

## CHAPTER ONE

**The Transatlantic Shift in Regulatory Stringency**

IN 1962, THE UNITED STATES<sup>1</sup> enacted regulations for the approval of drugs that were more stringent than those of Great Britain and Germany.

In 1969, the United States banned the artificial sweetener cyclamate, which remains permitted in each member state of the European Union.<sup>2</sup>

In 1975, catalytic converters were required for all new cars sold in the United States; they were required for all new cars sold in the EU beginning in 1992.

In 1979, the plant-growth regulator Alar was banned in the United States; all but one European country as well as the EU permits its use.

In 1985, the EU prohibited the administration of growth hormones to beef cattle; the United States allows them.

In 1989, the United States eliminated the use of lead in gasoline/petrol. The EU ended its use of this fuel additive in 2005.

Since 1992, the United States has approved more than one hundred genetically modified (GM) varieties for planting, feed, or food; the EU has approved twenty-eight, most of which are not in commercial use. Virtually all processed food in the United States contains GM ingredients, while virtually none sold in the EU does.

In 1997, the EU ratified the Kyoto Protocol, which committed its member states to reduce their emissions of six greenhouse gases (GHG); the United States has not done so.

In 1999, the EU banned the use of six phthalates in children's products; the United States adopted a similar restriction in 2008.

In 2003, the EU banned the use of six hazardous materials in electrical and electronic products beginning in 2006; the United States still permits their use.

<sup>1</sup>Unless otherwise noted, the "United States" or the "U.S." refers to the American federal government.

<sup>2</sup>The term "European Union" did not formally come into use until 1993, when it was adopted as part of the Treaty on European Union or "Maastricht" Treaty signed in 1992; prior to that date, the EU was called the European Economic Community or EEC. However, for purposes of clarity, I have chosen to use the current name throughout the text, though some quotations refer to the "Community" or the "European Community."

In 2006, the EU significantly strengthened and broadened its health and environmental regulations for chemicals; the last comprehensive statutory reform of American chemical regulation took place in 1976.

These and other comparisons among health, safety, and environmental regulations in the United States and Europe are the subject of this book. It describes and explains why, during the last half century, citizens in Europe and the United States have frequently perceived, and policy makers have often responded differently to, many similar consumer and environmental risks—in some cases temporarily and in other cases over an extended period of time.

Within political systems, there are important linkages among many health, safety, and environmental risk regulations. Their public issue life cycles overlap and they often follow parallel or convergent political trajectories.<sup>3</sup> This means that if a government is adopting more stringent regulations toward some consumer or environmental risks caused by business, then it is also more likely to address other risks with similarly strong measures. Alternatively, if it is not stringently regulating a specific health, safety, or environmental risk, then it is also less likely to adopt more risk-averse regulations for others. In short, risk regulations are both interdependent and shaped by similar political developments. These can be stable for long periods of time, but the policy equilibriums that underlie them can also change significantly.

A noteworthy discontinuity in the politics of regulatory stringency took place on both sides of the Atlantic in about 1990. If a new risk regulation was enacted on either side of the Atlantic during the three decades prior to 1990, then it is *more likely* that the American standard was initially, and in some cases has remained, more risk averse. However, if it was adopted on either side of the Atlantic after 1990, then it is *more likely* that the regulation adopted by the European Union was initially, and has often remained, more risk averse.

Why, then, since 1990, has the EU more stringently regulated a number of health, safety, and environmental risks caused by business than the United States, including in several areas that were previously regulated more stringently by the United States? What affects changes in the public's demand for protective regulations and the willingness of policy makers to respond to them? What happened to disrupt the previous pattern of policymaking on both sides of the Atlantic? These important shifts in the stringency of new risk regulations in both the United States and the EU raise a broader question: what explains significant shifts in policy-linked issue life cycles?

<sup>3</sup>For an influential case study of a public issue life cycle in the United States, see Christopher Bosso, *Pesticides & Politics: The Life Cycle of a Public Issue* (Pittsburgh: University of Pittsburgh Press, 1987).

These are important and challenging questions. Each regulatory decision or non-decision has distinctive and multiple causes, and no parsimonious explanation or single theory can adequately account for all the policy outcomes that have taken place in both Europe and the United States since 1960. I have developed a “big picture” explanatory framework that focuses on the role and interaction of three factors: the extent and intensity of public pressures for more stringent or protective regulations, the policy preferences of influential government officials, and the criteria by which policy makers assess and manage risks. Since around 1990, each has changed significantly in both the United States and the EU.

Prolonged periods of relative regulatory stringency, such as that which occurred in the United States between roughly 1960 and 1990 and in Europe beginning around 1990, are typically characterized by strong public demands for more stringent regulations, by the influence of policy makers who are more supportive of stringent regulatory controls over business, and by decision-making criteria that promote or permit the adoption of highly risk-averse regulations. Alternatively, prolonged periods when relatively few stringent regulations are adopted, such as has occurred in the United States since around 1990, are typically characterized by weaker public demands for more stringent risk regulations, by the increased influence of policy makers opposed to expanding the scope or stringency of health, safety, and environmental risk regulation, and by decision-making criteria that make it more difficult for highly risk-averse regulations to be adopted.

## THE TRANSATLANTIC SHIFT IN REGULATORY STRINGENCY

### *The Regulatory Leadership of the United States*

For approximately three decades, the United States was typically one of the first countries to identify new health, safety, and environmental risks and to enact a wide range of stringent and often precautionary standards to prevent or ameliorate them. Several important American consumer safety and environmental regulations, including rules for the approval of new drugs; many pesticide, food safety, and chemical standards; controls on automobile emissions, including lead in gasoline/petrol; and restrictions on ozone-depleting chemicals, were among the most risk-averse in the world. “The United States was the clear global leader in environmental policy in this era, and many other countries copied its policy initiatives.”<sup>4</sup>

<sup>4</sup>John Dryzek et al., *Green States and Social Movements: Environmentalism in the United States, United Kingdom, Germany, and Norway* (Oxford: Oxford University Press, 2003), 160.

