The Politics of Risk Regulation in Europe and the United States

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I. Introduction

This essay presents a comparative analysis of developments in risk regulation in the United States (US) and the European Union (EU). While drawing on legal material, its primary focus is on the politics underlying trends in risk management policies on both sides of the Atlantic. It is difficult to generalize about literally thousands of risk management decisions taken by the US, European countries and the European Communities (EC) over a period of roughly four decades. However, one can discern a trans-Atlantic shift in defining what constitutes politically acceptable health, safety and environmental risks since the mid 1980s. This essay describes and explains this shift and relates it to broader changes in regulatory policies and institutions on both sides of the Atlantic.

While the scope and stringency of consumer and environmental regulation of business has substantially increased in all rich democratic nations since the 1960s, there has also been considerable policy divergence. Between the 1960s and the mid 1980s, a number of US regulations were more stringent, innovative and comprehensive than those adopted by European countries and the EU. However, since themid 1980s, this pattern has changed. Now, in a number of significant areas of regulatory policy, EU regulations are more stringent, innovative and comprehensive than those adopted by the US. Prior to the mid 1980s, US policy-makers identified more products and processes as posing unacceptable risks to public health or the environment than did regulatory authorities in Europe. Now the latter regard a number of products and processes as posing politically unacceptable risks to consumers and the environment that US policy-makers do not. Since the mid 1980s, the political influence of constituencies favouring more risk averse regulatory policies has strengthened in Europe while since the early 1990s it has declined in the US. Likewise, since the mid 1980s regulatory politics and issues have become more politically salient in Europe, while since the early 1990s, they have declined in the US.

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The precautionary principle has emerged as a critical component of the new European approach to risk regulation as well as an important focus of disagreement between the US and Europe. The principle’s origins lie in the area of public health and safety, but it has increasingly been employed to inform environmental regulation as well. Its emergence in Europe reflects both a perception that previous efforts to combat environmental problems have been inadequate, and a belief that scientific expertise is often unable adequately to identify consumer and environmental risks. It seeks to give more weight to risk avoidance over cost/risk-benefit analysis, and to public preferences over scientific risk assessments. By lowering the threshold of scientific proof that is required before regulators can determine that a particular substance, product or process poses an unacceptable threat to public health or the environment and by legitimating public participation in regulatory decision-making, the precautionary principle has created a normative basis for enacting a number of new and more stringent regulatory standards. Much of the often heated debate and controversy surrounding the precautionary principle within and between Europe and the US stems from the diverse ways it can be interpreted and defined. Some elements of the precautionary

principle are unexceptionable. At one level, much consumer and environmental regulation is literally precautionary as it attempts to anticipate and thus avoid or reduce harm before it occurs. The avoidance of harm or injury ex ante is the rationale for the wide range of regulations that require prior approval for products with the potential to pose harm, such as medicinal drugs and equipment, food additives, pesticides, chemicals, and veterinary medicines, with the burden of proof generally placed on the manufacturer to demonstrate that its activity or product is not dangerous. In this sense, zoning, planning, and other prior approval requirements for factories or related industrial activities that might pose environmental or public health threats are also precautionary, as are environmental impact assessments and regulations to protect endangered species.

The notion that governments can or should impose restrictions on products and processes—even if the cause and effect relationship between the particular product or process being regulated and the harm being avoided or ameliorated is either unknown or unclear—is also neither novel nor controversial. Risk assessments or other available scientific data are seldom definitive. Accordingly:

> The basic elements of the precautionary principle (that is uncertainty, risk and lack of direct causal 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

[1] T. Christoforou, 'The Precautionary Principle, Risk Assessment, and the Comparative Role of Science', unpublished paper, 5.

values—often play an important role in the policy process. Thus governments can and frequently do choose 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]

Yet at the same time, it is obviously not feasible to deny regulatory approval or restrict any or allcommercial activities thatmight pose risks toconsumers or the environment. If conventional risk assessment often errs on the side of underestimating risks, then such a regulatory policy is likely to err on the side of overestimating them. Moreover, since it is often impossible to prove unequivocally that any particular product or processes will not harm or has not harmed public health or the environment, a literal application of the precautionary principle would impose unacceptably high economic costs as well as unnecessarily restricting many potentially beneficial commercial activities. In other words, risk avoidance cannot be the sole consideration in making regulatory policies; it must invariably be balanced against other claims and values.

Accordingly, governments must make often difficult choices. For example, regulators must assess both the likelihood of a potential risk and the magnitude of a potential harm in the absence of complete information. They must decide how much 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. In choosing between ex ante and ex post regulations, they must balance the costs and benefits of avoiding false negatives (where an initial finding of acceptable harm subsequently proves to be incorrect) versus the costs and benefits of avoiding false positives (when an initial finding of unacceptable harm subsequently proves to have been misinformed).

It is with respect to these kinds of issues that many European and US regulatory decisions have diverged. Through the mid 1980s, the US was

more likely to impose regulations on the basis of little or no clear evidence of harm, place a high value on risk avoidance, and aspire to reduce risks to as low a level as possible. Consequently, many American regulations were more risk averse or precautionary than their European counterparts.More recently, the obverse has become more common; many European regulations are now more precautionary or risk-averse than those issued by the US. While European policy makers have become more willing to issue ex ante regulations that reduce the probability of false negatives, US policy-makers have become more reluctant to do so in part because of their experience with regulatory failures stemming from false positives. In the final analysis, risk management policies, including the way in which the precautionary principle is interpreted and applied, rests on politics.

[2] Ibid., 12.

In an increasingly integrated trans-Atlantic economy, these differences have acquired an important international dimension. Europeans are seeking to widen the basis upon which a country may exclude products on the grounds that they pose either unknown or unacceptable risks, while the US is seeking to strengthen the role of risk-assessment in order to limit the ability of its trading partners to use regulations as non-tariff barriers.

This essay begins by providing an overview of the contrasts between European and US regulatory policies and politics from the 1960s through the mid 1980s. It then explores various US statutes and judicial rulings that illustrate the extent to which a precautionary approach to risk avoidance has informed much US regulatory policy-making. The essay then explores the contemporary pattern of European and US risk management policies. This in turn is followed by an explanation for the changes in European approaches to risk management and an analysis of the similarities between the US during the 1970s and 1980s and Europe during the 1990s. The next two sections focus on the development and application of the precautionary principle in Europe. The final two sections describe and explain contemporary developments in US and European regulatory politics and policies and explore the international implications of the divergence between contemporary European and US regulatory approaches to risk management.

II. European and US Risk Management in Historical Perspective

From the 1960s through the mid 1980s, a number of important consumer and environmental protection standards were more stringent in the US than in Europe. According to a comprehensive study of chemical regulation published in 1985, the US, the United Kingdom (UK), France and the Federal Republic of Germany ‘have compiled similar records in controlling substances suspected of causing cancer in humans’.[3] Yet the study also points to a number of cases of relative US stringency. For example, ‘British agencies generally require more definite evidence of carcinogenetic before initiating regulatory action than their Americancounterparts.’[4]More often than not, theUSwas the firstcountry to take significant restrictive action on suspected or confirmed human carcinogens.[5] For example, theAmerican Environmental Protection Agency (EPA) found the pesticides aldrin and deildrin to be carcinogenic, while on the basis of the same studies British authorities concluded that they did not present a risk of cancer.[6] The US subsequently banned most uses of these pesticides while Britain imposed no restrictions. Red Dye No. 2 was banned in the US, while its use was only restricted in Europe.[7] In 1971, EPA banned dichlorodiphenyltrichloroethane (DDT) while its use was only restricted in Britain,

[3] R. Brickman, S. Jasanoff, and T. Ilgen, Controlling Chemicals: The Politics of Regulation in Europe and the United States (Ithaca: Cornell University Press, 1985), 52.

[4] Ibid., 203. [5] Ibid., 48. [6] Ibid. [7] Ibid., 47.

Germany and France. Nearly a decade lapsed before it was banned by the EU.

Similarly the US imposed more extensive restrictions on 2,4,5-T/ dioxin than did Britain, France and Germany.

Furthermore, US chemical regulations were also more stringent and comprehensive. The 1959 Delaney clauses to the Food, Drug and Cosmetic Act, which prohibited the Food and Drug Administration (FDA) from permitting the use of any food or chemical additive found to induce cancer when ingested by animals, had no counterpart in any European country. The 1976 American Toxic Substances Control Act (TSCA) established regulations for both new and existing chemicals while the EU's 1979 Sixth Amendment only established regulatory procedures for approving new chemicals. (French, British and German national law did contain provisions for reviewing existing chemicals, but only in exceptional circumstances.) A similar pattern held with respect to pesticide approval and renewals; US statutes enacted in 1972 and 1978 required more comprehensive reviews of existing pesticides than did either EU regulations or those of any Member State.[8]

During the 1970s, the US adopted more stringent automotive emission standards earlier than Sweden.[9] A similar pattern held for American and EU automotive emission standards: the American automobile emission standards enacted in 1970 and 1977 were consistently stricter than the five increasingly stringent standards enacted by the EU between 1970 and 1985.[10] For example, while the US enacted legislation requiring all new cars to be equipped with catalytic converters, and thus only use unleaded petrol in 1970, the EUdid not adopt a similar requirement until 1989. During the 1980s, Sweden, Denmark and Germany, three of Europe's most consistent environmental innovators, phased in standards comparable to those of the US only after the US did.[11] Likewise, the automotive standards established in the 1990 Clean Air Act Amendments were more stringent than existing EUstandards.

Environmental impact assessments were adopted by the US in 1969; they were not required by the EU until 1985. The US Congress responded in 1971 to a sustained campaign by American environmentalists and voted to deny public funds to construct a supersonic aircraft after a coalition of American environmental groups argued 'the plane would create a dangerous sonic boom, increase upper atmosphere pollution and adversely affect the nation's weather patterns'.[12] In contrast, France and Great Britain continued to fund the commercial development of this aircraft.

[8] Ibid., 37.

[9] L. Lundqvist, The Hare and the Tortoise—Clean Air Policies in the United States and Sweden (Ann Arbor, MI: University of Michigan Press, 1980).

[10] H. Arp, 'Technical regulation and politics—the interplay between economic interests and environmental policy goals in EC car legislation', in J.D. Liefferink, P.D. Lowe, and A.P.J. Mol (eds), European Integration and Environmental Policy (London: Belhaven Press, 1993), 15–174;D. Vogel, Trading Up—Consumer and Environmental Regulation in a Global Economy (Cambridge: Harvard University Press, 1995), 63–77.

[11] Lundqvist, n. 9 above, 170–1; Arp, n. 10 above, 155.

[12] D. Vogel, Fluctuating Fortunes—The Political Power of Business in America (New York: Basic Books, 1989), 78.

