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Comparing Environmental Governance: Risk Regulation in the EU and the US

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I. Introduction

This paper compares trends in risk regulation in the United States (US) and the European Union (EU). The notion that governments can or should enact impose restrictions on products and processes in order to protect public health and the environment – even if the cause and effect relationship between the particular product or process being regulated and the harm being avoided or ameliorated is unclear – is neither novel nor controversial. Accordingly,

The basic elements of the precautionary principle (that is uncertainty, risk and lack of direct casual link) have been applied, consciously or unconsciously, since threats to public health from diverse sources, technological developments, substances, or the “scientific revolution” in general, were subjected to public regulatory control.¹

The public’s perception or tolerance of particular risks often differs from that of experts and in a democratic system the former’s preferences – and values – often play an important role in the policy process. Thus governments can and frequently do chose to err on the side of caution, seeking to avoid or reduce particular risks that many citizens regard as unacceptable, even if the available scientific evidence does not or cannot prove evidence of harm. As Christoforou writes, “It is generally agreed that defining the level of acceptable risk is a normative decision that belongs to the democratically elected and accountable institutions of a state.”²

At the same time, it is not feasible to deny regulatory approval or restrict any or all commercial activities that might pose risks to consumers or the environment. Risk avoidance cannot be the sole consideration in making regulatory policies; it must invariably be balanced against other claims and values. Governments must therefore often make difficult choices. For example, regulators must assess both the likelihood of a potentialrisk and magnitude of a potential harm, often in the absence of complete information. They must decide how much

¹ T. Christouforou, “The Precautionary Principle, Risk Assessment, and the Comparative Role of Science,” unpublished paper, 5.

weight to give scientific expertise or formal risk assessments, determine the role of cost and risk/benefit analysis and establish the level of politically acceptable risk. They must balance the potential damages of false negatives (where an initial finding of no acceptable harm subsequently proves to be incorrect), against those produced by false positives, (when an initial finding of unacceptable harm subsequently proves to have been misinformed.)

This paper begins by exploring the precautionary approach to risk regulation as it emerged in the US. It then turns to a detailed discussion of the development and application of the precautionary principle in Europe. The third section argues that while European and American approaches to risk regulation have become more similar in some respects, the EU and the US differ substantially in how they assess particular risks. While the number of politically unacceptable risks has been relatively stable in the US since the early 1990s, it has grown substantially in Europe.

II. The Precautionary Approach in the US

While the precautionary principle has no legal status in the US and has not explicitly informed in American policy debates, nonetheless “no country [has] . . . so fully adopted the essence of the precautionary principle in domestic law as the United States.”³ However, it has been defined and applied in diverse and often inconsistent ways. In some cases, the precautionary principle has required prior approval of potentially dangerous products or processes, while in others it has provided a framework for making regulatory decisions under conditions of scientific uncertainty. Within the latter category, American statutes and rules vary in terms of the emphasis placed on economic costs and technological feasibility in setting regulatory standards

² *Ibid*, p. 12

and defining their implementation. In the US, as in contemporary Europe, risk averse policies have been more likely to be applied to approvals for new products or processes than to restrict existing ones, in part because the economic costs of the latter are more visible and politically salient.

Many US laws require that actions be taken to anticipate and prevent risk, and many standards have been adopted in the absence of clear evidence of harm. US environmental and consumer statutes frequently require prior approval before a product, substance or process can be commercialized. These often incorporate margins of safety in standard-setting, err on the side of safety in risk management and shift the burden of proving safety to firms proposing new products or processes. For example, a precautionary approach underlies US food safety regulation, requiring public approval of the safety of food, color additives and veterinary drugs before they can be marketed.⁴ Likewise the Toxic Substances Control Act (1976) requires prior authorization for new chemicals, while the Federal Insecticide, Fungicide and Rodenticide Act (1972) places the burden of proof of safety on a manufacturer seeking to introduce a new agricultural chemical or pesticide. Under the Endangered Species Act (1966), a finding of potential irreversible harm to a threatened species can lead to an order to desist development activities.

A somewhat stronger and more explicit version of the precautionary approach underlies many US pollution control statutes enacted during the 1970s. The 1970 Clean Air Amendments required the Environmental Protection Agency (EPA) to apply “an adequate margin of safety” in

³ J. Cameron, “The Precautionary Principle” in G. Sampson and W. B. Chambers (eds.), *Trade, Environment and the Millennium* (New York: United Nations University Press, 1999), 250.