*The Policy Shift*

Around 1990, the locus of transatlantic regulatory policy innovation and global regulatory leadership began to shift. While American policy makers previously had been “quicker to respond to new risks, more aggressive in pursuing old ones,” more recently it is European policy makers who have been more likely to identify new risks and been more active in attempting to ameliorate existing ones.<sup>5</sup> Europe has not simply “caught up” to the United States; rather, many of the risk regulations adopted by the EU since 1990 are now more stringent and comprehensive than those of the American federal government. In “many policy areas [the EU] has taken over the role of world leader,”<sup>6</sup> a role formerly played by the United States.

The rate at which the federal government has adopted new stringent and comprehensive regulatory statutes and rules markedly declined after 1990. “Further building of the green state—at least at the national level—essentially stopped around 1990.”<sup>7</sup> By contrast, “[the] EU surged forward,” issuing a steady stream of “higher and tougher standards.”<sup>8</sup> To borrow Lennart Lundqvist’s influential formulation, which he used to contrast American and Swedish air pollution control standards during the 1970s, since around 1990 the American federal regulatory policy “hare” has been moving like a “tortoise,” while the pace of the European “tortoise” resembles a “hare.”<sup>9</sup> “It has become almost a constant trend to see more and more legislation being planned or adopted in Europe that sets higher standards to protect health or the environment than in the United States.”<sup>10</sup>

Not all American risk regulations enacted between around 1960 and 1990 were more stringent than those adopted by any European country or the EU. For example, the EU’s ban on beef hormones was adopted

<sup>5</sup>Sheila Jasanoff, “American Exceptionalism and the Political Acknowledgement of Risk,” in *Risk*, ed. Edward Burger (Ann Arbor: University of Michigan Press, 1993), 63.

<sup>6</sup>Quoted in Jonathan Wiener, “Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems,” *Journal of Comparative and International Law* 13 (2007): 214.

<sup>7</sup>Christopher Klyza and David Sousa, *American Environmental Policy, 1990–2006: Beyond Gridlock* (Cambridge, MA: MIT Press, 2008), 43.

<sup>8</sup>Quoted in Robert Donkers, “US Changed Course, and the EU Surged Forward,” *Environmental Forum* (March/April 2006): 49. The second quotation is from Alasdair Young and Helen Wallace, *Regulatory Politics in the Enlarging European Union: Weighing Civic and Producer Interests* (Manchester and New York: Manchester University Press, 2000), 9.

<sup>9</sup>Lennart Lundqvist, *The Hare and the Tortoise: Clean Air Policies in the United States and Sweden* (Ann Arbor: University of Michigan Press, 1980).

<sup>10</sup>Theofanis Christoforou, “The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the European Community and the US Legal System,” in *Green Giants? Environmental Policies of the United States and the European Union*, ed. Norman Vig and Michael Faure (Cambridge: MIT Press, 2004), 25.

in 1985, while during the 1970s and 1980s some European countries adopted restrictions on chemicals that were either comparable to or more risk-averse than those of the United States. Nor has every consumer safety or environmental regulation enacted by the EU or any of its member states since 1990 been more stringent than those adopted by the United States during the last two decades. For example, American mobile source or vehicular emission standards for health-related (criteria) pollutants have been steadily strengthened and remain stricter than those of the EU.

There has also been increased transatlantic convergence in some policy fields. Following changes in the regulatory policies of the Food and Drug Administration (FDA) that began in the late 1980s, but accelerated during the early 1990s, and the centralization of drug approval policies by the EU during the first half of the 1990s, the “drug lag” has disappeared: a new drug is now as likely to be first approved for use in the United States as in the EU. Both the EU and the United States have now imposed similar bans on lead and phthalates in children’s products, with the United States acting a few months earlier in the former case and the EU nine years earlier with respect to the latter.

Some differences in European and American risk perceptions and regulations are long-standing. For example, the health risks of traditional or natural food preparations have been accepted in Europe since medieval times. In 1949, the American FDA banned the sale of any milk product unless all of its dairy ingredients had been pasteurized, while the production and sale of cheeses made from unpasteurized milk is permitted in the European Union.<sup>11</sup>

While not *every* European and American consumer or environmental risk regulation is consistent with a transatlantic shift in regulatory stringency since 1990, a *disproportionate number* of the consumer and environmental regulations adopted, or not adopted, on either side of the Atlantic during the last five decades do fit this pattern. For roughly three decades, *relatively few important* risk regulations adopted by either individual European countries or the EU were more stringent than those of the American federal government. But since 1990, a *significant number of important* risk regulations adopted by the EU fall into this category.

In some cases, such as chemical regulation and restrictions on ozone-depleting substances, there has been a literal “flip flop,” with the United States and the EU switching places with respect to the adoption of more stringent and comprehensive regulations. But more commonly, the more

<sup>11</sup>Marsha Echols, “Food Safety Regulation in the European Union and the United States: Different Culture, Different Laws,” *Columbia Journal of International Law* 4 (Summer 1998): 525–43.

stringent regulations adopted by the EU since around 1990 address risks that were not previously regulated on either side of the Atlantic. Recent European regulations are likely to be more stringent and often more precautionary than those of the United States for those health, safety, and environmental risks that have emerged or become more salient since around 1990, such as global climate change, genetically modified food and agriculture, antibiotics in animal feed, hazardous materials in e-waste, and chemicals in cosmetics.

#### INTERNATIONAL ENVIRONMENTAL AGREEMENTS

The transatlantic shift in regulatory stringency and global leadership is reflected in changes in the pattern of support for international environmental treaties.<sup>12</sup> Beginning in the 1970s, the United States and the member states of the EU closely cooperated in the establishment of numerous environmental agreements, with the United States often playing a leadership role. At the 1972 Stockholm United Nations international conference on the environment, the United States was “a strong proponent of international action to protect the environment.”<sup>13</sup> The United States played a critical role in the negotiations that led to the adoption of the London Convention on Dumping at Sea (1972), the Convention on International Trade in Endangered Species and Fauna (1973), the decision of the International Whaling Commission to ban commercial whaling (1984), and the Montreal Protocol on Ozone Depleting Chemicals (1987).

