

# The New Politics of Risk Regulation in Europe

David Vogel

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# THE NEW POLITICS OF RISK REGULATION IN EUROPE

David Vogel

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This paper examines recent changes in the politics of risk regulation in Europe and compares them to developments in the United States. From the 1960s through the mid 1980s, the regulation of health, safety and environmental risks was generally stricter in the United States than in Europe. Since the mid 1980s, the obverse has often been the case: a wide array of European consumer and environmental regulations are now more restrictive than in the United States. In a number of important respects, European regulatory politics and policies over the last fifteen years resemble those of the United States between the late 1960s and the mid 1980s. They tend to be politicised, highly contentious and characterised by a suspicion of science and a mistrust of both government and industry.

This paper begins by reviewing comparative studies of health, safety and environmental regulation in Europe and the United States. It then describes a number of contemporary European regulatory policies. The next section argues that the shift toward more risk averse and more stringent regulatory policies in Europe is primarily due to three developments: broader public support for health, safety and environmental protection, the increased regulatory competence of the European Union and a series of regulatory failures at both the EU and national levels that have undermined public trust in government regulation.

European regulatory policies and institutions are currently changing. In particular, risk assessment and risk management are becoming more distinctive, the scientific capacity of government regulation is being strengthened and regulatory policy-making is becoming more open to public participation and more responsive to public concerns. At both the EU and national levels, the precautionary principle has emerged as an influential approach to both consumer and environmental protection.

Many European and American regulatory policies remain highly divergent. This is due to two factors. Firstly, specific regulatory priorities continue to differ across the Atlantic. Secondly, the political salience of consumer and environmental regulation has increased in Europe, but diminished in the United States.

## 1. Historical context

The extensive comparative literature on public health, safety and environmental regulation in the United States and Europe published during the 1980s revealed significant differences in American and European approaches toward the management of technological risks.<sup>1</sup> As a

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<sup>1</sup> See, for example, Vogel, D. National Styles of Regulation: Environmental Policy in Great Britain and the United States, Ithaca: Cornell University Press, 1986, Brickman, R., Jasanoff, S. and Ilgen, T. Controlling Chemicals: The Politics of Regulation in Europe and the United States, Ithaca: Cornell University Press, 1985 and Wilson, G. The Politics of Safety and Health Oxford: Clarendon Press, 1985.

general rule American regulatory politics tended to be more contentious, confrontational and adversarial than in Europe. There was less public trust in government officials and more widespread public scepticism about the benefits of new technologies. The American regulatory process was relatively legalistic, formal and open, with NGOs enjoying considerable access and influence. The decisions of regulatory agencies were politically visible and subject to extensive public review. Industry was often mistrusted and frequently found itself on the political defensive. By contrast, in Europe, “policy decisions about risk remained (closed to the public) . . . the preserve of experienced bureaucrats and their established advisory networks.”<sup>2</sup> NGOs had limited access to the regulatory process and public officials tended to work closely and cooperatively with business. In the United States, regulatory politics were often informed by competing representations of risk among NGOs, industry and regulators, while in Europe policy-making was more likely to reflect a scientific consensus between business and government experts.

These contrasts in regulatory politics and procedures were reflected in different risk policies across the Atlantic. In general, American regulatory agencies tended to be more risk-averse, with possible future harms frequently assigned considerable weight, especially if the public regarded such risks as intolerable. In virtually every case for which direct comparisons are possible, American health, safety and environmental standards were stricter than in most European countries. For example, following the Federal Drug Act amendments of 1962, the American Food and Drug Administration (FDA) became considerably slower to approve new drugs than its counterparts in Germany and Britain; the result was a substantial cross-Atlantic “drug lag”, with new drugs typically approved years earlier in Europe than the US. Similarly American automobile emission standards were consistently stricter than those in Europe as were American regulations governing the clean-up of hazardous wastes.

During the 1970s, US agencies designated as carcinogens a number of chemicals that most European officials did not consider a cancer risk to humans. The Environmental Protection Agency (EPA) banned the pesticides aldrin and dieldrin, while, on the basis of the same scientific evidence, British authorities permitted their use. The dioxin TCDD was banned in America while its use was only restricted in Britain. In 1989, the Natural Resources Defense Council, an American environmental NGO, waged a highly visible public campaign to ban the use of Alar, a chemical compound used as a plant-growth regulator by apple growers. Notwithstanding the lack of scientific evidence that the spraying of Alar on apples presented more than a de minimus cancer risk to consumers, the EPA was forced to ban the use of this chemical - making the US the only country in the world to do so.<sup>3</sup> The Delaney clause to the Food, Drug and Cosmetic Act, which banned the use of any food additive if tests revealed that it caused cancer in either laboratory animals or humans on the grounds that such chemicals could cause irreversible harms, had no counterpart in any European country.<sup>4</sup> More recently the American FDA imposed more restrictive policies on silicone breast implants than did any European regulatory authority.

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<sup>2</sup> Jasanoff, S. (1993) "American Exceptionalism and the Political Acknowledgement of Risk", in Risk, Burger, E.J. (ed.) Ann Arbor: University of Michigan Press, p. 66.

<sup>3</sup> See, for example, Harrison, K. and Hoberg, G. (1994) Risk Science and Politics, Montreal: McGill-Queen's University Press, chapter 4.

<sup>4</sup> Barnard, R.C. (1990) "Some Regulatory Definitions of Risk: Interaction of Scientific and Legal Principles", Regulatory Toxicology and Pharmacology, 11, pp. 201-11.

Ironically, notwithstanding strong American criticisms of the EU's use of the precautionary principle to prevent or delay the approval of genetically modified organisms, "no country has so fully adopted the essence of the precautionary principle in domestic law as the United States."<sup>5</sup> For example, a precautionary approach underlay American food safety regulation, requiring industry to establish the safety of a process or additive prior to approval. A precautionary approach also underlay many American environmental statutes enacted during of the 1970s. Both the 1970 Clean Air Amendments and Clean Water Act required the EPA to apply "an adequate margin of safety" in setting emission limits for hazardous pollutants. Regulatory agencies were often not required to wait for scientific proof of harm before establishing standards or imposing restrictions, and in some cases were explicitly prohibited from doing so. The 1997 Clean Air Act Amendments explicitly authorised EPA to "assess risk rather than wait for proof or actual harm," before establishing standards.<sup>6</sup> Under the Endangered Species Act, a finding of potential irreversible harm can lead to an order to desist all development activities.