During themid 1970s, the issue of ozone layer depletion emerged as a major political issue in the US. Though there was considerable scientific uncertainty about both the causes andmagnitude of this environmental problem, the 1997 Clean Air Act Amendments authorized restrictions on chlorofluorocarbons (CFCs) on the grounds that a 'reasonable expectation' of harm was sufficient to generate regulatory action.[13] However, even before this law was passed, EPA, acting under authority of the Toxic Substances Control Act (TSCA), moved to prohibit the use of CFCs as aerosol propellants in non-essential applications. This decision affected nearly 3 billion worth of household products. Within three years, nearly the entire US aerosol market had switched to non-CFC technologies. By contrast, in Europe, the issue of ozone depletion

was less politically salient and the political influence of chemical producers proportionally greater. Only Norway and Sweden, neither of which produced these chemicals, banned the use of CFCs as aerosol propellants. The EU initially refused to act. However in 1980, in response to US pressures, it agreed to a 30 per cent decrease from 1976 levels by 1981—a reduction characterized by one European scholar as 'a minimum solution'.[14] According to British environmental expert Nigel Haigh, '[t]here is reason to believe that the figure of 30 percent was chosen because it was known that it could be achieved without causing too much difficulty for industry'.[15]

Kunreuther et al.'s 1983 comparative study of the siting of liquefied energy gas (LEG) facilities in four countries provides a stark illustration of the differences between US and EC standards regarding the management of environmental risks, in this case specifically those of the UK.

> Recently California and the United Kingdom have approved sites for LEG terminals. In this, and perhaps this alone, they are the same. If the California siting criteria . . . were to be applied to the Scottish case, it would be impossible to approve [the site that was approved in Scotland], and if the United Kingdom criteria . . . were to be applied to the California case, any of the suggested sites could be approved, which means that the terminal would go to the first site to be suggested—Los Angeles harbor.[16]

This comparison is not atypical. According to Vogel's 1986 comparative study of British and American environmental policies, 'American regulations in the area of health and safety have frequently been significantly stricter than Britain's'.[17]

In the area of consumer protection, the US established more stringent standards for the approval of prescription drugs than did any European country. After the scandal surrounding the near approval of thalidomide by

[13] R.E. Benedict, Ozone Diplomacy (Cambridge: Harvard University Press, 1998), 25.
[14] Ibid., 25.
[15] Ibid.
[16] M. Thompson, 'A Cultural Basis for Comparison', in H. Kunreuther et al. (eds), Risk Analysis and Decision Process—The Siting of Liquefied Energy Gas Facilities in Four Countries (Berlin: Springer-Verlag, 1983), 233.
[17] D. Vogel, National Styles of Regulation—Environmental Policy in Great Britain and the United States (Ithaca: Cornell University Press, 1986), 149.

the FDA, in 1962 Congress enacted the Kefauver amendments to the Food, Drug and Cosmetic Act. This legislation significantly increased both the time and expense for securing approval for new prescription drugs in the US. The result was a substantial cross-Atlantic 'drug lag', with new drugs typically approved years earlier in Germany and the UK than in the US.[18] Nearly four times as many new medicines were introduced in the UK as in the US during the 1960s. According to a US Government Accounting Office study which tracked the introduction of 14 significant new drugs, 13 were available in Europe years before they were approved for use in the US. A West German study reported that while the US remained, by a wide margin, the leading producer of new drugs, it ranked ninth out of twelve countries studied in being the first nation to make drugs available to its citizens.

These differences in policy outcomes in part reflected differences in the policy-making process. As a general rule, US regulatory politics were more contentious, confrontational and adversarial. There was less public trust in government officials, and more widespread public scepticism about the benefits of technological innovation than in Europe. The US regulatory process was relatively open, with non-governmental organizations (NGOs) enjoying considerable access and influence, and often able to effectively challenge the political power of business.[19] US regulatory policies and priorities were highly politicized with public preferences playing a considerable role in both defining the regulatory agenda and influencing particular rules and standards—a dynamic which changes in American administrative law

during the 1970s reinforced.[20]

In contrast, public participation wasmore limited in Europe. In many cases, 'policy decisions about risk remained the preserve of experienced bureaucrats and their established advisory networks'.[21] NGOs enjoyed limited access to the regulatory process, and public officials often worked closely and cooperatively with business. In the US, regulatory politics frequently involved competing representations of risk among NGOs, industry and regulators, while in Europe policy-making was more likely to reflect a pragmatic consensus between business and government experts.

III. The Precautionary Principle in the US

Although the precautionary principle has no legal status in the US, and has a relatively small explicit role in American policy debates, 'no country [has] so

[18] The data in this paragraph is summarized in D. Vogel, 'When Consumer Oppose Consumer Protection', (1990) 10 Journal of Public Policy, 458.

[19] See for example, Vogel, n. 12 above.

[20] See M. Shapiro, Who Guards the Guardians? Judicial Control of Administration (Athens: University of Georgia Press, 1988).

[21] S. Jasanoff, 'US Exceptionalism and the Political Acknowledgement of Risk' in E.J. Burger (ed), Risk (Ann Arbor: University of Michigan Press, 1993), 66.

fully adopted the essence of the precautionary principle in domestic law as the United States'.[22] It has been defined and applied in diverse ways. In some cases, it has involved prior approval, while in other cases it has provided a framework for making regulatory decisions under conditions of scientific uncertainty. Within the latter category, US statutes and rules vary in terms of the role that should or can be played by economic costs and technological feasibility in setting regulatory standards. In the US, as in contemporary Europe, relatively risk averse policies have been more likely to inform approvals for new products or processes than to impose restrictions on existing ones, in part because the economic costs of the latter are more politically visible.

Many US laws require that actions be taken to avoid, anticipate and prevent risk, while 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; they 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, colour additives and veterinary drugs before they can bemarketed.[23] Likewise the 1976 Toxic Substances Control Act requires prior authorization for new chemicals, while the 1972 Federal Insecticide, Fungicide and Rodenticide Act places the burden of proof of safety on a manufacturer seeking to introduce a new agricultural chemical. Under the 1966 Endangered Species Act (ESA), a finding of potential irreversible harm to a threatened species can lead to an order to desist all development activities.

A somewhat stronger version of the precautionary approach underlies many US pollution control statutes enacted during the 1970s. The 1970 Clean Air Amendments required EPA to apply 'an adequate margin of safety' in setting emission limits for hazardous pollutants.[24] 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 allow specific decisions on permissions to incorporate considerations of technical feasibility.[25]

A precautionary approach toward risk regulation is also reflected in a number of judicial decisions, 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

22 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.
23 See C. Wilcox, 'The U.S. Food Safety System—The Uses of Precaution', presented at the 9th Annual European Food Law Conference (Brussels, 20 June 2000).
24 Cameron, n. 22 above, 251. 25 Ibid., 250.

danger, rather than the more demanding 'probable' threshold requested by the industrial plaintiff.[26] 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.[27]

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. [T]he statutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.[28]

In a related case, the District of Columbia (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.[29]

In EDF v. EPA (1978), which reviewed EPA's regulation of polychlorinated biphenyls (PCBs) under the Clean Water Act, the DC Circuit Court held that the intention of the statutewas to prevent the public and the environment from being 'exposed to anything resembling the maximum risk.[30] Not only was EPA required to provide a ''margin of safety'', but the margin was to be greater than ''normal'' or ''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.'[31] The court specifically permitted EPAto 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.'[32]

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.[33]

26 Reserve Mining Co. v. Environmental Protection Agency, 514 F.2d 492 (8th Cir. 1975).
27 J. Applegate, 'The Precautionary Preference—An American Perspective on the Precautionary Principle' (2000) 6 Human and Ecological Risk Assessment, 423.
28 D. Vogel, n. 10 above, 182.
29 G.D. Fullem, 'The Precautionary Principle—Environmental Protection in the Face of Scientific Uncertainty' (1995) 31 Willamette Law Review, 495.
30 EDF v. EPA, 598 F.2d 62 (D.C. Cir. 1978). 31 Applegate, n. 27 above, 425. 32 Ibid.
33 Hercules, Inc. v. EPA, 598 F.2d 91, 106 (D.C. Cir. 1978).

In Sierra Club v. Siegler (1983), the Supreme Court interpreted the environmental impact requirement of the National Environmental Policy Act as requiring a worst-case analysis on the grounds that it was needed 'to assist decision making in the face of scientific uncertainty'.[34] In Maine v. Taylor (1986) the court clearly based its decision on the precautionary principle:

> [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.[35]

In Natural Resources Council v. Administrator, U.S. EPA (1990), the court addressed the legality of a regulatory standard for particulate matter.[36] The court 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 that this pollutant posed a health threat at low levels of exposure was 'uncertain or conflicting', it 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.'[37]

Thus 'elements of the precautionary principle [are] firmly entrenched in US environmental law'.[38] Yet it would not be accurate to characterize US environmental policy as uniformly precautionary or risk averse. Broadly speaking, US environmental statutes fall into three categories.[39] Those that contain healthbased provisions, such as the Clean Air Act, are highly risk averse: they provide the EPA with considerable discretion in determining the stringency of 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 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.

[34] Applegate, n. 27 above; Sierra Club v. Sigler, 695 F.2d 957 (5th Cir. 1983).
[35] As cited in Christoforou, n. 1 above, 3; Maine v. Taylor, 477 US 131 (1986).
[36] NRDC (Natural Resources Defense Council) v. EPA, 907 F.2d 1146 (D.C.Cir. 1990).
[37] As cited in M. Shapiro, 'The Frontiers of Science Doctrine—US Experiences with the Judicial Control of Science-Based DecisionMaking', in C. Joerges, K.H. Ladeur, and E. Vos (eds), Integrating Scientific Expertise into Regulatory Decision-Making (Baden-Baden: Nomos Verlagsgesellschaft, 1997), 332–3. [38] Applegate, n. 27 above, 438–9.
[39] M. Powell, Science at EPA (Washington, D.C.: Resources for the Future, 1999), 10–11.

IV. The New European Regulatory Regime

Many US health, safety and environmental standards remain more stringent than European ones. Most US automotive emissions and fuel composition standards, most recently strengthened in 1990, remain stricter than those of the EU. Since the outbreak of mad cow disease, the US has banned the sale of British beef even though its sale has been reauthorized in the EU. US authorities will not accept blood donations from donors who have spent six months or more in the United Kingdom (UK); no European country has imposed a similar restriction. The US restricts sales of raw milk cheeses on health grounds, while the EU permits the sale of unpasteurized cheese. Many US state and local regulations on passive smoking are more restrictive than in Europe. In other areas, US and European regulatory policies have converged, most notably with respect to the approval of pharmaceutical products and bans on some chemicals, including CFCs, the phasing out of lead from petrol and other products, and restrictions on the use of asbestos.

But what is new and significant is the emergence of a substantial and growing number of EU health, safety or environmental policies that are either stricter or more innovative than in the US. The number of regulations which fall into this category has significantly increased since the mid 1980s. They

include regulations governing beef hormones (1985), milk hormones (1989), genetically modified crops and foods (1990, 1997), leg-hold traps (1991), biodiversity (1992), eco-labelling (1992), packaging wastes (1994), global climate change (1997, 2001), automobile recycling (2000),) animal feed (2000), biosafety (2000), and electronics recycling (2002). In all these areas, US rules are either more permissive or non-existent.

The regulation of genetically modified (GM) foods and crops illustrates a 'ships passing in the night' phenomena: the US regulatory approach resembles the cooperative regulatory style, and exclusion of public participation previously associated with Europe, while European policy-making echoes the adversarial style and extensive public participation previously associated with the US. US regulatory officials have worked closely with industry to facilitate the commercial development of a new technology.[40] There has been relatively little public participation in the regulatory process and little public scrutiny. By contrast, the European regulatory process has been highly politicized and contentious, with both the public and non-governmental organizations (NGOs) enjoying considerable access and influence. For its part, the biotechnology industry in Europe has found itself on the defensive, and much of the public along with policy-makers in some Member States appear relatively indifferent to its long-term financial viability.

