RISK, SCIENCE, AND POLITICS

KATHRY

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Risk, Science, and Politics

Regulating Toxic Substances in Canada and the United States

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and
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Preface

This book has its origins in a bi-national relationship. We met while in graduate school at the Massachusetts Institute of Technology – an American in political science, and a Canadian in chemical engineering in the process of transferring to political science. We both had professional interests in the regulation of risks to health, safety, and the environment, and immersed ourselves in the byzantine system of regulation in the U.S., both in our academic work and in work for the Congressional Office of Technology Assessment in Washington, DC. In 1987 we moved to British Columbia, where we were immediately struck by the differences in Canadian and U.S. risk regulation. We decided to undertake a more systematic comparison, and the idea for this book emerged.

At the University of British Columbia we were fortunate to have excellent graduate students who took keen interest in case studies for the project. Gregory Hein, now a doctoral student at the University of Toronto, co-authored the chapter on asbestos, perhaps the most complex in the book. Colleen Rohde, now the director of legislative services (municipal clerk) of the district of North Vancouver, co-authored the chapter on saccharin. Anjan Chaklader, now a graduate student at the University of Rochester, provided valuable assistance with the formaldehyde chapter. We apologize to each of them for what must have seemed an interminable delay in producing the complete project.

Along the way we have accumulated a number of debts. The Social Sciences and Humanities Research Council of Canada provided one of us with a research grant to undertake parts of this study and the

other with a doctoral fellowship. The research grant permitted the employment of invaluable research assistants: Jeff Waatainen, Randy Hansen, and Shannon Leggett.

A number of individuals have been kind enough to review parts of the manuscript or provide valuable advice, including Douglas Arnold, Steven Bayard, Alan Cairns, David Cohen, H.B.S. Conacher, J. Stefan Dupré, Michael Gough, John Harrison, Dale Hattis, James Henderson, Clyde Hertzman, Daniel Krewski, William Leiss, Ron Newhook, Len Ritter, and Andrew Ulsamer. Many government officials also provided information in interviews on a confidential basis. None of these people are responsible for any errors of fact or interpretation that we have made.

Some of this material has been published elsewhere. Parts of chapter 3 are based on Kathryn Harrison, "Between Science and Politics: Assessing the Risks of Dioxins in Canada and the United States," *Policy Sciences* 24 (1991):367–88. Parts of the section on alachlor in chapter 4 are based on George Hoberg, "Risk, Science, and Politics: Alachlor Regulation in Canada and the United States," *Canadian Journal of Political Science* 23 (June 1990):257–77. Finally, parts of chapters 3 and 8 are based on Kathryn Harrison and George Hoberg, "Setting the Environmental Agenda in Canada and the United States: The Cases of Dioxin and Radon," *Canadian Journal of Political Science* 24 (March 1991):3–27.

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Abbreviations

ADI	acceptable daily intake
ADt	air-dried tonnes
AHERA	Asbestos Hazard Emergency Response Act (U.S.)
AIA	Asbestos Information Association (U.S.)
AOX	adsorbable organic halogens
CANUF	Canadian Association of Urea-Formaldehyde Manufacturers
CAPCO	Canadian Association of Pesticide Control Officials
CBC	Canadian Broadcasting Corporation
CBS	Columbia Broadcasting System
CEPA	Canadian Environmental Protection Act
CGSB	Canadian General Standards Board
CHIP	Canadian Home Insulation Program
CIIT	Chemical Industry Institute of Toxicology
CMHC	Canada Mortgage and Housing Corporation
CPSC	Consumer Product Safety Commission (U.S.)
CSN	Confédération des syndicats nationaux (labour union, Quebec)
CSST	Commission de la santé et de la sécurité du travail (Province of Quebec)
DDC	District Court of the District of Columbia
DFO	Department of Fisheries and Oceans (Canada)
D.L.R.	Dominion Law Review
EDB	ethylene dibromide