A precautionary approach toward risk regulation was also reflected in and reinforced by a number of judicial decisions. In *Sierra Club v. Siegler*, the 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."<sup>7</sup> In a 1976 Court of Appeals decision upholding EPA's ambient air standard for lead, the court reasoned: "A statute allowing for regulation in the face of danger is, necessarily, a *precautionary* statute. Regulatory action may be taken before the threatened harm occurs . . . the statutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable"<sup>8</sup> (italics added). In *Reserve Mining*, the Supreme Court permitted the EPA to regulate an effluent based on only a "reasonable" or "potential" showing of danger, rather than on the more demanding "probable" finding requested by the industrial plaintiff. In sum, "elements of the precautionary principle (are) firmly entrenched in US environmental law."<sup>9</sup>

The criticism of the "irrationality" of EU regulatory policies toward GM foods and seeds made by American officials is also ironic. Responding to the demands for the separation of GM and non-GM foods, US Secretary of Agriculture Dan Glickman declared that "test after rigorous scientific test has proven these products to be safe. Sound science must trump passion."<sup>10</sup> Yet the history of American social regulation during the 1970s and 80s is replete with examples of "passion" dominating "sound science," of which the alar ban is only the most prominent example.<sup>11</sup> The American automobile emission regulations enacted by Congress in 1970 reflected political jockeying between President Nixon and prospective

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<sup>5</sup> Cameron, J. (1999) "The Precautionary Principle", in Sampson, G. and Chambers, W.B. (eds.) Trade, Environment and the Millennium New York: United Nations University Press, p. 250.

<sup>6</sup> Ibid. p. 251.

<sup>7</sup> Ibid.

<sup>8</sup> Quoted in Vogel, D. (1995) Trading Up, Cambridge: Harvard University Press, p. 182. Emphasis added.

<sup>9</sup> Applegate, J. (2000) "The Precautionary Preference: An American Perspective on the Precautionary Principle", Human and Ecological Risk Assessment vol. 6, no. 2, pp. 438-439.

<sup>10</sup> Urry, M. (1997) "Genetic products row worsens", Financial Times, June 20, p. 4.

<sup>11</sup> For a detailed description of the lack of science-based risk assessment in the United States, see Breyer, S. (1993) Breaking the Vicious Circle: Toward Effective Risk Regulation, Cambridge: Harvard University Press.

Democratic presidential candidate Senator Edmund Muskie - with each seeking to capture the political benefits from America's sudden passion for environmentalism by proposing progressively stricter standards. The regulations approved by Congress were not based on any scientific assessment of their health impacts, nor was there any effort to assess their costs or technological feasibility.

A decade later, Congress enacted "Superfund" legislation as a response to widespread public anxiety over the health effects of toxic waste disposal sites such as Love Canal - effects which subsequent evidence revealed to have been highly exaggerated. The health benefits of this very expensive federal regulatory programme have been extremely modest, yet Congress has been reluctant to reform it lest it be accused of being indifferent to the public's health. The Delaney clause, which distorted food safety standards in the US for more than a generation, was enacted in 1958 at the initiative of a single influential legislator whose wife had died of cancer.

Numerous studies of American health and safety standards have demonstrated the inconsistency of the risk assessments that underlie them.<sup>12</sup> Some relatively strict standards confer few or no benefits in terms of lives saved or diseases or injuries prevented, while some relatively lax standards place Americans at substantial risk of harm. This is primarily a function of the political and legal context in which American regulatory policy-making has been embedded. Both Congress and the political appointees who head regulatory agencies have been highly sensitive to public opinion and public pressures. Consequently, the more the American public has tended to worry about a particular risk, the more strictly American policy-makers are likely to regulate it. In short, much American regulatory policy, especially between the mid 1960s through the mid 1980s, was characterised by the triumph of "passion" over "sound science."

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'."<sup>13</sup> A British journalist observed: "We saw the Americans thrashing around from one pollution scare to the next, and we were mildly amused. One moment it was cyclamates, mercury the next, then ozone, lead, cadmium - over there they seemed set on working their way in a random manner through the whole periodic table."<sup>14</sup> Americans observing European regulatory procedures for assessing the health or environmental impact of each GMO might well echo this observation. Their criticisms of European GMO regulation, namely that it is slow, cumbersome, highly politicised, fragmented and without an adequate scientific basis, are strikingly similar to those repeatedly made of many American consumer and environmental regulations.

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<sup>12</sup> See for example, Sapolsky, H. (ed.) (1986) Consuming Fears: The Politics of Product Risks New York: Basic Books and Wildavsky, A. (1985) But Is It True: A Citizen's Guide to Environmental Health and Safety Issues, Cambridge: Harvard University Press.

<sup>13</sup> Quoted in Vogel, D. (1986) National Styles, p.182.

<sup>14</sup> Johnson, S. (1971) The Politics of the Environment: The British Experience, London: Tom Stacey, pp. 170-171.

## 2. The new European risk regime

Many American health, safety and environmental standards remain stricter than European ones. The US for example, enforces stricter regulations governing second-hand smoke than does either the EU or any European country. American automotive emissions and fuel composition standards remain stricter than those of the EU. The US continues to ban the sale of British beef while its sale is now permitted throughout the EU. American authorities will not accept blood donations from donors who have spent six months or more in the UK; no European country has imposed a similar restriction. More generally, US regulations governing potential carcinogens are stricter than those in Europe as are American standards governing the clean up and disposal of hazardous wastes.

In other areas, most notably the approval of ethical drugs and some chemicals, American and European regulatory policies have converged. And in still other areas, such as the elimination of lead from gasoline and other products and the banning of the use of asbestos, European standards have “caught up” to American ones. But what is new is the emergence of a number of regulatory policies in which European standards are now stricter than their American counterparts.

The most visible example is the regulation of genetically modified foods and crops. In this policy area, the American approach is similar to that of many European countries two decades ago. American regulatory officials have worked closely with industry to facilitate the commercial development of a new technology.<sup>15</sup> There has been relatively little public participation in the regulatory process and little public scrutiny. By contrast, the European regulatory process resembles American regulatory politics of the 1970s: it has been highly politicised and contentious, with both the public and non-governmental organisations enjoying considerable access and influence. For its part, industry has found itself on the defensive and experienced a number of political setbacks. The US regulates both GMO foods and seeds under existing laws, while the EU has established a distinctive and complex set of new regulatory requirements that apply only to this new agricultural technology. While issues regarding the safety and environmental impact of GM foods and seeds continue to surface in the United States, to date their policy impact has been remarkably modest, unlike in Europe where public opposition to GMOs has been extremely effective.<sup>16</sup>

The differences in policy have been substantial. The EU has issued eighteen licenses for biotechnology products, nine of which are for genetically modified crops.<sup>17</sup> By contrast, the USDA has issued approvals for fifty genetically modified crops,<sup>18</sup> while the EPA has

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<sup>15</sup> See, Eichenwald, K., Kolata, G. and Peterson, M. (2001) "Biotechnology Food: From the Lab to a Debacle", New York Times January 25. According to this article, “the control this nascent industry exerted over its own regulatory destiny . . . was astonishing.”

