on their understanding and application of the precautionary principle.

The advocate general next commented that “judicial review of the observance of the precautionary principle must be exercised with caution” given that the principle applies “in situations of great uncertainty.”<sup>82</sup> While application of the precautionary principle should not be removed “from the sphere of judicial review” entirely, it is important to recognize “that the courts can, in this field, only exercise minimal review since the political authorities must be granted a broad discretion.”<sup>83</sup> As applied in this case, the implication of this statement is that the courts will not second-guess the EU’s failure to apply the precautionary principle as diligently and stringently as some parties may advocate. This, of course, frees the Commission and Council to act with unfettered discretion in deciding when and how they apply the precautionary principle.

The advocate general then made the following insightful comment, suggesting that the precautionary principle will be viable only if it can accept some level of risk as acceptable and disavows a zero-risk approach:

[T]he precautionary principle has a future only to the extent that, far from opening the door wide to irrationality, it establishes itself as an aspect of the rational management of risks, designed not to achieve zero risk, which everything suggests does not exist, but to limit the risks to which citizens are exposed to the lowest level reasonably imaginable.<sup>84</sup>

The advocate general then observed that some risk of mad cow disease must be considered acceptable under the precautionary principle: “[T]he presence, which can clearly not be ruled out entirely, of an infected bovine animal amongst the animals satisfying the requirements of that scheme does not mean that the

consumption of its meat carries with it, per se, an unacceptable risk in light of the requirements of the precautionary principle.”<sup>85</sup> Of course, despite this and other admonishments of the need to establish some level of acceptable risk for the precautionary principle to survive, the goal of defining some nonzero level of acceptable risk under the precautionary principle remains unfulfilled.

Finally, the advocate general noted that the precautionary principle must be applied in conjunction with other principles that are “just as fundamental.”<sup>86</sup> The advocate general specifically pointed to “the principle of proportionality, which can be said to be inseparable from the precautionary principle, but also of the principle of non-discrimination.”<sup>87</sup> The advocate general criticized France for wanting the “meat from the United Kingdom to be risk-free, even though it is agreed that the BSE epidemic has, unfortunately, not spared French cattle-farming.”<sup>88</sup>

In only one case did the Court side with the member state’s argument that the Commission failed to follow the precautionary principle.<sup>89</sup> In that case, the plaintiff, once again the French republic, argued that the precautionary principle required that the Commission strictly observe the deadlines for inspection of cattle in its administrative export scheme. The court held that full compliance with the precautionary principle was warranted because of the nature and seriousness of the risks associated with BSE and the Commission’s inspection practices did not measure up to this strict standard. In this decision, unlike the other “mad cow” cases discussed already, the Court offered no discussion of the need to accept some risk from BSE but rather applied the precautionary principle as an inflexible hammer that tolerated no possibility of risk.

In one other EU case involving mad cow disease, a Northern Ireland slaughterhouse challenged under EU law the validity of stricter national measures to combat the spread of BSE.<sup>90</sup> The slaughterhouse deboned cattle heads imported from Ireland, then exported the cheek meat for human consumption to other parts of the United Kingdom and France. On the basis of an EU directive that allowed member states to take emergency measures in case of an



outbreak of epidemic, pending the adoption by the Commission of appropriate measures at the community level, the Department of Agriculture of Northern Ireland seized a consignment of bovine heads imported from Ireland by the slaughterhouse on the ground that it might contain contaminated material.

The slaughterhouse challenged the directive and complained that the bovine heads were condemned without actual inspection and the measures introduced qualitative restrictions on the free movement of goods without being either justified or authorized under community law. The Court held that EU law did not preclude adoption of stricter national interim protective measures. It determined that the national measures that allowed Northern Ireland to seize the cattle were justified and proportional. Therefore, until the Commission's adoption of the appropriate measures at the community level, the government of Northern Ireland was free to follow more restrictive policies as an emergency response. Although the Court in this decision appeared to apply a strict precautionary principle, no explicit mention of the precautionary principle was provided in this decision.

The five EU mad cow decisions demonstrate an inconsistent application of the precautionary principle to the risks of BSE. In some cases, the court applied the precautionary principle strictly, countenancing no possibility of risk, given the seriousness and nature of mad cow disease. In the other cases, the courts seemed determined not to interfere with the EU efforts to resume normal trade following the mad cow crisis.

In so doing, the courts disregarded credible scientific opinions that potential risks remained and stretched to find legal technicalities to dismiss the cases without addressing the merits. Moreover, to the extent that the courts did address the merits in these decisions, they stressed the importance of accepting some risk of BSE and discounted the importance of the precautionary principle. Taken together, this set of cases demonstrates that, in the absence of any agreed-on definition or criteria for the precautionary principle, reviewing courts will be inclined to apply the principle strate-

gically and arbitrarily to obtain outcomes favored for political or other reasons.

## 6 Conclusion

One legal commentator recently observed that the precautionary principle, both as conceived and as applied, is already in “disarray.”<sup>1</sup> Even strong supporters of the precautionary principle in Europe express frustration with its implementation.

For example, Michael Meacher, an ardent proponent of the precautionary principle, complained while serving as UK minister for the environment that “the precautionary principle perhaps got out of hand” because “people are increasingly reacting where there is no risk.”<sup>2</sup> Other EU experts have likewise expressed growing concerns that the precautionary principle is becoming unworkable in practice.<sup>3</sup>

This study of the implementation of the precautionary principle by the EU courts supports this contention, showing a pattern of inconsistent and arbitrary applications of the principle.

In some cases, the precautionary principle is construed as an absolute and draconian measure that mandates zero risk or as close to it as possible. Under this construction, the precautionary principle requires banning a product that has been used safely for many years and the EU’s own scientific advisory body has concluded it is unlikely to present any significant risk now.

In other cases, the importance of the precautionary principle is severely downplayed, with the court emphasizing the need to accept some risk and effectively giving no weight to the precautionary principle.<sup>4</sup>

This analysis also demonstrates that judicial review is unlikely to impose any constraints or criteria on the use of the precautionary principle by regulators, other than occasional, ad-hoc, and unpredictable rejections of decisions based on the precautionary principle. Given the lack of any definition or implementation criteria for the precautionary principle by EU regulators, one might have hoped that the EU courts would have tried to rein in the unprecedented regulatory discretion provided by the precautionary principle.

Instead, the EU courts themselves applied the precautionary principle without any definition or consistent criteria to reach their own predetermined outcomes. And while recognizing the vagueness and ambiguity of the precautionary principle, the courts responded by defaulting on their judicial review responsibilities, claiming that application of the precautionary principle is simply too discretionary to provide meaningful review, rather than trying to fix the problem by imposing some limitations on the use of the precautionary principle by the EU regulators.

In conclusion, this empirical analysis of the consideration of the precautionary principle by the EU courts confirms the fears of many skeptics of the precautionary principle that it provides an open invitation for arbitrary and unreasonable decisions by both regulators and judges.



