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**Improving the Quality of Risk Regulation:  
Lessons from the United States and the European Union**

David Vogel  
University of California, Berkeley

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## **Improving the Quality of Risk Regulation: Lessons from the United States and the European Union**

David Vogel  
University of California, Berkeley

This paper will focus on suggestions for improving the quality of regulatory policies that address health, safety, and environmental risks. This is both an important and challenging dimension of government regulation. It is important because as a result of technological changes and scientific advances, new potential or actual risks are continually emerging. It is also challenging because although there is a broad consensus that protecting environmental quality and public health and safety is a core responsibility of governments, there is often considerable disagreement about which specific risks government regulators should address.

Policy disputes over the appropriateness of specific risk regulations are often highly contentious. They often hinge on scientific data or evidence which the public may find difficult to understand or whose conclusions or policy implications can be ambiguous or disputed. Moreover, the public's risk perceptions can be highly emotional.

Moreover, risk regulations often involve considerable uncertainty: they are typically based on predictions about the costs of compliance and the seriousness of the harms or dangers policymakers are seeking to ameliorate or may or may not prove accurate. For this reason, there can be both false positive and false negative policy errors. Critics can often point to regulations that subsequently turned out to be unnecessarily strict or too lax, which in turns challenges the legitimacy of both policymakers and the regulatory policy process.

This essay reviews and compares a number of health, safety, and environmental regulations adopted by the United States and the European Union during the last half-century. Faced with similar or identical risks, how did regulators on both sides of the Atlantic respond to them? I plan to judge or assess their policy responses by two criteria. First, how effective were policymakers in protecting the public and the natural environment? For example, if the decision was made not to regulate, was the public or the environment made worse off? Alternatively, if a regulation was adopted, did it actually make people healthier or improve the quality of the natural environment? The second standard for assessing these regulations has to do with public acceptance and legitimacy. Did the policy that was made (or not) made meet with public approval? Did it strengthen or weaken public confidence in the regulatory process?

This approach provides a useful, if not unusual, opportunity to make such assessments for two reasons. First, because several of these regulatory policy decisions were enacted some time ago, we now have the benefit of hindsight: we can see what actually happened as a result of government action or inaction. Second, because European and American regulations often differed, we can use a comparative lens to assess them. My objective is not to judge whether on balance European or American risk regulatory policies were 'better' or 'worse. It is rather

to draw out the policy implications of their various decisions. What lessons can they teach us about how risk regulations can be improved?

One important category of risk regulations involves the safety of food products. Important examples are the decisions of the European Union to ban the use of beef hormones, to require approval of the milk hormone rBST and to restrict the use of genetically modified ingredients in food. In each of these cases, American and European policymakers made opposite choices: beef hormones were not banned in the US, rBST was approved for use in the US and the US has adopted a highly permissive policy toward the introduction of genetically modified ingredients into processed foods.

Importantly, each of the regulatory restrictions that were adopted lacked adequate scientific justification at the outset. In fact, there were few if any substantive differences between the risk assessments presented to policymakers on both sides of the Atlantic. At the times these decisions were made, there was a broad scientific consensus that there were no adverse health effects from consuming animal products produced with the use of hormones. Nor was there any evidence that the risks from consuming genetically modified food were any different from consuming food grown from seeds that had been cross-bred rather than genetically modified.

We now have the benefit of considerably more research on each of these risks. We also have what essentially amounts to a controlled experiment. We can actually make a reasonable assessment if, for example, the food processes or products banned or restricted in Europe but permitted in the United States have impaired the health of Americans and improved those of Europeans. On the basis of what we now know, the original risk assessments appear to have been correct. Measured by their achievement of their actual policy objectives, the restrictions or bans adopted by governments in each of these cases were ineffective. The risks they addressed turned out to have been exaggerated and thus they made no contribution to improving the public's health.

But if we judge each of these decisions by the criteria of public acceptability, then they were effective. There has been relatively little second-guessing of the legitimacy of these decisions by either the American or European public. Nor are European consumers upset that they do not have the option of consuming meat from cattle or dairy products from cows to whom hormones had been administered. Likewise public anxieties about the health risks of food from genetically modified seeds remains strong in Europe and the public generally regards the restrictions adopted by the EU as legitimate.

