

Research Methods and Approaches

Theorizing and Generalizing about Risk Assessment and Regulation through Comparative Nested Analysis of Representative Cases

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This article provides a framework and offers strategies for theorizing and generalizing about risk assessment and regulation developed in the context of an on-going comparative study of regulatory behavior. Construction of a universe of nearly 3,000 risks and study of a random sample of 100 of these risks allowed us to estimate relative U.S. and European regulatory precaution over a thirty-five-year period. Comparative nested analysis of cases selected from this universe of ecological, health, safety, and other risks or its eighteen categories or ninety-two subcategories of risk sources or causes will allow theory-testing and -building and many further descriptive and causal comparative generalizations.

I. INTRODUCTION

This article provides a framework and offers strategies for theorizing and generalizing about risk assessment and regulation developed in the context

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of an ongoing comparative study of regulatory behavior. Construction of a universe of nearly 3,000 risks and study of a random sample of 100 of these risks allowed us to estimate relative U.S. and European regulatory precaution or stringency over a thirty-five-year period (Hammitt et al. 2005; Swedlow et al. forthcoming). Comparative nested analysis of cases selected from this universe of ecological, health, safety, and other risks or its eighteen categories or ninety-two subcategories of risk sources or causes will allow theory-testing and -building and many further descriptive and causal comparative generalizations.

With some exceptions, testing and building general theories of risk assessment and regulation ultimately requires broad, representative data of high quality (see, e.g., King, Keohane, and Verba 1994; Brady and Collier 2004; Coppedge 1999, 2005, 2006; Lieberman 2005). The lack of such data also prevents accurate descriptive generalizations about interesting and important regulatory behavior. Unfortunately, scholars have not selected cases nor organized themselves and their research in a way that allows them to test and build general theories or to generalize about risk assessment and regulation (see Kagan 1995; Wiener 2003; Levi-Faur 2006 for related points).

In the initial phase of this research project, for example, we found a significant body of literature comparing the relative precaution embodied in European and U.S. risk regulation (cited in Hammitt et al. 2005 and Swedlow et al. forthcoming). Some scholars claim that Europe is more precautionary than the United States, and others claim that the United States is more precautionary than Europe. A variety of other patterns have also been suggested. Evidence to support these generalizations consists of comparative case studies, sometimes of one policy area, such as genetically modified food, or sector, such as workplace safety or chemical regulation, other times of diverse cases within one sector, such as environmental regulation, or various sectors, such as environmental, health, and safety regulation.

The varied and opposing generalizations are not surprising given the cases selected for comparison. When different scholars study different sets of regulatory cases of unknown and unestimable representativeness, they more likely than not will arrive at nongeneralizable and frequently contradictory conclusions. General theories of risk assessment and regulation cannot be validated on such inadequate empirical foundations. Unfortunately, these problems are ones that precautionary research shares with comparative regulatory research of all stripes (as further discussed in Wiener 2003).

While there are no studies of risk assessment and/or regulation that are based on a large set of representative case studies, nor, consequently, any studies that seek to test theories of risk assessment and/or regulation on such a representative population of cases, two studies embody elements of improved approaches to the study of risk assessment and regulation that we hope to build on here.

Allan Mazur's *True Warnings and False Alarms: Evaluating Fears about the Health Risks of Technology, 1948–1971* (2004) is an attempt to study a fairly large number of cases (thirty-one), systematically selected from a

larger set of cases (forty-five), less systematically selected by another scholar from an even larger number of cases (200+). Mazur's study suggests how it might be possible to conduct case studies that allow inferences about a larger population of cases. Moreover, Mazur's study demonstrates that a fairly large number of cases can be studied in sufficient depth to permit valid quantitative analysis of the results and shows how such analysis can be used to test four hypotheses about risk assessment and regulation (as further discussed in Swedlow 2005 and Swedlow et al. forthcoming).

Christopher Hood, Henry Rothstein, and Robert Baldwin's *The Government of Risk: Understanding Risk Regulation Regimes* (2001), meanwhile, compares three theories—regarding market failure, public opinion, and interest groups—for their ability to explain variation in the assessment and regulation of nine risks. These scholars do not claim that these nine risks, or their assessment and regulation, are representative of any larger population of risks. However, their methods of operationalizing rival theories and scoring the assessment and regulation of the nine risks on various dimensions of variation could be replicated with a larger set of representative cases and, as they recognize, the results could be quantified, allowing statistical analysis, and an estimate of the actual explanatory power of rival theories.

Hood, Rothstein, and Baldwin find that some of the variation in risk assessment and regulation that is not explained by the three theories they test is explained by the cultural theory developed by Mary Douglas, Aaron Wildavsky, and others, including Hood, an obvious candidate theory to test as an explanation for such variation.¹ Studying the assessment and regulation of the 100 representative risks will also help advance long-running debates in comparative studies of regulation about the relative influence of international, national, policy sector, and temporal influences on risk assessment and regulation (as discussed in Levi-Faur 2004; see also Vogel 1996).

As we will discuss, Hood, Rothstein, and Baldwin suggest that all regulatory regimes will have some common elements, implying that *any* theory of risk assessment and regulation would have to account for variation in these. After surveying theories of regulation, other scholars conclude that there are public, private, and institutionalist theories of regulation, and that *all* theories of regulation seek to explain certain aspects of regulation (Morgan and Yeung 2007).

These observations help support the development here of five empirical research questions that should be common to all theories of risk assessment and regulation. Answers to these five questions should allow the testing and building of many such theories. The five questions and the extent to which they have been answered by ongoing student research in courses taught by one of us will be briefly described in this article.

Finally, this article seeks to exploit recent advances in comparative research methods that combine qualitative, case-study approaches with quantitative, statistical ones. These methods of “nested analysis” require

some theory and some quantitative analysis of relationships in a large population of cases and use that theory and quantitative analysis to select specific cases for in-depth study (see Seawright and Gerring 2008; Lieberman 2005; and Coppedge 2005). This article will explain how “nested analysis” can be used to select cases for study from among the 100 representative risks.

In what follows, we describe the construction and categorization of our data-set or “risk matrix,” assess the representativeness of the sample of 100 risks that we randomly selected from it, outline how we characterize relative U.S. and European regulatory precaution regarding these representative risks, and summarize the results of our ongoing study thus far. Then, drawing on theories of risk assessment and regulation, we develop five empirical research questions and describe how these questions are being answered by students in courses taught by one of us. We next describe purposive and random case selection methods and provide examples of how one might use these methods to select matrix risks to advance theory development and descriptive generalizations about regulatory behavior. The purposive methods are all forms of nested analysis that combine quantitative and qualitative approaches to research. We close with a brief discussion of three research tracks along which we believe it will be most fruitful to proceed in order to theorize and generalize about risk assessment and regulation.

II. THE RISK MATRIX: A UNIVERSE OF HAZARDS THAT MAY BE ASSESSED AND REGULATED²

Threats to the environment and/or human health and/or safety are consistent candidates for risk assessment and regulation. Ecological, health, safety, and other risks thus provide a universe of hazards that may be assessed and regulated. All regulation may not be risk regulation, but risk regulation is an identifiable, very large subset of regulation. If the contents of this risk universe can be specified to a reasonable degree, we will be in a position to theorize and generalize about risk assessment and regulation.

As we were unable to identify a preexisting, ready-made risk universe from which to select cases for study, we developed a risk matrix: a nearly comprehensive list of risks. The matrix was constructed using an iterative search process. First, we identified lists of risks and pooled them. The task of finding risk lists began with a few well-known sources, such as Renn and Rohrman (2000), the U.S. Environmental Protection Agency’s (EPA; 1987) *Unfinished Business*, and numerous studies by Paul Slovic and colleagues (e.g., Axelrod et al. 1999; Englander et al. 1986; Fischhoff et al. 1991; Goszczynska et al. 1991; Hohenemser et al. 1983; Kraus and Slovic 1988; Lichtenstein et al. 1978; McDaniels et al. 1995). Next, we attempted to expand the risk list using a snowball method to pursue sources cited by these original sources. Third, we pursued other search methods, including

searching library databases and the World Wide Web, to ensure a thorough search for risk lists in the existing literature.