# Appendix

## Table of Cases

<i>Case Name and Citation</i>	<i>Court</i>
Case C-321/95, <i>Greenpeace Int'l v. Commission</i> , 1998 E.C.R. I-1651	ECJ
Case C-341/95, <i>Bettati v. Safety Hi-Tech Srl</i> , 1998 E.C.R. I-4355	ECJ
Case C-343/95, <i>Cali &amp; Srl v. Servizi Ecologici Porto Di Genova SpA (SEGA)</i> , 1997 E.C.R. I-1547	Advocate general
Case T-219/95, <i>Danielsson v. Commission</i> , 1995 E.C.R. II-3051	Court of 1st Instance
Case C-67/97, <i>Ditle v. Bluhme</i> , 1998 E.C.R. I-8033	Advocate general
Case C-184/97, <i>Commission v. Germany</i> , 1999 E.C.R. I-7837	Advocate general
Case C-293/97, <i>R. v. Sec. of State for the Env. and Min. of Agr.</i> , 1999 E.C.R. I-2603.	Advocate general
Case C-418/97 & C-419/97, <i>ARCO v. Minister</i> , 2000 E.C.R. I-4475	ECJ
Case C-36/98, <i>Spain v. Council</i> , 2001 E.C.R. I-779	ECJ
Case C-94/98, <i>R. v. Licensing Authority</i> , 1999 E.C.R. I-8789	ECJ
Case C-318/98, <i>Fornasar et al. v. Italy</i> , 2000 E.C.R. I-4785	Advocate general
Case C-318/98, <i>Fornasar et al. v. Italy</i> , 2000 E.C.R. I-4785	ECJ
Case C-352/98, <i>Lab. Pharm. Bergaderm SA v. Commission</i> , 2000 E.C.R. I-5291	Advocate general
Case C-352/98, <i>Lab. Pharm. Bergaderm SA v. Commission</i> , 2000 E.C.R. I-5291	ECJ
Case C-477/98, <i>Eurostock Meat Marketing Ltd. v. Dept. of Agr. for N. Ireland</i> , 2001 E.C.R. I-10695	ECJ
Case C-6/99, <i>Greenpeace France v. Ministere de l'Agriculture et de la Peche</i> , 2000 E.C.R. I-1651	ECJ
Case C-248/99, <i>French Republic v. Monsanto Co. &amp; Commission</i> , 2002 E.C.R. 0	Advocate general
Case C-248/99, <i>French Republic v. Monsanto Co. &amp; Commission</i> , 2002 E.C.R. 0	ECJ
Case C-512/99, <i>Germany v. Commission</i> , 2002 E.C.R. 0	Advocate general

<i>Issue</i>	<i>Role of PP<sup>a</sup></i>	<i>Decision Pro/Con PP?<sup>b</sup></i>
Construction of power plants	Minor	N/A
Ozone-depleting chemicals	Minor	Con
Maritime-accident pollution system	Minor	Pro
Nuclear testing	Minor	Con
Biological diversity (honeybees)	Minor	Pro
Water quality	Minor	N/A
Nitrates from agricultural runoff	Minor	Pro
Definition of waste	Minor	N/A
Water resources management	Minor	N/A
Pharmaceutical importation	Minor	Pro
Hazardous-waste disposal	Major	Pro
Hazardous-waste disposal	Major	Pro
Sun-protection product	Minor	Pro
Sun-protection product	Minor	Pro
Bovine spongiform encephalopathy	Minor	Pro
Genetically modified foods	Major	Con
Bovine somatotropin	Minor	Pro
Bovine somatotropin	Minor	Pro
Mineral wool	Major	Con

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<i>Case Name and Citation</i>	<i>Court</i>
Case C-514/99, <i>French Republic v. Commission</i> , 2000 E.C.R. I-4705	ECJ
Case T-13/99, <i>Pfizer Animal Health SA v. Council</i> , 1999 E.C.R. II-1961	Court of 1st Instance (president)
Case T-13/99, <i>Pfizer Animal Health SA v. Council</i> , 2002 E.C.R. II-3305	Court of 1st Instance
Case T-70/99, <i>Alpharma Inc. v. Council</i> , 2002 E.C.R. II-3495	Court of 1st Instance
Case T-326/99, <i>Olivieri v. Commission</i> , 2000 E.C.R. II-1985	Court of 1st Instance
Opinion 2/00, <i>R. v. Re the Cartagena Protocol on Biosafety</i> , 2001 E.C.R. I-9713	ECJ
Case C-1/00, <i>Commission v. French Republic</i> , 2001 E.C.R. I-9989	Advocate general
Case C-1/00, <i>Commission v. French Republic</i> , 2001 E.C.R. I-9989	ECJ
Case C-3/00, <i>Denmark v. Commission</i> , 2003 E.C.R. I-2643	ECJ
Case C-9/00, <i>Palin Granit Oy v. Lounais-Suomen Ymparistokeskus</i> , 2002 E.C.R. 0	Advocate general
Case C-9/00, <i>Palin Granit Oy v. Lounais-Suomen Ymparistokeskus</i> , 2002 E.C.R. I-3533	ECJ
Case C-24/00, <i>Commission v. France</i> , 2004 E.C.R. 0	ECJ
Case C-121/00, <i>Criminal proceedings against Walter Hahn</i> , 2002 E.C.R. I-9193	ECJ
Case C-459/00, <i>Commission v. Laboratoires Pharmaceutiques Trenker</i> , 2001 E.C.R. I-2823	ECJ
Case C-471/00, <i>Commission v. Cambridge Healthcare Supplies</i> , 2001 E.C.R. I-2865	ECJ
Case C-474/00, <i>Commission v. Bruno Farmaceutici</i> , 2001 E.C.R. I-2909	ECJ
Case C-475/00, <i>Commission v. Hanseler</i> , 2001 E.C.R. I-2953	ECJ
Case C-476/00, <i>Commission v. Schuck</i> , 2001 E.C.R. I-2995	ECJ
Case C-477/00, <i>Commission v. Laboratorios Roussel</i> , 2001 E.C.R. I-3037	ECJ
Case C-478/00, <i>Commission v. Laboratorios Roussel</i> , 2001 E.C.R. I-3079	ECJ
Case C-479/00, <i>Commission v. Gerot Pharmazeutika</i> , 2001 E.C.R. I-3121	ECJ
Case T-74/00, <i>Artegodan GmbH v. Commission</i> , 2002 E.C.R. II-4945	Court of 1st Instance



<i>Issue</i>	<i>Role of PP<sup>a</sup></i>	<i>Decision Pro/Con PP?<sup>b</sup></i>
Bovine spongiform encephalopathy	Minor	Con
Antibiotics in animal feed	Major	Pro
Antibiotics in animal feed	Major	Pro
Antibiotics in animal feed	Major	Pro
Medicinal product	Minor	Con
Biosafety protocol	Minor	N/A
Bovine spongiform encephalopathy	Minor	Con
Bovine spongiform encephalopathy	Major	Con
Sulphites, nitrites, and nitrate food additives	Minor	Con <sup>c</sup>
Definition of waste	Minor	Pro
Definition of waste	Minor	Pro
Nutritionally enhanced foodstuffs	Minor	Con
Pathogenic microorganisms	Minor	Pro
Obesity drug (phentermine)	Minor	Pro
Obesity drug (phentermine)	Minor	Pro
Obesity drug (amfepramone)	Minor	Pro
Obesity drug (norpseudoephedrine)	Minor	Pro
Obesity drug (norpseudoephedrine)	Minor	Pro
Obesity drug (clobenzorex)	Minor	Pro
Obesity drug (fenproporex)	Minor	Pro
Obesity drug (phentermine)	Minor	Pro
Obesity drugs	Major	Con