⁴ See C. Wilcox, “The US. Food Safety System.” a talk presented to the 9th Annual European Food Law Conference Brussels, 20 June 2000.

setting emission limits for hazardous pollutants.⁵ The Clean Water Act of 1972 adopted the precautionary and highly risk averse goal of zero effluents into navigable waters. The Clean Air Act Amendments of 1977 explicitly instructed EPA to “assess risk rather than wait for proof of actual harm” before setting emission standards, though it did permit specific permitting decisions to incorporate considerations of technical feasibility.⁶

A precautionary approach toward risk regulation is also reflected in a number of judicial decisions, thus further embedding it in the US regulatory regime. In *Reserve Mining* (1975), the Supreme Court permitted the EPA to regulate an effluent on the basis of a “reasonable” or “potential” showing of danger, rather than the more demanding “probable” threshold requested by the industrial plaintiff. It stated: “In the context of the [Clean Water Act], we believe that Congress used the term ‘endangering,’ in a precautionary or preventive sense, and therefore, evidence of potential harm as well as actual harm comes within the purview of the term.”⁷ In a 1976 Court of Appeals decision upholding EPA’s ambient air standard for lead, the court reasoned: “A statute allowing for regulation in the face of danger is, necessarily, a precautionary statute. Regulatory action may be taken before the threatened harm occurs. . . . the statutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.”⁸

In *EDF v. EPA* (1978), which reviewed EPA’s regulation of PCBs under the Clean Water Act, the D.C. Circuit Court held that the statute was intended to prevent the public and the environment from being “exposed to anything resembling the maximum risk. Not only was EPA required to provide a ‘margin of safety,’ but the margin was to be greater than ‘normal’ or

⁵ Cameron, 251.

⁶ *Ibid.*, 250.

⁷ J. Applegate, “The Precautionary Preference: An US Perspective on the Precautionary Principle” (2000) 6-2 *Human and Ecological Risk Assessment*, 423.

‘adequate.’ the margin was to be ‘ample.’ Clearly Congress intended that in dealing with toxic pollutants, margins of safety should be generous to ensure protection of human health and aquatic ecosystems to the greatest extent possible.”⁹ The court specifically permitted EPA to extrapolate from high-chlorinated PCBs, about which the agency had a great deal of data to low-chlorinated PCBs, about which it had little. It stated:“ This is exactly the structure of the precautionary principle: where initial, but not conclusive, evidence suggests a danger, preventive action can be taken in advance of obtaining more definitive data.”¹⁰ Similarly, in *Hercules, Inc. v. EPA* (1978), the court allowed EPA to establish a strict standard for various toxic water pollutants even though the agency could produce no evidence that they presented a public health danger.

In a related case, the DC Circuit Court held that forcing the EPA to delay setting health standards until it can “conclusively demonstrate” that public health is threatened is inconsistent with the statute’s precautionary and preventive nature. The court concluded: “Congress’ directive to the Administrator to allow an ‘adequate margin of safety’ alone plainly refutes the suggestion that the Administrator is only authorized to set primary air standards which are designed to protect against health effects that are known to be clearly harmful.”¹¹ In *Sierra Club v. Siegler* (1983), the Supreme Court interpreted the environmental impact requirement of the National Environmental Policy Act (NEPA) as requiring a worst-case analysis on the grounds that it was needed “to assist decision making in the face of scientific uncertainty.”¹² In *Main vs. Taylor* (1986) the court clearly based its decision on the precautionary principle:

⁸ Quoted in D. Vogel, *National Styles of Regulation: Environmental Policy in Great Britain and the United States* Ithaca: Cornell University Press, 1986, 182.

⁹ Applegate, 425.

¹⁰ *Ibid.*

¹¹ G. Fullem, “Comment: The Precautionary Principle in the Face of Scientific Uncertainty” (Spring 1995) *Willamette Law Review*, 8.

¹² *Ibid.*

[The state] has a legitimate interest in guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible. The constitutional principles underlying the commerce clause cannot be read as requiring the State . . . to sit idly by and wait until potentially irreversible environmental damage has occurred. . . . before it acts to avoid such consequences.¹³

In *Natural Resources Council v. Administrator, U.S. EPA* (1990), the Court addressed the legality of a regulatory standard for particulate matter. The Court explicitly characterized the Clean Air Act as “precautionary” because it authorizes EPA to act when an air pollutant “may reasonably be anticipated to endanger public health.” While acknowledging that the evidence of a health threat by a low levels of exposure to a particular pollutant was “uncertain or conflicting,” the Court nonetheless held that in implementing a precautionary statute EPA was entitled to draw conclusions “from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data . . . , and the like.”¹⁴

Thus “elements of the precautionary principle [are] firmly entrenched in US environmental law.”¹⁵ Yet it would be accurate to characterize US environmental policy as uniformly precautionary or risk averse. Broadly speaking, US environmental statutes fall into three categories.¹⁶ Those that contain health -based provisions, such as the Clean Air Act, are highly risk-averse: they provide EPA with considerable discretion in determining the standards necessary to protect public health. Technology-based provisions, such as those in the Safe Drinking Water Act, direct EPA to require polluters to use the “best conventional,” “best available” or “maximum achievable” control technology. These provisions require EPA to set standards that consider both technological feasibility

¹³ Christoforou, 3.