We attempted to find and include every study of risk perceptions and every risk-ranking exercise published in the United States or Europe since 1970. We focused on environmental, health, and safety risks, and ruled out sources that seemed to be exclusively about other kinds of risks. Although we did not include sources dealing exclusively with financial, business, or insurance risks, examples of these risks were on some of the lists we included, and so these types of risks are represented in our matrix (although not as diversely or frequently as if we had drawn lists from those literatures). The search was also limited to English-language sources and focused on sources from the United States and Europe. But, again, our search methods led us to include sources that covered other countries or regions. Thus, our risk matrix includes risk lists from many areas outside the United States and Europe.

While we intended to draw on a population of risk lists produced by scholars, governments, think tanks, and advocacy groups, our search resulted in a population drawn primarily from academic sources, particularly the literature on risk perception. We assume (1) that the risks appearing on scholarly lists reflect risks that are of concern to the people and organizations that scholars studied and (2) that the risk concerns of these people and organizations are representative of U.S. and European populations.

The search produced an original matrix of 11,992 “verbatim risks” (i.e., risks described exactly as on the list from which it was taken). These risks come from 403 risk lists³ from 252 sources.⁴ In almost all cases, the verbatim risks were associated with a geographic region. A total of 7,758 risks pertain to the United States, 1,712 to Europe, and 1,635 to both. The greater number of risks for the United States than for Europe may reflect the fact that the primary research was conducted in the United States with easier access to U.S. sources. It may also reflect a larger underlying volume of risk research produced in the United States than in Europe. We are unsure whether it could reflect a larger variety of risks having been of concern to scholars, policymakers, and the public in the United States than in Europe.

Since our study focused on the United States and Europe, the 887 risks (from twenty-nine risk lists and twenty-four sources) pertaining to other regions were deleted, leaving a total of 11,105 verbatim risks, 374 risk lists, and 228 sources. The final matrix includes only 10,869 risks because 122 unique risks were deleted when we decided they were not really risks or were too vague to study,⁵ and nineteen risks were inadvertently overlooked when transferring risks from one worksheet to another.

The matrix of 10,869 verbatim risks was condensed to 2,878 “unique risks” by combining essentially identical verbatim risks by reducing plurals and singulars to a common form, standardizing punctuation, and removing unique expressions.⁶

Although we attempted to develop as unbiased a process as practical for constructing the risk matrix, the snowball literature-search method we adopted may favor particular lines of research. We are confident, however, that if other researchers followed our procedures and criteria, they would produce a matrix substantively comparable to ours, albeit with some differences in distribution. While acknowledging these limitations of our matrix, we believe that given the time and resources available to us, it represents a nearly comprehensive list and a substantial improvement over previous studies.⁷ We believe our method of comprehensive literature search is superior to other possible methods such as surveying risks that are currently regulated, compiling lists from governmental publications, or focusing only on visible, salient risks (e.g., from news media coverage), because those methods omit risks that could be of concern but not yet regulated in one legal system or the other—precisely the kind of emergent risks that might in time be subject to precautionary regulation or that might illustrate interesting contrasts across the legal systems.

A. ECOLOGICAL, HEALTH, AND SAFETY RISKS

We initially decided to categorize matrix risks to get a sense of the geography and topography of the risk universe. What kinds of risks were there? And how many of each kind of risk were there? We also recognized that categorizing risks in this way could be useful in further studies of regulatory behavior. As we will discuss, our risk types provide a way to assess the representativeness of random samples drawn from the risk matrix, create a basis for purposive sampling, and can serve as controls for studying risks within categories and subcategories. Moreover, the categories and subcategories can be treated as units to be sampled as well as sampling frames, allowing two-stage sampling of matrix risks.

Recognizing that no method of classifying risks can serve all useful purposes (Morgan et al. 2000), we nevertheless developed two approaches to categorizing the universe of 2,878 unique risks: by endpoint (ecological, health, or safety) and by type of source or cause. The endpoint categories are not mutually exclusive, as a risk may pose ecological, health, and/or safety consequences. In contrast, the risk types are exclusive, so that each risk appears in exactly one risk-type category (although, as we will discuss, some risks can be assigned to more than one category).

We categorized risks as ecological, health, or safety depending on the endpoint, not the agent or vector. Although these terms are frequently used to describe risks, they are rarely defined, and definitions that do exist are often imprecise or conflicting. By our definition, health and safety risks threaten humans directly, while ecological risks threaten nonhuman endpoints. The U.S. EPA defines an ecological impact as “the effect that a man-caused or natural activity has on living organisms and their non-living

(abiotic) environment” (EPA 2002).⁸ We restate this definition as: *ecological risks are risks that may harm non-human organisms and their supporting physical conditions.* We describe these risks as ecological rather than environmental to encompass risks to both the abiotic environment and its organisms. We restrict attention to nonhuman organisms because risks to humans are classified under health and safety. Examples of ecological risks include biodiversity loss, oil spills, acid rain, pesticide and chemical pollution, and hazardous waste sites.

Distinguishing between health and safety risks is more difficult because both are risks to humans. Drawing from Center for Disease Control and Prevention (2003), Koren (1996), and *Webster’s Third International Dictionary* (1993),⁹ we define health as human physical, mental, and social well-being,¹⁰ where well-being is the unimpaired ability to perform vital functions. Characteristics that differentiate health risks from safety risks are identified by Kolluru (1996). Health risks typically derive from “chronic (long-term) exposure to low-concentrations” (*ibid.*: 4.6) and have long-latency, delayed effects. However, diseases can manifest years later from acute (short-term) exposures as well. Therefore, we define *health risks as risks that may cause latent illness, disease, or other impairments of health to humans as a result of acute or chronic exposure.* Examples of health risks include AIDS, pesticides in food, hazardous waste sites affecting humans, air pollution, cigarette smoking, and alcohol.

Kolluru (*ibid.*) states that “safety risks stem from acute hazards,” are usually characterized by a low probability of high exposure, high-consequence accidents, and have acute, immediate effects. “The endpoints are well defined: fatalities, injuries, and economic losses” (*ibid.*: 1.13). We define *safety risks as risks that may cause injury or fatality to humans as an immediate result of acute (i.e., short-term) exposure.* Safety risks include workplace accidents, automobile crashes, airplane crashes, bridge collapses, and terrorism. Although these safety risks may impair one’s health, these are immediate effects instead of long latency, so, for our purposes, we classify them as safety risks.

Table 1 reports the distribution of the 2,878 unique risks by endpoint category. Most risks affect more than one endpoint category. More than one-third of the risks affect all three endpoints, one-quarter affect two endpoints (usually health and safety), and one-third affect only a single endpoint. About 2 percent of the risks are classified as affecting none of these endpoints.¹¹ About three-quarters of the risks affect health or safety, and almost half affect ecological endpoints.

B. EIGHTEEN CAUSES OR SOURCES OF RISK IN NINETY-TWO SUBCATEGORIES

To categorize risks by cause or source, we read through the alphabetically organized list of 2,878 unique risks from top to bottom, assigning number 1 to the first risk and every risk that appeared similar to it, number 2 to the

Table 1. Ecological, Health, and Safety Risks

Endpoint category	Percentage in	
	Matrix	Sample
0 None	2.2	2
1.1 Ecological	2.7	3
1.2 Health	17.7	16
1.3 Safety	15.3	21
Total—one category	35.6	42
2.1 Ecological and health	4.2	1
2.2 Ecological and safety	3.6	2
2.3 Health and safety	17.2	16
Total—two categories	25.0	19
3 Ecological, health, and safety	37.2	39
Total—All	100.0	100
Total—All Ecological (1.1, 2.1, 2.2, 3)	47.7	45
Total—All Health (1.2, 2.1, 2.3, 3)	76.3	72
Total—All Safety (1.3, 2.2, 2.3, 3)	73.2	78

Table 1 previously appeared in Hammitt et al. (2005).

first risk that appeared different from category 1 and every subsequent risk that appeared similar to it, and so on. This helped us group similar risks together and allowed us to begin to see what subcategories might exist and how risks might have to be recategorized to gain the greatest logical coherence. This coding exercise also helped us to see that there was no one right way to code all risks, that there were tradeoffs in different coding systems, and that some risks resisted categorization.