<sup>16</sup> See for example, "Kraft recalls contaminated Taco Shells", Internet News Service, September 25, 2000.

<sup>17</sup> CNN Headline News, June 24, 1999; and "Genetically Modified Food: Food for Thought", The Economist, June 19, 1999.

<sup>18</sup> Burros, M. (1999) "U.S. Plans Long-Term Studies on Safety of Genetically Altered Foods", The New York Times, July 14, p. 16.

approved eight.<sup>19</sup> Nearly three-quarters of all genetically modified crops are grown in the United States, hardly any are grown in Europe. The EU and a number of Member States have enacted strict labelling requirements, while US labelling requirements are more modest, only requiring the labelling of products which differ from their non-genetically modified counterparts. On June 24 1999, the environment ministers of the EU indicated their support for a moratorium on biotechnology products, which would, among other things, limit the period of authorisation for a genetically modified product.<sup>20</sup> As of June 2001, the EU had not approved any new seed strains for nearly three years under Directive 90/220 while the marketing of new food products under the Novel Foods Regulation has been effectively halted.

These differences parallel those in other areas of agricultural policy. While the United States continues to permit the administration of growth hormones to cattle, the EU has banned the use of both synthetic and natural ones. Following extensive debate, the United States approved the use of a growth hormone for milk cows while the EU has continued to prohibit its use. The EU has banned the use of meat and bone meal in all animal feed, while their use is permitted in the US. The EU has adopted a much more extensive array of animal protection measures than the US, including for example rules governing cages for battery hens and the treatment of animals in transit.

Nor are these differences confined to agriculture. The European Commission has indefinitely extended its ban on the use of phthalate softeners in toys and child car articles, while the US has adopted a wait and see approach. European rules on the pre-marketing testing of new chemicals require more extensive testing than in the United States. EU recycling requirements are stricter than in the US, where they are governed by local rather than national laws. Europeans have made manufacturers responsible for the "life-cycle" of a wide array of goods, including cars and electronic products, and the EU is currently moving to phase out and ultimately prohibit the use of a number of heavy metals in electronic products and batteries in order to promote recycling and protect landfills. Neither regulation is on the political agenda in the United States, though there have been a number of voluntary initiatives by firms. Likewise public or quasi-public eco-labeling schemes exist both in the EU and in a number of European countries, but continue to play little role in the United States. The EU has also enacted more stringent rules governing the trapping of wild animals than the United States.

Over the last decade, in a number of areas the EU has replaced the leadership role of the United States in addressing global environmental problems. Through the 1980s, most major international environmental agreements - most notably CITES, the Montreal Protocol, and the International Whaling Convention - were initiated by the United States. More recently, both the Biosafety Protocol and the Basel Convention on Hazardous Wastes have been adopted by the EU, but not the US. The EU has strongly supported an international treaty to reduce the emissions of greenhouse gases, while the United States has refused to support such a treaty. Not only is the issue of global warming much more salient in Europe than the United States, but some European countries have established programmes to reduce carbon

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<sup>19</sup> Tait, N. (1999) "EPA Sued over Genetic Crop Approval", Financial Times, February 19, p. 6.

<sup>20</sup> Smith, M. (1999) "EU Set for Moratorium on New Modified Food Products", Financial Times, June 25, p. 1.



emissions, even in the absence of an international treaty. Such efforts have been still-born in the US, though there have been a number of private sector initiatives. Only with respect to placing environmental provisions in trade regimes has the US continued to play a global leadership role.

The change in the relative stringency of a number of European and American consumer and environmental standards over the last three decades can be seen in the pattern of trade disputes between the EU and the US.<sup>21</sup> Those disputes that revolved around regulatory policies enacted prior to the mid 1980s typically involved complaints by the EU or its Member States about the use of American regulatory standards as non-tariff barriers. Thus the former filed complaints in the GATT about Superfund taxes, American automotive fuel economy standards, and the American tuna import ban. But for those disputes which have revolved around regulations enacted since the mid 1980s, the pattern is reversed: it is now the US which has complained about the EU's beef hormone ban, the EU's leg-trap ban, EU eco-labeling standards, the EU's proposed directive on the take-back of electronic products and most importantly, European restrictions on the sale of crops grown with GM seeds.

In short, a broad range of European consumer and environmental regulations are now stricter than those of the United States. During the 1970s and 80s, the European health, safety and environmental agenda was strongly influenced by the US. Automotive emission standards, regulations for testing chemicals, the identification of and clean-up of hazardous wastes, the regulation of polyvinyl chloride - all moved from America to Europe. Now, as the case of GMOs illustrates, many regulatory policy issues first appear on the European public and political agenda - and then move across the Atlantic to America.

However it is important not to equate stringency with effectiveness. In some cases stricter regulations may provide better consumer or environmental protection while in other cases, the relative stringency of a particular standards may have little or no scientific basis. Thus to argue that many American standards were stricter than many European ones during the 1970s is not to claim that American regulations were more effective; in some cases they were while in others they provided few or no social benefits. The same holds true for the relative stringency of many contemporary European health, safety and environmental standards. Some better protect consumers and the environment, others do not.

### **3. Explaining the new European risk regime**

Over the last ten to fifteen years, European regulatory politics and policies have changed significantly. They have become more politically visible, more contentious and compared to both the United States and Europe in the past, many have become more stringent or risk averse. How can we account for these changes in Europe?

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<sup>21</sup> For a detailed discussion of such disputes see Vogel, D. (1997) Barriers or Benefits? Regulation in Transatlantic Trade, Washington DC: Brookings Institute.

## **Civic culture**

A critical part of the explanation has to do with political, social and cultural developments within Europe. Throughout most of the history of the EC, European attitudes toward environmental, health and safety regulations were geographically polarised. Germany, the Netherlands and Denmark consistently favoured stricter, often most risk-averse, regulations, while Britain, France and Italy equally consistently opposed them. Much of EC environmental policy-making during the 1970s and 80s represented a struggle between the EC's three "green" Member States, where constituencies representing civic interests enjoyed considerable public support and influence, and Britain, France and Italy, where they did not. Thus the directives for automobile emissions standards or recycling requirements represented a compromise among these Member States, though over the long-run European regulatory standards have been gradually strengthened.