¹⁴ M. Shapiro, “The Frontiers of Science Doctrine: US Experiences with the Judicial Control of Science-Based Decision Making” in C. Joerges, K.-H. Ladeur, and E. Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision-Making* (Baden-Baden: Nomos Verlagsgesellschaft, 1997), 332-3.

¹⁵ Applegate, 438-9.

¹⁶ M. Powell, *Science at EPA* (Washington, DC.: Resources for the Future, 1999).

and the cost or affordability of abatement technologies. Finally, some statutes, such as the FIFRA and TSCA, contain balancing provisions; they direct EPA to weigh the costs and benefits of protecting the public from “unreasonable risks.” However, even some ostensibly stringent statutes contain provisions that allow or compel an agency to moderate the application of highly risk averse rules, particularly when such rules would interfere with existing commercial activities.

American statutes also vary in their procedures for approving new commercial activities that might pose threats to the environment or public health. In the case of standards for air, water and solid waste pollution it is generally the responsibility of the government to propose restrictions or demand remediation, with the burden falling on regulatory officials to justify their proposed restrictions. In other cases, such as new chemicals, prior approval is required though it is the responsibilities of government officials to perform the appropriate risk assessments. In still other cases, not only is prior approval required but the burden of proof is on the firm to prove safety or no harm. This occurs most notably with ethical drugs and medical equipment, food additives, animal drugs and pesticides, as well as commercial activities that might harm endangered species.

III. The EU and the Precautionary Principle

The origin of the precautionary principle in Europe can be traced back to the concept of *Vorsorge* which emerged in West Germany during the 1970s. This word can be interpreted as “foresight” or “precaution” though it also implies “good husbandry” and “best practice.” One of its first appearances was in the 1976 environmental report of the federal government, which stated: “Environmental policy is not fully accomplished by warding off imminent hazards and the elimination of damage which has occurred. Precautionary environmental policy requires

furthermore that natural resources be protected and demands on them are made with care.”¹⁷

While in principle *Vorsorge* implies that authorities should attempt to minimize all risks, in practice its implementation was linked to the concept of proportionality, which incorporates considerations of both cost and technical feasibility.

Still, by permitting regulations to be enacted before there was conclusive proof of harm, it represented an important innovation in German regulatory policy. “The idea of precaution has played a powerful role in the German environmental policy process by setting ambitious goals and indicating a number of mechanisms through which policy should progress in order to achieve them.”¹⁸ As a 1984 government report on air quality put it, “damages done to the natural world . . . should be avoided in advance. . . . [precaution] means acting when conclusive ascertained understanding by science is not yet available.”¹⁹

During the 1980s, when Germany experienced strong economic growth and the Green Party enjoyed increasing political influence, the precautionary principle began to inform German environmental policies. Thus “precaution . . . emerged in a society experiencing unprecedented levels of support for environmental matters,” as well as efforts on the part of German industry to play a leadership role in the commercialization of “greener technologies.”²⁰ It was specifically employed by German authorities to justify the application of technology-based standards to reduce sulphur emissions in order to address the deterioration of Germany’s forests from acid rain (*Waldsterben*), then a highly visible political issue. Significantly, these

¹⁷ A. Jordan and T. O’Riordan, “The Precautionary Principle in UK Environmental Law and Policy” in UK Environmental Policy in the 1990s Tim Gray (ed.), Macmillan Press., 1995, 68.

¹⁸ S. Borhmer-Christainsen, “The Precautionary Principle in Germany – Enabling Government” in T. O’Riordan and J. Cameron (eds.), *Interpreting The Precautionary Principle* (London: EarthScan, 1994), 55.

¹⁹ E. Soule, “Assessing the Precautionary Principle” (2000) 14-4 *Public Affairs Quarterly*, 318.

standards were adopted before there was a clear scientific understanding of the causes of forest deterioration.

The precautionary principle also shaped international environmental policies in which Germany had a stake. The 1990 Ministerial Declaration on the North Sea represented the first introduction of the precautionary principle into international environmental law and also constitutes one of its strongest formulations. It urged governments to “apply the precautionary principle, that is to take action to avoid potentially damaging impacts of [toxic] substances. . . even when there is no scientific evidence to prove a causal link between emissions and effects.”²¹

The precautionary principle was officially introduced into EU environmental policy in Article 130 (the environmental section), of the 1993 Treaty of the European Union (Maastricht). Subsequently renumbered Article 174 in the 1999 Amsterdam Treaty). It states:

[EU] policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the [EU]. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should, as a priority, be rectified and that the polluter should pay.²²

Between 1994 and 1999, the precautionary principle was referenced in twenty-seven resolutions adopted by the European Parliament.²³ In April 1999, the Council of Ministers adopted a resolution urging the Commission to be guided by the precautionary principle in preparing legislative proposals and to develop “clear and effective guidelines for [its] application.”²⁴ The following year, the Commission issued such a document.²⁵ This communication, which

²⁰ A. Jordan and T. O’Riordan, “The Precautionary Principle in Contemporary Environmental Policy and Politics” in C. Raffensperger and J. Trickner (eds.), *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Washington, DC: Island Press, 1999), 21.