The coding effort required many judgment calls. For example, many risks could fall into more than one category (e.g., environmental tobacco smoke could be classified as tobacco or air pollution). As we will see, this coding challenge creates opportunities to strengthen causal inferences and generalizations. Many of the challenges involved whether to establish a new category or subcategory, what to name it, and how broad or specific to make it.

This process produced eighteen risk-type categories, which were then given labels that encompassed their contents. The same process was used to generate subcategories within the categories. We ended up with ninety-two of these, as can be seen in Table 2.

Table 3 lists our eighteen major risk-type categories together with the distribution of the 2,878 unique risks among them. The frequency distribution by category in the matrix of 2,878 risks is presented in the third column. The smallest category (construction risks) includes only 1.4 percent of the unique risks, while the largest category (occupational risks) includes fifteen percent of the unique risks.

Table 2. 100 Risks Randomly Selected from a Universe of 2,878 Risks (and Their Distribution Across 18 Risk Categories and 92 Risk Subcategories)

Risk Categories (18) and Subcategories (92)	100 Representative Risks
1. CRIME AND VIOLENCE RISKS	Burglary* Sabotage* Firearms*
2. ALCOHOL, TOBACCO, AND OTHER DRUG RISKS	Sake* Smoking regulations* Pot smoking*
Alcohol risks Tobacco risks Drug abuse (Non-prescription illegal drugs) risks	
3. MEDICATIONS AND MEDICAL TREATMENT RISKS	Shortage of medicines Caffeine—chronic effects* Childbearing* Radiation therapy*
Adverse drug reaction risks Medical procedure risks Medical error risks not elsewhere classified Vaccination risks X-ray risks Other medical risks	Vaccination—side effects* Health care facilities and services— exposure to physical agents Health care facilities and services* Genetic engineering*
4. TRANSPORTATION RISKS	Aerospace manufacture and maintenance— environmental and public health issues* Aviation—commercial—noise* Aviation—commercial—crashes* Airport and flight control Bus—transit* Drinking and driving* Train accident* Submarine—accidents Transportation noise Highway safety* Automobile—bicycle accident* Snowmobiles Motor vehicle traffic
Space vehicle risks Aircraft risks Automobile risks Pedestrian risks Motorcycle risks Train risks Ship risks Other transportation risks	
5. ACCIDENT RISKS NOT ELSEWHERE CLASSIFIED	Fire/explosion* Disaster preparedness*
Explosive risks Fire risks Accident risks not elsewhere classified	
6. RECREATION RISKS	Snowboarding
Transportation as recreation risks Mountain recreation risks	

Table 2. Continued

Risk Categories (18) and Subcategories (92)	100 Representative Risks
Water recreation risks Aerial recreation risks Sport risks not elsewhere classified	Hang gliding Horse riding—falls, including racing Rodeo performer Jogging
Recreation risks not elsewhere classified	Rollercoasters* Amusement park rides Circuses and amusement and theme parks
7. WAR, SECURITY, AND TERRORISM RISKS	Anti-ballistic missile* War and terrorism* Nuclear weapons—test*
8. TOXIC SUBSTANCE RISKS	Nitrocompounds—aromatic* Hexachlorophene* Formaldehyde—workers* Polyvinyl chloride—living nearby* Timber preservatives* Ammonia*
Asbestos risks Metal risks Poison risks not classified elsewhere Household chemical risks Toxic substance risks not elsewhere classified	Metal manufacturing Hazardous response personnel
9. FOOD AND AGRICULTURE RISKS	Unsuitable eating habits Dieting Genetic manipulation—animals Biotechnology—ingredients in products* Deliberate release of genetic engineered organisms* Food processing and distribution* Charcoal broiled steak Food coloring
Pesticide and herbicide risks Diet and nutrition risks Genetically modified food risks Food product risks Biologically contaminated food risks Food additives and preservatives risks Food irradiation risks Other food and agriculture risks	Forestry*
10. POLLUTION RISKS	Dredging and dredge disposal* Nonpoint source discharges to surface water*

Table 2. Continued

Risk Categories (18) and Subcategories (92)	100 Representative Risks
Drinking water pollution risks Groundwater pollution risks Air pollution risks not elsewhere classified Outdoor air pollution risks	Carbon monoxide* Smog* Sulfur dioxide* Air pollution*
Indoor air pollution risks Noise risks Land pollution risks not elsewhere classified Solid and hazardous waste risks Nonhazardous waste risks Pollution risks not elsewhere classified	Industrial chemical release* Urban pollution*
11. ENERGY PRODUCTION RISKS	
Nuclear power risks Natural gas risks Hydroelectric power risks Solar power risks Geothermal power risks Non-ionizing radiation risks Other electric power risks Fossil fuel risks	Oil refineries* Transport of oil—transcontinental pipelines* Liquid propane trains
12. POLITICAL, SOCIAL, AND FINANCIAL RISKS	
Financial risks Political risks Social risks	Social/ethical/cultural impacts of technology*
Political, social, and financial risks not elsewhere classified	
13. ECOGEOLOGICAL RISKS	
Storm risks Earthquakes and other land risks Organisms other than humans risks Weather related risks, other than storms Solar and background radiation risks Volcano risks Wildfire risks Ecogeological risks not elsewhere classified	Termites attacking fruit crops Flooding of dikes*
14. GLOBAL RISKS	
Climate change/Greenhouse effect risks Stratospheric ozone depletion risks Biodiversity and habitat risks Asteroids/near earth objects risks	Sea level rise

Table 2. Continued

Risk Categories (18) and Subcategories (92)	100 Representative Risks
15. HUMAN DISEASE/HEALTH RISKS	
Cancer risks	
Cardiovascular risks	
Infectious disease risks	Mononucleosis West Nile virus*
Pulmonary risks	
Other physical illness risks not elsewhere classified	Heat stroke*
Mental health risks	Cognitive disorders*
Other health risks (not elsewhere classified)	Sleep Genes—defects predisposing to illness Gallbladder Neurologic malfunction Biological agents—pet hair, skin, and excreta
16. OCCUPATIONAL RISKS	
Occupational health and safety risks	Occupationally acquired infections of the lung Occupational carcinogens* Workplace violence* Ergonomics—sleep deprivation* Safety culture and management
Service industry risks	Jewelry Laboratory worker Hotels and restaurants—health effects and disease patterns*
Manufacturing risks	Engineer (deaths) Rubber manufacture—ergonomics Semiconductor manufacturing Woodworking*
Other occupational risks not elsewhere classified	Work at high altitudes CEO deaths Workplace—performance measures and compensation Safety and health training* Stone quarries*
17. CONSUMER PRODUCT RISKS	
Appliance risks	Television
Information technology risks	
Consumer product risks not elsewhere classified	Carpets and rugs
18. CONSTRUCTION RISKS	

*Note: As of September 2008, the five research questions described in the text have been answered for these fifty-eight risks by student researchers, to the extent described in the text.

Table 3. 18 Risk Categories

Category	Percentage in	
	Matrix	Sample
1 Crime and violence	1.8	3
2 Alcohol, tobacco, and other drugs	3.0	3
3 Medication and medical treatment	6.8	8
4 Transportation	8.2	13
5 Accident risks not elsewhere classified	2.4	2
6 Recreation	5.5	8
7 War, security, and terrorism	1.5	3
8 Toxic substances	9.8	8
9 Food and agriculture	9.5	9
10 Pollution	7.5	8
11 Energy production	5.0	3
12 Political, social, and financial	3.4	1
13 Ecogeological	4.0	2
14 Global	2.2	1
15 Human disease/health	9.7	9
16 Occupational	15.0	17
17 Consumer products	3.4	2
18 Construction	1.4	0
Total percentage	100.0	100
Total number	2,878	100

Table 3 previously appeared in Hammitt et al. (2005).