[40] See K. Eichenwald, G. Kolata, and M. Peterson, 'Biotechnology Food—From the Lab to a Debacle' The New York Times, 25 Jan. 2001. According to this article, 'the control this nascent industry exerted over its own regulatory destiny. . . was astonishing'.

The US has chosen to regulate bothGMfoods and seeds under existing laws, while EU legislation has established a distinctive and complex set of new regulatory requirements that apply only to this new agricultural technology. When EUstandards for the commercial authorization and approval of agricultural biotechnology were first issued in 1990, they did not differ substantially from those of the US. However, after political opposition to GM seeds and products began to surface in Europe in 1996, European regulatory policy became transformed. To date, the EU has authorized 18 crops for import or cultivation. By contrast, the United States Department of Agriculture (USDA) has issued approvals for 50[41] while the EPA has approved eight.[42]More importantly, as of September 2002, the EU had not approved any new seed strains for nearly four years under Directive 90/220/EEC on the Deliberate Release into the Environment of GeneticallyModified Organisms (GMO Directive)[43] which governs the planting of GM crops, while the marketing of new food products under the EU'sNovel Foods Regulation (1997) has been effectively halted. This de facto moratorium on further commercial authorization will continue until agreement has been reached regarding new standards for the traceability and labelling of GM products, which at this point remains elusive.

In contrast, the US only requires that GM products be labelled if they would affect consumers differently than their non-GM counterparts. Consumer opposition to GM foods, combined with labelling requirements, has discouraged food processors from marketing products grown from GM seeds in Europe. But only a handful of US food processors produce GM-free products, although under US law foods labelled organic cannot include foods grown from GM seeds. Nearly three-quarters of all GMcrop acreage is in the US, and hardly any is in Europe.

These differences in policies toward GM foods and crops parallel those in other areas of agricultural policy. For example, the US approved the use of a growth hormone for milk cows in 1993, while the EU has imposed a moratorium on its use since 1989, though the EU does permit the importation of dairy products from cows to which it has been administrated. The US permits antibiotics to be used in animal feed; since 1989 the EU has not. US regulations

governing food irradiation are more permissive than those of the EU (1997, 1999, 2002). The EU has adopted a much more extensive array of animal protection measures than the US, including rules governing battery hen cages and the treatment of animals in transit (1999). In 2001, the EU banned the use of meat and bone meal in all animal feed, while they continue to be fed to animals other than cattle in the US.

Such differences are not confined to agriculture. In 1999, the European Commission banned the use of phthalate softeners in soft toys because of concerns that they represented a health hazard to children, while the US has

41 M. Burros, 'U.S. Plans Long-Term Studies on Safety of Genetically Altered Foods' The New York Times, 14 July 1999, A16.

42 N. Tait, 'EPA Sued over Genetic Crop Approval' Financial Times, 19 Feb. 1999, 6.

43 [1990] OJ L117/15.

only advised companies to restrict their use. The EU has imposed more stringent and extensive requirements for recycling packaging wastes (1994) than the US. The EU has made manufacturers responsible for the 'life-cycle' of a wide array of goods, including cars (2000) and electronic products (2002), while the ROHS Directive (Restriction on the Use of Hazardous Substances, 2002) bans heavy metals such as lead and cadmium in electronic products in order to keep these metals out of landfills. None of these regulations is on the American national political agenda, and there have been only a few modest initiatives at the state level. Likewise, while public or quasi-public eco-labelling schemes spread from Germany to much of Europe during the 1990s and were adopted by the EU in 1992, they continue to play relatively little role in the US, with the notable exception of organic labels. The EU banned the use of leg-hold traps for capturing wild animals in 1991, while the US only agreed to a partial ban following pressure from the EU in 1997.

There are also other indications of how the relationship between regulatory politics and policies in the US and Europe has shifted. During the 1970s and through much of the 1980s, European environmental policies were strongly influenced by the US. The US was the first country to enact stringent automobile emission standards, and these subsequently defined the debate over emission standards in Europe. 'The US standards of 1983—widely referred to as ''US 83''—became an important reference point for the debate over EC automobile emissions.'[44] The EU's Sixth Amendment, which established a system for approving new chemicals, was enacted only after passage of the TSCA and wasmodelled largely on the latter. Likewise, environmental impact assessments were first required by the US in 1969; they were subsequently adopted by the EU in 1985. Now it is the EU which is helping to define the American regulatory agenda. American restrictions on leg-traps and its ban on animal feed for cattle were both adopted as a response to EU policies, while European policy initiatives in the areas of both electronic recycling and global climate change have given these issues a more prominent place on the US policy agenda.

The EU has also replaced the leadership role of the US in addressing global environmental problems.Until the late 1980s, mostmajor international environmental agreements—most notably the Convention on International Trade in Endangered Species of Fauna and Flora (CITES), (1973) and the Montreal Protocol on Substances that Deplete the Ozone Layer (1987)—were initiated and strongly supported by the US, and subsequently ratified by either individual European countries or the EU. TheMontreal Protocol, in particular, represents a textbook illustration of the implementation of the precautionary principle, since restrictions on CFCs were adopted before there was clear scientific evidence that they threatened the ozone layer.

By contrast, the Basel Convention on Hazardous Wastes (1989) was ratified by every EU Member State by 1994, but has yet to be ratified by the US. Both

[44] Vogel, n. 10 above, 66.

the Convention on Biological Diversity (1992) and the Biosafety Protocol (2000) were signed by the EU, but not the US. The EU, along with a number of Member States, has strongly supported an international treaty to reduce carbon emissions, while the US has been unwilling to make binding commitments to restrict emissions of carbon dioxide. The US has not ratified the 1997 Kyoto Protocol, while the EU and all its Member States have done so.

This change in the relative stringency of European and US consumer and environmental standards can also be seen in the pattern of trade disputes between the EU and the US.[45] Earlier trans-Atlantic trade disputes typically involved complaints by the EU or its Member States about the use of US regulatory standards as non-tariff barriers. Thus the EU filed complaints about America's automotive fuel economy standards (adopted in 1975), Superfund taxes (adopted in 1986), and a ban on imports of tuna to protect dolphins (adopted in 1990). But for complaints based on policies of more recent origin, it is the US which has accused the EU of using consumer or environmental regulations as trade barriers. These include the EU's leg-trap ban (1991), eco-labelling standards (1992), the regulation of GMOs (1990, 1997–through present), and most recently, EU regulations for the recycling and composition of electronic products (2002). In none of these policy areas has the US filed a formal complaint with the WTO, though it threatened to do so in the case of the EU's leg-trap ban. (The EU's beef hormone ban, discussed in more detail below, is a partial exception to this pattern: it was adopted by the EU in 1985, though it did not go into effect until 1989.)

V. Explaining the New European Risk Regime

What accounts for these changes in European regulatory policies? Why has the EU recently adopted so many more stringent or extensive regulations compared to either the US or Europe before the mid 1980s? While any answer must remain speculative, three inter-related factors appear to have been critical: several regulatory failures and crises, increased political support for more risk-averse regulatory policies within Europe, and the growth in the EU's regulatory competence.

A . REGULATORY FAI LURES

An important factor contributing to the change in European risk management policies has been a series of regulatory failures and crises that have increased the political salience of regulatory issues and undermined public confidence in the ability of national or EU regulatory officials to adequately protect their health, safety and environment. A major wave of these occurred at the end of the 1980s. The Washington Post observed in December 1988:

[45] For a detailed discussion of these disputes see D. Vogel, Barriers or Benefits? Regulation in Transatlantic Trade (Washington, D.C.: Brookings Institution Press, 1997).

> Dead seals in the North Sea, a chemical fire on the Loire, killer algae off the coast of Sweden, contaminated drinking water in Cornwall. A drumbeat of emergencies has intensified the environmental debate this year in Europe, where public concern about pollution has never been higher.[46]

According to Elizabeth Bomberg, 'these disasters made an impact. In 1992, the protection of the environment and the fight against pollution had become an ''immediate and urgent problem'' in the view of 85% of EU citizens'.[47] During the latter half of the 1990s, the shortcomings of European regulatory structure for food safety became politically salient. The most important food safety regulatory failure involved mad cow disease. While bovine spongiform encephalopathy (BSE) was first detected in cattle in the UK in 1982, the European Commission accepted assurances from the British Ministry of Agriculture that it posed no danger to humans. Subsequently, Britain was forced to notify other EU Member States of a potential food safety problem, especially

after scientific studies showedthe disease was transmittable to mice.Following a massive outbreak of BSE in 1989–1990, the European Community banned human consumption of meat from infected cattle. Although concern among the British public over health effects of eating meat of BSE-diagnosed cattle continued to grow throughout the 1990s, the British government denied the legitimacy of the public's concerns. Its position was accepted by the European Commission, which placed only limited restrictions on the sale of British beef. The crisis over BSE broke in 1996 in the UK, when the British Government announcedthat ten cases of variant Creutzfeld-Jakob disease (variant CJD) had been diagnosed in humans, and that these cases were probably related to human exposure to the cattle disease of BSE. The Commission responded by issuing a global ban on the export of British beef and requiring a massive destruction of cattle in Britain, and to a lesser extent, in otherMember States. While both the Commission and its scientific advisory body eventually recertified British beef as safe for human consumption, the EU's failure to recognize its health hazards severely undermined public trust in EU food safety regulations and the scientific expertise on which they were based. To date, approximately 100Europeans have died from variantCJD.Thoughthisnumber is far lower than had been earlier feared, as one British scholar put it, 'the BSE scandal represents the biggest failure in UK public policy since the 1956 Suez Crisis'.[48] It also emerged on the heels of a long line of food scares in the UK, including an outbreak of e-coli in Scotland, salmonella in eggs, and listeria. The regulatory failure associated with BSE significantly affected the attitude of the European public toward GM foods.[49] This was especially true in Britain, where unfavourable press coverage of agricultural biotechnology

[46] R. Herman, 'An Ecological Epiphany' Washington Post National Weekly Edition, 5–11 Dec. 1988, 19.

[47] E. Bomberg, Green Parties and Politics in the European Union (London: Routledge, 1998), 13.

[48] E. Millstone, 'Comment and Analysis' Financial Times, 6 Oct. 2000, 19.

[49] S. Jasanoff, 'Civilization and Madness—The Great BSE Scare of 1996' (1997) 6 Public Understanding of Science—an International Journal of Research in the Public Dimensions of Science and Technology, 221–32.

increased substantially following the BSE crisis: between 1996 and 1998 the percentage of those strongly opposing GM foods rose from 29 per cent to 40 per cent. Its ramifications were felt throughout the EU. 'BSE has made people in Europe very sensitive to new technologies in the food supply industry, and very wary of scientists and government attempts to reassure them.'[50] An official from Monsanto commented on the British Government's long insistence that there were no human health risks from mad cow disease: 'that wound still has not healed. You have this low burn level of anxiety about food safety, and in the midst of all this you have a product introduction of genetically modified soybeans.'[51] A food sociologist observed, 'BSE was a watershed for the food industry in this country. For the first time people realized that merely attempting to ensure a culinary end product was safe to eat was not a good enough approach. We had to look at the entire process by which food is produced'.[52]

In 1999, a major public health scare emerged over dioxin contamination of food products produced in Belgium, leading to both the fall of the Belgian Government and the removal of all Belgian food products from stores throughout Europe, as well as a scandal involving the safety of Coca-Cola, which however turned out to have no scientific basis.[53] As a senior European official noted in 2000, 'the past years have seen a big dip in consumer confidence in the safety of the food supply and, as a consequence, inMember State authorities tasked with the job of overseeing the food industry. . . . There seems to be an endless supply of [food scares].'[54]

The regulatory failures associated with madcow disease and dioxin had

other important political consequences in Europe. They dramatically exposed the gap between the single market—which exposes all European consumers to goods produced anywhere within the EU—and the inability of European institutions to assure the safety of the products sold within that market. At the European level it led to the decision in December 2000 to create a European Food Safety Authority. It also called into question the functioning of the 'comitology' system, the EU's term for the structure of advisory bodies that it relies on for expert advice. After all, the European Commission had relied on the advice of the Scientific Veterinary Committee, which was chaired by a British scientist and primarily reflected the thinking of

50 C. Cookson and V. Houlder, 'An Uncontrolled Experiment' Financial Times, 13–14 Feb. 1999, 7.

51 R. Weiss, 'No Appetite for Gene Cuisine' Washington Post National Weekly Edition, 3 May 1999, 19.

52 Nigel Williams, 'Plant Genetics—Agricultural Biotech Faces Backlash in Europe' Science, 7 Aug. 1998, 768–71.

53 The links are observed by journalists with titles such as 'Mad Coke Disease', J. Lanchester, The New York Times Magazine, 4 July 1999, 7–8.