<i>Case Name and Citation</i>	<i>Court</i>
Case T-147/00, <i>Laboratoires Servier v. Commission</i> , 2003 cv	Court of 1st Instance
Case T-174/00, <i>Biret International SA v. Council</i> , 2002 E.C.R. 0	Court of 1st Instance
Case T-210/00, <i>Biret et Cie SA v. Council</i> , 2002 E.C.R. 0	Court of 1st Instance
Case T-344/00, <i>CEVA Sante Animale SA v. Commission</i> , 2003 E.C.R. 0	Court of 1st Instance
Case C-95/01, <i>Criminal proceedings against John Greenham</i> , 2002 E.C.R. 0	Advocate general
Case C-95/01, <i>Criminal proceedings against John Greenham</i> , 2004 E.C.R. 0	ECJ
Case C-192/01, <i>Commission v. Denmark</i> , 2003 E.C.R. 0	Advocate general
Case C-192/01, <i>Commission v. Denmark</i> , 2003 E.C.R. 0	ECR
Case C-220/01, <i>Lennox v. Industria Lavorazione Carni Ovine</i> , 2002 E.C.R. 0	Advocate
Case C-236/01, <i>Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri</i> , 2003 E.C.R. 0	Advocate general
Case C-236/01, <i>Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri</i> , 2003 ECR 0	ECJ
Case C-241/01, <i>Nat. Farmers' Union v. Sec. General of the French Gov.</i> , 2002 E.C.R. I-9079	Advocate general
Case C-241/01, <i>Nat. Farmers' Union v. Sec. General of the French Gov.</i> , 2002 E.C.R. I-9079	ECJ
Case C-393/01, <i>France v. Commission</i> , 2003 E.C.R. 0	ECJ
Case C-440/01, <i>Commission v. ArtegoDan</i> , 2002 E.C.R. 0	ECJ
Case C-491/01, <i>R. v. Sec. of State for Health</i> , 2002 E.C.R. 0	Advocate general
Case C-93/02, <i>Biret International SA v. Council of the European Union</i> , 2003 E.C.R. 0	ECJ
Case T-369/03 R, <i>Arizona Chemicals BV v. Commission</i> , 2004 E.C.R. 0	Court of 1st Instance (president)
Case T-422/03 R, <i>Enviro Tech Europe Ltd v. Commission</i> , 2003 E.C.R. 0	Court of 1st Instance (president)

<i>Issue</i>	<i>Role of PP<sup>a</sup></i>	<i>Decision Pro/Con PP?<sup>b</sup></i>
Obesity drugs	Minor	Con
Hormone-treated beef and veal	Minor	N/A
Hormone-treated beef and veal	Minor	N/A
Veterinary hormones	Minor	Con
Food supplements	Minor	N/A
Food supplements	Minor	Pro
Vitamins	Major	Pro
Vitamins	Major	Con
Imports of sheep	Minor	Pro
Genetically modified corn	Major	Pro
Genetically modified corn	Minor	N/A
Hormone-treated beef and veal	Major	Con
Hormone-treated beef and veal	Major	Con
Bovine spongiform encephalopathy	Minor	Pro
Obesity drugs	Minor	Pro
Tobacco products	Minor	Pro
Hormone-treated beef and veal	Minor	N/A
Hazardous substances	Minor	N/A
Hazardous substances	Minor	N/A

Source: Authors' research

a. The role of the precautionary principle in the court's decision is rated as "minor" or "major." Minor means that the precautionary principle was raised by one or more parties and/or the courts but played no express role in the court's decision and was not a primary argument asserted by any of the parties. Major means that the precautionary principle played a role expressly in the court's judgment, and/or was one of the primary arguments asserted by one or more parties.

b. Pro means that the court decided the case in favor of the party asserting the precautionary principle and in favor of greater environmental or health protection, whereas Con means that the court decided the case adverse to the party asserting the precautionary principle for a more protective outcome. When more than one issue is presented in a case and the court's decision is split between the two parties, the decision is classified as Pro the precautionary principle if one or more issues are decided favorable to the precautionary principle, and the real-world impact of that favorable decision is not invalidated by other parts of the same decision.

c. While the decision in this case was consistent with the argument made by the party asserting the precautionary principle, the court expressly rejected application of the precautionary principle as argued by the prevailing party.





# Notes

## Chapter 1: Introduction

1. See John S. Applegate, "The Precautionary Preference: An American Perspective on the Precautionary Principle," *Human Ecology and Risk Assessment* 6 (2000): 413, 415 ("It is little more than a truism that regulatory action precedes 'full' scientific certainty, because regulators always act without *full* certainty.").
2. Gary E. Marchant, "From General Policy to Legal Rule: The Aspirations and Limitations of the Precautionary Principle," *Environmental Health Perspectives* 111 (2003): 1799.
3. See, e.g., Frank B. Cross, "Paradoxical Perils of the Precautionary Principle," *Washington and Lee Law Review* 53 (1996): 851; Julian Morris, "Defining the Precautionary Principle," in *Rethinking Risk and the Precautionary Principle*, Julian Morris, ed., 1 (Oxford: Butterworth-Heinemann, 2000); Jonathan B. Wiener, "Precaution in a Multi-Risk World," Duke Law School Law and Legal Theory Working Paper no. 23, December 2001.

## Chapter 2: The Precautionary Principle: Background

1. See, e.g., Talbot Page, "A Generic View of Toxic Chemicals and Similar Risks," *Ecology Law Quarterly* 7 (1978): 207; M. Granger Morgan and Max Henrion, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis* (Cambridge: Cambridge University Press, 1990).
2. Applegate, "The Precautionary Preference."
3. *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 11503 (D.C. Cir. 1980).
4. National Research Council, *Science and Judgment in Risk Assessment* (Washington, D.C.: National Academy Press, 1994).
5. See Gregory Conko, "Safety, Risk, and the Precautionary Principle: Rethinking Precautionary Approaches to the Regulation of Transgenic Plants," *Transgenic Research* 12 (2003): 639, 642.