²¹ Soule, 318.

²² A. Jordan, “The Precautionary Principle of the European Union” in T. O’Riordan, J. Cameron, and A. Jordan, *Reinterpreting the Precautionary Principle* (London: Cameron May, 2001), 148.

²³ “The Precautionary Principle,” Working paper: Scientific and technological options assessment series, Feb. 2000.

sought to clarify the role of the principle in regulatory policy-making, was in part addressed to the international community. It both sought to “calm the fears of those who perceive that the precautionary principle serves. . . . to legitimate decisions which are irrational other than in terms of their capacity to serve protectionist goals,”²⁶ as well as to strengthen the EU’s ability to defend highly precautionary regulations before dispute panels of the World Trade Organization. At the same time, the Commission wanted to clarify its role within the EU itself. Specifically, it wanted to prevent the Member States from using the principle to legitimate regulatory policies that undermined the single market while at the same time reassure the European public of its commitment to a high level of consumer and environmental protection.

The Commission emphasized the need for regulatory policies to be scientifically based. Thus the precautionary principle should be invoked when “potentially dangerous effects deriving from a phenomenon, product or process” have been identified but “a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.”²⁷ The application of the former generally presupposes some kind of scientific risk assessment, since otherwise there is no way of identifying “potentially dangerous effects.” Accordingly, “every decision must be preceded by an examination of all the available scientific data and, if possible, a risk evaluation that is objective and as comprehensive as possible.”²⁸ The Commission specifically warned against the

²⁴ Giandomenico Majone, “What Price Safety? The Precautionary Principle and its Policy Implications,” unpublished paper, p. 10

²⁵ For an analysis, and critical summary of this communication, see Natalie McNelis, “EU Communication on the Precautionary Principle,” *Journal of International Economic Law* (2000), 545 – 551.

²⁶ Joanne Scott and Ellen Voss, “The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO,” in *Good Governance in Europe’s Integration Market* Christian Joerges and Renaud Dehousse, eds. Oxford University Press, 2002 p. 278

²⁷ Communication from the Commission on the Precautionary Principle (2000) 1, 2 Feb. 2000, 15.

²⁸ A. Jordan, 158.

“unwarranted recourse to the precautionary principle as a disguised form of protection, adding that “reliance on the precautionary principle is no excuse for derogating from the general principles of risk management.”²⁹ It also stated that precautionary “measures should be reviewed in light of scientific progress and amended as necessary,” and be proportionate to both the economic costs of a regulation and the potential risks of delaying regulatory action.

Yet at the same time the Commission also emphasized that that the EU, and thus presumably Member States as well, had the “right to establish the level of protection . . . that it (they) deem[s] appropriate.”³⁰ It reinforced this point by stating that cost-benefit analysis should encompass not only an evaluation of economic costs but also non-economic considerations such as public acceptability. Thus “what is adjudged to be efficient will depend, inter alia, upon public sentiment as to the acceptability of the risk”³¹ Accordingly, it is appropriate for risk management decisions to explicitly incorporate evidence regarding the level of risk the public considers appropriate.

The resolution on the precautionary principle adopted by the heads of government at the December 2000 Nice summit modified the European Commission’s communication in two respects.³² Firstly, while the Commission had stressed the importance of undertaking a comprehensive scientific risk evaluation, the Nice summit adopted a more flexible approach, stating that such an evaluation may not always be possible due to either insufficient data or the urgency of the risk. Secondly, it emphasized the importance of civic participation in the formulation of regulatory policies. Thus it urged that mechanisms be established to make

²⁹ Commission Communication, p. 3, 18

³⁰ Commission Communication p. 3

³¹ Scott and Voss, p. 279

³² “EU Leaders Back Precautionary Principle,” *ENDS Daily*, 13 Dec. 2000.

sure that all legitimate public views are heard in the decision-making process.

The latter is particularly significant since EU administrative procedures formally separate risk assessment and risk management. The former is the responsibility of scientific or technical experts, who may or may not also offer policy recommendations. But risk management decisions are made by politicians. A memo from the EC emphasizes that while risk management decisions “must be science based. . . it is not up to individual scientists to decide on the acceptable level of risk imposed on the society as a whole.”³³ Although the two are encouraged to exchange information at each stage of the regulatory process, it is the latter who are responsible for implementing the precautionary principle since “. . .in the end, the decision is always a political one.”³⁴ The later decision can only be made by policy-makers who are politically accountable.