EDF	Environmental Defense Fund (environmental group, U.S.)
EPA	Environmental Protection Agency (U.S.)
ERC	Environmental Reporter Cases
f/cc	fibres per cubic centimetre
FDA	Food and Drug Administration (U.S.)
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act (U.S.)
FR	Federal Register
FTA	Free Trade Agreement (Canada/U.S.)
GAO	General Accounting Office (U.S.)
GATT	General Agreement on Trade and Tariffs
GRAS	generally recognized as safe
HUD	Housing and Urban Development (U.S. Department of)
IARC	International Agency for Research on Cancer
ILO	International Labour Organization
mg/kg/day	milligram per kilogram of body weight per day
MP	member of Parliament
MTD	maximum tolerated dose
NAFTA	North American Free Trade Agreement
NAS	National Academy of Sciences (U.S.)
NCAMP	National Coalition against the Misuse of Pesticides (U.S.)
NDP	New Democratic Party
NOAEL	no observed adverse effects level
NRC	National Research Council (U.S.)
NRDC	Natural Resources Defense Council (U.S.)
OMB	(White House) Office of Management and Budget (U.S.)
OSHA	Occupational Safety and Health Administration (U.S.)
o-TS	ortho-toluenesulforamide
PB-PK models	physiologically based pharmacokinetic models
PCDD	polychlorinated dibenzodioxins
PCDF	polychlorinated dibenzofurans
pCi/l	picocuries per litre
PCPA	Pest Control Products Act (Canada)
pg/kg/day	picograms per kilogram of body weight per day
ppm	parts per million
ppq	parts per quadrillion
ppt	parts per trillion
R.S.C.	Revised Statutes of Canada
R.S.Q.	Revised Statutes of Quebec
SAB	(EPA) Science Advisory Board (U.S.)

TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin (dioxin) or 2,3,7,8-TCDD
TSCA	Toxic Substances Control Act (U.S.)
UDMH	unsymmetrical demethylhydrazine
UFFI	urea-formaldehyde foam insulation
U.S.	United States Reports (of Supreme Court decisions)
U.S.C.	United States Code
U.S.C.A.	United States Code Annotated
U.S.C.S.	United States Code Service
VSD	virtually safe dose
WARF	Wisconsin Alumni Research Federation
WL	working levels
WLM	working level months

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1 Policy Making amid Scientific Uncertainty

THE CHALLENGE OF REGULATING TOXIC SUBSTANCES

The emergence of environmental concern in recent decades has presented modern industrialized countries with a common challenge: how to protect their citizens from the risks of hazardous substances while simultaneously reaping the benefits of the activities that produce the hazards. Uncertainty, particularly with respect to the magnitude of risks posed by many substances, complicates the problem of balancing the risks and benefits of toxic substances. Scientists often cannot answer policy makers' questions about the risks. Faced with the possibility of lives at risk, however, policy makers seldom have the luxury of waiting for scientific consensus.

The demand for policy making amid uncertainty complicates already difficult choices. Rather than "simply" choosing between the health benefits and the economic costs of control measures, policy makers must consider the possibility that their factual premises are not correct. They must balance the possibility of incorrectly assuming that a substance is harmless, with potentially tragic consequences, against the possibility of falsely assuming that a substance is harmful, at substantial unnecessary cost to business, consumers, and workers.[1]

Two neighbouring countries, Canada and the United States, have approached the policy dilemma of toxic substances within subtly different social contexts and more sharply divergent political institutions and processes. In many ways the two countries have distinctive

"regulatory styles."[2] The principal purpose of this study is to evaluate the consequences of those regulatory styles for the regulation of toxic substances. The case studies in this volume compare the decisions the two countries made and the manner in which they made them. In comparing Canada and the U.S. our intent is not to arrive at facile conclusions about which country is doing a "better job" of regulating toxic substances. Rather, we believe that comparative studies can offer a better understanding of the strengths and weaknesses of both regulatory systems. Each country has much to learn from its own and the other's experience.

We have chosen cancer risk assessment as an illustration of governmental decision making about uncertain environmental health risks for a number of reasons. Cancer is a dreaded disease that is the cause of death for roughly 25 percent of Canadians.[3] The public in both countries is concerned, if not preoccupied, with chemical carcinogens. Although there is an unresolved debate over the significance of synthetic carcinogens relative to natural carcinogens and lifestyle factors, such as diet and smoking,[4] it is nevertheless true that, given high mortality rates associated with many types of cancer, each additional case of the disease can be tragic.