54 R. Ellard, 'Back to the Future—From sci-fi food scares to a culture of food safety' (2000) Consumer Voice, Special Edition.

the British Ministry of Agriculture, Fisheries and Food—advice which subsequently proved flawed.[55]

Regulatory policies and politics in Europe have also been affected by the perceived shortcomings of regulatory policies in areas unrelated to food safety. During the 1990s, the French government was widely criticized for responding too slowly to the public health and workplace dangers associated with the use of asbestos.[56] In spite of substantial evidence that asbestos constituted a serious health hazard, killing approximately 2,000 people a year according to a French government study, its manufacturing, importation and sale were not severely restricted until 1996, nearly two decades after the US had begun to take regulatory action, and well after it had been banned in seven other European countries. Shortly after restrictions were finally imposed in France in 1996, President Jacques Chirac made a dramatic announcement: all 40,000 students would be immediately transferred from France's largest university because of the serious health risks posed by asbestos contamination. Far from reassuring the public, this decision prompted citizens to wonder why the government had allowed students, staff and faculty to be exposed for so long in the first place.

Another, far more consequential scandal was the apparent failure of French governmental officials and doctors to adequately protect haemophiliacs from blood contaminated with the AIDS virus.[57] This issue, which also became highly visible during the early 1990s, led to the resignation and criminal indictment of three senior government officials, including the Prime Minister. Three senior medical officials were convicted of criminal negligence and fraud and were sentenced to prison. Officials were accused of failing to adequately screen blood donors, delaying the approval of a US technology to test blood in order to benefit a French institute, and allowing contaminated blood to be given to patients. The deaths of more than 1,000 haemophiliacs were linked to these decisions. While haemophiliacs were given contaminated blood in several countries, their rate of HIV infection was significantly higher in France. As in the case of asbestos, the French government's regulatory failure was widely attributed to its placing economic interests over public health.

The 'sang contamine´' (contaminated blood) scandal in France, like themad cow disease in the UK, had significant domestic repercussions. It shocked

55 See G. Chambers, 'The BSE Crisis and the European Parliament', in C. Joerges and E. Vos (eds), EU Committees—Social Regulation, Law and Politics (Oxford: Hart Publishing, 1999),

95–108.

[56] For an extended discussion of this issue, see F. Chateauraynaud and D. Torny, Les sombres pre´curseurs—une sociologie pragmatique de l'alerte et du risque (Paris: Editions de l'Ecole des Hautes Etudes en Sciences Sociales, 1999), Ch. 3–7.

[57] There is extensive literature on this issue, including M. Setron, Pouvoirs contre SIDA—de la transfusion sanguine au de´pistage (Paris: Seuil, 1993); B. Kriegel, Le sang, la justice, la politique (Paris: Plon, 1999); O. Beaud, Le sang contamine´ (Behemoth: Presses Universitaires de France, 1999). It should be noted that many scholars believe the scandal has been overblown and the prosecution of government officials for it was both ethically and legally problematic. But this point of view has not affected public perceptions.

French public opinion, calling into question the public's historic high regard for the competence of the public sector in a highly paternalistic state. It also continues to haunt French politicians, making them highly risk-averse, particularly with respect to potential threats to public health. Significantly, ministers have accepted nearly every recommendation of L'Agence Francaise de Securite´ Sanitaire des Aliments (AFSSA), France's recently established food safety agency, which has statutory responsibility for reviewing all government food safety policies—lest they be accused of (again) endangering public health, and possibly face legal penalties.

B. P O L I TICAL DEVELOPMENTS

A second, related, explanation for the change in European risk management politics and policies has to do with political developments. Through the 1980s, support for strict environmental, health and safety regulations in Europe tended to be geographically polarized. Germany, the Netherlands, and Denmark consistently favoured stricter, often more risk-averse, regulations, while the UK, France and Italy opposed them with equal consistency.

Much of EU environmental policy-making during the 1970s and 1980s represented a struggle between the EU's three 'green' Member States, where constituencies representing civic interests enjoyed considerable public support and influence, (the Green Party has played an important role in Germany since 1983), and the UK, France, and Italy, where they did not. The EU directives for automobile emissions standards and packaging recycling requirements represented a compromise between these coalitions of Member States, though over the long-run European regulatory standards have generally strengthened.

But strong public interest in and support for stricter health and environmental standards has since spread south and west within Europe. More specifically, in a number of critical respects, the UK and France are no longer regulatory 'laggards.' During the 1990s, British public opinion and public policy became 'greener' and the UK's green lobbies increasingly influential. In 1990, as part of a broader re-examination of its environmental policies, the UK formally adopted the precautionary principle as one of the 'basic aims and principles supporting sustainable development'.[58] The application of this principle has affected a number of the UK regulatory policies, including the dumping of sewer sludge in the North Sea and domestic water pollution standards. It has also strained the UK's consultative regulatory style, challenging the ability of regulators to justify lax controls or regulatory delays on the grounds that they have inadequate knowledge of harm and forcing them to take preventive action in advance of conclusive scientific opinion.

[58] A. Jordan and T. O' Riordan, 'The Precautionary Principle in UK Environmental Law and Policy', in T. Gray (ed), UK Environmental Policy in the 1990s (New York: St. Martin's Press, 1995), 70–1.

The creation of the National Rivers Authority in 1989 and the Environment Act of 1995 allowed British enforcement agencies to adopt a more arm's length relationship with firms, and this new relationship has fostered a tougher approach toward enforcement. The UK has also played a leadership role in moving the EU toward a system of integrated pollution control. It was

also the strongest advocate of the EU's leg-trap ban, and British public opinion has been extremely hostile toward genetically modified organisms (GMOs). The Environment Act of 1995 incorporated sustainable development into UK law, and in 2000 the Prime Minister established the UK Sustainable Development Commission.

While the policy changes in France have been less dramatic, the French Environment Minister under the Juppe´ Government, Corinne Lepage, was a leading public critic of GMOs, opposing the Ministry of Agriculture. In 1997, following the election of Prime Minster Jospin, the Green Party joined the French Government for the first time and the Party's president, Dominique Voynet, became Environmental Minister. In 1995, the French government formally adopted the precautionary principle. According to the Loi Barnier, 'the lack of certainty, given the current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures aiming at preventing at an economically acceptable cost serious and irreversible risk of environmental damage'.[59] While this statute explicitly recommends that the precautionary principle be applied to environmental damage, it has subsequently been applied to food and health risks as well. The 2001 French decision to ban the feeding of farines, not just to cattle, but to all farm animals in order to prevent further outbreaks of mad cow disease was based on the precautionary principle since there was no evidence that the farines posed a danger to either public or animal health.[60] This principle also informed French opposition to the planting of GM seeds as well as France's refusal to lift its ban on the sale of British beef until threatened by the prospect of an adverse ruling from the European Court of Justice (ECJ) in the fall of 2002. Moreover, Italy, responding to public health scares, was among the first nations to pressure for the beef hormone ban. More recently, the health hazards of electromagnetic transmissions have emerged as an important political issue, prompting a large-scale review of government regulatory policies. Prior to the 2001 elections, the Green Party was represented in Italy's governing coalition. In 1999, the Green Party joined the government of Belgium for the first time. In sum, while substantial national differences in regulatory priorities persist within the EU, political support for more stringent protective regulations has grown within Europe.

[59] Ph. Kourilsky and G. Viney (eds), Le Principe de Precaution: Rapport au Premier Ministre (Paris: Odile Jacob et la Doumentation Franc¸aise, 2000).

[60] 'Le gouvernement peaufine un plan d'interdiction des farines animales' Le Monde, 12–13 Nov. 2000, 6.

C . THE ROLE OF THE EU

EU regulatory policies and politics have also been influenced by institutional changes at the European level. Not coincidently, the changes in European risk regulation described in this essay began shortly after the enactment of the Single European Act (SEA) in 1987. The EU itself has played a critical role in changing the dynamics of European regulatory policies: each subsequent revision of the Treaty of Rome has accorded civic interests greater weight in the policy process. The SEA gave environmental policy a treaty basis for the first time, specifying that preventive action should be taken whenever possible and requiring that harmonized standards take as a base 'a high level of protection.' The Treaty on the European Union (1993) made precaution a guiding principle of EU environmental policy:

> Community policy shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken . . . [61]

In 1995, the Consumer Policy Service of the European Commission was established as a new directorate-general, DG XXIV (the EU had previously

established an Environment Directorate, DG IX). The Treaty of Amsterdam (1997) called upon the Council and the Parliament to achieve high levels of health, safety, environmental and consumer protection in promulgating single market legislation, and Article 153 EC explicitly defined consumer policy and health protection as 'rights' of citizens. EU treaties have also steadily expanded the role of the European Parliament, a body in which consumer and environmental interests have been relatively influential, in shaping European legislation.[62] The SEA granted it legislative power under 'cooperation' procedures, and these were expanded by the Maastricht Treaty, which established 'co-decision' procedures, thus giving the Parliament and the Council of Ministers co-responsibility for writing legislation. The latter's purview over environmental legislation was further expanded by the Amsterdam Treaty. 'Despite the limitations of co-decision, its use as the legislative procedure for environmental measures considerably strengthens the Parliament's role in the adoption of new environmental legislation.'[63]

As Majone has noted, the EU is primarily a regulatory state: issuing rules is its most important vehicle for shaping public policy in Europe.[64] Notwithstanding frequent criticisms of the EU's 'democratic deficit', its institutions have played an important role in strengthening the representation of civic or diffused interests. The Green Party has been an important political presence

[61] Jordan and O' Riordan, n. 58 above, 68–9.
[62] See E. Bomberg, Green Parties and Politics in the European Union (London: Routledge, 1998).
[63] W. Grant, D. Matthews, and P. Newell, The Effectiveness of European Union Environmental Policy (Basingstoke: Macmillan Press, 2000), 35.
[64] G. Majone, Regulating Europe (London: Routedge, 1996).

in the European Parliament since 1989, when it captured 37 seats, a representation which it regained after the 1999 elections. The Parliament has often been an effective source of pressure on the Council to adopt more stringent regulations. The European Consumers Union led the successful campaign for the EU beef hormone ban, while Greenpeace, along with Green Parties at the national and EU level, played a critical role in mobilizing public and political opposition to the approval of GMOs in Europe. Greenpeace also played an instrumental role in the EU's ban on phthalate softeners in toys and childcare articles. In short, the EU has provided substantial political space for the representation of civic interests, and the latter have taken considerable advantage of these opportunities.