But strong public interest in and support for stricter health and environmental standards is no longer confined to northern Europe: over the last decade it has spread south and west. In a number of critical respects, Britain and France are no longer regulatory "laggards." During the 1990s, British public opinion and public policy became "greener" and Britain's green lobbies increasingly influential. In 1990, as part of a broader reexamination of its environmental policies, Britain formally adopted the precautionary principle as one of the "basic aims and principles supporting sustainable development."<sup>22</sup> Significantly, this approach toward the management of environmental and public health risks had first been introduced in Europe in Germany, historically the EU's "greenist" Member State. The application of this principle has affected a number of British regulatory policies, including the dumping of sewer sludge in the North Sea and domestic water pollution standards. It has also strained Britain'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. Britain has also played a leadership role in moving the EU toward a system of integrated pollution control, it was the strongest advocate of the EU's leg-trap ban, and public opinion has been extremely hostile toward GMOs.

While the policy changes in France have been less dramatic, the French Environment Minister under the Juppé Government, Corinne Lepage, was a leading public critic of GMOs, opposing the position of the Ministry of Agriculture. In 1997, following the election of Prime Minister Jospin, the Green Party joined the French Government for the first time with the Party's president, Dominique Voynet becoming Environmental Minister. In 1996 the French government formally adopted the precautionary principle and three years later it established a quasi-independent food safety agency. In 2001, France became the second European nation to ban the use of animal feed (farines) to all farm animals in order to prevent further outbreaks of mad-cow disease, a decision based on the precautionary principle since there was no evidence that the farines posed a danger to either public or animal health.<sup>23</sup> And

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<sup>22</sup> Jordan, A. and O'Riordan, T. (1995) "The Precautionary Principle in UK Environmental Law and Policy", in Tim Gray, (ed.) UK Environmental Policy in the 1990s, New York: St. Martin's Press, pp. 70-71.

<sup>23</sup> "Le gouvernement peaufine un plan d'interdiction des farines animales", Le Monde November 12-13, 2000, p. 6.

French public opinion and public policy has been among the most hostile to GMOs in Europe.

These developments in Great Britain and France, two of the EU's largest and more important Member States, are highly significant for European regulatory politics. Moreover they reflect a broader phenomenon. Italy, responding to public health scares, was among the first nations to pressure for the beef hormone ban and 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 the governing coalition. In 1999, the Green Party joined the government of Belgium for the first time. Thus at the turn of the century, the Green Party was represented in five European governments: the Netherlands and Germany, where it has been historically strong, and in France, Italy and Belgium, where it was previously not represented.

In sum, public support for stricter health, safety and environmental standards is no longer confined to northern Europe. Rather in recent years, much of western Europe appears to have developed a common civic culture, one which is more risk-averse than in the past, especially with respect to issue of public health and which shares higher expectations about the role of government in protecting both consumers and the environment. This shift in attitudes may in part have been triggered by the 1986 Chernobyl disaster which made many Europeans more aware of their common vulnerability to technological risks and may also reflect the spread of post-industrial politics throughout the more affluent parts of Europe. It may also have been affected by the increased visibility and influence of a European-wide media.

### **The European Union**

It is not coincidental that the emergence of a new European approach to social regulation during the mid 1980s corresponded to the enactment of the Single European Act (1987). Nor it is a coincidence that the constitutional structure of the EU more closely resembles that of the United States than it does any Member State: it is the only European political institution with a formal separation of powers and, unlike all but a few European states, it has a federal structure.

The EU 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 harmonised 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."<sup>24</sup> In 1995 the Consumer Policy Service of the European Commission became established as a new directorate-general, DG XXIV (the EU had previously established an Environment

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<sup>24</sup> Jordan, A. and O'Riordan, T., op cit., pp. 68-69.

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 explicitly defined consumer policy and health protection as “rights.” It also extended the precautionary principle to consumer protection.

EU treaties have also steadily expanded the role of European Parliament, a body in which consumer and environmental interests have been relatively influential, in shaping European legislation.<sup>25</sup> The Single European Act 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 European Council co-responsibility for writing legislation. The latter’s purview over environmental legislation was 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.”<sup>26</sup>

As Majone has noted, the EU is primarily a regulatory state: issuing rules is its most important vehicle for shaping public policy in Europe.<sup>27</sup> 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. These interests have been better represented at the European level than in many Member States. The Green Party has long been represented in the European Parliament and European consumer groups and environmental groups have often been influential in Brussels, with some enjoying close relationships with the DGs for environment and consumer protection. The European Consumers Union lead the successful campaign for the beef hormone ban while Greenpeace, along with Green Parties at the national and EU level, has played a critical role in mobilising public and political opposition to the approval of GMOs in Europe. Thus as in the case of the separation of powers within the United States, the fragmentation of policy-making at the European level has expanded the opportunities for political participation by non-producer interests, especially when these have been backed by strong public pressures. In short, the EU has provided more political space for the representation of civic interests, and the latter have taken considerable advantage of these opportunities.

In addition, the EU’s own political and economic imperatives have contributed to strengthening European consumer and environmental standards. Since the 1970s environmental policy has been employed by the EU to legitimate its claim to promote and represent the interests of European citizens. More recently, the EU has sought to strengthen European consumer protection standards as the lack of public confidence in the European food supply threatens the functioning of the single market.

Unlike in the United States, where the constitutional authority of the states over regulatory policies that affects interstate commerce is sharply circumscribed, Member States within the

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<sup>25</sup> See Bomberg, E. (1998) Green Parties and Politics in the European Union, London: Routledge.

<sup>26</sup> Grant, W., Matthews, D. and Newell, P. (2000) The Effectiveness of European Union Environmental Policy, New York: St Martin’s Press, p. 35.

<sup>27</sup> Majone, G. (1996) Regulating Europe, London: Routledge.

EU continue to play an important role in making consumer and environmental regulations, a role which the principle of subsidiarity has enhanced. In the case of GMOs, as in many other regulatory policy areas, many of the most restrictive regulatory policies have been issued at the national level, at times in defiance of the EU. The dynamics of regulatory policy-making at the national level have created a “race toward the top”, with governments often competing both among themselves and with the EU to respond to public pressures by issuing standards that better protect public health and the environment. The continued role of the Member States in regulatory policy-making has also provided civic interests with multiple opportunities to place an issue on the European regulatory agenda, since the issuing of a regulation by any Member State invariably places it on the agenda of the other fourteen, as well as Brussels.