On one hand, the precautionary principle cannot be divorced from science since “a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates.”³⁵ But on the other hand, the growing popularity of the precautionary principle in Europe reflects a widely shared the perception that scientific knowledge is an inadequate guide to regulatory policy. The principle’s proponents thus both support the extension of scientific knowledge while at the same time they acknowledge the possible intrinsic limitations of scientific knowledge in providing the appropriate information in good time.”³⁶ Thus the precautionary principle simultaneously both increases public expectations of science and reflects

³³ Comments from the European Commission Services to the Codex Secretariat, published on the Internet at: http://europa.eu.int/comm/food/fs/ifsi/eupositions/ccgp/ccgp01_en.html, 14.

³⁴ J. Dratwa, “The Precautionary Principle,” Scientific and Technological Options Assessment Unit of the European Parliament, January 2000, p. 9.

³⁵ Cameron, p. 244.

³⁶ O. Godard, “Social Decision-Making Under Conditions of Scientific Controversy, Expertise and the Precautionary Principle” in C. Joerges, K.-H. Ladeur, and E. Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision-Making: National traditions and European Innovations* (Baden-Baden: Nomos Verlagsgesellschaft, 1997), 65.

the public's skepticism of the value of scientific risk assessments. By encouraging regulatory action in advance of a scientific consensus about harm, it "curtails the ability of politicians to invoke scientific uncertainty as a justification for avoiding or delaying the imposition of more stringent protection measures."³⁷ Yet by emphasizing the importance of gathering additional knowledge to reduce uncertainty, the principle maintains a faith in the ability of scientific knowledge to ultimately inform risk management decisions.

These tensions or ambiguities are reflected in the way the EU has applied the precautionary principle. Consider, for example, the highly politically salient case of mad cow disease. The 1998 decision of the European Court of Justice (ECJ) to uphold the EC's decision to ban all exports of British beef following evidence that mad cow disease could be transmitted to humans was informed by the precautionary principle, though the principle itself was not mentioned by the ECJ. The Court found that "at the time when the contested decision was adopted, there was great uncertainty as to the risks posed by live animals, bovine meat and derived products."³⁸ Accordingly, the ban was justified.

However, in October 1999, the European Scientific Steering Committee unanimously concluded that, provided Great Britain actually implemented the European Commission's recommendations, British beef was no more risky to eat than other European beef. Indeed, given the relative stringency with which British cattle was inspected, it was "undoubtedly the safest among all European beef."³⁹ Accordingly, Member States were told to lift their bans on imports of British beef. However, France's recently established food safety agency issued a report that concluded that the risk was not "totally under control." It recommended that the French Government maintain its ban on British beef, which the French Government did. By keeping out

³⁷ Jordan and O'Riordan, 71.

³⁸ Christoforou, 5.

British beef on safety grounds, the French Government implicitly assured French consumers that French beef was safe. “This phase of the mad cow case [illustrates] how the precaution principle can serve as a folding screen to a symbolic risk management intended at gaining public opinion’s confidence rather than establishing a reasonable system of risk management.”⁴⁰ The European Commission successfully challenged the French ban in the ECJ on the grounds that the French government was unable to produce any evidence that British beef was unsafe. France was finally forced to finally lift the ban in 2003.

The Commission has sought to restrict the application of the precautionary principle by Member States to cases when national regulatory authorities can either supply new scientific evidence that was not considered by the EU’s own scientific committees or faces unique circumstances. While Member States do have the discretion to err on the side of caution, “they must however deliver some evidence of scientific uncertainty. They must adduce evidence of a specific concrete risk and not merely of potential risk based on a general preventive approach.”⁴¹ The ECJ has struck down numerous health and safety standards adopted by Member States on the grounds that they lacked adequate scientific justification.⁴² For example, in *Reinheitsgebot*, the ECJ declared unlawful a German statute prohibiting the sale of beer with additives on the grounds that there was no evidence that restriction protected public health.

On other occasions, when there does appear to be reasonable scientific uncertainty about the risks imposed by a particular product or substance, the EJC has deferred to Member State decisions, permitting them to “take protective measures without having to wait until the reality

³⁹ Godard, 2000, 24.

⁴⁰ *Ibid.*, 24-5.

⁴¹ *Ibid.*, 11.

⁴² V. Heyvaert, “The Changing Role of Science in Environmental Decision-Making in the European Union” (1999) .. *Law and European Affairs* [December, 1999], 426-43.

and seriousness of the risks becomes fully apparent.”⁴³ Thus the Commission permitted four Member States to maintain their ban on creosote, a chemical compound used as a wood preservative, whose use the EU had only restricted, on the grounds that there was sufficient scientific uncertainty surrounding the health effects of exposure levels. It found these “national measures . . . justified in light of the precautionary principle.”⁴⁴

IV. Europe and America Compared

There are some signs of convergence in risk management policies in the EU and the US. At both the Member State and EU level, regulatory decision-making is becoming increasingly transparent, subject to both intense public scrutiny and many cases of judicial review. Two decades ago, “policy decisions [in Europe] about risk in Europe remained the preserve of experienced bureaucrats and their established advisory networks” while competing representations of risk, then the norm in the US, were typically the exception in Europe.⁴⁵ Since then, the opportunities for public participation and the weight policy-makers attach to public preferences have both increased substantially. Over the last two decades, courts in Europe at both the national and EU levels have become increasingly engaged in reviewing the legality or constitutionality of health, safety and environmental regulations – a phenomena similar to that which emerged somewhat earlier in the US.⁴⁶ On both sides of the Atlantic, courts rely heavily on expert scientific opinion in formulating their decisions. In the US such opinions are generated by regulatory agencies while Europe employs separate scientific advisory bodies.