6. See, e.g., Paul Harremoës et al., eds., *The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings* (London: Earthscan Publications, 2002).
7. John N. Hathcock, "The Precautionary Principle – An Impossible Burden of Proof for New Products," *AgBioForum: The Journal of Agrobiotechnology Management and Economics* 3 (2000): 255 ("The term 'precautionary principle' is seductively attractive because it sounds like something that everyone should want and no one could oppose").
8. Peter Montague, "The Uses of Scientific Uncertainty," *Rachels' Environment and Health News* (July 1, 1999): 5 ("Precautionary action immediately makes sense to people. Everyone can understand the wisdom of, 'Do unto others as you would have others do unto you' and, 'Better safe than sorry.'") (available at [http://www.rachel.org/bulletin/index.cfm?issue\\_ID=1508](http://www.rachel.org/bulletin/index.cfm?issue_ID=1508)).
9. See James E. Hickey and Vern R. Walker, "Refining the Precautionary Principle in International Environmental Law," *Virginia Environmental Law Journal* 14 (1995): 423, 432–36 (listing fourteen international environmental agreements and declarations that had adopted the precautionary principle as of 1995).
10. United Nations Conference on Environment and Development, Rio Declaration on Environment and Development, June 14, 1992, 31 I.L.M. 874, 879.
11. San Francisco Precautionary Principle Ordinance, available at [http://www.ci.sf.ca.us/sfenvironment/aboutus/policy/legislation/precaution\\_principle.htm](http://www.ci.sf.ca.us/sfenvironment/aboutus/policy/legislation/precaution_principle.htm).
12. Peter T. Saunders and Mae-Wan Ho, "The Precautionary Principle Is Coherent," Science, Technology and Innovation Program Viewpoints, Center for International Development, Harvard University (Nov. 28, 2000) (available at [http://www.cid.harvard.edu/cidbiotech/comments/comments\\_109.htm](http://www.cid.harvard.edu/cidbiotech/comments/comments_109.htm)).
13. Applegate, "The Precautionary Preference," 415.



14. Wybe T. Douma, "The Precautionary Principle," European Environmental Law Webpage Dossier (available at <http://www/eel.nl/virtue/prevprin.htm>), p. 11.
15. See Applegate, "The Precautionary Preference," 415 ("the precautionary principle is just that – a principle, and not an operational standard for conduct"); Katherine Barrett and Carolyn Raffensperger, "From Principle to Action: Applying the Precautionary Principle to Agricultural Biotechnology," *International Journal of Biotechnology* 4 (2002): 4, 6 (the precautionary principle "is a guiding principle, not a set of binding rules"). See also Konrad von Moltke, "The Relationship between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle," in *The Precautionary Principle and International Law*, D. Freestone and E. Hey, eds., 97 (The Hague: Kluwer Law International, 1996).
16. J. Thornton, *Pandora's Poison: Chlorine, Health, and a New Environmental Strategy* (Cambridge, Mass.: MIT Press, 2000).
17. See, e.g., W. Gullett, "The Precautionary Principle in Australia: Policy, Law and Potential Precautionary EIAs," *Risk: Health, Safety, and the Environment* 11 (2000): 93; Paul Stein, "A Cautious Application of the Precautionary Principle," *Environmental Law Review* 4 (2000): 1; Felicity Nagorcka, "Saying What You Mean and Meaning What You Say: Precaution, Science and the Importance of Language," *European Public Law Journal* 20 (2003): 211, 221.
18. See Douma, "The Precautionary Principle," 11; Marchant, "From General Policy to Legal Rule," 1801–02.
19. O. McIntyre and T. Mosedale, "The Precautionary Principle as a Norm of Customary International Law," *Journal of Environmental Law* 9 (1997): 221; James Cameron and Juli Abouchar, "The Status of the Precautionary Principle in International Law," in *The Precautionary Principle and International Law*, D. Freestone and E. Hey, eds., 29 (The Hague: Kluwer Law International, 1996).
20. European Commission, "Communication for the Commission on the Precautionary Principle," COM(2000)1, 02.02.2000 [hereafter, European Commission PP Communication].

21. See, generally, P. L. Stein, "Are Decision-Makers Too Cautious with the Precautionary Principle?" *Environmental and Planning Law Journal* 17 (2000): 3 (reviewing cases).
22. See, e.g., Douma, "The Precautionary Principle," 11 ("The precautionary principle is developing from a mere policy guidance ('soft law') into 'hard law'").
23. *Nicholls v. Director-General of National Parks and Wildlife*, 1994 NSWLEC 155 (29 Sept. 1994) (available at <http://www.austlii.edu.au/cgi-bin/disp.pl/au/cases/nsw/NSWLEC/1994/155.html?query=title+%28+%22nicholl%22+%29>).
24. Steve E. Hrudehy and William Leiss, "Risk Management and Precaution: Insights on the Cautious Use of Evidence," *Environmental Health Perspectives* 111 (2003): 1577 ("The key question, we suggest, is not whether to be precautionary, but how precautionary we ought to be in specific cases ...").
25. The Wingspread Consensus Statement on the Precautionary Principle (January 1998), available at <http://www.sehn.org/wing.html> (hereinafter Wingspread Statement).
26. Harremoës et al., eds., *The Precautionary Principle in the 20th Century*.
27. See Marchant, "From General Policy to Legal Rule," 1799; John D. Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," *Journal of Risk Research* 5 (2002): 371, 375.
28. David Santillo and Paul Johnston, "Is There a Role for Risk Assessment within Precautionary Legislation?" *Human and Ecology Risk Assessment* 5 (1999): 923, 925 ("The precautionary principle is, in very simple terms, an expression of the ethic that 'prevention is better than the cure'").
29. *Ibid.*, 925 (the precautionary principle "has developed from a recognition of the need to make decisions in the face of considerable, and frequently, irreducible uncertainties surrounding the properties of the system under study and the nature of the threats to the system (including their magnitude and likelihood)").
30. Jonathan B. Wiener and Michael D. Rogers, "Comparing Precaution in the U.S. and Europe," *Journal of Risk Research* 5

(2002): 317, 321; Richard B. Stewart, "Environmental Regulatory Decisionmaking under Uncertainty," *Research in Law and Economics* 20 (2002): 71; Hrudehy and Leiss, "Risk Management and Precaution," 1580.

31. Bernard D. Goldstein, "The Precautionary Principle and Scientific Research Are Not Antithetical," *Environmental Health Perspectives* 107 (1999): A594.

32. John D. Graham and Jonathan Baert Wiener, *Risk vs. Risk: Trade-offs in Protecting Health and the Environment* (Cambridge, Mass.: Harvard University Press, 1995). See also Cross, "Paradoxical Perils"; Wiener, "Precaution in a Multi-Risk World."

33. Wiener, *ibid.*, 1 (arguing for "optimal precaution").

34. See Christopher D. Stone, "Is There a Precautionary Principle?" *Environmental Law Reports* 31 (2001): 10790 (it is inappropriate to refer to "the" precautionary principle in the singular); Hickey and Walker, "Refining the Precautionary Principle," 424 ("references to precaution reveal a variable, vague, and often confusing 'principle,' for states to follow ..."); John D. Graham, "Perspectives on the Precautionary Principle," *Human and Ecology Risk Assessment* 6 (2000): 383 ("There is no such thing as 'the' precautionary principle").

35. Per Sandin, "Dimensions of the Precautionary Principle," *Human and Ecology Risk Assessment* 5 (1999): 889.

36. See Montague, "The Uses of Scientific Uncertainty," 3 ("Some people would say that the threatened harm must be serious or irreversible, but others point out that this does not allow for the cumulative effects of relatively small insults").