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 fifteen Member States, as well as Brussels. It is one thing for a citizen to trust the regulatory officials of his or her own government (though as noted below such trust has in fact diminished), but it requires a considerable leap of faith for such a citizen to trust the competence of officials in each of the other fourteen member states, let alone Brussels. The EU has thus unwittingly fostered increased citizen mistrust of government regulation in Europe, which has pressured many governments, as well as in the EU itself in some cases, to adopt more rigorous regulatory standards.

### **Regulatory Failures**

A third factor that has contributed to the adoption of more risk-averse policies in general in Europe has been a series of regulatory failures that have undermined public confidence in the ability of regulatory officials at both the national and EU level to adequately protect the public’s health and safety. These failures and the political response to them have, to use Douglas and Wildavsky’s<sup>28</sup> framework, helped shift Europe’s political culture from a relatively hierarchical one, characterised by deference to authority and technical expertise, to a more egalitarian one, defined by public mistrust of authority, technology, and scientific expertise.

During the latter half of the 1990s, the shortcomings of the EU’s regulatory structure for food safety became highly visible. The most important food safety regulatory failure involved mad-cow disease. While BSE (bovine spongiform encephalopathy) 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 showed the disease was transmittable to mice. Following a massive outbreak of BSE in 1989-1990, the European Community banned human consumption of meat from the sick cattle. While 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, and its position was accepted by the European Commission which placed no restrictions on the sale of British beef.

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<sup>28</sup> Douglas, M. and Wildavsky, A. (1982) Risk and Culture, Berkeley: University of California Press.

The crisis over BSE broke in 1996 in the UK, when the British Government announced that ten cases of Creutzfeld-Jakob disease had been diagnosed in humans, and that these cases were likely to be related to exposure to the cattle disease 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 other Member States. While both the Commission and its scientific advisory body subsequently certified British beef as safe for human consumption, the EU's belated failure to recognise its health hazards severely undermined public trust in EU food safety regulations and the scientific expertise on which they were based. It also significantly increased public awareness of food safety.

It is impossible to exaggerate the significance of the regulatory failure associated with BSE on the attitude of the European public toward GM foods.<sup>29</sup> This was especially true in Britain, where unfavourable press coverage of agrobiotechnology increased substantially following the BSE crisis: between 1996 and 1998 the percentage of those strongly opposing genetically modified foods rose from 29 percent to 40 percent. But 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."<sup>30</sup> According to an official from Monsanto, "That wound [about the British Government's long insistence that there were no human health risks from mad-cow disease] 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."<sup>31</sup> A food sociologist observed, "BSE was a watershed for the food industry in this country. For the first time people realised 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."<sup>32</sup>

The regulatory failure associated with mad-cow disease has had important political consequences in Europe. It dramatically exposed the gap between the single market - which exposes all European consumers to products 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 both the strengthening of the role of DG XXIV and the decision to create a European food safety agency, which was formally made at the Nice summit in December 2000. It has 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. The European Commission had relied on the advice of the Scientific Veterinary Committee which was chaired by a British scientist and which primarily reflected the thinking of the British Ministry of Agriculture, Fisheries and Food - advice which subsequently proved flawed.<sup>33</sup> European officials are seeking to devise institutional arrangements that will reduce

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<sup>29</sup> Jasanoff, S. (1997) "Civilization and Madness: The Great BSE Scare of 1996", Public Understanding of Science, 6, pp. 221-232.

<sup>30</sup> Cookson C. and Houlder, V. (1999) "An Uncontrolled Experiment", Financial Times, Feb. 13/14, p. 7.

<sup>31</sup> Weiss, R. (1999) "No Appetite for Gene Cuisine", Washington Post National Weekly Edition, May 3, p. 19.

<sup>32</sup> Williams, N. (1998) "Plant Genetics: Agricultural Biotech Faces Backlash in Europe", Science, Aug 7, pp. 768-771.

<sup>33</sup> See Chambers, G., (1999) "The BSE Crisis and the European Parliament", in EU Committees: Social Regulation, Law and Politics, Joerges, C. and Vos, E. (eds.), Oxford: Hart Publishing, pp. 95-108.

the likelihood of regulatory “capture” reoccurring.<sup>34</sup> The mad-cow crisis has also affected regulatory institutions and policy making at the national level, leading for example, to the creation of a consumer protection “super ministry” in Germany and the establishment of national food safety agencies in both Great Britain and France.

The mad-cow crisis shows no sign of diminishing. In the fall-winter of 2000-2001, diseased cows were discovered in both France and Germany.<sup>35</sup> France responded by banning the use of animal feed for all farm animals, a decision with major economic consequences for French agriculture, while in Germany two cabinet ministers resigned and a member of the Green Party was appointed Minister of Agriculture. Other Member States responded by banning imports of French beef. During 2000, approximately 1,700 infected cows were discovered in continental Europe and European beef sales plummeted by 27%. The EU responded by further tightening its regulatory controls - it has issued more than 80 directives since the disease was first discovered - and the total costs to the EU and national governments are likely to reach \$20 billion within the next two years. To date approximately 90 people have been afflicted, all but a few in Britain. But the long incubation period makes it impossible to predict how many more will succumb. In short, mad-cow disease represents a European economic and health crisis of historic dimensions.

Not surprisingly, mad-cow disease has shaped the way Europeans have framed the potential risks associated with GMOs. In the case of the former, an industrial food production technology which scientific experts had assured the public was safe turned out to have serious long-term adverse health effects - effects which no scientists had predicted and whose magnitude and links to particular patterns of food consumption and animal husbandry are still not fully understood. If the experts were wrong about the safety of meat produced by cows who had been fed farines, might they also be mistaken in their appraisal of the safety of food produced with yet another even more novel and unproven food production technology? Moreover, in both cases, efforts to improve agricultural productivity appeared to provide consumers with no benefits, only increased risks. Mad-cow thus helped put the issue of food safety, and its links to methods of food production, at the forefront of European public consciousness. In doing so, it made public acceptance of food produced from GMOs much more problematic.