⁴³ Scott and Voss, p. 266

⁴⁴ Scott and Voss, p. 269

⁴⁵ S. Jasanoff, “US Exceptionalism and the Political Acknowledgement of Risk,” in E.J. Berger, ed Risk (Ann Arbor: University of Michigan Press 1993, p. 66

⁴⁶ see Stephen Breyer and Veerle Heyvaert, “Institutions for Regulating Risk,” in Environmental Law, the Economy, and Sustainable Development Richard Revesz, Phillippe Sands, and Richard Steward, eds, Cambridge: Cambridge University Press, 2000, pp. 283-353

Two important dimensions of regulatory policy-making are the use of cost benefit analysis and risk assessment. Since the Reagan Administration, each presidential administration has issued an Executive Order requiring that all new regulations be accompanied by a formal cost –benefit analysis. Yet for all the controversy this rule has created, in fact this administrative requirement has not prevented the adoption of a considerable number of new, relatively stringent regulatory standards including, most recently, an EPA rule establishing emission standards for off-road vehicles. Moreover, some important American regulatory statutes explicitly prohibit the use of cost-benefit analysis in establishing standards. Significantly, in a recent decision upholding the Clinton Administration’s EPA rules mandating more stringent standards for particulates and ground level ozone, the Supreme Court essentially closed the door to the use of cost-benefit analysis in setting air quality standards. In *Whitman v. American Trucking Association Inc. (2001)*, the Supreme Court held that EPA was only required to demonstrate that its proposed standards produced health benefits; they were not required to demonstrate that they were cost-effective.

The EU has no formal requirement for quantitative cost-benefit analyses. However, a close EU counter-part is the doctrine of proportionality, which holds that the benefits of a regulation should be proportionate to the burdens it imposes on commerce. This principle has been applied in a number of ECJ decisions and has been explicitly incorporated into the precautionary principle. In addition, a number of Member States have qualified the precautionary principle by requiring that economic factors be considered in formulating regulatory rules. In 2002 the EC issued a new Action Plan on Improving Regulation which calls for consolidated impact assessment of new regulations and statutes. The Commission subsequently issued guidelines requiring that all major regulatory actions clearly identify their goals, as well as both

negative and positive impacts; the latter must include trade-offs as well as economic consequences. If these guidelines are adopted, EU regulatory procedures will more closely resemble those of the US.

A comparison of the role of risk-assessment in the EU and the US presents a similar picture. American regulatory policy making changed significantly after the 1980 decision of the Supreme Court in *AFL-CIO v. Petroleum Institute*. In this case, the court struck down a standard for benzene exposure in the workplace issued by the U. S. Occupational Safety and Health Administration. It held that an agency could not issue regulations on the basis of speculations or assumptions about uncertain risk. Instead it had to produce evidence of “significant risk” before regulating. While recognizing that there was often considerable scientific uncertainty regarding the harm posed by a product or production process, the court nonetheless required regulatory agencies to justify their rule-making by providing “substantial evidence of [risk in] the record as a whole.”⁴⁷ The result of this decision was to make reliance on the methodology of risk assessment obligatory for all American agencies engaged in risk regulation. As a result, “the risk-based approach is now the central element in environmental and public health decision-making in the United States. . . . US government agencies have adopted risk assessment as the methodical way to defend and insulate the decision-making process.”⁴⁸ Agency rules must have a solid scientific bases for action or inaction.

No such requirements exist in the EU, though as noted above, the EC does consider scientific risk assessment as a essential component of the precautionary principle and both European and American courts place similar reliance on the research and advice of scientific advisory bodies. A number of ECJ decisions that have struck down various Member State health

⁴⁷ quoted in Shapiro, pp. 329 - 330

and safety regulations suggest that the scientific standards of risk demanded by the ECJ do not differ substantially from those that demanded of regulatory agencies by American courts. As Weiner notes, the basis for the ECJ judgment overturning the French ban on British beef because of the alleged “risk” of BSE is “quite reminiscent of the reasoning [of the US Supreme Court] in *Benzene*.” In the former case, the ECJ held that “Member State governments may not invoke precaution to regulate risks that the Commission has deemed insignificant – a view with which few American judges would disagree.”⁴⁹