The dynamics of regulatory policy-making in Europe have also been affected by the success of the single market. An important consequence of the single market has been to make all European consumers increasingly dependent on, and thus vulnerable to, the regulatory policies of all 15 Member States, as well as Brussels. This has increased pressure on the EU to promulgate stricter European-wide rules, since a regulatory failure in any Member State endangers the single market as a whole. In addition, protecting the health and safety of Europeans as well as the European environment has become critical to the EU's legitimacy and its claim to represent the broader interests and concerns of Europeans. As Breyer and Heyvaert suggest:

> [Regulatory] Centralization may be the expression of a growing feeling or unity among the citizens of Europe, of a growing desire to protect the common European heritage across national boundaries, and of a rising expectation among Europeans that, when they move from country to country, they will benefit from the same high level of health and environmental protection.[65]

VI. EU and US Parallels

In a number of important respects, EU regulatory policies and politics since around 1990 resemble those of the US from the 1960s through 1990. During those three decades, an influential segment of US elite and public opinion became highly risk-averse, often focusing on the risks of new technologies

rather than their potential benefits. For example, there is a striking parallel between the 1970s debate in The US over public funding of supersonic transport, and the 1990s debate in Europe over GMOs. In both cases, a significant segment of the public saw no benefits associated with the proposed new technology, only increased risks. The relative indifference of many Europeans to the future of agricultural biotechnology in Europe evokes the attitudes of many in the US during the 1970s toward the economic viability of

[65] S. Breyer and V. Heyvaert, 'Institutions for Managing Risk', in R. Revesz, P. Sands, and R. Stewart (eds), Environmental Law, the Economy and Sustainable Development—the United States, the European Union and the international community (Cambridge: Cambridge University Press, 2000), 327

the US chemical industry. As a British social scientist observed in 1979, 'Americans seem to have taken an excessively strict interpretation of risk, reducing ''reasonable risk'' practically to ''zero risk'' '.[66]

The US, like Europe, also experienced a series of alleged or actual regulatory failures that eroded public confidence in government regulation. The thalidomide scandal (1962), Rachael Carson's Silent Spring (1962), Ralph Nader's Unsafe at Any Speed (1965), Love Canal (1977), Three Mile Island (1979), and the Exxon Valdez oil spill (1989), were the US counterparts to Europe's mad cow disease, dioxin in the food supply, and contaminated blood. Each of these regulatory failures led to a significant tightening of regulatory standards. The significant membership expansion and increased political influence of public interest lobbies in the US during the 1970s parallels the growth of NGOs and the growing influence of Green Parties in Europe since the mid 1980s. Both developments played critical roles in expanding the regulatory agenda and facilitating the enactment of stricter and extensive regulations.

Both the EU and the US also experienced institutional changes that increased the access of representatives of civic interests to the policy process. On both sides of the Atlantic, regulatory policy-making became more fragmented. The US system of regulatory administration was more fragmented at the outset due to the constitutional separation of powers. But this fragmentation substantially increased during the early 1970s: the autonomy of federal regulatory agencies was reduced as the courts, Congress, Congressional committees and the Presidency began to assume greater roles in regulatory policy-making, forcing the agencies to democratize their procedures. As a result, the regulatory process became more open and the ability of business to dominate outcomes was reduced.

A similar dynamic occurred in Europe. The growing regulatory competence of the EU has harmonized many European laws, but at the same time it has fragmented the making of regulatory policy. First, regulatory policy-making within the EU has itself become more decentralized, due to the increased influence of the European Parliament (EP) as well as the important role played by the ECJ in interpreting EU treaties. A second equally important but less widely appreciated development has been the fragmentation of policy-making, which is a defining feature of European regulatory federalism. In a sense, the Member States play a role functionally equivalent to the US judiciary and Congressional hearings: they represent 15 distinctive institutional settings in which policies can be proposed, debated, and challenged. If an activist group succeeds in shaping regulatory policy in any one Member State, then it is highly likely that this policy will appear on the agenda of the other 14, as well as Brussels, due to the legal and economic interdependence created by the single market. Thus, just as in the US, the fragmentation of regulatory policy-making has increased the access of previously marginalized groups to the policy process.

[66] Vogel, n. 17 above, 182.

VII. The EU and the Precautionary Principle

The precautionary principle represents a critical component of the new EU approach to risk management. The evolution of this principle 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.[67]

While in principle Vorsorge implies that authorities should attempt to minimize all risks, in practice its implementation has been linked to the concept of proportionality, which incorporates considerations of both cost and 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.[68]

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.'[69] Vorsorge was also associated with the concept of 'ecological modernization,' which views strong environmental standards as a source of competitive advantage.

During the 1980s, when Germany experienced strong economic growth and the Green Party enjoyed increasing public support, 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'.[70] It

[67] As cited in Jordan and O'Riordan, n. 58 above, 68. See alsoMarr and Schwemer, elsewhere in this volume.

[68] 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.

[69] As cited in E. Soule, 'Assessing the Precautionary Principle' (2000) 14 Public Affairs Quarterly 4, 318.

[70] 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, D.C.: Island Press, 1999), 21.

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 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. Following the enactment of its own restrictions on sulphur emissions, Germany pressured for the enactment of a European Directive on combating air pollution from industrial plants. This Directive, which was enacted in 1994, restricted stationary source emissions through the EU. The 1990 Ministerial Declaration on the North Sea represents 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 not scientific evidence to prove a causal link between emissions and effects'.[71]

The precautionary principle was officially introduced into EU environmental policy by its incorporation into Article 130 EC (the environmental section), of the 1993 Treaty of the European Union (Maastricht Treaty) (it was subsequently renumbered Article 174 EC 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.[72]

Between 1994 and 1999, the precautionary principle was referenced in 27 resolutions adopted by the EP.[73] A Communication from the European Commission in February 2000 explicitly broadened its scope from environmental protection to encompass human, animal, or plant health. As a response to both the comments of the Appellate Body in the Hormones case[74] (discussed below) and complaints by World Trade Organization (WTO) Members about its vagueness and potential as a rationale for protectionist policies, the Commission also sought to clarify its role in regulatory policy-making.[75]

[71] Soule, n. 69 above, 318.

[72] 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.

[73] 'The Precautionary Principle', working paper: Scientific and technological options assessment series, Feb. 2000.

[74] EC – Hormones, WT/DS26/AB/R, WT/DS 48/AB/R, 16 Jan. 1998.

[75] For an analysis, and critical summary of this communication, see N. McNelis, 'EU Communications on the Precautionary Principle', (2000) 3 Journal of International Economic Law, 545–51.

According to the Commission, the precautionary principle should be invoked when 'potentially dangerous effects deriving from a phenomenon, product or process' have been identified, and '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'.[76] 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'.[77]

Nonetheless, actual regulatory policies, i.e. risk management decisions, can and should incorporate a much broader range of considerations, including 'an examination of the costs and benefits of both action or inaction as well as the level of risk the public considers appropriate'. The Commission also emphasized that precautionary 'measures should be reviewed in light of scientific progress and amended as necessary', and that they should be proportionate to both the economic costs of a regulation and the potential risks of delaying regulatory action. Finally it stressed the need to 'avoid unwarranted recourse to the precautionary principle, which in certain cases could serve as a justification for disguised protectionism.'

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.[78] 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 helping to formulate regulatory policies, stressing that

public participation should be ‘multidisciplinary, independent and transparent’, in order to ensure that all views are heard. It also stated that any examination of the costs or benefits of action or inaction should take into account not only their social and environmental costs but also ‘public acceptability’ of the final decision.

The latter is particularly significant since EU administrative procedures formally separate risk assessment and risk management. While the former is the responsibility of scientific or technical experts, who may or may not also offer policy recommendations, risk management decisions are made by politicians. 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

[76] Communication from the Commission on the Precautionary Principle COM(2000)1, 2 Feb. 2000, 15.

[77] A. Jordan, ‘The Precautionary Principle in the European Union’ in O’Riordan, Cameron, and Jordan, n. 72 above, 158.

[78] ‘EU Leaders Back Precautionary Principle’ ENDS Daily, 13 Dec. 2000.

always a political one’.[79] A memo from the European Commission 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’.[80] An important purpose of the precautionary principle is precisely to make explicit the relative role of scientific and ‘other legitimate factors’ in shaping risk management decisions.

While the precautionary principle cannot be seperated from science—since ‘a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates’—in fact, its growing popularity in Europe reflects the perception that scientific knowledge is an inadequate guide to regulatory policy.[81] It is located precisely between a logic that requires the extension of scientific knowledge and one which acknowledges ‘the possible intrinsic limitations of scientific knowledge in providing the appropriate information in good time’.[82] It thus simultaneously both increases public expectations of science, and reflects the public’s scepticism 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’.[83] Yet at the same time, 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.

Notwithstanding the EU’s repeated efforts to clarify its meaning, important elements of the principle remain ambiguous. Its application raises five critical questions, none of which have been clearly or consistently answered by the EU. First, how much uncertainty is required before it should be invoked? After all, there is always some measure of uncertainty about the risks or benefits of a product or process. Secondly, how much scientific consensus is required to identify a hazard? For example, how much weight should be accorded to minority scientific views? Thirdly, how high must the risk be to trigger regulatory action? Should it be probable, possible or only conceivable? Fourthly, what level of risk is needed to justify action? In other words, how serious should the potential risk be? Finally, what role should economic costs and benefits play in establishing regulatory policies?

There is a fundamental tension or ambiguity at the core of the precautionary principle. On one hand, it emphasizes that regulatory decisions should be non-arbitrary, rational, and based on objective risk assessments. On the other hand, it stresses the importance of public acceptability and public participa-

[79] J. Dratwa, ‘The Precautionary Principle’, Scientific and Technological Options Assessment

Unit of the European Parliament, Jan. 2000, 9.
80 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.
81 Cameron, n. 22 above, 244.
82 O. Godard, 'Social Decision-Making Under Conditions of Scientific Controversy, Expertise and the Precautionary Principle', in Joerges, Ladeur, and Vos, n. 37 above, 65.
83 Jordan and O'Riordan, n. 58 above, 71.

tion. But what if the public's perception of the degree of scientific (un)certainty or the magnitude of a particular risk differs substantially from that of scientists? A wide gap between the assessment of risks and/or uncertainty by scientists on one hand and the public on the other is a pervasive feature of US regulatory policy, and not surprisingly, increasingly in Europe as well.[84] If the US experience with highly risk-averse approaches to regulatory policymaking offers any guidance, 'precautionary measures . . . are most likely to be applied when public opinion is instinctively or knowledgeably risk-averse', as the next section clearly reveals.[85]

VIII. Applying the Precautionary Principle in the EU

The challenges the EU has faced in applying the precautionary principle can be seen in the cases of both mad cow disease and GMOs, two policy areas in which public attitudes have played a critical role. The complex history of European policies in both areas demonstrates how the EU has both sought to prevent the precautionary principle from being used by Member States to oppose regulatory policies that many of their citizens happen to dislike, while at the same time responding to public demands for more risk averse or more stringent regulatory standards.