37. United Nations Conference on Environment and Development (UNCED), Rio Declaration on Environment and Development, UN Doc. A/CONF.151/5/Rev. 1 (1992) (emphasis added).

38. Wingspread Statement.

39. European Commission PP Communication.

40. *Ibid.*

41. Kenneth L. Mossman and Gary E. Marchant, "The Precautionary Principle and Radiation Protection," *Risk: Health, Safety, and the Environment* 13 (2002): 137.
42. Daniel Bodansky, "Scientific Uncertainty and the Precautionary Principle," *Environment* (September 1991): 4–5.
43. Cass R. Sunstein, "Beyond the Precautionary Principle," *University of Pennsylvania Law Review* 151 (2003): 1003, 1004.
44. *R. v. Secretary of State for Trade & Industry, ex parte Duddridge*. 1994. Case No. 1995 Env L R 151, Queen's Bench Division, London, UK.
45. Wingspread Statement.
46. Carol Raffensperger and Joel Tickner, "Introduction: To Foresee and Forestall," in *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, Carol Raffensperger and Joel Tickner, eds., 1 (Washington, D.C.: Island Press, 1999).
47. Wingspread Statement.
48. Some proponents of the precautionary principle argue that it does not apply to established risks, such as the effects of PCBs on marine environments, because such application is "hardly precautionary." Santillo and Johnston, "Is There a Role for Risk Assessment?" 927.
49. See, e.g., *ibid.*, 930–31.
50. *Ibid.*, 930.
51. "Greenpeace International, Chlorine Crisis: Time for a Global Phase-Out," cited in Applegate, "The Precautionary Preference," 418.
52. As the EU communication states, "Measures based on the precautionary principle must not ... aim at zero risk, something which rarely exists" (European Commission PP Communication, 18).
53. Conko, "Safety, Risk, and the Precautionary Principle," 640.
54. See National Academy of Sciences/National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: National Academy Press, 1983).

55. See Santillo and Johnston, "Is There a Role for Risk Assessment?" 930 ("The principle cannot be effectively incorporated as a tool within risk-based approaches."); Philippe Grandjean, "Implications of the Precautionary Principle for Primary Prevention and Research," *Annual Review of Public Health* 25 (2004): 199, 205 ("Risk assessment has therefore become part of the problem and not part of the solution."); Mary O'Brien, *Making Better Environmental Decisions: An Alternative to Risk Assessment* (Cambridge, Mass.: MIT Press, 2000), vi (supporting a "paradigm shift away from risk assessment and toward the principle of precautionary action").
56. European Commission PP Communication, 13.
57. See Conko, "Safety, Risk, and the Precautionary Principle," 643 ("The reluctance of precautionary principle advocates to define what purports to be a fundamental principle makes confusion and mischief inevitable").
58. A. Jordan and T. O'Riordan, "The Precautionary Principle in Contemporary Environmental Policy and Politics," in Raffensperger and Tickner, eds., *Protecting Public Health and the Environment*, 15–35.
59. John Harris and Soren Holm, "Extending Human Lifespan and the Precautionary Paradox," *Journal of Medicine and Philosophy* 27 (2002): 355, 361.
60. Gary E. Marchant, "The Precautionary Principle: An 'Unprincipled' Approach to Biotechnology Regulation," *Journal of Risk Research* 4 (2001): 143, 145.
61. Aaron Wildavsky, "Trial and Error versus Trial without Error," in Morris, ed., *Rethinking Risk and the Precautionary Principle*, 22, 24.
62. A recent European academic analysis of the implementation of the precautionary principle in the EU concluded that "those situations where it has been used to restrict or prohibit the use of a product or procedure often appear to be arbitrary and politically motivated rather than being based predominantly upon sound scientific evaluation of any potential risk posed." Caoimhin

- MacMaolain, "Using the Precautionary Principle to Protect Human Health: *Pfizer v Council*," *European Law Review* 28 (2003): 723, 724.
63. See, e.g., Alan McHughen, *Pandora's Picnic Basket: The Potential and Hazards of Genetically Modified Foods* (Oxford, UK: Oxford University Press, 2000); Marchant, "From General Policy to Legal Rule," 1801.
64. *EFTA Surveillance Authority v. Norway*. 2001. Case E-3/00, 2 C.M.L.R. 47, European Free Trade Association Court, Luxembourg.
65. Case C-24/00, *Commission v. France*, 2004 E.C.R. 0, ¶67 (ECJ).
66. Case C-192/01, *Commission v. Denmark*, 2003 E.C.R. 0 (Advocate General).
67. EU, *Proposal for a Council Regulation on State Aid to the Coal Industry*, O.J. C 304 E/202 (Oct. 30, 2001).
68. J. Bohannon, "Zambia Rejects GM Corn on Scientists' Advice," *Science* 298 (2002): 1153.
69. Justin Gillis, "Debate Grows over Biotech Food," *Washington Post*, November 30, 2003, A1.
70. *Ibid.*
71. See, e.g., Wingspread Statement ("The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties."); David Kriebel and Joel Tickner, "Reenergizing Public Health through Precaution," *American Journal of Public Health* 91 (2001): 1351, 1353 ("Participation and transparency are essential components of a more precautionary approach to public health decision making.").
72. *Leach v. National Parks and Wildlife Service and Shoalhaven City Council*. 1993. Case No. 10376. 81 LGERA 270. Land and Environment Court of New South Wales, Sydney, Australia.
73. B. J. O'Brien, "Risking Australia's Future with the Precautionary Principle," *Australian Academy of Technological Sciences and Engineering (ASTE) Focus*, no. 114, November/December 2000 (available at <http://www.atse.org.au/publications/focus/focus-obrien2.htm>).
74. See, e.g., National Foreign Trade Council, Inc., "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound

Science” (May 2003) (available at [www.nftc.org](http://www.nftc.org), giving examples of protectionist trade barriers based on the precautionary principle); Stone, “Is There a Precautionary Principle?” 10791 (“There is concern that, as long as the precautionary principle remains nebulous, trading nations will mask as ‘precautionary health protection measures’ border controls actually designed to shield domestic producers from foreign competition”).

75. Bernard D. Goldstein, “Use and Abuse of the Precautionary Principle,” *Risk Policy Report*, March 20, 2000, 39–40. The EU’s reliance on the precautionary principle was retroactive in that it did not refer to the precautionary principle in its initial decision to ban North American beef, but rather injected the principle as part of its defense of that decision when challenged under World Trade Organization procedures.

76. World Trade Organization (1997). Panel Report on “EC Measures Concerning Meat and Meat Products (Hormones),” WT/DS48/R/CAN (Aug. 18, 1997) at 8.16–8.17.

77. United Nations General Assembly, *World Charter for Nature*, U.N. G.A. Resolution 37/7 (1982).

78. European Commission PP Communication, 16.

### Chapter 3: The Precautionary Principle in the European Union

1. European Union, “European Union Institutions and Other Bodies” (available at [http://europa.eu.int/institutions/index\\_en.htm](http://europa.eu.int/institutions/index_en.htm), last visited February 23, 2004).