If one turns to the United States, there was never any public pressure to ban beef hormones, and while the approval of RBST was initially quite controversial, public concern about its risks quickly faded. Likewise, public concerns about the safety of genetically modified foods has been episodic rather than sustained. Most Americans still remain unaware that they are consuming them. In short, if we measure these American regulatory policies by the criteria of legitimacy and public acceptance, each of them was effective.

These differences between the two measures of effectiveness described above are not unusual. Numerous scholars have observed significant differences between the public's risk perceptions and those of scientific experts. This in turn, raises a critical question for policymakers: what should they do in such cases? To whom should they defer: the perceptions of the public or the advice of their scientific advisors? Clearly, there are no easy answers to these critical questions. One possible strategy to adopt in such cases is to make regulatory bans or prohibitions provisional – an approach which the EU's precautionary principle officially endorses in cases of scientific uncertainty – but which it has rarely adopted in practice. This would enable policymakers to respond to intense public pressures, which they often must do retain to their legitimacy, but to do so in a way that leaves open the possibility that the public's risk perceptions might change. They could subsequently issue new regulations which were more closely aligned with scientific assessments of effectiveness, and then gauge the response of the public to them to determine if the salience of the earlier perceived risks had diminished. In the interval, regulators could embark on a public education strategy to change and better inform to the public's risk perceptions.

There is of course another policy option, namely for regulators to hold firm and not yield to the public's (mis) perceptions. This is the choice made in the United States with respect to the controversy over the approval of the milk hormone rBST. There was substantial public opposition to approving its use; some critics claimed that its introduction threatened the purity of milk, while others argued that use raised health and safety risks. The FDA responded to these concerns by conducting extensive testing. It concluded that dairy products from cows who had been treated with rBST were essentially indistinguishable from those that had not received the growth hormone. Since the public's risk perceptions were misinformed they agency decided it could not act on them. Accordingly, since there was no scientific basis for withholding approval of rBST, the agency proceeded to authorize its use

This decision was subsequently vindicated: no contrary evidence as to its health risks subsequently ever emerged and the political controversy over the agency's decision to approve its use proved short-lived. Thus this decision did not impair the agency's reputation or the legitimacy of its policy judgment. What did happen, however, was that a number of dairy farmers and producers of consumer dairy products decided not use the hormone. They labeled their products as "BST or hormone free". As an increasing number of consumers indicated their preference for dairy products made without the use of the hormone, over time the use of rBST has steadily declined. Thus the market rather than regulators enabled some consumers to avoid consuming products that they considered unsafe. But at the same time, the economic benefits of the hormone were available to many dairy farmers, which was not the case in the European Union.

The dangers of being too responsive to the public's risk perceptions are clearly revealed by American drug approval policies. In response to substantial and intense public concerns that the FDA's procedures for assessing the safety of drugs was too lax, federal drug approval procedures were significantly tightened in the early 1960s. This policy shift certainly strengthened public legitimacy of American drug approval policy as the agency was being responsive to heightened concerns about drug safety. But it also created new health and safety risks. For drug approval procedures, can many other risk regulations, involve trade-offs.

Specifically, if it is more difficult or time-consuming for new drugs to be approved, fewer consumers may be harmed by consuming approved drugs that turn out to be unsafe. But more patients may be made worse off by having to wait longer to be allowed to use drugs that turn out to be beneficial i.e. both safe and effective. Alternatively, it is easier for a new drug to be approved, more patients may be injured by consuming unsafe drugs, but fewer may be harmed by the unavailability of drugs that turned out to be safe.

Politically, the policy choices made the FDA certainly made sense: they were responding to public fears about unsafe approved drugs. Where the agency erred was in not continually reviewing the effectiveness of its regulations. The policies it had adopted in response to the perceived Thalidomide policy failure of the early 1960s persisted, notwithstanding increasing criticisms of its “overly” stringent regulatory approval procedures. Moreover, the FDA could have readily assessed the relative harms of the two kinds of risks by following developments in Europe, where drug approval procedures had not been significantly strengthened in the early 1960s. For it turned out that in this case, European regulatory officials had chosen a more effective regulatory strategy. In fact, no more European patients were harmed by taking unsafe drugs than in the United States. But, significantly, many more had benefited from their access to many safe and effective drugs that were available only much later in the United States. The fact European drug approval policies had remained insulated from public pressures turned out to be welfare-enhancing.