The 1998 decision of the 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'.[86] However, in October 1999, the European Scientific Steering Committee unanimously concluded that, provided the UK actually implemented the European Commission's recommendations, consumption of British beef posed no more risk than consumption of other European beef. Indeed, given the relative stringency with which British cattle was inspected, it was 'undoubtedly the safest among all European beef'.[87] Accordingly,Member States were told to lift their bans on imports of British beef. Nonetheless, France's recently established food safety agency AFSSA 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

84 S. Breyer and V. Heyvaert, 'Institutions for Regulating Risk', in Revesz, Sands, and Stewart, n. 65 above, 283–352. See also B. Durodie, 'Plastic Panics—European risk regulation in the aftermath of BSE' in J. Morris (ed), Rethinking Risk and the Precautionary Principle (Oxford: Butterworth, 2000), 140–66.
85 Jordan and O'Riordan, n. 58 above, 61.
86 As cited in Christoforou, n. 1 above, 5.
87 O. Goddard, The precautionary principle—matching economic axiomatics and reasoned heumistics to tackle collective risks, 4th Journe´es GREEN-CIRANO 'Environmental and resource economics', Montreal 17–18 November 2000, published on the Internet at: http://ceco. polytechnique.fr/ CHERCHEURS/GODARD/#7.

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.[88]

For its part, the European Commission strongly denounced the French decision though it waited until 2002 before legally challenging it.

The regulation of GMOs provides another illustration of the challenge the EU faces in applying the precautionary principle. The EU's market authorization procedures for GMOs seek to employ scientific expertise in a cautious and transparent way. Each request for market authorization is examined by a committee of experts on a case by case basis. Member States are asked to exchange information on each file, and risk assessments have been made progressively more rigorous. Yet these procedures have been inadequate to assuage public anxieties over the safety of GM foods.

The case of transgenic corn provides a good illustration of the EU's inability to forge either a scientific or political consensus on GMOs. France was the first country to review the application as it had received the original application from Novartis. The French government transmitted the file to the European Commission and recommended that the application be approved. The European Commission then requested advice from the other Member States, seven of whom rejected the French file 'because it did not present all the necessary safety requirements'. The European Commission consequently initiated another consultation under Article 21 of the GMO Directive which provides for the creation of a committee of Member States' representatives in case of disagreement regarding the authorization of GMOs. The 'Committee 21' consultation was unable to reach agreement, and the file was then transferred to the Council of (Environmental) Ministers, who refused to vote on authorization. Since no decision was made for more than three months, the Commission then transferred the file to three scientific committees. In December 1996, each scientific committee issued a favourable opinion regarding the market authorization of Novartis' corn, and the EC accordingly authorized its cultivation on 23 January 1997.

The French Ministry of Agriculture officially authorized the corn on 4 February 1997 but the Environmental Minister urged Prime Minister Juppe´ to block the authorization, which he did a week later. In May 1997, parliamentary elections led to the replacement of the Juppe´ government by the Jospin government, which officially authorized cultivation on 5 February 1998 'although the state of scientific knowledge had not changed'.[89] Immediately

[88] O. Goddard, The precautionary principle—matching economic axiomatics and reasoned heumistics to tackle collective risks, 4th Journe´es GREEN-CIRANO 'Environmental and resource economics', Montreal 17–18 November 2000, published on the Internet at: http://ceco.polytechnique.fr/ CHERCHEURS/GODARD/#7. 24–5.

[89] C. Noiville and P.H. Gouyon, 'Principe de Pre´caution a` Organisms Ge´ne´tiquement Modifie´s—Le case du Mais Transge´nique', in Kourilsky and Viney, n. 59 above, 295–304.

following this second authorization, several NGOs including Ecoropa, Greenpeace, Friends of the Earth, and the Confe´de´ration Paysanne filed a lawsuit with the Conseil d'Etat, France's highest administrative court. Their challenge to the FrenchGovernment's decisionwasbasedonthe precautionary principle, whose procedures they claimed the French government had not adequately followed and which would have allowed France to prohibit the growing of the corn despite its European authorization. Their brief noted the incompleteness of Novartis' risk assessment file presented to French authorities, irregularities in the functioning of the Commission du Ge´nie Biomolle´lucaire (CGB), which was in charge of reviewing applications for the Ministry of Agriculture, and the Ministry of Agriculture's transgression of the authorization procedure.

In September 1998, the Conseil d'Etat ruled that the French Government had not adequately applied the precaution principle. It then referred the case to the ECJ, which decided in November 1999 that the approval of GMOs was a matter of 'joint competence' with the EU, hence invalidating its regulatory clearance.[90] The ECJ stated: 'Observance of the precautionary principle is reflected. . . in the right of any Member State . . . provisionally to restrict or prohibit the use/or sale on its territory of a product which has received

consent where it has justifiable reasons to consider that it constitutes a risk to human health or the environment.'[91]

Austria, Luxembourg, Germany, and Italy have also blocked the circulation of allGMcorn within their territories, even though fourGMcorn products have been approved by the European Commission. According to the EU's relevant scientific committees, these countries were unable to provide any significant new information that Brussels had not already considered, and they did not submit any evidence that these products represented a danger to human health. Yet to date, the Commission has hesitated to challenge legally the more conservative risk management decisions made by these four Member States. Indeed, in July 1999, fearing an additional loss of both legitimacy and its authority, the Commission suspended all new GMO approval procedures.

More recently, the Commission has found itself increasingly frustrated by its inability to establish a regulatory framework for GMOs that would break the current logjam over new approvals and permit the free circulation of those products or processes which have already been approved. While the EC has undertaken its own extensive biosafety research program, investing more than 60 million in more than 400 laboratories over a 12-year period, the results of this research have failed to produce a consensus within Europe regarding the safety of this new agricultural technology. The Commission has warned that the de facto moratorium on approving new varieties of GM crops is undermining the EU's efforts to improve the competitiveness of European industry. According to the Commission, 'Europe cannot afford to miss the

[90] A. Roy and P.B. Joly, 'France: Broadening Precaution Expertise' (2000) 3 Journal of Risk Research, 247–54.

[91] As cited in Christoforou, n. 1 above, 2.

opportunity that these new sciences and technologies offer. Biotechnology research efforts can and should be used to develop new GM varieties to improve yields and enable cultivation by small-scale and poor farmers'.[92]

Yet the EU's own endorsement of the precautionary principle has complicated Europe's efforts to realize these opportunities.

The Commission has sought to restrict the application of the precautionary principle by the Member States to cases when a Member State can supply new scientific evidence that was not considered by the EU's own scientific committees or when it 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'.[93] And in fact, the ECJ has struck down numerous health and safety standards adopted by Member States on the grounds that they lacked adequate scientific justification.[94]

In some cases,Member State regulations have either lacked any conceivable scientific support (e.g. Cassis de Dijon), or were relatively uncontroversial.[95] But for regulations that were politically or scientifically problematic, the same scepticism about scientific expertise that underlay the adoption of the precautionary principle by the EU also informs the policies of the Member States.

The latter 'are increasingly distrustful of the findings of the Community's scientific committees and seek increasingly to adhere to the findings of their own national bodies to support protective measures'.[96] As Corrine Lepage, the former French Environment Minister under whose aegis the original application forGMcorn was denied, writes in her book on the precautionary principle: 'The precautionary principle precisely responds to the need for prudence when faced with the consequences of technological progress, whose repercussions are exponential and unknown'.[97] Formany environmentalists, this is precisely one of its most important attractions. Indeed, the principle has

'become the repository for a jumble of adventurous beliefs that challenge the status quo'.[98] These range from a rejection of risk assessment and/or costbenefit analysis, to bans on any existing products or processes suspected of

[92] M. Skapinker, 'How Monsanto Got Bruised in a Food Fight' Financial Times, 8 Mar. 2002, 9.
[93] Ibid., 11.
[94] V. Heyvaert, 'The Changing Role of Science in Environmental Decision-Making in the European Union' (1999) Revue des Affaires Europe´ennes, 426–43.
[95] Case 120/78, Rewe Zentrace v. Bundesmonopolverwaltung fu¨ r Brantwein [1979] 3 CMLR 494.
[96] J. Scott and E. Vos, 'The Juridification of Uncertainty—Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO', in C. Joerges and R. Dehousse (eds), Good Governance and Administration in an 'Integrated' Market (Oxford: Oxford University Press, 2000), 16.
[97] C. Lepage and F. Guery, La Politique de Precaution (Behemoth : Presses Universitaires de France, 2001), 144. For a collection of essays that are generally sympathetic to this position, primarily by US authors, see C. Raffensperger and J. Tickner (eds), Protecting Public Health and the Environment—Implementing the Precautionary Principle (Washington, D.C.: Island Press, 1999). For a wide-ranging critique of the precautionary principle as both law and philosophy, see J. Morris, Rethinking Risk and the Precautionary Principle (Oxford: Butterworth, 2000).
[98] Jordan and O'Riordan, n. 70 above, 16.

causing harm, to requiring that the proponent of a new product or technology unequivocally demonstrate its safety before its use is authorized. Thus, ironically, a principle in part adopted by theEUto defend its regulatory policies vis-a`-vis its trading partners, has become increasingly used by activists in Europe, as well as a number of regulatory authorities from the Member States, to defend their decisions from the EU.

IX. Contemporary Risk Management in the US and the EU

Since key elements of a precautionary approach were firmly entrenched in US law prior to the formal adoption of the precautionary principle by the EU, why has the latter development not produced increased trans-Atlantic policy convergence? After all, while EUregulations were becoming increasingly stringent and comprehensive, the US could also have continued to enact relatively stringent and comprehensive regulations in areas such as GM foods and seeds, carbon emissions and electronic recycling. As noted above, during the 1970s and 1980s the US government banned or restricted numerous chemicals or pollutants based on risk assessments comparable to those employed by the EU to restrict the planting and consumption of GMOs. Not only have US regulators frequently been as risk averse as their European counterparts, but during the 1970s and 1980s they were typically more precautionary. However, while the US has continued to enact some highly precautionary regulations compared to Europe prior to the mid 1980s or the US since the 1990s, US consumer and environmental regulations have been less stringent, comprehensive and innovative. For the most part, the relatively stringent regulatory standards enacted during the 1970s and 1980s continue to be in force. But since 1990, when Congress enacted three important environmental statutes, the pace at which new US legislation has been enacted and new regulations have been issued has considerably slowed. The US legal structure of regulation has not significantly changed. What has changed are public attitudes and regulatory politics.

A. POLITICAL FACTORS

There are important political differences between contemporary Europe and the US. NGOs and Green parties have become steadily more influential in Europe since the mid 1980s. In 1999, the Green Party was represented in four European governments: Germany, where it has historically been strong, and France, Italy, and Belgium, where it has not. Moreover the party had nearly 150 members in 11 of the EU's 15 national legislatures. By contrast, the political strength of consumer and environmental lobbies has either stabilized or eroded in the US since 1990. The Republican Party's control of one or more Houses of Congress since 1994, combined with the growing conservatism

of Republican legislators, has significantly enhanced the influence of

business over regulatory policies and the policy agenda. US NGO's spent much of the 1990s seeking to prevent the rolling back of existing statutes, thus reducing their ability to place new issues on the regulatory agenda.