C. 100 RANDOMLY SELECTED RISKS

Recognizing that we could not possibly study all risks in the risk universe, we constructed the risk matrix so that we could select a subset of representative risks to study. To get a representative subset of risks, we drew a simple random sample of 100 risks from the final matrix of 2,878 unique risks.¹² The random sample appears to be highly representative of our universe of unique risks, as indicated by a chi-square test and by the sample's distribution across risk-type categories. A chi-square test provides no evidence to reject the hypothesis that the sample is a random draw from the final matrix ($\chi^2_{17} = 13.4$, $p = 0.7$).¹³ As shown in Table 1, the sample includes risks from all eighteen major risk-type categories except one, construction, which has the smallest number of unique risks and hence the smallest probability of being sampled. The largest number of risks (seventeen) comes from the largest category, occupational risks. The difference between the percentage of the random sample of 100 and the percentage of the matrix of 2,878 is 2.5 percentage points or less for all categories except transportation, which includes 13 percent of the random sample but only 8.2 percent of the matrix, a difference of 4.8 percentage points. The randomly selected risks span about half of the ninety-two risk subcategories, as can be seen in Table 2.

III. CHARACTERIZING RELATIVE U.S. AND EUROPEAN REGULATORY PRECAUTION

While we recognized that study of the assessment and regulation of these representative risks would answer a wide range of questions about regulatory behavior, the question we initially sought to answer was how precautionary the United States and Europe were relative to each other regarding the regulation of these risks. This section outlines our first efforts to characterize relative precaution and summarizes our findings thus far. The balance of the article then suggests how the matrix can be used to theorize and generalize about risk assessment and regulation, utilizing purposive and random sampling of matrix risks. In this further discussion we will occasionally refer back to this initial analysis of relative regulatory precaution.

To evaluate relative precaution between the United States and Europe, we compared regulation of the 100 randomly selected risks from 1970 through 2004. The first step was to gather all relevant regulatory information for each of the sampled risks in both regions over the past thirty-five years. The goal was to collect information about all major regulations, including date of enactment, quantitative measures of stringency, narrative legal language, expressions of or allusions to the Precautionary Principle or precaution, and other relevant information. Researchers scoured numerous sources for such information, including U.S. statutes, the *Federal Register*, and the Code of Federal Regulations; U.S. state laws and regulations; EU legislation, directives, and regulations; European national (member state) laws and regulations; judicial decisions (case law) in these jurisdictions; and scholarly commentaries, the World Wide Web, and library catalogs and databases. For each risk, a dossier was prepared synthesizing this research and scoring relative precaution over the thirty-five-year period. Challenges encountered in assembling and assessing this information and the ways in which we tried to address those challenges are discussed in greater detail in Hammitt et al. (2005) and Swedlow et al. (forthcoming).

We evaluated the information on U.S. and European regulations to determine which polity was more precautionary in each year from 1970 to 2004. We measured precaution by two components: earliness and stringency (Wiener 2002: 1513–14). The polity that regulates a risk earlier and more stringently than the other is considered more precautionary. We developed a comparison of the stringency of existing regulations in each year from 1970 through 2004. Regulations were analyzed by the date of enactment, not the date of implementation. This choice reflects which region first took action. Neither compliance nor effectiveness of regulations was considered in this task due to the extreme time and effort required to evaluate those highly contextual attributes. Our results thus reflect announced standards more than actual standards in practice. If there is a systematic tendency of one legal system to use more precautionary language, but to enforce that language less stringently than the other legal system, our scoring results

would reflect the language alone. Our comparison of regulatory stringency is purely categorical. In each year, we judge whether the United States or Europe has the more stringent regulation, but we did not attempt to distinguish cases where one regulation is only slightly more stringent than another from cases where one regulation is much more stringent than the other. We also did not attempt to determine the date at which information or awareness about a risk began to arise, and so we cannot compare earliness of regulation, relative to emerging information, across risks. Nor could we assess relative precaution in terms of earliness of regulation compared to the eventual manifestation of a risk.

For each year, a polity received one point if its overall regulation of a particular risk is more stringent than regulation in the other polity in that year. The score for a year is +1 if the European regulations are more stringent, -1 if the U.S. regulations are more stringent, and 0 if the regulations are equally stringent or if we were unable to determine which are more stringent. Therefore, positive scores represent greater European precaution, and negative scores represent greater U.S. precaution. Each risk received a score for each of the thirty-five years from 1970 through 2004. The more stringent (and thus precautionary) polity receives one point every year until a change in regulation occurs. When a change occurs, we evaluate how the change influences relative stringency. This approach automatically incorporates the earliness component because if one polity regulated a risk before the other, then until the second polity started to regulate that risk, the former is considered more precautionary. We calculated the average score for each risk over time, which is bounded between -1 and +1. An average score at the boundary of -1 or +1 would be achieved for a risk where the U.S. regulations were more stringent than the European regulations in *all* thirty-five years, and a risk where the European regulations were more stringent than the U.S. regulations in *all* thirty-five years, respectively.

We developed confidence weights to indicate our degree of assurance about which polity had the more stringent regulations in each year. The confidence weights range from 0 to 3, with 0 representing no confidence and 3 representing very high confidence in the relative-precaution score. Weighted scores were calculated for each year as the product of the confidence weight and the precaution score and normalized so the weighted scores are bounded by -1 and +1. This approach gives less weight to precaution scores that may be less reliable due to incomplete information. We prefer to rely on the confidence-weighted scores rather than the unweighted scores, as the confidence-weighted scores provide a more accurate picture of our judgments about relative precaution. To evaluate overall precaution and trends in precaution, we averaged the weighted and unweighted scores across risks.

Scores were assigned by two of the authors (Kall and Zhou), working independently. As described in Hammitt et al. (2005) and Swedlow et al. (forthcoming), the two sets of scores are similar, which provides some evidence for the reliability of the scoring process. The two sets of scores and

confidence weights were combined to provide a single set of consensus scores and confidence weights for analysis (consensus weighted scores for each risk and year are the product of the corresponding consensus confidence weight and consensus score). In cases where the researchers assigned the same score or weight, that value became the consensus value. In cases where they assigned different values, the consensus value was achieved by discussion. This method permitted sharing information and understanding between the researchers. Empirically, the consensus values are similar to a simple average of the two scores.

IV. SUMMARY OF TRENDS IN U.S. AND EUROPEAN REGULATORY PRECAUTION, 1970–2004

This section summarizes our estimates (developed in Hammitt et al. 2005 and Swedlow et al. forthcoming) of the extent to which one or the other region has exhibited more precautionary regulation of these representative risks, reporting both average trends and trends for each of the 100 risks over the thirty-five-year period. The risks take on nine of ten possible trends.

Relative regulatory precaution or stringency is of course only one regulatory area where the United States and Europe may be similar or different. And to describe trends is not to explain their causes or to assess their consequences. This summary of trends in relative regulatory precaution is consequently merely meant to be illustrative of the kind of systematic, generally valid results that can be obtained by studying our representative sample of regulatory activities.

Figure 1 shows the resulting patterns for the average of the 100 risks. The results are weakly consistent with David Vogel's (2001, 2003) flip-flop hypothesis. The unweighted score suggests that the United States exhibited greater precaution than Europe from 1970 through the late 1980s, including increasing relative U.S. precaution during 1980–89, and that Europe became relatively more precautionary during the 1990s and early 2000s. The confidence-weighted score suggests a relatively static balance of relative precaution from 1970 through the late 1980s, followed by increasing relative precaution in Europe during the 1990s and early 2000s. In contrast to the unweighted score, the weighted score is uniformly greater than zero, suggesting Europe was more precautionary on average in the 1970s as well as in later periods. Both scores, but especially the unweighted values, suggest a shift toward greater relative precaution in the United States during the 1980s, but the estimated magnitude of the change in average relative precaution is quite modest.