The 1992 Rio “Earth Summit” marks a shift in global regulatory leadership from the United States to the EU. While every major environmental agreement supported by the United States has been ratified by the member states of the EU and/or the EU itself, since the early 1990s the United States has not ratified twelve important international environmental agreements ratified by the EU and/or its member states.<sup>14</sup> These include the 1992 Convention on Biological Diversity, the 1997 Kyoto Protocol on climate change, the 2000 Cartagena Protocol on Biosafety, and the 2001 Stockholm Convention on Persistent Organic Pollutants.<sup>15</sup>

<sup>12</sup>For a complete list of international environmental agreements since 1959 and their legal status in both the United States and Europe, see Miranda Schreurs, Henrik Selin, and Stacy VanDeveer, “Expanding Transatlantic Relations: Implications for Policy and Energy Policies,” in *Transatlantic Environment and Energy Politics: Comparative and International Perspective*, ed. Schreurs, Selin, and VanDeveer (Burlington, VT: Ashgate, 2009), 8–9.

<sup>13</sup>Donkers, “US Changed Course, and the EU Surged Forward,” 49.

<sup>14</sup>Schreurs, Selin, and VanDeveer, “Expanding Transatlantic Relations,” 8, 9.

<sup>15</sup>Robert Falkner, “American Hegemony and the Global Environment,” *International Studies Review* 7 (2005): 585.

## THE SHIFTING PATTERN OF TRANSATLANTIC TRADE DISPUTES

The shift in transatlantic regulatory stringency is also evident in the changing pattern of European-American trade disputes.<sup>16</sup> The earlier wave of disputes over the use of protective regulations as non-tariff trade barriers (NTBs) between Europe and the United States primarily involved European challenges to, or complaints about, the barriers to transatlantic commerce created by more stringent American regulatory standards. The EU and/or various European governments filed formal complaints with the General Agreement on Tariffs and Trade (GATT) over the excise tax provisions of the 1986 Superfund reauthorization, the American secondary boycott of tuna imports from Spain and Italy (which was based on the Marine Mammal Protection Amendments of 1984 and 1988), and American corporate fuel economy standards (CAFE), which were adopted in 1975 and amended in 1980. European officials were also highly critical of the testing requirements for new chemicals adopted by the United States in 1976.

However, more recent transatlantic regulatory-related trade disputes have revolved primarily around American complaints about the trade barriers posed by more stringent European regulations. In 1996, the United States filed a formal complaint with the World Trade Organization (WTO) that challenged the legality of the EU's ban on the sale of beef from cattle to whom growth hormones had been administered, which was applied to American beef imports in 1989. In 2003, the United States filed a complaint with the WTO challenging the EU's procedures for the approval of genetically modified organisms (GMOs), as well as the unwillingness of some member states to permit GMO varieties approved by the European Commission. In 2009, the American government filed a complaint with the WTO over the EU's refusal to permit imports of processed poultry treated with anti-bacterial chemicals such as chlorine dioxide, a processing method that differed from the method required by the EU in 1997.

American officials and firms have also complained to the EU about the obstacles to transatlantic commerce posed by a wide range of other European consumer and environmental regulations, including its ban

<sup>16</sup>For a summary and analysis of several trade disputes stemming from more stringent European standards, see Sebastiaan Princen, *EU Regulation and Transatlantic Trade* (Hague: Kluwer Law International, 2002). For case studies of EU-U.S. trade disputes over risk regulations, see David Vogel, *Benefits or Barriers? Regulation in Transatlantic Trade* (Washington, DC: Brookings Institution Press, 1998). For a more general discussion, which includes case studies of transatlantic risk-related disputes, see Ernst-Ulrich Petersmann and Mark Pollack, eds., *Transatlantic Economic Disputes: The EU, the US, and the WTO* (New York: Oxford University Press, 2003).

on the milk hormone rBST, its ban on human-use antibiotics as growth promoters in livestock feed, its electronic recycling requirements and bans on hazardous toxic substances in electronics, and the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), the EU's stricter and more comprehensive chemical approval and testing regulation adopted in 2006.<sup>17</sup> The latter statute was strongly opposed by American government officials and American-based chemical firms. American-based airlines have also objected to the 2008 decision of the EU to regulate the greenhouse gas emissions of foreign airlines that take off and land in Europe.

While previously it was the United States that had sought to protect its more stringent regulations from legal challenges by other countries, more recently the EU has become the primary advocate of changes in WTO rules in order to make them more compatible with the protective regulations it has adopted.<sup>18</sup> The EU has supported new trade rules that would clarify the relationship between the WTO and multilateral environmental agreements—many of which have been signed by the EU and several other countries but not the United States. It also has requested that the WTO accord legal recognition to the precautionary principle in order to “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.”<sup>19</sup> The latter proposal has been strongly opposed by the United States on the grounds that it would become a “guise for protectionist measures.”<sup>20</sup>

<sup>17</sup>For an extensive list of American business criticisms of EU regulatory policies, their lack of scientific basis, and the harm they pose to American firms, see *Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science* (Washington, DC: National Foreign Trade Council, 2003); Lawrence Kogan, *Unscientific “Precaution”: Europe’s Campaign to Erect New Foreign Trade Barriers* (Washington, DC: Washington Legal Foundation, 2003); *EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three-Dimensional Trade Strategy That Ignores Sound Science* (Washington, DC: American Foreign Trade Council, 2003); Lawrence Kogan, *Precautionary Preference: How Europe’s New Regulatory Protectionism Imperils American Free Enterprise* (Princeton, NJ: Institute for Trade, Standards and Sustainable Development, 2005).

<sup>18</sup>For a more detailed discussion of the shifts in European and American positions on the trade rules governing consumer and environmental regulations as non-tariff trade barriers, see David Vogel, “Trade and the Environment in the Global Economy: Contrasting European and American Perspectives,” in *Green Giants? Environmental Policies of the United States and the European Union*, ed. Norman Vig and Michael Faure (Cambridge, MA: MIT Press, 2004), 231–52. See also *EU’s Environmental Agenda* (Cuts Centre for International Trade, Economics & Environment, 2001), and Dirk De Bievre, “The EU Regulatory Trade Agenda and the quest for WTO Enforcement,” *Journal of European Public Policy* 13, 6 (September 2006): 851–966.