In this context it is significant that while many scientists on both sides of the Atlantic, though perhaps more in Europe, regard the most important risks associated with GMOs as environmental, and the risks to human health as ranging from minimal to non-existent, it is the latter which have dominated public discourse in Europe. This is a direct response to mad-cow disease, which has heightened European anxiety over food safety. The overwhelming public support for the labelling of foods which have been genetically modified - which has emerged as an important source of trade conflict with the United States - reflects the view of many European consumers that they have a *right* to know how the foods they are eating were produced - so that they, and not some government agency or business firm, can make appropriate purchasing decisions. And both mad-cow and the debate over GMOs have

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<sup>34</sup> See the other contributions in *ibid.*

<sup>35</sup> "Economic Slaughter", Business Week (European Edition) February 5, 2001, pp. 18-19.

prompted a public discussion of the future of Europe's "productivist" approach to agriculture.

While mad-cow disease has reduced public confidence in government regulation at the EU level - which admittedly was not especially high to begin with - public confidence in national regulatory officials and institutions has also diminished in a number of European countries. The impact of the British Government's widely perceived regulatory failures over mad-cow require little elaboration. British policy clearly failed to address the challenges of governance presented by BSE. As one British scholar put it, "the BSE scandal represents the biggest failure in UK public policy since the 1956 Suez Crisis."<sup>36</sup> It also emerged on the heels of a long line of food scares in the United Kingdom, including an outbreak of e-coli in Scotland, salmonella in eggs, and listeria.

In 1999, a major public health scare emerged over dioxin contamination of food products produced in Belgium, leading to both the fall of the Belgium Government and the removal of all food products from Belgium from food shelves throughout Europe, as well as scandal involving the safety of Coca-Cola.<sup>37</sup> 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, in Member State authorities tasked with the job of overseeing the food industry. There seems to be an endless supply of (food scares.)"<sup>38</sup> Since those words were written, Europe has been faced with a new food crisis, namely the outbreak of foot and mouth disease among sheep in several European countries. While this disease does not affect humans, it has contributed to public anxieties about food safety.

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 criticised for responding too slowly to the public health and workplace dangers associated with use of asbestos.<sup>39</sup> In spite of overwhelming evidence that asbestos constituted a serious health hazard, killing approximately 2,000 people a year according to a government study, its manufacturing, importation and sale was not banned until 1996, nearly two decades after it was outlawed in the United States and after it had been banned in seven other European countries. Shortly afterward on Bastille Day, 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 so long in the first place.

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<sup>36</sup> Millstone, E. (2000) "Comment and Analysis", Financial Times, October 6, p. 19.

<sup>37</sup> The links are observed by journalists with titles such as "Mad Coke Disease", John Lanchester, The New York Times Magazine, July 4, 1999: 7-8.

<sup>38</sup> "Back to the Future", Consumer Voice, Special Edition, 2000.

<sup>39</sup> For an extended discussion of this issue, see Chateauraynaud, F. and Didier, T. (1999) Les Sombres Precurseurs (the Dark Forrunners) Paris: Editions De L'Ecole Des Hautes Etudes En Sciences Sociales, chapters 3-7.



Another, far more consequential scandal was the apparent failure of governmental officials and doctors to protect haemophiliacs from blood contaminated with the AIDS virus.<sup>40</sup> This issue, which 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 sentenced to prison. Officials were accused of failing to adequately screen blood donors, delaying the approval of an American technology to test blood in order to benefit a French institute, and giving blood to patients that they knew to be contaminated. The deaths of more than 300 haemophiliacs were linked to one or more of 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 government's regulatory failure was widely attributed to its placing economic interests over public health.

“Le sang contaminé” (contaminated blood) scandal in France, like the mad-cow disease in the UK, had significant domestic repercussions. It shocked 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 Française de Sécurité Sanitaire des Aliments*, 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 facing legal penalties. The French decision to maintain its ban on imports of British beef, made in defiance of the EU and against the advice of the Ministry of Agriculture, was taken in response to the recommendations of the AFSSA. The haste with which the French government responded to an increase in the number of BSE cases among French cattle in November 2000 by banning the feeding of animal waste to all animals - without even waiting for a scientific assessment by AFSSA - reflects the continuing impact of the contaminated blood scandal on French health and safety policies, as in part do French policies toward GMOs.

#### **4. Changes in European policies and institutions**

Over the last decade, the precautionary principle has come to play an increasingly important role in shaping risk management policies in Europe. Since it is mentioned but not defined in the TEU, the EU has subsequently sought to articulate its role in policy-making. According to a communication from the European Commission in February 2000, its scope has broadened from environmental protection, the policy area in which it originated, to encompass human, animal, or plant health. It is intended to be invoked when “potentially dangerous effects deriving from a phenomenon, product or process have been identified, and . . . scientific evaluation does not allow the risk to be determined with sufficient certainty”

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<sup>40</sup> There is an extensive literature on this issue, including Setbon, M. *Pouvoirs contra Sida* Editions Du Seuil, 1993, Kriegel, B. *Le sang, la justice, la politique*, Paris: Plon, 1999, and Beaud, O. *Le sang contaminé*, Paris: Behemoth 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.

because “of the insufficiency of the data or their inconclusive or imprecise nature.”<sup>41</sup> In principle, the application of this principle is not biased toward action or delay, approval or denial. And indeed its application requires an examination of the potential benefits and costs of action as well as the enactment of regulatory policies that are proportional to the level of protection being chosen. In addition, “measures should be reviewed in the light of scientific progress and amended as necessary.”

The resolution on the precautionary principle adopted by the heads of government at the December 2000 Nice summit modified the Commission’s communication in two respects.<sup>42</sup> 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 either to insufficient data or the urgency of the risk. Secondly, it opened up the possibility of greater civic participation during risk assessment, stressing that public participation should be “multidisciplinary, independent and transparent,” in order to insure that all views are heard. It stressed that any examination of the costs and benefits of action or inaction should take into account not only their social and environmental costs but also “public acceptability” of the final decision.

While the precautionary principle cannot be divorced from science - since “a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates” - in fact its growing popularity in Europe reflects the perception that scientific knowledge is an inadequate guide to regulatory policy.<sup>43</sup> It is located precisely between a logic that requires the extension of scientific knowledge and one which acknowledges the “the possible intrinsic limitations of scientific knowledge in providing the appropriate information in good time.”<sup>44</sup> It thus simultaneously both increases public expectations of science and reflects the public’s scepticism of scientific knowledge. In effect, it reduces the scientific threshold for regulatory policy-making. By mandating the taking of regulatory action, or inaction, in advance of scientific proof of 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.”<sup>45</sup>

The spread of the precautionary principle within Europe reflects a significant change in European regulatory policy-making. While its legal significance at both the EU and national level remains unclear, its practical effect has frequently been to permit, even mandate, the adoption of more risk-averse policies. Its also explicitly both promotes and legitimates the politicisation of regulatory decision-making by enabling policy-makers to take into account a wide variety of non-scientific factors, including public opinion and social values, in making regulatory policies. “The stringency with which the precautionary principle is applied depends upon and is also a useful barometer of deeper social and economic changes.