B . PUB L I C PRESSURES

During the 1990s, public confidence in technology, business, and government regulation increased in the US, just as they declined in Europe. Significantly, while 90 per cent of US citizens believe the USDA's statements on biotechnology, only 12 per cent of Europeans trust their national regulators.[99] Public anxiety about pervasive threats to public health, safety and the environment, and a lack of trust in government's capacity to adequately protect them, has diminished in the US over the last 10 to 15 years, while it has increased in much of Europe. According to one polling firm, America's faith in major corporations rose in the 1980s and 1990s, helping to 'produce a politics that has been reluctant to impose new regulatory burdens on business that might diminish corporate profits'.[100] Two accounts provide striking evidence of how public anxiety has diminished in the US and risen in the EU. In 1982, at the height of the US precautionary regime, Douglas and Wildavsky wrote in Risk and Culture:

> Try to read a newspaper or news magazine . . . ; on any day some alarm bells will be ringing. What are US afraid of? Nothing much, really except the food they eat, the water they drink, the air they breathe . . . . In the amazingly short space of fifteen to twenty years, confidence about the physical world has turned into doubt. Once the source of safety, science and technology has become the source of risk.[101]

To illustrate how closely contemporary European views mimic this worldview, consider the following observation published in the Washington Post in the spring of 2001:

> . . . wealthy, well-educated Europe is regularly swept by frightening reports of new dangers said to be inherent in contemporary life. The lack of scientific basis for many of the worries doesn't staunch the flood. Americans have health concerns, too, but not on this scale. The year is two months old and already in 2001 public opinion and public officials have been rattled by alarms over risks—proven and not—from genetically modified corn, hormone-fed beef and pork, 'mad-cow' disease, a widely used measles vaccine, narrow airline seats said to cause blood clots and cellular phones said to cause brain damage.[102]

Small wonder that the UK's Prime Minister Tony Blair has expressed concern about a 'loss of faith in science' in Europe or that many European observers

[99] J. Enriquez and R. A. Goldberg, 'Transforming Life, Transforming Business—The Life Science Revolution' (2000) 78 Harvard Business Review 4, 94.

[100] D. Callahan, 'Private Sector, Public Doubts' New York Times, 15 Jan. 2000, A 23.

[101] M. Douglas and A. Wildavsky, Risk and Culture (Berkeley: University of California Press, 1982), 10.

[102] T.R. Reid, 'Be Careful What you Eat, Where you Sit and . . . 'Washington Post NationalWeekly Edition, 12–18 May 2001, 15.

are now voicing concerns about Europe's 'culture of fear,' and 'retreat from scientific reason', in terms similar to those previously voiced by critics of America's regulatory policies.[103]

C . REGULATORY FAI LURE S

The change in the US is in part due to the absence ofmajor regulatory failures in the US since 1989—certainly none on the scale of those that surfaced in Europe during the second half of the 1990s. There have been periodic consumer safety and environmental crises, including some involving the health and environmental impacts of GMOs, but their political impact has been short-lived. More broadly, over the last decade or so, the US has experienced fewer cases of regulatory failure than Europe due to the government's inability to anticipate dangers or risks which subsequent evidence revealed to have been significant. According to a group of US scholars:

> The precautionary principle has arisen because of the perception that the 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].[104]

This perception did characterize the US two decades ago. It now however more accurately characterizes contemporary Europe.

Moreover, the US citizenry may well have become somewhat less risk-averse. In the US, beginning in the late 1980s and continuing in the 1990s, the market-oriented values of competitive individualism became increasingly influential. For many in the US, technological change and innovation became associated with the glamour and wealth of high-technology industries and products, rather than with cancer or environmental degradation. This may partially explain the degree of public acceptance of GMOs—a technology which if it had been introduced in the US two decades earlier may well have received a more sceptical public reception. If, as cultural theory suggests, 'those who regard the environment as inherently robust and capable of withstanding sustained human impact will tend to be less precautionary than those who regard human impact on nature as unpredictable and potentially calamitous', then it appears that over the last decade or so, US citizens have moved closer to the former world view, and Europeans to the latter.[105]

[103] See e.g., F. Furedi, Culture of Fear (London: Cassell, 1997). For a sociological analysis of the contemporary politics of risk in Europe, see U. Beck, World Risk Society (Cambridge: Polity Press, 1999). Beck's analysis parallels Douglas' and Wildavsky's (n. 101 above) in a number of important respects.

[104] D. Kriebel, et al., 'The Precautionary Principle in Environmental Science' (2001) 109 Environmental Health Perspectives 9, 871.

[105] Jordan, n. 72 above, 155.

D. DIMENSIONS OF REGULATORY FAI LURE

Europeans have been preoccupied with regulatory failures stemming from false negatives: mad cow disease represents the most dramatic example. By contrast, regulatory failures associated with false positives have become more politically salient in the US. Over the last 10 to 15 years, policy-makers in the US have recognized 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.[106]

There are numerous examples of the latter phenomena.[107] For example, strict standards for the approval of new drugs not only denied US residents access to many life-saving medical products that were available in other countries, but because these standards were not applied to existing drugs, they prolonged the use of some older, more harmful medical products. The decision to remove asbestos-containing materials from public schools not only produced few or no health benefits—since the typical exposure level was about the same concentration found outdoors—but removal operations shifted fibres into breathable air and created hazards for workers involved in the removal process. In 1992, the 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. If one adds up the harms associated with digging up, removing and transporting these wastes, Superfund legislation may well have made Americans less healthy.

During the late 1980s, in response to pressures from AIDS activists, US drug approval policies were radically changed to expedite the approval process.[108] This change was informed by a recognition thatmore Americans were likely to

be harmed by delays in drug approval that subsequent evidence revealed were relatively safe and effective, than were likely to be harmed if drugs were approved that subsequent evidence revealed to be unsafe or ineffective—precisely the opposite of the precautionary logic that had informed the 1962 Amendments to the Pure Food and Drug Act. In 1996, Congress finally reformed the Delaney Clause by enacting the Food Quality Protection Act. This statute replaced an absolute prohibition on pesticides that might induce cancer with a risk-benefit standard for pesticide residues. The new law provided the EPAwith the 'flexibility to consider the seriousness of a carcinogenic

106 For an inventory of this category of regulatory failures in the US, see F. Cross, 'The Paradoxical Perils of the Precautionary Principle' (1996) 53 Washington and Lee Law Review 3, 851.

107 Ibid., M. Fumento, Science Under Siege (New York: William Morrow and Company, 1993).

108 D. Vogel, 'When Consumers Oppose Protection—The Politics of Regulatory Backlash' (1990) 10 Journal of Public Policy, 458–61.

pesticide's dietary risk, as well as the pesticide's benefit to society in making tolerance decision'.[109]

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 clean-up that had contributed nothing to public health. The Economist, detailing one implementation of the 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.[110]

As Daniel Bodansky observes:

> Not only has the precautionary principle [in the US] 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, this resulted from the Reagan-era opposition to environmental regulation generally. But in part it reflects a more widespread concern about the perceived over-stringency and inefficiency of many precautionary standards.[111]

Consistent with these concerns, US courts are increasingly undertaking 'hard look' reviews of rule-making by regulatory agencies, often questioning regulations that they deemed too protective or costly—a judicial doctrine which became more influential due to the large numbers of conservative federal judges appointed by Presidents Reagan and Bush. These reviews have in turn required agencies to place increased emphasis on quantified risk estimates and cost-benefit analyses. The 1980 decision of the Supreme Court in AFLCIO v. Petroleum Institute not only confirmed the legitimacy of quantitative risk assessment, but effectively made reliance on this methodology obligatory for all American agencies engaged in risk regulation.[112] As a result, 'the riskbased 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'.[113] Moreover, Congress and the Reagan Admin-

109 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, 1369.

110 'Muck-spreaders' Economist, 21 Apr. 2001, 27.

111 D. Bodansky, 'The Precautionary Principle in US Environmental Law', in O'Riorden and Cameron (eds.) n. 70 above, 203–28.

112 AFL-CIO v. Petroleum Institute, 448 US 607, 615 (1980).

113 J. Trickner and C. Raffensperger, 'The US View of the Precautionary Principle', in O'Riordan,

Cameron, and Jordan, n. 70 above, 139.

istration's Executive Order, have pressured agencies to undertake elaborate quantitative risk, risk comparison and risk-benefit analyses before taking regulatory action—all of which can be seen as a response to the perception of previous regulatory 'excesses'. 'Domestically. . . the US regulatory arrangements . . . like solid scientific bases for action or inaction, profound peer group review, and the balancing of personal risks against possible benefits.'[114]

X. The Multi-National Dimension

The precautionary principle also has an important international dimension. It has informed both international environmental and trade agreements, and emerged as a source of conflict between the EU and the US.

In some cases, the US has explicitly endorsed the precautionary principle. The 1985 Vienna Convention on Ozone Depleting Substances, which the US initiated, recognized the importance of taking 'precautionary measures' to address the dangers of ozone depletion.More explicit precautionary language was included in the 1990 London Amendments, which was also accepted by the US. 'The Parties to this Protocol are determined to protect the ozone layer by taking precautionary measures to control equitable total global emission of substances that deplete it . . . '[115] The US also signed the 1992 Rio Declaration which emerged from the UN Conference on Environment and Development. This Declaration, which is widely regarded as among the most influential international statements of the precautionary principle, states:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capacities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[116]

In 1996, the President's Council on Sustainable Development issued a report which implicitly endorsed its application to American environmental policy. Despite Department of Defense opposition to a worldwide ban on the ocean dumping of radioactive waste on the grounds that there was no scientific evidence that the wastes were dangerous, EPA Administrator Carol Browner supported the ban due to its consistency with the precautionary principle.Her decision was backed by the Clinton Administration in late 1993. The following year the precautionary principle was explicitly endorsed by CITES, to which the US is a signatory. Resolution Conf. 9.24 'RESOLVES that when considering any proposal to amend [the list of species] the Parties shall

[114] T. O'Riordan, J. Cameron, and A. Jordan, The Evolution of the Precautionary Principle in T. O'Riordan, J. Cameron, and A. Jordan (eds), Reinterpreting the Precautionary Principle (London: Cameron May, 2002) 28.

[115] As cited in J. Cameron, 'The Status of the Precautionary Principle', in Riordan and Cameron, n. 68 above, 270.

[116] Trickner and Raffensperger, n. 113 above, 184.

apply the precautionary principle so that scientific uncertainty should not be used as a reason for failing to act in the best interest of the conservation of the species'.[117]

After the US Department of Commerce and the State Department had actively lobbied on behalf of the toy and phthalate industries against European efforts to ban the use of phthalates in polyvinyl chloride (PVC) children's toys on the grounds that the ban lacked scientific justification, Vice President Albert Gore wrote a letter to members of Congress in which he stated:

> We recognize and respect each nation's right to set legitimate public health and environmental standards and to take appropriate precautionary action. [The United States] should refrain from any actions to discourage individual countries, whether in the European Union or elsewhere, from implementing precautionary measures they deem appropriate to restrict the marketing or use of products containing

phthalates.[118]

More recently however, as American and European notions as to what constitutes a politically acceptable risk have diverged, the precautionary principle has become a source of trans-Atlantic tensions. An important example of the differences between their approaches to risk management—and the only one which to date has been the focus of a formal international trade dispute—involved the EU's ban on beef hormones. This ban, which reduced US beef exports to Europe by approximately 120 million annually, was successfully challenged by the US under the terms of the Sanitary and Phytosanitary Agreement (SPS), which became part of theWTO following the Uruguay Round.