<sup>19</sup>Quoted in Vogel, “Trade and the Environment in the Global Economy,” 252.

<sup>20</sup>Quoted in *ibid.*

## THE PRECAUTIONARY PRINCIPLE

The EU's adoption of the precautionary principle has become a major focus of transatlantic tension in other forums as well. It reflects and has reinforced an important difference between the EU and the United States about the appropriate criteria for regulating risks. The precautionary principle has increased the discretion of Europeans policy makers by enabling them to impose restrictions on commercial activities whose risks are uncertain, unproven, or disputed. The application of this principle underlies many of the more stringent risk regulations adopted by the EU. The precautionary principle has in turn been strongly criticized by American-based firms and American government officials. They have argued that it undermines the importance of scientific risk assessments as a guide to risk management decisions and is likely to lead to regulations based on public fears or "phantom risks" rather than on "sound science."<sup>21</sup>

These transatlantic differences in risk assessment criteria have become highly contentious. As Jonathan Wiener notes:

Some observers see a civilized, careful Europe confronting a risky, reckless and violent America. To this group, the precautionary principle is an antidote to industrialization, globalization, and Americanization. On the other hand, other observers see a statist, technophobic, protectionist Europe trying to rise to challenge a market-based, scientific, entrepreneurial America. To this group, the precautionary principle is an obstacle to science, trade, and progress.<sup>22</sup>

According to Alan Larson, the former U.S. Under Secretary of State:

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 most hypothetical risk of the most remote theoretical uncertainty.<sup>23</sup>

<sup>21</sup>For defenses of its approach to risk assessment and management, see, for example, Carolyn Raffensperger and Joel Tickner, eds., *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Washington, DC: Island Press, 2003); Joel Tickner, ed., *Environmental Science and Public Policy* (Washington, DC: Island Press, 2003); and Nancy Myers and Carolyn Raffensperger, eds., *Precautionary Tools for Reshaping Environmental Policy* (Cambridge, MA: MIT Press, 2006). For criticism, see, for example, Frank Ross, "Paradoxical Perils of the Precautionary Principle," *Washington and Lee Law Review*, 21 (1996): 851–925; Julian Morris, ed., *Rethinking Risk and the Precautionary Principle* (Oxford: Butterworth-Heinemann, 2000); and Cass Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).

<sup>22</sup>Jonathan Wiener, "Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems," *Journal of Comparative and International Law* 13 (2007): 214–15.

<sup>23</sup>Quoted in M. Eli, "The Precautionary Principle—What the US Thinks," *European Affairs* 1, no. 2 (1987): 85.

But Pascal Lamy, the former EU trade commissioner, counters that, “in the U.S. they believe that if no risks have been proven about a product, it should be allowed. In the EU it is believed that something should not be authorized if there is a chance of risk.”<sup>24</sup>

In many respects, we have come full circle: many of the criticisms by American officials of the more stringent risk regulations recently adopted by the European Union echo those made earlier by European officials about many American ones. Formerly, it was Europeans who often accused Americans of acting too hastily to impose highly stringent risk regulations that lacked adequate scientific justification. More recently, American officials and firms have criticized many of the more stringent risk regulations adopted by the EU in identical terms.

## HISTORICAL PARALLELS AND DISCONTINUITIES

### *Parallels*

There are a number of parallels between the periods of relative regulatory stringency on both sides of the Atlantic. During the 1970s and 1980s, American regulatory policies often served as a benchmark for European consumer and environmental activists: they often criticized the EU for its unwillingness to adopt regulatory standards as stringent as those of the United States, most notably for automotive emissions, the lead content of fuel, and chemicals that harmed the ozone layer. More recently, many American consumer and environmental activists have urged the United States to follow Europe’s regulatory lead.<sup>25</sup> They have criticized American policy makers for not giving Americans the same level of environmental, health, and safety protection now enjoyed by citizens of the EU.<sup>26</sup> At the same time, many of the criticisms previously made about many American protective regulations, namely that they were often unnecessarily strict, too burdensome, and diminished rather than enhanced public welfare, have also been made about many European ones.<sup>27</sup>

<sup>24</sup>Wiener, “Whose Precaution After All?” 213–14.

<sup>25</sup>See, for example, Myers and Raffensperger, eds., *Precautionary Tools for Reshaping Environmental Policy*.

<sup>26</sup>See, for example, Mark Shapiro, *Exposed: The Toxic Chemistry of Everyday Products: Who’s at Risk and What’s at Stake for American Power* (White River Junction, VT: Chelsea Green Publishing, 2007).

<sup>27</sup>For American criticisms of American risk regulations, see, for example, Harvey Sapolsky, ed., *Consuming Fears: The Products of Product Risks* (New York: Basic Books, 1986); Edith Efron, *The Apocalyptic: Cancer and the Big Lie* (New York: Simon & Schuster, 1984); and Michael Fumento, *Science Under Siege: Balancing Technology and the Environment* (New York: William Morrow, 1993). For European criticisms of European ones, see Frank Furedi, *Culture of Fear: Risk Taking and the Morality of Low Expectation* (London:

During both periods of relative regulatory stringency, regulatory policymaking became more centralized, moving from states to the federal government in the United States and from member states to the EU, though both American states and national governments in Europe continue to play important policy roles.<sup>28</sup> This centralization of regulatory policymaking played an important role in the strengthening of many regulatory standards in the United States and the EU. However, while the regulatory policy regime established by the federal government during the late 1960s and early 1970s remains in place, the policies it produced changed substantially after 1990.

### *Discontinuities*

There is, however, an important difference between the two periods. Many of the relatively stringent American regulations enacted during the 1970s and 1980s either directly or indirectly influenced European regulatory policies. “European states were heavily influenced by U.S. environmental policy developments in the 1960s and 1970s. Many policy ideas and programs diffused across the Atlantic.”<sup>29</sup> During the 1970s, Sweden’s automotive emission standards were modeled on those of the United States, while the National Environmental Policy Act (NEPA) of 1969 shaped the development of environmental policy in Germany. America’s more stringent automobile emissions standards contributed to the EU’s decision to progressively strengthen its own emissions standards, including for restrictions on lead in motor fuels. The EU’s Sixth Amendment, enacted in 1979, which tightened controls over the approval of new chemicals, was a direct response to the more stringent regulatory standards of the Toxic Substances Control Act (TSCA), enacted by the United States three years earlier. America’s restrictions on ozone-depleting chemicals also shaped subsequent policy developments in Europe. In fact, during the 1980s some European policy makers argued:

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Cassell, 1997); Christopher Booker and Richard North, *Scared to Death: From BSE to Global Warming: Why Scares Are Costing Us the Earth* (London: Continuum, 2007); and Morris, ed., *Rethinking Risk and the Precautionary Principle*.