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<sup>41</sup> EU Commission, Communication from the Commission on the precautionary principle, Brussels: Feb 2, 2000, p. 15.

<sup>42</sup> “EU Leader back precautionary principle”, ENDS Daily, December 13, 2000.

<sup>43</sup> Cameron, J. op cit, p. 244.

<sup>44</sup> Godard, O. (1997) “Social Decision-Making Under Conditions of Scientific Controversy Expertise and the Precautionary Principle”, in “Integrating Scientific Expertise into Regulatory Decision-Making”, Joerges, C., Lateur, K-H. and Vos, E. (eds.), Baden-Baden: Nomos Verlagsgesellschaft, p. 65.

<sup>45</sup> Jordan, A. O’Riordan, T., op cit. p. 71.

Precautionary measures, for example, are most likely to be applied when public opinion is instinctively or knowledgeably risk-averse.<sup>46</sup> In a sense, the application of the precautionary principle protects politicians as much as the public. Significantly, although French law provides that ten steps must be followed before it can be applied, ranging from an economic analysis to a comparative risk assessment, in the case of GMOs they were for the most part either poorly applied or ignored.<sup>47</sup>

The frequency with which the precautionary principle has been evoked in Europe among both activists and policy-makers also has an ideological dimension. It reflects not only a decline in the role of science as a guide to policy-making, but also a decrease in public confidence in the benefits of technological innovation. Frequently underlying its invocation is the assumption that modern technology poses dangers of which we are unaware and that to avoid future harms we need to regulate it more stringently. As Corrine Lepage, the former French Environment Minister put it 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.”<sup>48</sup> For many environmentalists, one of its important attractions is that it enables regulatory decisions to be made in the absence of evidence regarding a causal relationship between the regulatory policy being advocated and the harm it is intended to avoid since the principle, by definition, is intended to operate precisely when scientific knowledge is unclear or unknown.

The precautionary principle thus both reflects and reinforces a greater role for both public opinion and NGOs in shaping risk management decisions in Europe. It has also made regulatory policy-making more divisive and divided since different governments apply it differently. While in part designed to enable the EU to defend its regulatory policies in international forums, it also has been frequently employed by Member States to justify more stringent regulations that undermine the single market. In turn, the EU is seeking to rein in Member States’ application of this principle by requiring them for example to undertake additional research to reduce uncertainty within a reasonable time limit.

Yet somewhat paradoxically, European regulatory administration is also becoming more scientifically based. At both the national and the EU level, there is increased recognition of the need to strengthen the capacity of government agencies to conduct risk assessments and improve the quality of scientific information available to decision-makers. An important factor underlying this development is an increase in judicial review of regulatory decisions at both the European and international levels. Just as American regulatory agencies strengthened their scientific expertise in order to defend their decisions in federal court from challenges by both public interest groups and business, so has the need of both national and

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<sup>46</sup> Ibid., p. 61.

<sup>47</sup> Kourilsky, P. and Viney, G. (2000) The Principe de Precaution, Paris: Editions Odile Jacob, pp. 99-151.

<sup>48</sup> Lepage, C. and Guery, F. (2001) La Politique de Precaution, Paris: Presses Universitaires de France, p. 144. (translation by author). For a collection of essays generally sympathetic to this position, primarily by Americans, see Protecting Public Health and the Environment: Implimenting the Precautionary Principle, Raffensperger, C. and Tickner, J. (eds.), Washington: Island Press, 1999. For a wide-ranging critique of the precautionary principle as both law and philosophy, see Rethinking Risk and the Precautionary Principle, Morris, J. (ed), Oxford: Butterworth-Heinemann, 2000.

European authorities to defend their decisions before the European Court of Justice and World Trade Organisation dispute panels prompted them to engage in more rigorous scientific risk assessments. While in America such judicial scrutiny primarily took place under the Administrative Procedures Act, within the EU the ECJ has the responsibility for deciding if a particular national regulation that restricts trade is justified under Article 30, which permits import restrictions to be justified on the grounds of “the protection of health and life of humans, animals or plants.”<sup>49</sup>

Another important defining feature of regulatory policy-making in Europe is the effort to separate risk assessment from risk management. The former is the advice or information scientists provide to policy-makers; the latter is what policy-makers decide. This separation, which formally exists at the EU - each EU regulatory agency only makes recommendations to the Commission - is also being adopted by a number of Member States. This separation has a number of purposes. Most obviously, it is designed to prevent regulatory “capture” by making regulatory policy-making more transparent; to the extent that risk assessments are made public, the public can determine the extent to which political officials are accepting or ignoring the relevant scientific advice. It also enables policy-makers to take into account non strictly scientific considerations in making regulatory decisions, as for example, under the terms of the precautionary principle. Thirdly, it protects the integrity of the risk assessors since their only role is that of providing scientific information to policy-makers. But perhaps most importantly, it makes policy-makers morally, politically and in the case of France, also legally, responsible for regulatory policy-making: if irreversible harm results from their decision or non-decision, it is now clearer whom to blame.

## 5. Europe in comparative perspective

In a number of important respects, contemporary European regulatory politics resemble those of the United States from the late 1960s through the mid 1980s. During this period, an influential segment of American elite and public opinion became more risk-averse, often focusing on the dangers of new technologies rather than their potential benefits. Indeed, there is a striking parallel between the debate in America during the early 1970s over public funding of a supersonic transport and European views on GMOs: in both cases, a significant segment of the public saw no public benefits associated with the proposed new technology, only increased risks. The significant expansion and increased political influence of public interest lobbies in the United States during the 1970s parallels the growth of NGOs and the Green Party in Europe during the 1990s. The expanded regulatory role of the American federal government is the counterpart of the increased regulatory competence of the EU. Both developments provided increased opportunities for the representation of civic interests and led to a wide range of relatively stringent regulatory standards. Indeed, as already noted,

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<sup>49</sup> Quoted in Breyer, S. and Heyvaert, V. (2000) "Institutions for Regulating Risk", in Revesz, R., Sands, P. and Stewart, R. (eds.), Environmental Law, the Economy, and Sustainable Development, Cambridge: Cambridge University Press, p. 316. For a comparison of judicial review of regulatory policy in both the EU and the US, see Breyer and Heyvaert, in *ibid*, pp. 283-252. For a detailed analysis of European legal developments, see Heyvaert, V. (1999) "The Changing Role of Science in Environmental Regulatory Decisionmaking in the European Union", 9 Law and European Affairs, pp. 426-443.

the constitutional structure of the EU - with its separation of powers and federal division of responsibilities - resembles that of the United States.