2. Treaty on European Union, *Official Journal* C 191, July 29, 1992 (available at [http://europa.eu.int/eur-lex/en/treaties/dat/EU\\_treaty.html](http://europa.eu.int/eur-lex/en/treaties/dat/EU_treaty.html)).

3. *Ibid.* §174(2) (as amended).

4. European Commission PP Communication.

5. *Ibid.*, 13.

6. *Ibid.*, 17.

7. *Ibid.*, 13.

8. *Ibid.*, 15.

9. Food and Drug Administration (FDA)/U.S. Department of Agriculture (USDA), A U.S. government submission to the Committee on General Principles of the Codex Alimentarius Commission (March 22, 2000) (available at <http://www.fsis.usda.gov/OA/codex/confpaper.htm>).

10. European Commission PP Communication, 13.

11. *Ibid.*, 14 (“A scientific evaluation of the potential adverse effects should be undertaken based on the available data when considering whether measures are necessary to protect the environment, the human, animal or plant health. An assessment of risk should be considered where feasible when deciding whether or not to invoke the precautionary principle... However it is not possible in all cases to complete a comprehensive assessment of risk, but all effort should be made to evaluate the available scientific information.”).

12. See, e.g., Santillo and Johnston, “Is There a Role for Risk Assessment?”

13. Opinion of the Economic and Social Committee on the “Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Development of Public Health Policy in the European Community,” OJ 1998 C407/21, 24 (28.12.1998), ¶13.8.5.

14. Opinion of the Economic and Social Committee on the “Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: Life Sciences and Biotechnology – A Strategy for Europe,” OJ 2003 C61/22, March 14, 2003.

15. Opinion of the Committee of the Regions on: The “Communication from the Commission on the Reform of the Common Fisheries Policy (“Roadmap”), et al.,” OJ 2003 C128/6, 7, May 29, 2003.

16. Case T-74/00, *Artogodan GmbH v. Commission*, 2002 E.C.R. II-4945, ¶183.



17. Amended Proposal for a Regulation of the European Parliament and of the Council concerning Traceability and Labelling of Genetically Modified Organisms and Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, COM92002 515 final, OJ 2002 C331E/308, 310, 31.12.2002.

18. *Ibid.*

#### **Chapter 4: The European Union Courts and the Precautionary Principle: Overview**

1. This analysis covers only the opinions of the official general jurisdictional courts of the EU, consisting of the European Court of Justice, the Court of First Instance, and the advocate generals. It does not include opinions by the courts of individual EU nations or of specialized EU courts.

2. In another twelve cases in which the precautionary principle played a minor role, the court's decision could not be classified as either pro or con the precautionary principle, because the court failed to reach the merits of the issue for which the precautionary principle was invoked (e.g., the case was decided on procedural grounds or other substantive issues).

3. As the Court of First Instance remarked, "Neither the Treaty nor the secondary legislation ... contains a definition of the precautionary principle." Case T-13/99, *Pfizer Animal Health SA v. Council* 2002 E.C.R. II-3305 (Ct. of 1st Instance), ¶117; Case T-70/99, *Alpharma Inc. v. Council*, 2002 E.C.R. II-3495 (Ct. of 1st Instance), ¶138. See also Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (Advocate General), ¶135 ("The precautionary principle has not yet been fully defined in the case-law of the Court of Justice.").

4. Case T-74/00, *Artogodan GmbH v. Commission*, 2002 E.C.R. II-4945 (Ct. First Instance).

5. *Ibid.*, ¶185.

6. *Ibid.*, ¶186.

7. Graham and Wiener, *Risk vs. Risk*; Cass R. Sunstein, "Health-Health Tradeoffs," *University of Chicago Law Review* 63 (1996): 1533; Ralph L. Keeney, "Estimating Fatalities Induced by the Economic Costs of Regulations," *Journal of Risk and Uncertainty* 14 (1997): 5; Randall Lutter and John F. Morrall, "Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation," *Journal of Risk and Uncertainty* 8 (1994): 43.
8. *Artegoda* ¶¶27–72.
9. *Ibid.*
10. *Ibid.*, ¶211.
11. *Ibid.* ¶¶194, 220. The European Court of Justice subsequently reinstated the Commission's decision in an opinion that did not rely on the precautionary principle. Case C-440/01, *Commission v. Artégoda*, 2002 E.C.R. 0 (ECJ).
12. Case C-94/98, *The Queen v. The Licensing Authority*, 1999 E.C.R. I-8789, ¶29, n. 45.
13. Case C-318/98, *Fornasar et al. v. Italy* 2000 E.C.R. I-4785 (Celex No. 6980 C318) (opinion of advocate general).
14. Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (advocate general), ¶108.
15. Case C-318/98, *Fornasar et al. v. Italy*, 2000 E.C.R. I-4785 (2000) (Celex No. 6980C318), ¶37.
16. T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance), ¶146.
17. Case C-192/01, *Commission v. Denmark*, 2003 E.C.R. 0 (Advocate General), ¶101.
18. *Ibid.* ¶¶9, 56, 142–146.
19. Case C-192/01, *Commission v. Denmark*, 2003 E.C.R. 0 (ECJ), ¶¶46, 48.
20. Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (advocate general), ¶137 (emphasis added, footnote omitted).
21. *Ibid.*, ¶138 (emphasis added).
22. *Ibid.*, ¶151.

23. Case C-341/95, *Bettati v. Safety Hi-Tech Srl*, 1998 E.C.R. I-4355, ¶47.
24. Case T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance), ¶145.
25. Case C-241/01, *Nat. Farmers' Union v. Sec. General of the French Gov.*, 2001 OJ C245/7 (opinion of advocate general), ¶76.
26. Case C-184/97, *Commission v. Germany*, 1999 E.C.R. I-7837, ¶27 (opinion of advocate general).
27. Case T-13/99, *Pfizer Animal Health SA v. Council*, 1999 E.C.R. II-1961 (Celex No. 699B00113) (1999) (president of Ct. of 1st Instance), ¶76.
28. *Ibid.*
29. See, e.g., Case C-318/98, *Fornasar et al. v. Italy*, 2000 E.C.R. I-4785 (Celex No. 6980C318) (opinion of advocate general), ¶133 (the European Court of Justice has “recognised the binding nature of this general [precautionary] principle.”); Case C-241/01, *Nat. Farmers' Union v. Sec. General of the French Gov.*, 2001 OJ C245/7 (opinion of advocate general), ¶71 (“the precautionary principle has been enshrined in the Community legal order, both by primary law and case-law, as well as by the positions adopted by the Commission and the European Council”).
30. Case T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance).
31. Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (advocate general). The European Court of Justice subsequently remanded the case to the Italian national court to determine whether Italy’s action was justified, taking into account the precautionary principle. Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (ECJ).
32. Case C-95/01, *Criminal Proceedings against John Greenham*, 2004 E.C.R. 0.
33. *Ibid.*, ¶¶18–19.
34. *Ibid.*, ¶42.
35. *Ibid.*, ¶43.

36. *Ibid.*

37. *Ibid.*, ¶48.