A complementary method for evaluating patterns of relative precaution is to identify a set of possible patterns and investigate how many risks are consistent with each pattern. Figure 2 reports the number of risks in our sample of 100 that are consistent with each of ten alternative patterns (using

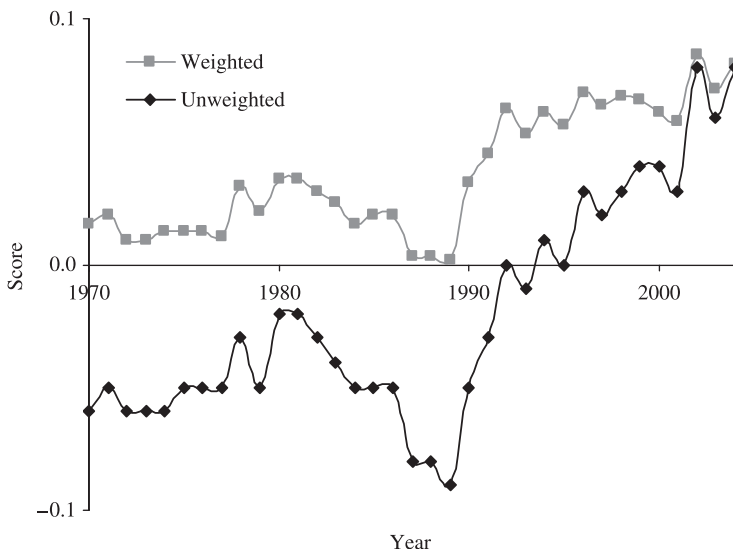


Figure 1. Trends in Relative Precaution (All Risks). Figure 1 previously appeared in Hammitt et al. (2005).

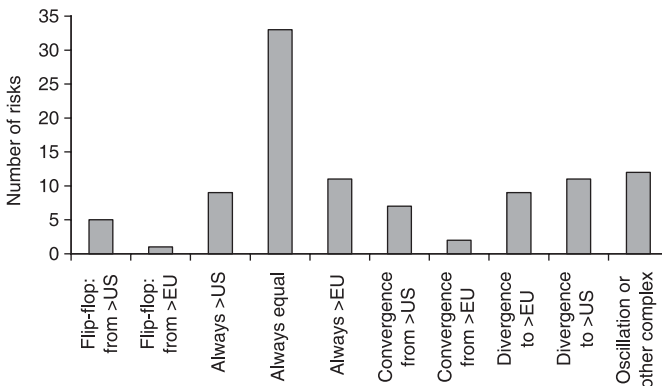


Figure 2. Patterns of Relative Precaution. Figure 2 previously appeared in Hammitt et al. (2005).

the unweighted scores). By far the most common pattern we identified (accounting for thirty-three risks) is that the United States and Europe are equally precautionary over the thirty-five-year period. To some extent, this finding of equal precaution reflects our inability to obtain full information about regulations in each region, and to make confident judgments about which of two sets of multidimensional regulations is, on balance, more stringent. But even excluding those risks we could not score for lack of information, equal precaution remains the modal pattern, at twenty-one risks.

Patterns reflecting a difference but no change in the direction of relative precaution are also common, accounting for twenty risks. These cases are almost exactly divided between the eleven cases where Europe appears to be more precautionary over the entire period and nine cases where the United States appears to be more precautionary. Of the cases in which there was a change in relative precaution, the change is more often toward greater relative precaution in Europe, but even here many cases show the opposite result. The direction of movement was toward greater relative precaution in Europe for twenty-one cases and toward greater relative precaution in the United States for fourteen cases. Only five cases took on Vogel's flip-flop pattern.

A fuller comparison of regulatory approaches would require collecting more information about how and why and with what results these risks are assessed and regulated the way they are. The next three sections describe steps that are being taken and might be taken to collect additional information on the assessment and regulation of matrix risks and to test and build theories of risk assessment and regulation.

V. CONTINUING THEORY-GUIDED RESEARCH ON RISK ASSESSMENT AND REGULATION OF MATRIX RISKS

Social scientists generally agree that data gathering should be guided by theory (see, e.g., King, Keohane, and Verba 1994; Brady and Collier 2004; Coppedge 1999, 2005, 2007; and Lieberman 2003, 2005). Since we cannot possibly study everything about subjects like risk assessment and regulation, the argument goes, we need theory to focus our empirical inquiries, to tell us what is important to study and what can be set aside. Social scientists also generally agree that theories should be as broadly stated as possible: general theories are preferable to theories of restricted range (King, Keohane, and Verba 1994). And that to validate broad, general theories, they need to be tested on data of equally broad range (King, Keohane, and Verba 1994).

Students of risk assessment and regulation have developed three general types of theories of regulation—public, private, and institutionalist theories—with several variants (surveyed in Morgan and Yeung 2007). However, students of risk assessment and regulation have not yet been able to test their broad theories on equally extensive data and certainly not on extensive representative data of high quality. The preponderance of general theories of risk assessment and regulation makes it difficult to find collaborators with shared theoretical interests, while collecting data to test regulatory theories of such broad scope would appear to require such collaboration. What, if anything, can be done to advance regulatory studies under these circumstances? Is there any common ground that suggests a way forward?

We think that there is. According to the authors of a recent text surveying the field, theories of regulation may be conceived of as expecting different answers to a common set of empirical questions:

A theory of regulation is a set of propositions or hypotheses about *why* regulation emerges, *which actors* contribute to that emergence and *typical patterns of interaction* between regulatory actors, [where]. . . regulation is seen as encompassing all forms of social control, whether intentional or not, and whether imposed by the state or other social institutions. (Morgan and Yeung 2007: 3–4, 16; emphases in original)

If research questions can be framed in ways that allow these empirical questions to be answered, then perhaps enough scholars will collaborate to answer them for a sufficiently broad range of regulatory activities to test various general theories of regulation.

Other regulatory scholars have suggested that in all regulatory systems

There must be some capacity for *standard-setting*, to allow a distinction to be made between more or less preferred states of the system. There must also be some capacity for *information-gathering* or monitoring to produce knowledge about current or changing states of the system. On top of that must be some capacity for *behaviour-modification* to change the state of the system (Hood, Rothstein, and Baldwin, 2001: 23; also quoted with approval in Morgan and Yeung 2007: 3; emphases in original).

If all regulatory systems indeed share these characteristics, then general theories of risk assessment and regulation should seek to explain similarities and differences in standard setting, information gathering, and behavior modification. And, again, these shared features point toward the possibility of posing a common set of empirical research questions.

One of us (Swedlow) has developed five empirical questions about risk assessment and regulation, the answers to which will answer the foregoing empirical questions that should be common to all general theories of risk assessment and regulation:

(1) How is the risk defined and assessed?

How do different public and private actors, including experts, interest groups, the media, and government agencies, define and assess the risk?

(2) Who regulates the risk?

What public and private actors, including international regulatory and non-governmental organizations, and federal, state, regional, county, and city level governments, regulate this risk?

(3) How is the risk regulated?

What statutes, regulations, judicial decisions, executive orders, legislative oversight, economic and other incentives, information provision and other policy instruments, discretionary actions, customs, or norms are used to regulate the risk?

(4) Why is the risk assessed and regulated the way that it is?

What political, economic, cultural, organizational, ideological, scientific, psychological, and other factors cause the risk to be assessed and regulated the way that it is?

(5) What are the consequences of assessing and regulating the risk the way that it is?

Is the risk reduced or eliminated as a result of regulation? Does regulating, reducing, or eliminating this risk, decrease, increase, or create other risks?¹⁴

Initial answers to these questions are being gained through case studies executed by students as research papers in Swedlow's graduate and undergraduate courses. Each student is asked to answer these five questions about one of the 100 representative risks. Research and interview guides that specify and elaborate what the answers to these five questions should contain are provided to student researchers. So far, the research guide is fourteen single-spaced pages and the interview guide is nine pages.

To this point, more guidance has been provided for answering descriptive questions 1–3, than causal questions 4–5. Guidance for question 4 consists of some operationalization of competing political cultural and economic theories regarding differences in risk assessment and regulation,¹⁵ as well as a list of potential causes and consequences of risk assessment and regulation culled from the literature (to answer questions 4 and 5, respectively), a list that was also given to scholars comparing precautionary cases in Wiener et al. (forthcoming). This listing is meant to sensitize student researchers to potential causes and consequences they might encounter in researching the assessment and regulation of their risks.

So far, this guidance has proved adequate to directing students to obtain comparable information regarding those aspects of descriptive questions 1–3 that are easiest to answer and therefore are being answered first in their research papers. Once these three questions are answered, additional guidance can be provided for answering questions 4–5, according to the theoretical interests of collaborating faculty.