<sup>28</sup>For an analysis of the legal and policy implications of this development, see R. Daniel Keleman, “Environmental Federalism in the United States and the European Union,” in *Green Giants? Environmental Policies of the United States and the European Union*, ed. Norman Vig and Michael Faure (Cambridge, MA: MIT Press, 2004), 113–34. For a more extensive analysis of European regulatory federalism that demonstrates its similarities to the United States, see R. Daniel Keleman, *The Rules of Federalism: Institutions and Regulatory Politics in the EU and Beyond* (Cambridge, MA: Harvard University Press, 2004).

<sup>29</sup>Schreurs, Selin, and VanDeever, “Expanding Transatlantic Relations,” 7.

With the advent of global markets, the standard of product acceptability for international consumers would be increasingly set by the country with the most stringent pollution control standards. Thus . . . Europe would only be able to take full advantage of economies of scale in globally competitive markets provided that it legislated *for high environmental standards on a par with those found . . . in the USA*.<sup>30</sup>

More recently, the EU's decision to employ a cap-and-trade scheme for regulating greenhouse gas emissions from stationary sources drew upon the successful emissions trading schemes established by the Clean Air Act Amendments of 1990. The EU's "Better Regulation" initiatives have also been influenced by American administrative practices.

By contrast, there has been much less regulatory policy diffusion *from* the EU *to* the American federal government. The United States has affected European regulatory policies over the past five decades far more than it has been affected by them. With the notable exception of American drug approval policies—which have drawn on and been influenced by European policy approaches—European regulatory policies and politics have had much less national policy impact in the United States than American regulatory policies previously had in Europe. Rather, as before around 1990, federal regulatory policies remain relatively autonomous: they are shaped primarily by domestic politics.

#### THE EU'S GLOBAL REGULATORY IMPACT

The response—or lack thereof—of Washington to Brussels is atypical. For the EU has been highly successful in "exporting" many of its regulations to other countries. The European Commission has repeatedly urged other countries to adopt its more stringent consumer and environmental standards and has put considerable efforts into encouraging them to do so. As Rockwell Schnabel, the former U.S. ambassador to Brussels, observes, "Europe is increasingly seeking to act as the world's economic regulator."<sup>31</sup>

The EU's active efforts to "globalize" its protective regulations stem from several motives. One is economic. Just as the harmonization of national regulatory requirements creates a level playing field for firms within the EU, so does the adoption of European regulations by other

<sup>30</sup>Emphasis added. Quoted in Albert Weale, "Environmental Rules and Rule-Making in the European Union," in *Environmental Policy in the European Union: Actors, Institutions and Processes*, ed. Andrew Jordan (London: Earthscan, 2002), 204.

<sup>31</sup>Tobias Buck and George Parker, "Washington Bridles at EU's Urge to Regulate," *Financial Times*, May 12, 2006.

countries mean that the global competitors of European firms will be forced to meet similar requirements in their home markets. Another is defensive: the more countries that adopt its regulations, the greater is their legitimacy. It is “a lot harder to argue that a risk management regime is unnecessary, disproportionate or unfair if it is endorsed by a significant proportion of the world’s population.”<sup>32</sup>

The EU’s efforts to export its regulations are “an attempt to reel other regions into the European sphere of influence.” They are a key component of its

. . . strategy to increase stability in the regions surrounding the EU through the regularization of public administration along a familiar format, and a way of creating kinship and interdependence by opening scope for cooperation and exchange, in which the EU, as the original architect of the regulatory format, is poised to take a central role.<sup>33</sup>

They represent a form of “empire building” through the exercise of “soft” power.<sup>34</sup> The EU’s “global [regulatory] project has . . . given Europe’s elites a new mission.”<sup>35</sup> It has enabled the EU “to carve out an identity and a profile for itself as a ‘normative’ or ‘civilian’ power on the world stage.”<sup>36</sup>

The significant expansion of the EU’s membership itself has directly expanded the geographic scope of Brussels’ regulatory impact, as its twelve accession states are brought into compliance with the *acquis communautaire*, the body of EU regulations and directives which are legally binding on all member states. Because of their extensive commercial ties with the EU, many of the risk regulations of Norway and Switzerland are similar to those of the EU, and many Russian regulations have been based on those adopted by Brussels.

But the geographic impact of EU regulations extends beyond Europe. As a report to the European Commission observed, “frequently the world looks to Europe and adopts the standards that are set here.”<sup>37</sup> Many countries have adopted EU regulations in order to retain access to its large internal market. For global firms, adopting EU rules confers an important advantage: because they are typically the world’s most stringent, if their

<sup>32</sup>Veerle Heyvaert, “Globalizing Regulation: Reaching Beyond the Borders of Chemical Safety,” *Journal of Law and Society* 36, no. 1 (March 2009): 116.

<sup>33</sup>*Ibid.*, 116–17.

<sup>34</sup>*Ibid.*, 116.

<sup>35</sup>J. Zielonka, “Europe as a Global Actor: Empire by Example,” *International Affairs* 84, no. 3 (2008): 479.

<sup>36</sup>R. Daniel Kelemen, “Globalizing European Union Environmental Policy,” *Journal of European Public Policy* 17, no. 3 (2010): 338.

<sup>37</sup>Tobias Buck, “Standard Bearer: How the European Union Exports its Laws,” *Financial Times*, July 10, 2007.

products comply with EU standards, they can be marketed anywhere in the world.