In defending its hormone ban, the EU argued that the precautionary principle had become a 'general custom of international law' or at least 'a general principle' and therefore should be applied to Articles 5.1 and 5.2 of the SPS Agreement.[119] This claim was challenged by the US, which argued that the precautionary principle was not a part of international law, but only 'an approach'. The US further claimed that Article 5.7, which permits nations to enact provisional methods where the relevant scientific evidence is insufficient, already incorporates a precautionary approach. But it went on to argue that the application of this provision could not create a risk assessment where there was none, nor could a 'principle', create 'sufficient scientific evidence' where there was none.[120]

The WTO's Appellate Body, in upholding the ruling of the dispute panel against the EU, concluded that the precautionary principle did not apply because it could not override the explicit wording of Articles 5.1 and 5.2 which required that measures under the SPS Agreement be based on evidence from a risk assessment. The Appellate Body recognized that one of the

[117] B. Dickson, 'The Precautionary Principle in CITES', (1999) 39Natural Resources Journal, 219.
[118] As cited in Trickner and Raffensperger, n. 113 above, 185.
[119] Ibid., 137. [120] Ibid.

issues in the EU's appeal was 'whether, or to what extent, the precautionary principle is relevant in the interpretation of the SPS Agreement' but opined that since this principle was 'the subject of debate among academics, law practitioners, regulators and judges . . . the status of the precautionary principle in international law was something they should not rule on'. They accordingly concluded that, 'the precautionary principle cannot override our finding . . . namely that the EC import ban . . . in accordance with good practice, is from a substantive point of view, not based on risk assessment'.[121]

They added that while such assessments need not come to a monolithic conclusion, its results must 'reasonably support the SPS measure at stake. [T]here must be a rational relationship between the measure and the risk assessment'[122]—a relationship which the EU's brief did not provide. However they also concluded that nothing in the SPS Agreement should preclude 'responsible governments from acting from a perspective of prudence when they determine 'sufficient scientific evidence'.[123]

Ironically, this ruling was not substantially inconsistent with the EU's official explication of the precautionary principle nor with the way it has been interpreted by the ECJ. The latter has consistently required Member States to provide evidence that national measures that interfere with the single market are necessary for the protection of human health or the environment. And while recognizing that in the face of scientific uncertainty the evidence that a Member State must submit is reduced, the ECJ has nevertheless continued to insist that Member States must provide, as a minimum, evidence of scientific uncertainty. This demand does not substantially differ from the request of the WTO Appellate Body. Indeed, the endorsement of the Appellate Body of the finding of the Dispute Resolution Panel 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 basis for a ban under the SPS Agreement, is strikingly similar to the jurisprudence of the ECJ in cases such as the German Beer case.[124]

The beef hormone ruling has had two important consequences. First, it has encouraged the EUto strengthen its capacity to conduct risk assessments. The establishment of regulatory bodies such as the Food Safety Authority, which will issue analyses based on the scientific expertise of the Member States, along with its extensive studies of the health and environmental impacts of GMOs, are intended not only to enhance the ability of the European Commission to formulate common standards but to defend them from challenges from both the Member States in the ECJ and by the US in the WTO. Thus, ironically, while the SPS Agreement was widely criticized by activists on the grounds that it would undermine the capacity of governments to protect their

[121] As cited in Cameron, n. 68 above, 138. [122] Scott and Vos, n. 96 above, 19.

[123] J. Cameron, ‘The Precautionary Principle in International Law’, in O’Riordan, Cameron, and Jordan, n. 72 above 138.

[124] Case 178/84, Commission v. Germany [1987] ECR 1227, as cited in G. Majone, ‘What Price Safety? The Precautionary Principle and its Policy Implications’, unpublished paper, 9.

citizens, it has played a role in strengthening the scientific regulatory apparatus of governments.

In addition to strengthening their capacity to conduct risk assessment, the EU has sought to incorporate the precautionary principle into international trade law. Its strategy has been to have this principle incorporated in as many international environmental agreements as possible and then to have these agreements accorded some kind of legal status by the WTO. For its part, the US wants to maintain the legal supremacy of the SPS Agreement, as its more demanding scientific standards for trade-restrictive regulatory policies enabled the US to prevail in its dispute over the EU’s ban on beef hormones.

Not surprisingly, there were sharp differences between the EU and the US over whether the precautionary principle should be included in the Montreal Convention on Biological Diversity. As a compromise, Article 10 of the Protocol incorporates the precautionary principle though without explicitly mentioning it: a country is permitted to reject the importation of GMOs where there is ‘lack of scientific consensus due to the insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity’.[125] Most observers believe that this language effectively reduces the amount of scientific evidence that would be needed to justify an import ban. Accordingly, if a country should choose to reject GMOs on the basis of their environmental risks, they would be protected from the accusations and penalties associated with unfair protectionism.

During the Uruguay Round negotiations in the early 1990s, it was the US which had insisted on changes in the SPS Agreement to make it easier for relatively risk-averse regulatory standards to pass the scrutiny of WTO dispute panels. This position reflected the relative stringency of many US health, safety, and environmental standards when compared to the rest of the world, including the EU. But over the last decade, the EU has adopted a number of standards which are stricter than their US counterparts. Accordingly, it is now the EU which is insisting that WTO rules be modified so that they can more easily defend their more stringent regulatory standards from trade challenges, including those from the US.

One such modification would be for theWTO to accord legal recognition to the precautionary principle—in effect harmonizing EU and WTO approaches to regulatory policy formation in the face of scientific uncertainty. While the European Commission believes that measures based on the precautionary

principle are a priori compatible with WTO rules, it nonetheless wishes to 'clarify this relationship' and, in addition, 'to promote the international acceptance of the precautionary principle.' The EU believes that, 'this will help ensure that measures based on a legitimate resort to the precautionary principle, including those that are necessary to promote sustainable development, can be taken without the risk of trade disputes'.[126] According to the

[125] Soule, n. 69 above, 315. [126] The 'Non-Trade Implications'.

EU, such a review is 'necessary to ensure the right balance between prompt, proportional action, where justified, and the avoidance of unjustified precaution', adding that 'the basic concept of the precautionary principle is already present in the WTO'.[127]

However, the US does not consider a change in WTO rules to be necessary. The US position is that not only is a 'precautionary element . . . fully consistent with WTO rules, [but] it is an essential element of the US regulatory system'.[128] The US cautions that 'precaution [must] be exercised as part of a science-based approach to regulation, not a substitute for such an approach'. While this is not necessarily inconsistent with the way the Commission has interpreted the precautionary principle, the US remains concerned that, as applied by the EU in the context of trade disputes with the US, there is a danger that the precautionary principle will become a 'guise for protectionist measures'. The US is satisfied with provisions of the SPS Agreement which permit a country to set high standards even when the scientific evidence on risk is uncertain, with the stipulation that such standards be regarded as provisional and thus subject to modification as more evidence becomes available. But the US is concerned that 'explicitly embedding a precautionary principle in the SPS or Technical Barrier to Trade (TBT) sections of the WTO framework would . . . allow countries to block imports on environmental or health grounds in the absence of any scientific evidence of significant risk'.[129]

While the EU anticipates that an international consensus will emerge regarding the role of the precautionary principle in international law, and that this consensus can then be applied to the regulation of GMOs, the gap between European and USattitudes toward this technology make this unlikely. According to a recent Eurobarometer survey, two-thirds of Europeans stated that they would not buy GM fruits even if they had better taste.[130] Two EC officials recently wrote: ' . . . the bottom line for us is that where there is scientific uncertainty and risk of significant hazard, we cannot simply give a ''go-ahead'' decision'.[131] German foreign minister Joschka Fischer has stated: 'Europeans do not want geneticallymodified food—period. It does not matter what research shows; they just do not want it and that has to be respected.'[132] Not surprisingly, Alan Larson, the US Under Secretary of State for Economic, Business and Agricultural Affairs, has commented: ' . . . for some in Europe, the ''precautionary principle'' appears to mean that, when it suits European authorities, they may withhold approval until the risk assessment process has convinced even the most irrational consumer of the absence of even the more hypothetical risk of the most remote theoretical uncertainty'.

[127] Cameron, n. 68 above, 133.
[128] Declaration of Principles.
[129] M.Weinstein and S. Charnowitz, 'The Greening of theWTO' Foreign Affairs,Nov./Dec. 2001.
[130] P. Laget and M. Cantley, 'European Responses to Biotechnology—Research, Regulation and Dialogue', (2001) 17 Issues in Science and Technology.
[131] Ibid., 41.
[132] J.A. Moore, 'More than a Food Fight' (2001) 17 Issues in Science and Technology.

According to the Food Industry Codex Coalition, 'the precautionary principle would be easily misconstrued to support irrational fears about the food supply, and be a basis for unjustified barriers to trade'.[133] The US frustration

over the EU's use of the precautionary principle to delay the approval of GMOs can be seen in the US comments to the EC's Communication to the Codex Secretariat on the precautionary principle. The US asked, almost rhetorically: 'since complete scientific certainty is the exception, rather than the norm, how does the Commission's proposed precautionary principle differ from most decisions that must be taken when implementing regulatory measures?'[134] From the US point of view, it appears that no amount of scientific evidence could ever persuade the EU that GMOs do not constitute a significant risk to either consumers or nature.

XI. Conclusion

A series of regulatory failures, changes in European politics, and the growth in regulatory competence of the EU, have made European and American approaches to regulating risks more similar. For example, the EU is simultaneously strengthening its scientific capacity to conduct risk assessments and encouraging public participation in the making of regulatory policies—both of which occurred in the US during the 1970s. Just as the US expanded the number of quasi-independent regulatory agencies during the 1970s, the EU as well as a number of Member States have recently established new regulatory agencies. During the 1970s the US created several mechanisms designed to reduce agency capture by business interests—a problem which both the EU and the Member States are now addressing by making the regulatory process more transparent. In Europe, the courts are playing a more active role in reviewing the regulations of both the EC and theMember States, just as the US judiciary has been doing for more than three decades. The criteria these review bodies are applying to determine the constitutionality and legality of risk regulations are similar: both require that regulations have a scientific basis, while at the same time affording officials wide latitude to determine the level of risk they consider appropriate.[135] In this context, the proportionality principle can be seen as the European counterpart of costbenefit analysis in the US.

The convergence of approaches across the Atlantic should not be overstated, however. The legal structure of regulatory policy-making remains different. In the US, risk assessment and risk management are handled by

[133] M. Eli, 'The Precautionary Principle—What the US Thinks' (1987) 1 European Affairs 2, 85.

[134] A US Government submission to the Committee on General Principles of the Codex Alimentarius Commission for the Committee's 10–14 Apr. 2000 meeting, published on the Internet at: http://www.fsis.usda.gov/OA/codex/confpaper.htm.

[135] For a detailed discussion of the increasingly important role played by science in ECJ decisions, see Heyvaert, n. 94 above; Shapiro, n. 37 above, 325–43.

the same institution, while in Europe they are formally separated. Precautionary elements tend to be built into risk assessment in the US, while in Europe the precautionary principle primarily informs risk management. US regulatory agencies are generally required to submit risk assessments as part of regulatory rule-making; there is no such requirement in Europe. The US has established a body of independent regulatory agencies which can conduct or commission scientific studies as well as make and enforce regulatory rules, while European agencies aremore akin to networks of national and European regulators, and their authority remains highly circumscribed. However, these differences have not prevented either political system from adopting a wide array of regulations that act cautiously in the face of risks which the public considers unacceptable.

The substantive differences between EU 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. For 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 regulations is now greater in Europe than in the US that a number of regulations enacted by the EU are now more risk averse or ‘precautionary’ than those in the US.
42 Vogel