Because students are answering these five questions with thickly described case study narratives (in which the five research questions serve as headings) rather than entering their answers into a spreadsheet, explanatory variables do not need to be classified at the outset as political, economic, cultural, organizational, ideological, scientific, or psychological. The same is true for other variables, including the consequences of risk assessment and regulation. Narrative case study contents can be classified by subsequent researchers in any way they wish. The information in these comparable case study narratives can be transformed into quantitative form by scoring the narratives on the answers to the five questions (or on any other criteria that the answers will support). In other words, the methods we used to score relative U.S. and European precaution can be extended to this data. As discussed in the introduction, exemplars of such scoring methods applied to case studies of risk assessment and regulation also can be found in Hood, Rothstein, and Baldwin (2001) and Mazur (2004). Mazur's methods are discussed further in Swedlow (2005) and Swedlow et al. (forthcoming).

Answers to these five research questions will also allow answers to empirical questions common to all general theories of regulation, as discussed above. That is, answers to questions 2–4 will answer questions common to all theories regarding "*why* regulation emerges, *which actors* contribute to that emergence and *typical patterns of interaction* between regulatory actors." And answers to questions 1, 3, and 5 will answer, respectively, questions

about information gathering, standard setting, and behavior modification. It is also important to emphasize that in addition to providing answers to theoretical questions, answers to these five questions will answer many descriptive questions of interest to a broad range of risk, regulatory, and other scholars.

Our study of relative U.S. and European regulatory precaution, for example, will be advanced by this ongoing study because it allows us to investigate whether the precautionary similarities and differences we find extend from adopted standards (the “law on the books”) to their implementation, including enforcement and compliance (the “law in action”); whether these precautionary similarities and differences are the same for definitions of precaution that differ from the one we used, allowing, for example, investigation of the relationship between risk assessment and regulation; whether these precautionary similarities and differences are the same *within* the United States and Europe at the level of member states and other political jurisdictions as they appear to be between the two regions; and, very importantly, this ongoing study will allow us to investigate the causes and consequences of any precautionary similarities and differences we find. Finally, this ongoing study creates a basis for extending our study of precautionary regulation to other polities around the world.

In the ongoing study, Swedlow’s students are asked to focus on how matrix risks are assessed and regulated in the United States at the federal level, and in Illinois at the state and local level. This allows us to utilize proximity and language skills, which facilitates the study of implementation and lays the groundwork for comparisons of member states and other political jurisdictions, such as counties and cities.

The first three of our five research questions have been provisionally answered for fifty-eight of the 100 representative risks for the United States and Illinois, with answers to questions 2 and 3 generally being more developed than answers to question 1. Several of the risks have been studied more than once—sometimes by the same student, other times by different students—deepening the answers to these questions, sometimes by going beyond Internet and library research to interview local regulators and regulatees regarding implementation of and compliance with regulations.

When collaborators join this research effort, it will be able to take on a “horizontal” comparative aspect, as faculty in other U.S. states and in Europe enlist their students in studying these same risks in their political jurisdictions, answering the same five questions about them.

A. THEORY-TESTING AND -BUILDING THROUGH COMPARATIVE NESTED ANALYSIS OF MATRIX RISKS

Scholars interested in using the matrix to test and build theories of risk assessment and regulation can also use the matrix to exploit advances in

comparative research methods. Political science methodologists have recently proposed ways to combine quantitative and qualitative research approaches so that they leverage each others' strengths and offset each others' weaknesses (see, e.g., Ragin 1987, 2000; Tarrow 1995; Coppedge 1999, 2005, 2007; Lieberman 2003, 2005; Bennett 2002; Brady, Collier, and Seawright 2004; and Seawright and Gerring 2008). These methods will be very helpful for theory-testing and -building regarding the assessment and regulation of matrix risks, and they also will help accelerate the gathering of data on matrix risks by providing rationales for selecting particular risks or risk categories or subcategories for intensive study and by providing guidance in interpreting the implications of these case studies. These are purposive rather than random methods of case selection, and they are also types of nested inference or analysis of cases.

Seawright and Gerring (2008) provide an extensive "menu" of purposive case selection techniques all of which begin with some quantitative analysis but do not require in-depth familiarity with each case. They define typical, diverse, extreme, deviant, influential, most-similar, and most-different cases and explain how to identify such cases within a large-N population, how each type of case can be used to test or build theory, and in what way(s) each type of case is representative of other cases. All of these case selection techniques can be used to select matrix cases, but only four will be discussed here to illustrate the potential the matrix holds for exploiting these techniques and to suggest how studies of risk assessment and regulation may be advanced by using them. Purposive case selection methods to be discussed here include variants of typical, deviant, most-similar, and most-different case selection techniques. We use our findings on relative U.S. and European precaution for 1970–2004 to illustrate how these case selection techniques might be operationalized using matrix cases.

We begin with most-similar and most-different research designs. Since we know which risks (and which risk categories) are most-similar and most-different in relative regulatory precaution, we can use that knowledge to select risks or risk categories for study. For example, researchers might expect risks within categories to be regulated by the same set of actors and institutions operating under similar conditions, so that where risks within a category are regulated with differences in relative precaution or other variables of interest, it should be relatively easy to pinpoint which one or few variables led to these differences.

A number of categories displayed significant within-category variation in precautionary regulation, with one or more risks regulated with greater precaution by the United States and one or more risks regulated with greater precaution by Europe. Of the three risks (burglary, sabotage, and firearms) falling in the crime and violence risks category, for example, burglary is regulated with greater precaution by the United States, while firearms are regulated with greater precaution by Europe. Why is this so?

Whatever the reason(s), variation in regulatory agencies and actors are not likely to be prominent among them. As this example illustrates, categories can serve as controls for studying regulatory variation within them. Subcategories of risks should provide even more significant controls. Why, for example, are childbearing risks regulated with greater precaution by Europe, while radiation therapy is regulated with greater precaution by the United States? Both of these risks are in the subcategory of medical procedure risks and are therefore likely to be regulated by the same institutions and actors, so the causes of these regulatory differences probably lie elsewhere.

Conversely, where researchers are interested in understanding how a series of differences compound to maximize differences in precaution or other aspects of regulatory behavior, they can investigate risks in categories that are likely to be regulated by distinct actors and institutions operating under dissimilar conditions and focus on those risks across these categories that were regulated with the greatest differences in precaution.¹⁶ For example, alcohol, tobacco, and other drug risks are regulated by the United States with a greater “precautionary margin” over Europe than exhibited by the United States or Europe for any other category of risk. Meanwhile, war, security, and terrorism risks are regulated by Europe with a greater precautionary margin over the United States than Europe displays for any other category of risks. The three risks (sake, smoking regulations, and pot smoking) falling in the alcohol, tobacco, and other drug risks category are regulated with very similar differences in precaution. Consequently, there is more variation to explain between these two categories than among the individual risks within the alcohol, tobacco, and other drugs category.¹⁷ Thus, one might ask why this category of risks is regulated with greater precaution by the United States, while war, security, and terrorism risks are regulated with greater precaution by Europe. Whatever the answer, it probably has something to do with differences in regulatory agencies and actors.

This same logic should apply to studying, explaining, and understanding the consequences of regulatory similarities and differences other than precautionary ones.

Additional purposive case selection methods can be found in the “nested inference” proposed and practiced by Coppedge and Lieberman (and endorsed by Brady, Collier, and Seawright 2004) as a way of productively combining quantitative and qualitative research methods. This type of nested inference or analysis is the result of selecting typical and/or deviant cases to study from Seawright and Gerring’s menu.

In a compelling demonstration of the power of this technique, Coppedge operationalizes existing economic and regional explanations for democratic development with existing quantitative data and shows that these variables explain a significant portion of the democratic decline in Venezuela. Coppedge then turns his attention to explaining those aspects of Venezuela’s democratic

deterioration that are not accounted for in the quantitative analysis. This “residual” decline is best explained by a series of interconnected institutions, actors, and events unique to Venezuela, analyzed in typical qualitative fashion. Coppedge then restates these Venezuelan causes for democratic decline in more general terms, specifying when and how existing explanations for democratic decline may need to be modified to account for cases similar to Venezuela (Coppedge 2005).