The EU's strong support for multilateral environmental agreements has been a critical component of its efforts to "manage globalization" and assert a leadership role in global regulatory governance.<sup>38</sup> "The EU has been the chief *demandeur* of every major environment agreement since the early 1990s."<sup>39</sup> It has played an active role in promoting global agreements that are based on its own regulatory policies, including for biodiversity and biosafety, hazardous waste exports, global climate change, and persistent organic pollutants. A number of these treaties explicitly reference the precautionary principle, which the EU has sought to make an international legal norm. This principle is now incorporated in more than fifty international agreements.

Government regulation of business represents one of the EU's most successful "exports." "Over the last decade, [the EU] has proven that it has the capacity to shape international economic governance across a host of regulatory domains."<sup>40</sup> The marked increase in Europe's global regulatory influence, which extends beyond health, safety, and environmental regulations and includes, for example, anti-trust policy, data policy, data privacy, and technical standards for automobiles and mobile telephones, is obviously linked to the large size of the EU's internal market, especially following the EU's expansion to central Europe.

But this is only part of the explanation. For "a sizeable market must be coupled with powerful and capable regulatory institutions."<sup>41</sup> The growth in the EU's regulatory capacities has also been critical. The institutional capacities and legal principles that have been developed to create and govern a single market among the EU's member states have given EU officials the technical and administrative expertise to promote global regulatory policy coordination.<sup>42</sup> European officials have taken many of

<sup>38</sup>Kelemen, "Globalizing EU Environmental Policy," 336; see also Wade Jacoby and Sophie Meunier, "Europe and the Management of Globalization," *Journal of European Public Policy* 17, no. 3 (2010): 299–317.

<sup>39</sup>Emphasis in original Kelemen, "Globalizing," 337.

<sup>40</sup>Abraham Newman, *Protectors of Privacy: Regulating Personal Data in the Global Economy* (Ithaca, NY: Cornell University Press, 2008), 121.

<sup>41</sup>David Bach and Abraham Newman, "The European Regulatory State and Global Public Policy: Micro-institutions, Macro-influence," *Journal of European Public Policy* 14, no. 6 (September 2007): 82.

<sup>42</sup>For an analysis of the EU's regulatory architecture, and why it readily lends itself to adoption by other countries, see Charles Sabel and Jonathan Zeitlin, "Learning from Difference: The New Architecture of Experimentalist Governance in the EU," *European Law Journal* 14, no. 3 (May 2008): 27–327; and Charles Sabel and Jonathan Zeitlin, eds., *Experimentalist Governance in the European Union: Towards a New Architecture* (Oxford University Press, 2010).

the principles and practices that underlie “vertical” regulatory integration within Europe and extended them “horizontally” outside its borders.

As a result of the EU’s economic importance—with its expansion to twenty-seven countries the EU’s GDP is now roughly 30 percent larger than that of the United States and its population is twice as large—the growth of its regulatory capacity, *and* the relative stringency of its regulatory standards, global business regulations are increasingly being “made in Brussels.”<sup>43</sup> As the *Wall Street Journal* observes, “Americans may not realize it, but the rules governing the food they eat, the software they use and the cars they drive increasingly are set in Brussels.”<sup>44</sup> European regulations have forced “changes in how industries around the world make plastics, electronics, toys, cosmetics and furniture.”<sup>45</sup>

According to an American corporate lobbyist based in Brussels, “Twenty years ago, if you designed something to U.S. standards you could pretty much sell it all over the world. Now the shoe is on the other foot.”<sup>46</sup> Jeffrey Immelt, the chairman and CEO of General Electric, observes that “Europe in many ways is the world’s global superpower. It can speak with one voice and a degree of certainty.”<sup>47</sup> For many of GE’s businesses, ranging from light bulbs to plastic, “almost 99% of new regulations will, over time, come from the EU.”<sup>48</sup> The successful global diffusion of many European regulatory policies also means that many important American environmental, health, and safety standards are not only less stringent and comprehensive than those of the EU, but that some are now weaker than those of many developed and developing countries, including China.

### *Alternative Mechanisms of Policy Diffusion*

As a response to a perceived regulatory vacuum at the national level, a number of American states have adopted protective regulations that are similar to and often modeled on those of the EU. Several American states have imposed restrictions on greenhouse gas emissions, banned some heavy metals from landfills, required manufacturers to take back electronic equipment for recycling, and banned various hazardous substances and chemicals restricted by the EU but not by the federal government. The EU’s regulatory influence has been felt most strongly in California,

<sup>43</sup> “Charlemagne: Brussels Rules OK,” *The Economist*, September 22, 2007.

<sup>44</sup> Brandon Mitchener, “Increasingly, Rules of Global Economy Are Set in Brussels,” *Wall Street Journal*, April 23, 2002.

<sup>45</sup> Marla Cone, “Europe’s Rules Forcing US Firms to Clean Up,” *Los Angeles Times*, May 16, 2005.

<sup>46</sup> Mitchener, “Increasingly, Rules of Global Economy Are Set in Brussels.”

<sup>47</sup> Marc Gunther, “Cops of the Global Village,” *Fortune*, June 27, 2005.

<sup>48</sup> Mitchener, “Increasingly, Rules of Global Economy Are Set in Brussels.”

historically America's "greenest" state, which has adopted a wide range of risk regulations similar to and often modeled on those of the EU.<sup>49</sup>

The dynamics of "trading up" or the ratcheting of regulatory standards upward thus continues, but the nature and mechanisms of global regulatory emulation and policy diffusion have shifted.<sup>50</sup> Now it is the EU, rather than the American federal government, whose regulatory policies are playing an important role in strengthening the risk regulations of many of its trading partners. The "California effect," a term that describes the process by which a government's more stringent regulatory standards are diffused to other political jurisdictions, has become the "EU effect." While California formerly served as a vehicle for the "export" of more stringent American environmental standards *to* Europe, more recently it has become an "importer" of several more risk-averse and comprehensive regulations *from* Europe.

In addition to changing what products they produce or how they produce them in order to retain access to the EU's large internal market, many global firms have also chosen to comply with some, or all, EU regulations for many of the products they sell outside Europe, including in the United States. They have done so both to protect their global brands and reputations and because it is often more efficient for them to market similar products globally. Many American food processors and retailers also produce and sell food products that conform to European health, safety, and environmental standards. These private, market-based forms of "trading up" have reduced the gap between some European standards and American business practices.