38. Case C-418/97 & C-419/97, *ARCO v. Minister*, 2000 E.C.R. I-4475 (2000), ¶42.

39. Case C-491/01, *R. v. Sec. of State for Health*, 2002 E.C.R. O, ¶¶228–229.

40. Case T-326/99, *Olivieri v. Commission*, 2000 E.C.R. II-1985 (Ct. of 1st Instance).

41. *Ibid.*, ¶14.

42. *Ibid.*, ¶15.

43. *Ibid.*, ¶77.

44. Case C-6/99, *Greenpeace France v. Ministere de l'Agriculture et de la Peche*, 2000 E.C.R. I-1651.

45. *Ibid.*, ¶5 (describing the requirements of Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of GMOs).

46. *Ibid.*, ¶6.

47. *Ibid.*, ¶7. If no other member state objects to the proposed approval, the Commission shall give its consent to placing the product on the market. If one or more member states raises objections, however, the Commission must evaluate those objections on the merits and make its own decision on whether the product should be approved based on the available evidence and following the procedure laid out in Article 21 of Directive 90/220. This latter procedure was followed in the instant case.

48. *Ibid.*, ¶7.

49. *Ibid.*, ¶11.

50. *Ibid.*, ¶19.

51. *Ibid.*, ¶¶24–39. Article 16 of EU Directive 90/220 provides that a member state that discovers new information that a properly approved GMO product presents a risk to public health or the environment may take provisional measures to protect against such risks and immediately notify the Commission and other member states of such action, which requires the Commission to make a determination within 90 days whether the initial product

approval should be retained or modified to take account of the new information. *Ibid.*, ¶9. France was not relying on this provision in considering whether it could change its mind on whether to issue an initial approval for the GM corn at issue in this case.

52. *Ibid.*, ¶40.

53. Case C-512/99, *Germany v. Commission*, 2002 E.C.R. 0 (opinion of advocate general).

54. *Ibid.*, ¶6 (citing Article 95 of the EC treaty).

55. *Ibid.*, ¶¶15–22.

56. *Ibid.*, ¶80.

57. *Ibid.*, ¶88.

58. *Ibid.*

59. Case T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance), ¶¶170–171. The court identified one of the guarantees provided by the community legal order as “the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case.” *Ibid.*, ¶171.

60. Case C-241/01, *Nat. Farmers' Union v. Sec. General of the French Gov.*, 2001 OJ C245/7 (opinion of advocate general), ¶78.

61. *Ibid.*, ¶71.

62. Case C-3/00, *Denmark v. Commission*, 2003 E.C.R. I-2643, ¶103.

63. Case C-1/00, *Commission v. French Republic*, 2001 E.C.R. I-9989.

64. *Ibid.*, ¶77.

65. *Ibid.*, ¶83.

66. Case T-219/95, *Danielsson v. Commission*, 1995 E.C.R. II-3051 (Ct. of 1st Instance).

67. *Ibid.*, ¶¶13, 44.

68. *Ibid.*, ¶74.

69. Case T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance), ¶170.

70. Case C-241/01, *Nat. Farmers' Union v. Sec. General of the French Gov.*, 2001 OJ C245/7 (opinion of advocate general), ¶¶73, 75.

71. Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community, Art. 174 (2002)

(available at [http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/c\\_325/c\\_32520021224en00010184.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/c_325/c_32520021224en00010184.pdf)).

72. Case C-341/95, *Bettati v. Safety Hi-Tech Srl*, 1998 E.C.R. I-4355, ¶35.

73. Case C-1/00, *Commission v. French Republic*, 2001 E.C.R. I-9989, ¶¶20–23.

74. *Ibid.*, ¶89.

75. Case T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance); Case T-70/99, *Alpharma Inc. v. Council*, 2002 E.C.R. II-3495 (Ct. of 1st Instance).

76. Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (advocate general), ¶151.

77. *Ibid.*, ¶27.

78. *Ibid.*, ¶¶27, 29. See also *ibid.*, p. ¶45 (paraphrasing EU Commission's argument that "it was undisputed that the foods did not represent a threat to the environment or human health").

79. *Ibid.*, ¶22.

80. *Ibid.*, ¶¶135–151.

81. Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. 0 (ECJ).

82. Case T-344/00, *CEVA Sante Animale SA v. Commission*, 2003 E.C.R. 0 (Ct. of 1st Instance), ¶¶19–35.

83. *Ibid.*, ¶66.

84. *Ibid.*, ¶¶101–102

## **Chapter 5: The European Union Courts and the Precautionary Principle: Three Case Studies**

1. *General Electric Co. v. EPA*, 53 F.3d 1324, 1328–29 (D.C. Cir. 1995). A similar doctrine that applies in the EU is known as the principle of the protection of legitimate expectations, Case T-489/93, *Inifruit Hellas v. Commission*, 1994 E.C.R. II-1201 (1994), ¶51 or the principle of legal certainty, Case T-70/99, *Alpharma Inc. v. Council*, 2002 E.C.R. II-3495, ¶112 (which "requires Community legislation

to be clear and its application foreseeable for all inter-ested parties”).

2. Case C-318/98, *Fornasar et al. v. Italy*, 2000 E.C.R. I-4785 (1999, advocate general) (Celex No. 6980C318); Case C-318/98, *Fornasar et al. v. Italy*, 2000 E.C.R. I-4785 (2000) (Celex No. 6980C318).
3. Case C-318/98, *Fornasar et al. v. Italy*, 2000 E.C.R. I-4785 (1999, advocate general) (Celex No. 6980C318) ¶134.
4. *Ibid.*, ¶44.
5. Case C-318/98, *Fornasar et al. v. Italy*, 2000 E.C.R. I-4785 (2000) (Celex No. 6980C318), ¶ Ruling 1.
6. Ian Phillips *et al.*, “Does the Use of Antibiotics in Food Animals Pose a Risk to Human Health? A Critical Review of Published Data,” *Journal of Antimicrobial Chemotherapy* 53 (2004): 28, 29.
7. Case T-13/99, *Pfizer Animal Health SA v. Council*, 2002 E.C.R. II-3305 (2002) (Ct. of 1st Instance) (hereafter *Pfizer*).
8. Case T-70/99, *Alpharma Inc. v. Council*, 2002 E.C.R. II-3495 (Ct. of 1st Instance) (hereafter *Alpharma*).
9. Directive 70/524, Art. 24.
10. *Pfizer*, ¶53.
11. Directive 70/524, as amended by Directive 96/51, Art. 8(1).
12. *Pfizer*, ¶269.
13. *Ibid.*, ¶53
14. *Ibid.*
15. *Alpharma*, ¶44.
16. *Ibid.*, ¶273.
17. *Ibid.*, ¶45.
18. *Ibid.*, ¶53.
19. *Pfizer*, ¶113; *Alpharma*, ¶134.
20. *Pfizer*, ¶¶145, 143; *Alpharma*, ¶156.
21. *Pfizer*, ¶155.
22. *Pfizer*, ¶142; *Alpharma*, ¶155. See also *Pfizer*, ¶160 (“Unless the precautionary principle is to be rendered nugatory, the fact that it is impossible to carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures

appear essential given the level of risk to human health which the authority has deemed unacceptable for society”).