It took more than a quarter-century for American drug approval policies to be brought more closely in line to those in Europe and for the trans-Atlantic “drug lag” to finally end. But in the meanwhile, American policies had actually harmed many of the patients they were intended designed to protect. This case underlines four important lessons. First, it is important for regulators to continually reassess and review the actual impact of their policies. Second, regulators also need to also closely follow and possibly learn from different decisions made by other officials in other jurisdictions. Third, it is important to recognize that more stringent regulations may only not be more effective; they may actually be welfare diminishing. Finally, it is important to acknowledge that many important regulatory decisions involve trade-offs: reducing some risks may increase others.

Another important category of risk regulation involves environmental risks. During the 1970s and 80s, two new risks emerged on the policy agenda on both sides of the Atlantic. They were linked to airborne lead emissions and a category of widely used chemicals, known as CFCs. The American and European responses to the risks of these risks differed substantially: the United States moved much more rapidly than individual European countries and the European Union to phase or restrict their use.

The initial available data about the significance of the risks posed by emissions of lead was suggestive rather than conclusive. But American officials were persuaded that the lead from automotive exhaust did pose “an immediate threat to public health,” and accordingly proceeded to restrict its addition to gasoline. A federal court then agreed with a suit brought by the manufactures of lead additives challenging this restriction on the grounds that it was “arbitrary and capricious”. The court went on to argue that the Environmental Protection Agency was required to demonstrate “actual harm, rather than just significant risk” - a

standard of scientific proof or certainty that EPA was unable to meet. However, a higher court reinstated the lead restriction. It held that EPA *could* act on the basis of “significant risk.” According to the court, the Clean Air Act on which the lead restriction had been based was “precautionary in nature and does not require proof of actual harm before regulation in appropriate.”

This judicial discretion enabled American regulatory authorities to progressively restrict the lead content of gasoline until its use was finally phased out, which essentially eliminated airborne lead emissions. While these policy decisions meet with public approval, they were not taken as a response to public pressures. Rather they flowed from a regulatory agency’s understanding of its responsibilities to protect public health and its ability to make policies on the basis of risks that were potentially dangerous, but which available scientific evidence had been unable to establish with sufficient certainty.

By contrast, European officials were initially much more reluctant to move against the lead content of motor fuel. They insisted on a higher level of scientific proof of harm. An advisory body to the European Commission reported that there was no compelling scientific evidence that “lead posed an immediate danger to public health.” After reviewing several scientific studies, the *British Medical Journal* concluded that “there is, so far as we are aware, no new evidence to justify [the argument] that there is a strong likelihood that lead in petrol is permanently reducing the IQ of many of our children.” For its part, the Royal Commission on Environmental Pollution observed that the average concentration of lead in the blood of the British population was 25% less than the level required to produce overt symptoms of blood poisoning.

In the United States, the EPA did not require public pressure to conclude that the risks of airborne lead were credible and unacceptable. But it took substantial public pressures in Great Britain, before in the words of the *Economist*, its regulatory authorities decided to “play it safe and go for a ban on lead despite the cost and scientific uncertainty.” With the support of Great Britain and Germany, the EU reversed its position and began to progressively reduce the lead content of motor fuels. However lead was not finally banned from petrol sold in the European Union until 2005 – more than fifteen years after it had been banned in the United States.

In the case of this gap between the public’s risk perceptions and those of scientific experts, the former’s assessment proved to be more accurate. As a result, European citizens were exposed to higher amounts of lead for a longer period of time than their counterparts in the United States. What European policymakers did learn from this and other policy failures was the need to adopt a more flexible approach to risk assessments – specifically to not require a high degree of scientific certainty before issuing a regulation, especially in cases when “potentially dangerous effects,” had been identified. Had the EU adopted this precautionary principle earlier, it would have been more likely to restrict lead sooner.