In undertaking this study, we were struck by the differences between the U.S. and Canadian government positions in a number of highly publicized cases of regulation of potential carcinogens, including saccharin, asbestos, and urea-formaldehyde foam insulation (UFFI). Often based on the same scientific evidence, one government (though not always the same one) would conclude that a substance posed unreasonable risks and respond by adopting control measures, while the other would reach the opposite conclusion. Why? In light of scientific uncertainty, did the two governments reach different conclusions about the *magnitude* of the risks, or did they weigh the risks and benefits differently, leading to different conclusions about the *acceptability* of the risks? To date such risk management controversies have received much more scholarly attention in the United States than in Canada. This book subjects the Canadian experience with regulation of toxic substances to closer scrutiny while also attempting to explore the reasons for U.S./Canada differences.

Finally, government decisions concerning potential carcinogens provide a fascinating example of the interplay of science and values in policy making. In particular, scientific uncertainty about whether there can be a "safe" level of exposure to carcinogens has important policy implications. In recent years many policy makers have abandoned the notion of absolute safety in favour of a probabilistic conception of risk. Rather than offer a qualitative assessment that a

substance is either "safe" or "unsafe," they describe risks quantitatively in terms of exposed individuals' statistical chances of contracting cancer. From a probabilistic perspective, it follows that even minute quantities of a carcinogen in the environment may present an unacceptable risk of cancer if human exposure is sufficiently widespread. The implications of this shifting paradigm are particularly profound in light of continuing improvements in our ability to detect trace levels of environmental contaminants. In contrasting the Canadian and U.S. experiences, this volume also uses the case of governmental regulation of carcinogens to explore the role of science in policy making in the two countries.

While our focus here is thus limited to carcinogens, the dilemmas for policy makers are similar to those found in other areas of health, safety, and environmental regulation. Other health concerns such as reproductive risks, or environmental concerns such as ozone depletion, global warming, or species preservation, also pose policy makers with the vexing regulatory dilemma of how to choose among policy options in the face of extensive scientific uncertainties.

In this introductory chapter we first explore the difficulties in drawing boundaries between science and policy considerations. We then introduce some of the differences between the processes by which the U.S. and Canada make regulatory decisions. The final section of this chapter provides a brief overview of the case studies and describes the evaluative criteria used in each.

SCIENCE AND TRANS-SCIENCE

In the early 1970s Alvin Weinberg observed that policy makers were increasingly being called upon to make policy decisions based on uncertain science.[5] Concerns about the impacts of modern technology on the environment compel decision makers to act despite uncertain advice because the possible consequences of waiting (e.g., global warming, adverse health effects, and depletion of the ozone layer) are perceived to be too pressing. Since Weinberg's seminal paper, a considerable literature has grown on the role of science in environmental and health policy making. The enterprise between politics and conventional science, combining elements of both in an often uneasy relationship, has been variously called trans-science, science policy, regulatory science, and mandated science.[6] Following Jasanoff's example we have adopted the terms regulatory science and research science to distinguish between policy-relevant science and more traditional laboratory science.

Salter has observed that regulatory science must combine the "truth-seeking" features of science with the "justice-seeking" features of the

legal process, resulting in an enterprise with characteristic institutions, participants, and procedures.[7] A common theme in the literature on regulatory science is that policy decisions based on uncertain scientific advice inevitably contain political or value judgments, either implicitly or explicitly. Those who make policy decisions, whether politicians, bureaucrats, or scientists, must invoke their own or others' values in choosing among a number of scientifically plausible alternatives. Thus scientific and policy choices become enmeshed.

Although scientific uncertainty underlies virtually all regulatory science debates, political conflict often exacerbates and sustains disagreements about scientific questions. Conflicting personal views and political stakes in the outcome lead different participants in the policy debate to advocate different scientific positions.[8] Lynn has showed that scientists working in industry, government, and academia tend to adopt different positions in a number of scientific controversies associated with the regulation of carcinogens.[9] Those employed by industry tend to adopt more risk-tolerant scientific assumptions than scientists working in government or academia. Graham and his coauthors observed that, contrary to the common assumption that additional scientific research will reduce uncertainty and thus political conflict, new research findings can actually stimulate conflict by clarifying the winners and losers in the political debate.[10]

The field of risk assessment developed in response to demands on regulators to make decisions about the safety of substances or activities in the absence of conclusive evidence. Risk assessment has been defined as "the characterization of the potential adverse health effects of human exposure to environmental hazards."[11] The practice of risk assessment involves applying scientific evidence and knowledge to questions beyond the normal scope of science, a trans-scientific activity to use Weinberg's term. The process of assessing and managing risk can been conceptualized by an idealized five-step model.[12]

1 Hazard Identification: An attempt is made to answer the question of whether or not the substance causes cancer.
2 Risk Characterization: The magnitude and distribution of human health risks are estimated based on assessments of the carcinogenic potency of the substance under review and the extent and nature of human exposure.
3 Identification and Comparison of Control Alternatives: Costs, technical and administrative feasibility, and distributive consequences of alternative control strategies are reviewed.
4 Choice of Risk Management Strategy: An acceptable level of risk and the means to achieve it are chosen based on intuitive or political

rationales or more formal decision criteria including risk-benefit analysis, cost effectiveness, "best available technology," or health protectiveness without regard to cost or feasibility.