23. *Pfizer*, ¶144.

24. *Ibid.*, ¶162.

25. EU Commission PP Communication.

26. *Pfizer*, ¶123. See also *ibid.*, ¶149 (the Commission’s communication on the precautionary principle “may be taken as a codification of the law as it stood at the time when the contested regulation was adopted”).

27. *Ibid.*, ¶130.

28. *Ibid.*, ¶172.

29. *Ibid.*, ¶194 (“Far from having ignored the SCAN opinion, the Council relied primarily on certain matters analyzed in the opinion, although it decided not to accept the conclusions expressed there by SCAN”). In addition to the SCAN opinion, the EU also relied on a new scientific study produced by the Danish authorities after the initial SCAN opinion, as well as the conclusions and recommendations of a number of national and international bodies. *Ibid.*, ¶186. These latter “items of scientific evidence” were of secondary importance to the SCAN opinion, however. The new Danish animal study was dismissed by SCAN in a supplementary report as providing no new evidence (*ibid.*, ¶¶153, 297), and the court itself recognized the study had important methodological limitations. *Ibid.*, ¶298. The court also concluded that it is “evident” “that the Community institutions took the conclusions and recommendations in the various reports from international, Community and national bodies into account only as supplementary material.” *Ibid.*, ¶304.

30. *Ibid.*, ¶209.

31. *Ibid.*, ¶189.

32. *Ibid.*, ¶209.

33. *Ibid.*, ¶231.

34. *Ibid.*, ¶205.

35. *Ibid.*, ¶269.



36. *Pfizer Animal Health SA v. Council* 1999 E.C.R. II-1961 (Celex No. 699B0 0113) (1999) (order of president of the Ct. of 1st Instance), ¶74.
37. *Ibid.*
38. *Ibid.*, ¶76.
39. *Alpharma*, ¶282.
40. *Ibid.*, ¶377.
41. *Ibid.*, ¶356 (irrelevant that “bacitracin zinc had been used for a very long period”).
42. *Ibid.*, ¶314.
43. See chapter 5, note 29.
44. Indeed, Alpharma introduced evidence that court noted but simply ignored that the ban on bacitracin zinc would have “significant negative effects on human and animal health,” by, for example, increasing the risk of bacterial contamination of meats and causing the increased use of other antibiotics with a greater health risk for humans than bacitracin zinc. *Alpharma*, ¶¶327–28.
45. MacMaolain, “Using the Precautionary Principle,” 734.
46. See chapter 2, note 32 and accompanying text.
47. *Alpharma*, ¶327 (“Relying more particularly on the evidence of Professor M. W. Casewell and Professor H. Hellig, Alpharma submits that the ban on bacitracin zinc will probably have significant negative effects on human and animal health”); *Pfizer*, ¶420 (“The adoption of the contested regulation will actually result in an increased – instead of a reduced – risk of resistance developing in humans”).
48. *Alpharma*, ¶328; *Pfizer*, ¶420.
49. *Alpharma*, ¶328.
50. *Ibid.*
51. Phillips *et al.*, “Does the Use of Antibiotics?”
52. *Ibid.*, 43.
53. *Ibid.*, 42 (citations omitted).
54. *Ibid.*, 44.
55. *Alpharma*, ¶¶335, 336; *Pfizer*, ¶425.
56. *Alpharma*, ¶338; *Pfizer*, ¶428.

57. Case C-1/00, *Commission v. French Republic* 2002 E.C.R. I-9989, ¶127.
58. *Ibid.*, ¶129.
59. Case C-477/98, *Eurostock Meat Marketing Ltd. v. Dept. of Agr. for N. Ireland* 2001 E.C.R. I-10695, 1 C.M.L.R. 32 (2001).
60. *Ibid.*, ¶139.
61. Case C-514/99, *French Republic v. Commission* 2000 E.C.R. I-4705.
62. *Ibid.*, ¶123.
63. *Ibid.*, ¶¶112, 22.
64. *Ibid.*, ¶122.
65. *Ibid.*
66. *Ibid.*, ¶¶140–49.
67. Case C-1/00, *Commission v. French Republic* 2001 E.C.R. I-9989.
68. Cited in *ibid.*, ¶132.
69. *Ibid.*, ¶199.
70. *Ibid.*, ¶100.
71. *Ibid.*, ¶101.
72. *Ibid.*, ¶89.
73. EU Commission PP Communication, 17 (“Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised”); *ibid.*, p. 17 n. 2 (“In some cases, the very existence of divergent views, presented by qualified scientists who have investigated the particular issue at hand, may indicate a state of scientific uncertainty”).
74. *Ibid.*, ¶77.
75. *Ibid.*, ¶83.
76. Case C-241/01, *Nat. Farmers’ Union v. Sec. General of the French Gov.*, 2001 OJ C245/7 (opinion of advocate general).
77. *Ibid.*, ¶3.
78. *Ibid.*, ¶66.
79. *Ibid.*, ¶67.
80. *Ibid.*, ¶71.
81. *Ibid.*, ¶72.

82. *Ibid.*, ¶¶73–74.

83. *Ibid.*, ¶¶74–75.

84. *Ibid.*, ¶76.

85. *Ibid.*, ¶77.

86. *Ibid.*, ¶78.

87. *Ibid.*

88. *Ibid.*, ¶79.

89. Case C-393/01, *French Republic v. Commission*, 2001 OJ C348/17.

90. Case C-477/98, *Eurostock Meat Marketing Ltd. v. Dept. of Agriculture for N. Ireland*, 2001 E.C.R. I-10695, 1 C.M.L.R. 32 (2001).

## Chapter 6: Conclusion

1. Stone, “Is There a Precautionary Principle?” 10799.

2. “Minister: Precautionary Principle Has ‘Got Out of Hand,’” Spiked-Central, March 15, 2001, available at <http://www.spiked-online.com/Articles/000000005527.htm>. Meacher’s comments were in reference to the reaction to the 2001 foot-and-mouth outbreak in the United Kingdom.

3. See, e.g., Pat Phibbs, “Focus Shifts from Precautionary to Regulatory Analysis in EU, Analyst Says,” *BNA Environment Daily* (December 12, 2002) (summarizing a recent speech by Ragnar Lofstedt, director of the Risk Management Centre at King’s College, London, as follows: “While officials from some EU countries, such as Sweden and Germany, have promoted use of the precautionary principle, other EU organizations have begun to be concerned about the concept.”).

4. These latter decisions are consistent with the trend noted by Professor Jonathan Wiener that “the more binding the legal instrument in which the PP is ensconced, the more moderate is its application.” Wiener, “Precaution in a Multi-Risk World,” 11. The dynamic Wiener identifies seems to be relevant for at least some of the cases in the EU courts; namely, as decision makers are forced to confront the potentially extreme and absolute implications of the precautionary principle, they find ways to

soften its blow. As shown in the present study, however, this is not always the case, at least in the EU courts, as the courts sometimes apply a harsher version of the precautionary principle.





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