Ironically, the highly controversial decision of the WTO’s Appellate Body, which upheld the ruling of WTO dispute panel ruling that the EU’s ban on imports of hormone-feed violated its WTO treaty obligations, stated that their ruling did not preclude “responsible governments from acting from a perspective of prudence when they determine sufficient scientific evidence – a holding not dissimilar to that employed by the ECJ.” Indeed, the Appellate Body’s endorsement of the finding of the Dispute Resolution Panel (the WTO body of first review) that “theoretical uncertainty” arising because “science can never provide absolute certainty that a given substance will never have adverse health effects” does not constitute an adequate bases for a ban . . . “is quitesimilar to the jurisprudence of the ECJ in cases such as the German Beer case.”⁵⁰

Yet, despite some of the broad similarities between the precautionary “approach” of American regulatory policy and the precautionary “principle” of the EU, as well some recent

⁴⁸ J. Trickner and C. Raffensperger, “The US View of the Precautionary Principle” in O’Riordan, Cameron, and Jordan, 199.

⁴⁹ Jonathan Wiener, “Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems,” *Duke Journal of Comparative and International Law* Vol. 13 (2003) p. 211

⁵⁰ Quoted in Majone, p. 9

signs of convergence in standards for judicial review, European and American risk management policies are increasingly diverging

Consider, for example, the Commission 2001 White Paper on the future of chemical regulation in Europe. This paper proposed a new regulatory system called REACH (the Registration, Evaluation and Authorization of Chemicals.) Under this plan, which currently being debated in the EU, chemical companies will be required to supply safety data for all chemicals produced in amounts of more than one ton. The use of both high volume chemicals as well as those which are deemed to create possible health hazards will then be evaluated by a newly established Chemical Agency. Chemicals that are determined to be of “high concern” will need to be authorized on a continual basis and will ultimately be phased-out by regulators unless firms can prove that the risks associated with their use are negligible. REACH essentially treats a broad category of chemicals the same way as new medical products are now regulated in both the US and the EU, with the burden of proof placed on companies to demonstrate their safety. In addition to radically reversing the burden of proof – under current EU and US law risk assessments for chemicals are the responsibility of regulators, not firms – REACH represents another important policy departure. “Very high concern” chemicals will be evaluated not according to the actual risks created by their use but rather on the much more sweeping basis of “hazard assessment.” The Commission will also seek to determine the availability of less harmful or hazardous substitutes.

The proposed REACH Directive is indicative of a much broader phenomena. In a number of critical policy areas, the range of politically acceptable risks has widened in the EU while it has stabilized in the US.⁵¹ For example, in 2002, the EU approved a directive that will phase out the use of some heavy metals in electronics and electronics equipment to promote their recycling

and make landfills and incineration less hazardous. That same year, the EU approved a directive prohibiting the use of antibiotics as growth promoters in animal feed as part of an effort to combat the threat to human, animal and plant health posed by potential antimicrobial resistance. None of these regulations have appeared on the American political agenda. Likewise the EU has adopted considerably more stringent regulations for the approval and labeling of foods derived from genetically modified seeds than has the US. American and European policies with respect to global climate change also differ markedly, with the EU adopting much more precautionary policies than the US.

These recent differences in risk management policies between Europe and the US can in part be understood by returning to the distinction between the two types of regulatory failures noted at the beginning of the paper. Recent European regulatory policies stem in large measure from a series of regulatory failures caused by false negatives. These false negatives – of which mad-cow disease is the most prominent example – have made influential segments of the European public, as well as many European policy-makers more risk averse or precautionary. They regard a more cautious approach to addressing potential risks as critical not only to protecting public health, safety and the environment, but also to restoring public confidence in the regulatory process. These regulatory failures have also undermined public confidence in the capacity of “science” to adequately identify and prevent future harms. More generally,

The precautionary principle has arisen [in Europe] because of the perception that that pace of efforts to combat [environmental] problems has been too slow and that environmental problems continue to grow more rapidly than society’s ability to identify and correct them . . . Confidence in the ability of environmental science and policy to identify and control hazards [has weakened].⁵²

⁵¹ See David Vogel, “The Hare and the Tortoise,” *British Journal of Political Science* Fall 2003

⁵² D. Kriebel *et al.*, “The Precautionary Principle in Environmental Science”(2001) 109-9 *Environmental Health Perspectives*, 871.