#### CLARIFYING THE ARGUMENT

The fact that many European protective regulations are now more stringent than American ones does *not* mean that European consumer and environmental regulations are "better." Whose regulations are "better" or "worse" depends on one's policy preferences and values. If one considers more stringent or precautionary regulations to be welfare-enhancing, then the United States was formerly "ahead" of Europe, but now "lags behind" the EU. However, if one is more skeptical of the benefits of more stringent regulations, then the recent pattern of American regulatory policymaking would be considered salutatory. Supporters of more stringent

<sup>49</sup>Jim Wasserman, "California Becoming Nation's New Gateway for European Environmental Laws," *SF Environment*, July 24, 2003.

<sup>50</sup>David Vogel, *Trading Up: Consumer and Environmental Regulation in a Global Economy* (Cambridge, MA: Harvard University Press, 1995).

regulations would like the United States to “catch up” to Europe by adopting its precautionary approach to many health, safety, and environmental risks, while critics of European regulatory policies hope that the EU will emulate the United States by relying more on scientific-based risk assessments and cost-benefit analyses.

Since around 1990, in part as a response to many widely publicized examples of “over-regulation,” American policy makers have placed more emphasis on avoiding false positives, i.e., unnecessarily stringent regulations (Type I policy errors), while their European counterparts, responding to a wide range of policy failures attributed to “under-regulation,” have placed greater priority on reducing false negatives, i.e., insufficient stringent regulations (Type II policy errors). Defenders of more stringent regulations tend to emphasize the risks of false negatives, while critics of protective regulations focus on the shortcomings of false positives.

But both kinds of policy errors can be harmful. The harms of false negatives include exposing both citizens and the natural environment to preventable, and possibly irreparable, risks, while the harms of false positives include imposing unnecessary costs on both producers and consumers, reducing technological innovation, and needlessly exacerbating public anxieties. Moreover, there are often risk-risk tradeoffs: reducing some risks can increase others. For example, making it more difficult to approve new drugs may deprive patients of helpful medicines. The use of diesel engines promotes fuel economy but adversely affects ambient air pollution, while restrictions on diesel engines improves local air quality but also increases emissions of greenhouse gases.

Citizens, policy makers, managers, and scientists in both Europe and the United States can and do disagree about which specific regulations adopted, or not adopted, on either side of the Atlantic during the last five decades are in the public interest. While the science of risk assessment has become highly sophisticated, risk assessments can be interpreted differently or based on different data, assumptions, questions, or values, and scientists themselves may not always agree. In the face of scientific uncertainty and public pressures, policy makers may choose to be more or less risk-averse. As Mary Douglas and Aaron Wildavsky observe, “Acceptable risk is a matter of judgment and . . . judgments differ.”<sup>51</sup> As I note in the preface, the purpose of this book is not to demonstrate or determine whose or which risk regulations are “better.” It is rather to describe and explain many of the often different regulatory choices made by the United States and Europe during the previous five decades.

<sup>51</sup>Mary Douglas and Aaron Wildavsky, *Risk and Culture* (Berkeley: University of California Press, 1982), 194.

An exhaustive statistical comparison of risk assessment and regulation in the United States and the EU concludes, “by far the most common pattern we identified . . . is that the United States and Europe are equally precautionary over a thirty-five-year period.”<sup>52</sup> This research also finds that, according to one measure, “the United States exhibited greater precaution than Europe from 1970 through the late 1980s, including increasing relative U.S. precaution during 1980–89, and that Europe became relatively more precautionary during the 1990s, and early 2000s.”<sup>53</sup> While the latter finding is broadly consistent with my analysis, the relevance of this research to my study is limited by the fact that it also includes risks such as crime and violence, war, security, and terrorism. The claim that there has been a temporal change in European and American regulatory stringency is explicitly challenged by Jonathan Wiener,<sup>54</sup> but his analysis also includes a number of policies that fall outside the scope of my analysis, including speed limits, teenage consumption of alcohol and tobacco, choking hazards embedded in food, gun ownership, restraints on potentially violent persons, and terrorism.

I do not describe or attempt to explain risk regulations in general, or compare policy responses to very different kinds of risks. Rather, my focus is on a subset of risks, namely those that involve health, safety, and environmental risks caused by business. Public policies toward them follow similar political dynamics that do not necessarily hold for public policies toward other kinds of risks.

The list of other risks to which the public may be exposed, and which governments may or may not address, is substantial: it includes different kinds of crime, guns, sexually transmitted diseases, other communicable diseases, the consumption of drugs and alcohol, vaccines, financial fraud and excessive financial risk-taking, lack of access to medical care, unemployment, inflation, natural disasters, poverty, energy dependence, and domestic and international terrorism—to name but a few.<sup>55</sup>

But European and American approaches toward health, safety, and environmental risks caused by business *cannot* be extrapolated to their policies toward the many other kinds of risks citizens may face. For example, American and European policy responses to the risks posed by

<sup>52</sup>Brendon Swedlow et al., “Theorizing and Generalizing about Risk Assessment and Regulation through Comparative Nested Analysis of Representative Cases,” *Law & Policy* 31, no. 2 (April 2009): 252. For an earlier and broader version of their analysis, see James Hammit et al., “Precautionary Regulation in Europe and the United States: A Quantitative Comparison,” *Risk Analysis* 25, no. 5 (2005): 1215–28.

<sup>53</sup>Brendon Swedlow et al., “Theorizing and Generalizing about Risk Assessment,” 251.

<sup>54</sup>See Jonathan Wiener, “Whose Precaution After All?” 225–43.