Finally, the United States, like Europe, experienced a decline in public confidence in government regulation due to the perception that it was ineffective: Rachael Carson's *Silent Spring*<sup>50</sup>, Ralph Nader's *Unsafe at Any Speed*<sup>51</sup>, Love Canal and the Exxon Valdez oil spill were the American counterparts to mad-cow disease, dioxin in the food supply, and contaminated blood. And just as the United States created a new set of regulatory institutions and administrative mechanisms to improve public accountability, so is Europe in the midst of transforming its regulatory structures to make them more transparent and accountable.

Yet though the politics of regulatory policy-making in Europe during the 1990s resemble that of the United States during the 1970s, there is little sign of increased policy convergence. This is partially due to the fact that NGOs, the public and policy-makers in Europe and the United States have worried about different product or processes and therefore focus on different issues. During the 1970s, Americans were preoccupied with the environmental and health effects of chemicals, especially cancer risks, while in Europe in recent years a disproportionate amount of public concern and regulatory policy-making has focused on food safety and agricultural production. Because Americans have been more concerned about the risk of cancer than Europeans, the United States established a separate set of regulatory procedures for handling potential carcinogens which treated them differently, and more strictly, than products or processes which posed health dangers other than cancer. (This in part explains the relative stringency of American anti-smoking regulations).

By contrast, no European regulation treats potential carcinogens differently than any other public health hazard. In the case of GMOs, the pattern is precisely the opposite: US law treats the environmental and health risks from GMOs no differently than from any other food product or food production technology while Europe, by contrast, has established a distinctive, and more rigorous, set of regulatory requirements for GMOs. Indeed, to the extent that the application of the precautionary principle to GMOs requires evidence of zero risk to both the environment and consumers, it may well represent the European counterpart to the Delaney Clause.

There is also an historical reason for the lack of convergence of European and American regulatory policies. Contemporary European regulatory politics resemble those of America in the 1970s, not America of the 1990s. And in some respects, American regulatory politics during the 1990s resemble those of Europe prior to the mid 1980s. In recent years, public confidence in technology, business and government regulation have increased in the United States, just as they have declined in Europe. (Significantly, while 90 percent of Americans believe the USDA's statements on biotechnology, only 12% of Europeans trust their national regulators<sup>52</sup>). The degree of public anxiety about the pervasiveness of threats to public

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<sup>50</sup> Carson, R. (1962) *Silent Spring*, New York: Fawcett Crest.

<sup>51</sup> Nader, R. (1965) *Unsafe at Any Speed*, New York: Grossman Publishers.

<sup>52</sup> Enriquez, J. and Goldberg, R. (2000) "Transforming Life, Transforming Business: The Life Science Revolution", *Harvard Business Review*, March-April.

health, safety and the environment, coupled with a lack of faith in the capacity of governments to adequately protect them from business, has diminished in the United States over the last ten to fifteen years, while it has increased in much of Europe.

Part of this shift in the United States may be due to the absence of any major regulatory failures - or certainly none on the scale of contaminated blood in France, dioxin in animal feed in Belgium or mad-cow disease in Great Britain. There have been periodic consumer safety and environmental scares, but they have been relatively minor and their political impact has been short-lived. While the EU is struggling to put into place a regulatory structure capable of adequately protecting the safety of food produced in fifteen Member States, each with their own regulatory institutions, and each Member State is attempting to upgrade its own regulatory institutions, the United States has in place a relatively well-established set of national regulatory bodies which appear to function reasonably well. In a sense, while the American regulatory structure underwent its baptism of fire, Europe is only beginning to address the challenge of balancing scientific risk assessment with the maintenance of public confidence.

In addition, it may well be that Americans have become somewhat less risk adverse. In the United States, beginning in the 1980s and continuing in the 1990s, the market-oriented values of competitive individualism became increasingly influential. For many Americans, 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 well partially explain the degree of public acceptance of GMOs - technologies which one suspects had they been introduced into the United States two decades earlier may well have received a rather different public reception. Moreover, the faith of many Americans in the capacity of risk assessment to objectively define a product or technology as "safe" or "unsafe" stands in sharp contrast to the situation in Europe, where the public embrace of the precautionary principle appears to reflect a post-modern view of science, one in which scientific truth and thus risk assessment is socially constructed - and thus indeterminate.

Yet it is not the case that American health, safety or environmental standards have been weakened. The two most important exceptions - the 1996 Food Quality Protection Act amended the Delaney Clause with regard to pesticide residues and the FDA's drug approval policies have been significantly liberalised (while twenty years ago it was rare for a drug to be first approved for use in the United States, now it is typical) - are widely regarded as having improved rather than weakened the effectiveness of American consumer protection. Yet at the same time, the pace of American regulatory policy-making has clearly slowed. The 1990 Clean Air Act Amendments, along with the Oil Pollution Act enacted during the same year, represent the only important pieces of environmental legislation enacted into law during the last twelve years. The Clinton Administration did issue executive orders strengthening various standards, most notably in the area of air pollution, and the courts have

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come to play a more active role in shaping regulatory policy, mostly notably through law suits against the tobacco industry, but these developments are exceptional.

While regulatory policies have become more politicised, politically visible and contentious in Europe, their political salience in the US declined during the 1990s. While NGOs and Green parties have become more influential in Europe, the political strength of consumer and environmental lobbies has either stabilised or eroded in the United States. While the regulatory agenda continues to expand in Europe, it has stabilised in the United States. Thus a wide range of regulatory policies are now stricter in Europe than in the United States.

## **6. Conclusion**

As noted at the outset of this paper, comparative studies of risk regulation in the United States have generally emphasised the distinctiveness of the American approach to health, safety and environmental regulation. But developments in Europe over the last ten to fifteen years require us to revise this portrait of American exceptionalism. In a number of important respects the “American style of regulation” is no longer confined to the United States: it has also emerged in Europe, though with respect to different issues. This paper represents a preliminary effort to develop a more general theory of the politics of consumer and environmental regulation and the policies which flow from it - one which can illuminate both the growing similarities in regulatory politics and processes and the continued divergence in policy outcomes among the advanced industrial economies of the west.

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