For his part, Lieberman (2005) seeks to turn Coppedge’s demonstration of nested inference and Lieberman’s own efforts at such inference (2003) into more generally applicable (and operational) guidance on blending quantitative and qualitative approaches in fruitful ways. Like Coppedge’s approach, Lieberman’s “nested analysis” “combines the statistical analysis of a large sample of cases with the in-depth investigation of one or more cases contained in the large sample” (Lieberman 2005: 435–36). In both approaches, preliminary statistical analysis is used to test rival theories or explanations for patterns in the sample. If the statistical analysis allows the researcher to rule out particular theories, Lieberman proposes that “model-testing” case studies from the sample be used to establish that statistically correlated variables are indeed causally related (through “process-tracing”). These “typical” cases are “on-line cases” in a regression analysis. If the statistical analysis cannot rule out rival explanations, “model-building” case studies from the sample are used to specify rival (or new) explanations in ways that will allow them to be tested by further statistical analysis of the sample. These “deviant” cases are “off-line cases” in a regression analysis.

Both Coppedge and Lieberman begin their forms of nested analysis by operationalizing theory with existing quantitative data. “Indeed, the very feasibility of nested analysis is a product of the increasing availability of datasets produced by other scholars and international organizations, obviating the need for significant independent data collection, at least at this preliminary stage [of the nested analysis],” Lieberman notes (2005: 438). Coppedge, by contrast, while relying on existing data for his nested analysis of Venezuelan democratic decline, believes that fruitfully combining quantitative and qualitative approaches will require researchers to “collect different data and more data and do it more systematically and rigorously” (Coppedge 1999: 465). “The lack of high quality data for large samples is the main reason why the potential of large-N comparisons has not been realized more fully.” Quantitative analysts’ “units of analysis are countries and years, at best” (*ibid.*: 473–74).

Our data set has some of the characteristics that both Lieberman and Coppedge ascribe to existing data sets, and it has the potential to become the kind of high quality data set Coppedge envisions. The more information is collected across data-set cases through case-study narratives answering our five research questions, the more capacity the data set will have to support

nested analysis of and theorizing and generalizing about risk assessment and regulation. If quantitative data exist that will allow the investigation of hypothesized relationships between risk assessment and regulation and their causes, consequences, or other correlates, that data should be used to conduct those investigations. If, however, quantitative data do not exist that will allow the investigation of hypothesized relationships, as Coppedge thinks is commonly true, then researchers may wish to collect data on matrix risks to facilitate such analysis. We found ourselves in the latter situation when we tried to study the relative regulatory precaution of the United States and Europe. There were no data sets that we could identify that would allow us to conduct such a study. This is why we constructed the risk matrix.

It may be worth noting here that while the more readily obtained answers to research questions 1–3 may be thought of as mostly descriptive in character, they will permit causal analysis of certain relationships and hence can form the basis for selecting model-testing and model-building cases in the way outlined by Lieberman. Most obviously, answers to questions 1 and 3—how is the risk defined, assessed, and regulated?—will allow analysis of the relationship between risk assessment and regulation. If we begin with the baseline hypothesis, as Hood and colleagues do (2001), that more dangerous risks will be regulated more severely, then we can examine cases that conform to this expectation (to see if this is the real reason assessment and regulation are in alignment) as well as those that deviate from it (to see what other influences may be at work). The former are model-testing case studies, the latter model-building case studies. To the extent other influences are responsible for observed regulatory behavior (e.g., interest groups) student researchers can be directed to collect data on those influences across the 100 risks rather than on the larger set of potential influences, focusing and thereby accelerating the data collection effort. A new model including these influences should better explain the relationship between risk assessment and regulation and the causes of regulation. And it too can be tested and further developed by another iteration of case selection of both typical or model-testing cases and deviant or model-building cases. This process will help identify further important influences on regulation (perhaps market failure, public opinion, or political culture). Student researchers can then be directed to collect data on those particular influences rather than on a wider range of potential causes, leading to the construction of improved theory and another round of nested analysis of cases that are typical or deviant from the perspective of that theory, and so on.

B. THEORY-TESTING AND -BUILDING THROUGH FURTHER RANDOM SAMPLING OF MATRIX RISKS

Finally, it should be noted that our sample of 100 representative risks does not exhaust the possible uses of random sampling to advance theory-testing

and -building regarding risk assessment and regulation. Additional samples of both larger and smaller size might be drawn to advance various kinds of studies, including the ones discussed here. Clearly, larger samples of perhaps 200–500 cases would increase the power of statistical inferences about risk assessment and regulation of matrix risks. Larger samples also would allow inferences to be made about the assessment and regulation of risk categories and subcategories that presently have too few of the 100 risks in them to support such inferences. The primary reason not to draw a larger sample is the amount of effort it would take to study a larger number of cases. However, that challenge might be met by more focused data collection resulting from nested analysis of the 100 cases and by a division of labor among a larger number of student researchers, when collaborating faculty and their students join this effort.

Smaller samples might also be drawn, perhaps of twenty-five to sixty cases, in a second stage of sampling from the 100 risks. A smaller sample would continue to support inferences about the assessment and regulation of matrix risks, but would allow even fewer, if any, inferences to be made about categories and subcategories of risks. However, a second stage sample of sixty risks would probably be sufficient to support theory-testing and -building and generalizations about ecological, health, and safety risk categories that have over fifty risks each in them (see Table 1). The main reason to take a second, smaller random sample from the 100 cases is that it would accelerate data collection in the absence of achieving a more focused collection of data through nested analysis. Such an approach would also be likely to keep a wider set of scholars engaged in conducting this research, since a broader set of data can more easily be collected about a smaller number of risks. Also, a smaller, second stage sample would continue to support nested analysis, perhaps accelerating its contribution to focusing the data collection effort.

The matrix's categories and subcategories of risk also permit various kinds of stratified random sampling. For example, we have already randomly drawn but have not yet attempted to study the assessment and regulation of one risk from each of the ninety-two risk subcategories. Another stratified sampling technique would use the risk categories and subcategories to conduct multistage sampling. For example, twenty to twenty-five risk subcategories could be selected at random from the ninety-two risk subcategories, and then perhaps twenty risks could be selected randomly from each of these subcategories. This two-stage sample would allow strong inferences to be made about the twenty to twenty-five risk subcategories as well as preserve the ability to make inferences about the overall risk matrix. Also, the inferential power of these cases could be increased by allowing those risks that might be classified as fitting in more than one category to support inferences about all categories to which they could be assigned. This would be consistent with the classification of ecological, health, and safety risks, which were not treated as mutually exclusive categories.

Random samples drawn by any of these methods would continue to provide a basis for the nested analysis purposive sampling techniques just described.

VI. CONCLUSION

We believe, and hope that other scholars will agree, that the risk matrix creates unprecedented opportunities to advance theorizing and generalizing about risk assessment and regulation through comparative nested analysis of representative cases. We invite other scholars of regulatory behavior to think about how to use the risk matrix to answer research questions of interest to them.

To preserve the ability to theorize and generalize about risk assessment and regulation and not just about particular aspects of regulatory behavior, such as precautionary regulation, and to allow testing of many theories and not just one or a few, our inclination is to proceed along three interrelated research tracks.

On one track, Swedlow will continue to enlist his students in answering the five empirical research questions outlined above for each of the 100 randomly selected risks for U.S. federal and Illinois state and local regulation. On this research track, answers to questions 2 and 3—who regulates the risk and how the risk is assessed and regulated—will probably emerge first for the 100 risks. Answers to questions 1, how the risk is defined and assessed, and 4 and 5, what the causes and consequences of assessing and regulating the risk are, will require more fieldwork and therefore more money and time. (This is also true regarding gaining answers to questions 2 and 3 with respect to gathering information on implementation of regulations.)

On a second research track, consequently, we suggest a more focused research effort. To the extent sufficient theory and data are available to conduct nested analysis, such analysis can be used to select a few of the 100 cases for in depth study. If purposive sampling is not immediately possible or desired, a second stage of sampling of perhaps twenty-five to sixty of the 100 representative risks could help focus the research effort, allowing archival research and interviews to flesh out the answers to the five research questions for these risks more quickly than for the 100 risks.