In the case of chemicals that could adversely affect the ozone layer, American and European policy-makers again initially made very different decisions: the United States moved much more rapidly to phase out their use than did individual European countries or the

EU. That lead was dangerous had been known at least since Roman times; where European and American authorities specifically differed was whether the amount of lead released in the atmosphere by the burning of motor fuels posed an unacceptable public health risk. But in the case of CFCs, the initial evidence as to the dangers it posed was much more tangential. It emerged as a result of a 1974 scholarly paper that suggested that the environmental release of CFCs might deplete atmosphere ozone. This in turn would enable more ultraviolet light to penetrate to ground level, thus increasing the risks of skin cancer.

Importantly, this finding of a link between CFCs and ozone depletion was theoretical; there was as yet to empirical evidence that the ozone layer was actually thinning. Not surprising, the paper's findings found little to no acceptance by scientists on both sides of the Atlantic. A British atmospheric scientist dismissed the ozone depletion theory as "utter nonsense," an appraisal that was shared by many of his American counterparts. What prompted the marked differences in the responses of public authorities across the Atlantic was public opinion. The risks of environmental cancer had recently become more politically salient in the United States, and the power of environmental lobbies had increased. Environmentalists were urging the American government to ban all CFCs and these public pressures forced public officials to take the study's findings seriously.

Fueling public engagement in the United States was the extensive media coverage of this issue. This in turn made the public aware that an important source of CFC emissions was the widespread use of aerosol hairsprays and deodorants. "The fear of skin cancer from the depletion of stratospheric ozone due to the use of CFCs as aerosol propellants in spray cans personalized the risks for many people . . . The public came to view the risks of using CFC-based aerosols as unacceptable." These risk perceptions meet with a political response.

A task force convened by the American government issued a study that supported the CFC/ozone depletion theory and its links to skin cancer. It placed the burden of scientific proof on the critics of the original study, concluding that a regulatory response was appropriate unless its findings were clearly challenged. A year later the National Academy of Sciences confirmed the assessment of the task force, but also indicated that was unable to specify the urgency of the health and safety risks posed by CFCs. In 1977, Congress included language in its amendments to the Clean Air Act that authorized the Environmental Protection Agency to regulate any substance affecting the atmosphere which may "reasonably be anticipated to endanger public health or welfare." In response, the following year, the United States acted in a precautionary manner by banning all nonessential uses of CFCs.

An important factor prompting the relative lack of regulatory response in Europe - which made only token reductions in CFC usage - was the absence of public pressure. Revealingly, while there had been a massive boycott of personal hygiene products that used aerosol propellants in the US, demand for such products remained high in Europe. Indeed, the American manufacturers that had decided to stop using CFC propellants in the personal hygiene products they sold in in Europe saw their sales decline. This lack of consumer engagement in turn reinforced the view of European regulatory authorities that that the American regulations were "over-hasty" and were decisions on disputed scientific evidence.

In short, public preferences vindicated or reinforced the views of European policymakers, who decided not to take the risks of ozone depleting chemicals seriously.

It took the dramatic 1985 finding by a British scientific study team that there was a fact a large hole in the ozone layer over Antarctica to change European public policy. As one scientist observed, ‘now we’ve got a hole in our atmosphere that you could see from Mars . . . it is label to label [it] as just a computer hypothesis.’ Yet even now important transatlantic policy differences persisted with the Americans, who had already banned the use of roughly half of all CFCs, more willing to enact stricter controls on the remaining uses of the chemicals than their European counterparts.

In this case, the risk perceptions on the American public – and the willingness of American regulatory authorities to take them seriously – result in a better regulation. For subsequent evidence revealed that the CFCs did pose both a creditable and unacceptable public health threat. The initial decisions on both sides of the Atlantic were legitimate in that both were a response to public pressures and were widely accepted. But by being too responsive to (the lack of) public preferences and consumer choices, European officials failed to take the initial risks of CFCs sufficiently seriously, thus delaying the international cooperation needed to address them.

There are two important lessons from this case. The first is that public risk perceptions should not be dismissed; they deserve to be taken seriously. Policymakers need to engage in additional research to determine if the public’s fears, concerns and anxieties are valid. Sometimes, they may prove to be; other times they are not. The second is that regulators need to seriously consider the risks of delaying regulations until there is unambiguous evidence of harm.