5 Implementation, Review, and Adjustment of Control Strategy: Implementation of the control strategy is monitored to assess its effectiveness and to change the strategy if performance is not satisfactory.

The case studies in this volume focus primarily on the first four stages of risk assessment and management. In light of our interest in the role of science in policy making, the chapters focus in particular on the hazard identification, risk characterization, and risk management steps. The important task of comparing policy implementation in Canada and the U.S. remains for future work. We do, however, analyze one key component of that implementation stage: risk communication. The process by which regulators communicate information about risks to the public and attempt to justify their actions to the public is a fundamental element of the regulatory process.[13]

William Lowrance first proposed a rationalist distinction between risk assessment and risk management.[14] The essence of the distinction is that risk assessment seeks the answer to a question of fact – what is the risk? – while risk management seeks to answer a question of values – what should we do about it? Both U.S. and Canadian regulatory authorities purport to distinguish between risk assessment and risk management.[15]

Inasmuch as the assessment of risk clearly relies on science and the choice of risk management strategies clearly depends on values and politics, there has been a tendency to depict the risk assessment/risk management distinction as a separation between science and politics.[16] A more realistic appraisal recognizes that political considerations and values invariably enter into the risk assessment step, just as scientific understanding of risks constrains the risk management step.[17] Although risk assessment poses a question of fact, policy makers typically cannot answer it factually. In light of scientific uncertainty, they cannot avoid making value-laden choices among alternative scientifically plausible assumptions.

In practice risk assessment and risk management decisions are not always sequential, as the idealized model suggests. Even in the absence of scientific uncertainty, subjective values are engaged in deciding which questions of fact the risk assessment will address.[18] For instance normative conclusions about the reasonable limits of manufacturers' culpability could lead policy makers attempting to assess the risks posed by hazardous products, such as pesticides, to consciously ignore certain worst case scenarios, such as the extreme exposure that could

result from blatantly disregarding safety precautions. Moreover, risk assessors could unconsciously adopt other assumptions based on their own conclusions about the feasibility of different risk management strategies. Finally, decision making may be influenced by selfish interests and political power, quite apart from the purely rational and ethical criteria implied by the rational model.

While we acknowledge the incongruence between the real world of policy making and the rational model of risk assessment and risk management, we nevertheless offer it as an ideal. While it is true that both scientific and policy judgments are involved at each stage, we believe that it is worthwhile to distinguish between factual and ethical questions, however imperfect our available knowledge and institutions may render the answers. Thus we do not go as far as the so-called "social constructivist" school that emphasizes the extent to which risks are a social construct, with values so inevitably clouding risk estimation that any effort to separate the factual and value bases of decision making is fruitless.[19]

In doing so we place ourselves in a camp of "neoseparationists"[20] who continue to emphasize a distinction between risk assessment and risk management. There are two reasons for this. First, we begin from the premise that some substances do present greater risks than others and that the norms and methods of science, while imperfect, constitute our best bet for distinguishing among them. Second, we believe that some allocations of risks and benefits are more just than others, and that democratic institutions and processes are our best hope to approximate equitable solutions. While there is undoubtedly a grey area between conventional science and politics in which the two are inseparable, if we define the entire policy-making enterprise as within the grey area, we leave ourselves vulnerable to political decisions made by scientists and scientific judgments made by politicians. Our preference would be to acknowledge that policy and scientific judgments are both made at each step of the process, while encouraging regulatory scientists and political decision makers to make explicit the basis for their decisions so that we can explore the boundary where scientific advice ends and value judgments begin.[21]

PATTERNS OF POLICY MAKING IN CANADA AND THE UNITED STATES

While the policy problems the two countries face are very similar, they have often addressed them in very different ways. A growing comparative policy literature suggests that there are different "national styles of regulation."[22] The U.S. style has been characterized as open,

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