On a third research track, we would suggest enlisting collaborators in other political jurisdictions who could replicate the study of the 100 risks and either nested analysis or study of the twenty-five to sixty randomly selected risks along these two tracks. This would maintain a cross-country, cross-state comparative aspect in this research, allowing theory-testing and generalizations about risk assessment and regulation across political jurisdictions.

As theories are refined and as data become available, the roles of the various causal variables and the extent of particular consequences can then be read off these case studies in a scoring effort that will compress all this

information and convert it to a quantitative form allowing further statistical analysis. This is consistent with Lieberman's vision of successive iterations of "large N" and "small N" analysis that inform each other and further specify and test rival theoretical explanations. This iterative process of theory-testing and -building should allow researchers to assess the relative explanatory power of the public, private, and institutionalist theories surveyed by Morgan and Yeung (2007), and the market failure, public opinion, interest group, and political cultural explanations investigated by Hood, Rothstein, and Baldwin (2001), among others.

Of course, some theories and concepts will undoubtedly need to be operationalized in ways that cannot be captured by coding rules developed and applied retroactively to the data generated by case studies answering the five questions. Some research questions will surely require gathering additional information regarding risks already studied or the selection of additional risks to study, perhaps by one of the methods outlined above, perhaps by other methods (see Flyvbjerg 2004 and Swedlow forthcoming for related discussion). Where possible, gathering of additional information or selection of these additional risks might be done in ways that build on or remain in constructive dialogue with information accumulated about risks already studied. The idea would be to cumulate knowledge and leverage existing theory and information as much as possible in asking and answering additional questions about risk assessment and regulation.

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NOTES

1. Cultural theory has been used to explain variation in regulation and administration by a number of scholars (see, e.g., Coyle 1993, 1994; Verweij 2000; Swedlow 1994, 2002a, 2002b; Hood 1998; Wildavsky 2006; Lodge, Wegrich, and McElroy 2008) and has emerged as the primary alternative to psychometric theories in explanations of variations in risk perception (see, e.g., Douglas and Wildavsky 1982; Wildavsky and Dake 1990; Wildavsky 1993; Jenkins-Smith and Smith 1994; Adams 1995; Ellis and Thompson 1997; Marris, Langford, and O'Riordan 1998; Slovic et al. 2000; Weber and Hsee 2000; Kahan and Braman 2003; and the ongoing research of the "cultural cognition" group at Yale Law School (<http://research.yale.edu/culturalcognition>)). For an overview of cultural theory applications to risk assessment and regulation, see the bibliography in Wildavsky (2006), also available at the cultural theory Web site (<http://users.fmg.uva.nl/vmamadouh/ggct/agate/basics.html>).
2. To maintain clarity regarding our methods and results, much of this section and the next two—Sections II, III, and IV—draws directly from our prior article on this topic, Hammitt et al. (2005). Where that article or forthcoming work provides information beyond that discussed here, we so indicate by in-text citation.
3. The 403 risk lists are not unique, because some were replicated in articles or book chapters. We include not only tables of risks, but also multiple risks appearing in figures, tables of contents, and even risks appearing in text. Case studies including two or more risks were also included.
4. Citations for these 252 sources can be found at Duke University's Center for Environmental Solutions Web site (http://www.env.duke.edu/solutions/precaution_project.html).
5. We used strict criteria to eliminate as few risks as possible, but some initially included in the matrix appeared unsuited to regulation (e.g., friend does not appreciate a gift) or too broad or vague (e.g., lifestyle, children, all accidents, exposure) to permit study of regulation. We erred on the side of including risks if we believed it was at all possible to study their regulation, leaving many difficult-to-study risks in the matrix.
6. For example, "police work" became the common label for risks that appeared as "policework" and "being a policeman." More controversial relabeling collapsed different aspects of the same risk into the relabeled risk. For example, if nuclear power was selected, a reasonable person would consider nuclear power plants, nuclear power accidents, radiation from nuclear power plants, employees at nuclear power plants, residents living near nuclear power plants, and so forth. Therefore, any unique risk that would clearly be studied if one was studying nuclear power was labeled as nuclear power. (Nuclear waste risks were kept distinct from nuclear reactor risks.) Unique risks that were more specific and might be considered in a case study were labeled more specifically. More specific risks were usually hyphenated with the more general risk first, followed by specifics. For example, the unique risk "East European nuclear power plants" was relabeled as "nuclear power—East European."
7. Developing a workable approach to constructing a risk universe, assembling the list of 11,992 verbatim risks from 252 sources, reducing it to 2,878 unique risks, organizing these into eighteen categories and ninety-two subcategories, coding the risks on various other characteristics (including environmental, health, and safety endpoints), and helping develop the sampling strategy, took approximately one year of work by a full-time postdoctoral fellow (Swedlow) and six part-time research assistants (including Kall). Finalizing the assembly and

categorization of risks, researching and scoring the sample of 100, and helping develop the sampling strategy, took an additional year of work by two full-time graduate research associates (Kall and Zhou), plus a few additional temporary research assistants.

8. EPA (2002) defines ecological/environmental risks as “the potential for adverse effects on living organisms associated with pollution of the environment by effluents, emissions, wastes, or accidental chemical releases; energy use; or the depletion of natural resources.” This definition includes humans, but not the abiotic environment. Kolluru’s (1996: 1.11) description of ecological/environmental risks focuses on habitat and ecosystem impacts. Risk characteristics include “subtle effects, myriad interactions among populations, communities, and ecosystems (including food chains) at micro and macro level.”
9. *Webster’s Third International Dictionary* (1993) defines health as “the condition of an organism or one of its parts in which it performs its vital functions normally or properly; the state of being sound in body or mind.” Similarly, the Center for Disease Control and Prevention (2003) defines health as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.” Koren’s (1996: 191) definition is comparable: “the avoidance of disease and injury and the promotion of normalcy through efficient use of the environment, a properly functioning society, and an inner sense of well-being.”
10. We include social and mental well-being for their own sake and where they influence physical well-being.
11. Examples include burglary and social/ethical/cultural impacts of technology.
12. We relied on Microsoft Excel software to generate the simple random sample of 100 risks.
13. The chi-square test statistic is the sum over the eighteen categories of $(O - E)^2 / E$, where O is the observed number of risks drawn from that category and E is the expected number if the risks are drawn randomly. From Table 1, for category 1 (crime and violence) the observed number is 3, the expected number is 1.8, and so the calculation yields $1.2^2 / 1.8 = 0.8$. Doing the analogous calculation for the other 17 categories and summing yields $Z = 13.4$. Under the hypothesis of random sampling, Z has a chi-squared distribution with 17 degrees of freedom (18 bins minus 1, because the sum of the observed frequencies must be 100%). The p -value is about 0.71, so we cannot reject the hypothesis that the sample is a random draw from the population.
14. Various kinds of risk trade-offs are discussed in Graham and Wiener (1995).
15. In addition to the cultural theory developed by Mary Douglas, Aaron Wildavsky, and others cited in note 1, the “post-materialistic” cultural theory developed by Ronald Inglehart and others (see, e.g., Inglehart 1990; Grendstad and Selle 1997; Carriere and Scruggs 2001) and the theory of American political cultures developed by Daniel Elazar and others (see, e.g., Elazar 1986, 1994; Dran, Albritton, and Wyckoff 1991; Gove and Nowlan 1996) are operationalized in the students’ research guide.
16. This technique is not exactly most-different case selection as defined by Seawright and Gerring (who indicate that the conditions allowing such selection rarely occur) but comes closer to being a hybrid method combining most-different selection with John Stuart Mill’s “method of difference,” which seeks to “maximize variance on both the dependent and control variables in order to eliminate variables that are less likely to exercise a causal effect on the different outcomes since they appear in both cases” (Levi-Faur 2006: 23). This technique may help facilitate temporal comparisons, as discussed by Levi-Faur (2004), as well as study of “path dependent” regulatory developments (such as those analyzed by Coppedge, discussed below).

17. Meanwhile, the war, security, and terrorism risks category has significant within-category variation to explain, with antiballistic missiles and nuclear weapons testing regulated with much greater precaution by Europe than war and terrorism risks, regarding which the United States is actually slightly more precautionary than Europe over the period. Here, one might seek to identify the causes of within-category variation in addition to discovering sources of between-category variation in regulatory precaution, using the categories as controls, as discussed above.

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