<sup>55</sup>For a broader analysis of the role of government in responding to the risks faced by their citizens, see David Moss, *When All Else Fails: Government as the Ultimate Risk Manager* (Cambridge, MA: Harvard University Press, 2002).

genetically modified crops and food on one hand, and international terrorism on the other, represent mirror images of each other.<sup>56</sup> The American case for the invasion of Iraq was in part based on precisely the same precautionary principle that the EU has invoked to justify its restrictions on genetically modified agriculture, namely that the lack of clear evidence of harm is not evidence of the absence of harm. As President George W. Bush put it, “if we wait for threats to fully materialize, we will have waited too long.”<sup>57</sup> His position precisely echoes the support for precautionary consumer and environmental regulations by Robert Coleman, the European Commission’s director general for health and consumer protection, who argues, “those in public office have a duty not to wait until their worst fears are realized.”<sup>58</sup>

As one journalist observed: “President Bush argued that the risk of WMDs [Weapons of Mass Destruction] was great enough to warrant an attack, without absolute proof that Iraq was hiding such weapons . . . That’s the PP [precautionary principle], American style.”<sup>59</sup> In the case of the war in Iraq, many European critics of American policy argued that an invasion was not justified because there was insufficient evidence that Iraq had WMDs. Likewise, many Americans have criticized European policies toward GMOs on the grounds that agricultural biotechnology should not be restricted because there is insufficient evidence that it threatens consumer safety or biodiversity. Thus, while policy makers on both sides of the Atlantic may believe that “it is better to be safe than sorry,” they have applied this precautionary principle to different kinds of risks. (In light of the fact that no weapons of mass destruction were found in Iraq, the United States arguably made an important risk management decision based on a false positive policy error.)

In brief, my argument is not that the EU has become more risk-averse than the United States, but rather that it has become more risk-averse

<sup>56</sup>This analysis is developed in more detail in Diego Fossati, *Theoretical Perspectives on Risk Regulation: A Transatlantic Comparative Analysis in Two Policy Areas* (Raleigh, NC: Lulu.com, 2006). For a similar comparison of European and American approaches to regulatory and non-regulatory risks, see Cass Sunstein, “On the Divergent American Reactions to Terrorism and Climate Change,” *AEI-Brookings Joint Center for Regulatory Studies*, Working Paper 06-13 (May 2006).

<sup>57</sup>Wiener, “Whose Precaution After All?” 229.

<sup>58</sup>Samuel Loewenberg, “Old Europe’s New Ideas,” *Sierra Magazine*, January/February 2004, available at <http://www.samloewenberg.com/articles/sierraeuenvironmental.html>, accessed 11/20/2010.

<sup>59</sup>Samuel Loewenberg, “Precaution is for Europeans,” *New York Times*, May 29, 2003, 4, 14. For a more extensive analysis of the adoption of the European-style precautionary principle in U.S. national security policy, see Jessica Stern and Jonathan Wiener, “Precaution Against Terrorism,” in *Managing Strategic Surprises: Lessons from Risk Management and Risk Assessment*, ed. Paul Bracken, Ian Bremmer, and David Gordon (Cambridge: Cambridge University Press, 2008), 110–83.

toward a broad range of health, safety, and environmental risks caused by business activities.

### THE SCOPE OF THE BOOK

The next chapter discusses several alternative explanations for the divergence in transatlantic risk regulation and then further develops my own explanation for the policy shifts that have taken place on both sides of the Atlantic since around 1990. Chapters three through six contain several case studies which compare a wide range of regulatory policies. Chapter three focuses on European and American policies toward the risks of food safety and agricultural production methods, chapter four compares regulations that address the risks of air pollution, chapter five compares policies toward the risks of chemicals and hazardous substances, and chapter six examines European and American policies toward a range of consumer safety risks—other than for food—including drugs, children’s products, and cosmetics. I compare and explain both regulatory statutes and specific regulatory decisions, including judicial ones.

The cases discussed in chapters three through six present a selective comparison of consumer and environmental risk regulations on either or both sides of the Atlantic during the last five decades. Thus, they do not by themselves “prove” a historical transatlantic shift in regulatory stringency with respect to consumer and environmental risks caused by business.<sup>60</sup> However, I believe the cases I have chosen to discuss *are* representative of the politics and policies of risk regulation on both sides of the Atlantic between 1960 and 2010. They are also sufficiently important in their own right to warrant an explanation for them. I also discuss and explain important cases that do not confirm to this overall pattern: some demonstrate increased policy convergence and others, continued American regulatory stringency.

Much of my analysis focuses on regulatory decisions and non-decisions made on either side of the idea of the Atlantic since 1990, since my primary objective is to compare and explain the changes in risk regulations that have occurred since then. As I am interested in how governments

<sup>60</sup>For other comparative case studies of European and American consumer and environmental regulations some of which overlap mine, see Miranda Schreurs, Henrik Selin, and Stacy VanDeveer, eds., *Transatlantic Environment and Energy Policies: Comparative and International Perspectives* (Burlington, VT: Ashgate, 2009); and Jonathan Wiener, Michael Rogers, James Hammitt, and Peter Sand, eds., *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (Washington, DC: Resources for the Future, 2011), chapters 2–12.

address risks, other dimensions of consumer and environmental regulation, such as conservation or land-use planning, fall outside my analysis.

While the American constitutional system has remained stable, comparing America to “Europe” is more complex. Prior to the passage of the Single European Act of 1986, European risk regulations were primarily made at the national level. Accordingly, in discussing European regulatory policies before the mid-1980s, I often compare the United States to selected European countries. As the authority to make regulatory policies has increasingly shifted to the EU, much of this study compares the regulations adopted by the EU with those of the American federal government and American states.

My study begins around 1960, and thus includes important early examples of relative American regulatory stringency, namely the 1958 Delaney Amendment to the Federal Food, Drug, and Cosmetic Act, which prohibits the addition of carcinogenic chemicals to food, and the 1962 Kefauver Amendments to the same legislation, which transformed American policies for drug approval. However, the significant expansion of federal environmental regulation began around 1970 and thus much of my analysis of the politics of risk regulation in the United States focuses on developments since then. My study ends in December 2010. As I suggest in the concluding chapter, the divergence in transatlantic regulatory stringency of the last two decades show no signs of diminishing.

Chapters seven and eight place my explanatory framework for changes in the transatlantic politics of risk regulation in historical perspective. Chapter seven explores changes in public opinion and the preferences of influential policy makers, while chapter eight describes how and explains why American regulatory policies have moved away from and European policies moved toward a precautionary approach to assessing and managing risks. In chapter nine, I discuss the broader implications of my study.