Significantly, “precautionary measures . . . are most likely to be applied when public opinion is instinctively or knowledgeably risk-averse.”⁵³ Clearly, in a wide variety of policy areas, European public opinion is now more risk averse than in the US. Significantly, a recent collection of essays sponsored by the European Environment Agency reviewed twelve examples of “regulatory failures” in both Europe and the US. In every case, these failures were due to the fact that regulatory policy-makers had been insufficiently proactive. The Agency was unable to come up with a single example of public welfare being undermined by too stringent regulations. The report’s introduction noted that in part as a result of regulatory policies that were too little or too late, “public trust in the politicians and scientists who are trying to protect people and the planet is very low, especially in Europe.”⁵⁴

By contrast, regulatory failures associated with false positives have become more politically salient in the United States. Over the last ten to fifteen years, policy-makers in the United States have come recognize what numerous critics of US risk management policies have been claiming since the 1970s, namely that an overly precautionary approach to risk regulation can actually impair public health.⁵⁵

For example, strict standards for the approval of new drugs denied US residents access to many life-saving medical products that were available in other countries. The decision to remove asbestos-containing materials from public schools not only produced little or no health benefits – since the typical exposure level was about the same concentration found outdoors – but removal operations shifted fibers into breathable air and created hazards for workers involved in the

⁵³ Jordan and O’Riordan, 61.

⁵⁴ The Precautionary Principle in the 20th Century Earthscan, 2002, p. 9

⁵⁵ For an inventory of this category of regulatory failures in the United States, see F. Cross, “The Paradoxical Perils of the Precautionary Principle” (1996) 53-3 *Washington and Lee Law Review*, 851.

removal process.⁵⁶ In 1992, EPA publicly admitted that it had mismanaged the affair and that the literally billions of dollars spent by school districts had been wasted since exposure to low levels of asbestos poses no health hazard. Similarly, strict standards for the clean-up of toxic wastes sites have increased worker exposure to toxic substances, but appear to have provided little or no benefit to those living near such sites.⁵⁷ If one adds up the harms associated with digging up, removing and transporting these wastes, Superfund legislation may well have made Americans less healthy. Significantly, in 1996, Congress reformed the highly precautionary Delaney Clause by enacting the Food Quality Protection Act. This statute replaced an absolute prohibition on food additives that might induce cancer with a risk-benefit standard for pesticide residues. The new law provided EPA with the “flexibility to consider the seriousness of a carcinogenic pesticide’s dietary risk, as well as the pesticide’s benefit to society in making tolerance decision.”⁵⁸

Under the Clinton Administration, the implementation of the Superfund program was substantially reformed in order to permit economic development on “brownfield” sites without having to undertake previously mandated levels of cleanup that had contributed nothing to public health. The Economist, detailing one implementation of EPA’s new “risk based clean-up” approach, wrote:

Along the way, public reaction to environmental contamination has grown less hysterical. Last year, construction of a . . . development in Chicago was halted when traces of radioactive thorium from an old lantern factory were found on the site. Two decades ago, that would have caused a media frenzy and a “Chernobyl-style solution” . . . Instead, the developer removed the radiation hazard and continued building. Tests by EPA several months later found no signs of radiation.⁵⁹

⁵⁶ Aaron Wildavsky, But Is It True? Cambridge: Harvard University Press, 1995, pp. 185 - 200

⁵⁷ Wildavsky pp 153-184 and John Hird, Superfund John Hopkins Press, 1994

⁵⁸ S. D. Bauer, “The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation” (1997) 75 *North Carolina Law Review*, April 1997, 1369.

As Daniel Bodansky observes:

Not only has the precautionary principle [in the United States] not produced the expected result; it has led to a backlash. During the last decade, US environmental law has increasingly stressed risk assessment and cost-benefit analysis, both of which, unlike the precautionary principle, presume that we have sufficient knowledge to measure risk and calculate the appropriate responses. Thus, just as international institutions . . . have begun to discover the precautionary principle, US environmental law has moved away from it. In part . . . it reflects a more widespread concern about the perceived over-stringency and inefficiency of many precautionary standards.⁶⁰

Thus in important respects risk management policies in Europe and the US are moving in different directions. While European policy makers are reacting to policy failures stemming from inadequate regulation, their counterparts in America are seeking to minimize policy failures stemming from overly stringent regulations. While science and scientific expertise as a basis for legitimating regulatory decisions has become more accepted in the US, they have become less acceptable in Europe. While public trust in regulatory officials has declined in Europe, it has increased in the US. While European regulatory officials are seeking to restore public trust in regulatory institutions through increased public participation, regulatory decision-making in the US has become more technocratic.

The substantive differences between European and US regulatory policies do not stem from the fact that the EU and several Member States have formally adopted the precautionary principle, while the US has not. The precautionary principle does not reflect a distinctive European approach to risk management. Key elements in its official exposition by the EU -- the right to act under conditions of uncertainty, the importance of public participation and consent, and the priority accorded to risk avoidance -- have long characterized many US regulatory policies. It is rather because political support for more stringent health, safety and environmental

⁵⁹ "Muck-spreaders" *Economist*, 21 Apr. 2001, 27.

⁶⁰ Daniel Bodansky, "The Precautionary Principle in US Environmental Law," in *Interpreting the Precautionary Principle*, T. O'Riordan and James Cameron eds, Cameron and May, 1994, 205.

regulations is now greater in Europe than in the United States that a number of regulations enacted by the EU are now more risk averse or “precautionary” than in the US.