Smart Regulation and Risk Management

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by

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Executive Summary

This paper places the discussion of "smart regulation" in historical context – first, the history of controlling health and environmental risks in modern economies, second, the more recent history of the preceding decade, during which reviews of regulatory effectiveness have taken place. The history of risk regulation itself is the story of how modern societies constructed an "invisible shield" around individuals and social groups, in areas such as finance and markets, criminal behaviour, family and child welfare, public health, and industrial workplaces. Taken as a whole, these protective measures have become a dense structure of overlapping provisions for personal security – what is referred to as a "risk regulation regime." This structure is dynamic and not static and is in fact changing constantly. It is also a dense and complex structure, and so any attempt to revitalize it (in terms of effectiveness and efficiency) must be done with due care and attention to public expectations.

This is followed by a short explanation of the "risk-based approach," which lies at the heart of any risk regulation regime. Then we turn to the more recent history of regulatory review, which has taken us through concepts such as regulatory efficiency, regulatory effectiveness, and regulatory burden; "instrument mix" (referring to the array of policy instruments through which we seek to implement regulatory objectives); and the optimal policy mix. Each of these concepts is briefly explored.

The paper includes a proposal for "a way forward," in which it is suggested that we should develop the capability to conduct controlled experiments with regulatory structures. This paper makes the following specific recommendations:

1. Central agencies should establish an Office of Integrated Risk Management to oversee and assess the risk/risk tradeoffs that occur as a matter of course.
2. The Government of Canada should create and implement a wider set of policy instruments for risk regulation than what now exists.
3. A credible and transparent methodology for assessing the comparative efficiency and effectiveness of policy instruments for risk regulation should be developed.
4. The federal government should design and implement a robust method for risk forecasting.
5. Canada should be in the forefront of the creation of additional international assessment organizations to assist our national risk regulation regime.
6. Canada should undertake controlled experiments, using a transparent evaluation methodology, in seeking to improve the efficiency and effectiveness of our risk protection structures.

A. Introduction.

Health and environmental risk management – and the subset of that activity which may be called risk regulation – has been an active area of public policy debate, in Canada and elsewhere, during the past decade or more. Very active debates have occurred in both the United States and Australia during this period, for example.[2] In Canada, these debates have been oriented around such episodes (at the federal level) as the introduction of the "Regulatory Efficiency Act" (Bill C-62, 1994); the renewal of the *Canadian Environmental Protection Act* (1999); and, currently, Health Canada's proposals for "renewal" of the traditional basis of its legal and regulatory authority, the *Food and Drug Act*.[3]

Along the way, a good deal has been written about such concepts as "regulatory burden," "voluntary initiatives," an "optimal policy mix" for environmental policy, and others. I take the view that the present discussion about "smart regulation" ought to be understood as another step in this broader discussion, and what I have to say in this paper is framed accordingly. The second consideration, which also frames my analysis, is the need for an awareness of the long history of health and environmental risk management in Western democracies, stretching back over more than a century and a half. Again, in my view, no current discussion which ignores that history – and the challenges which are still presented to us, as recent episodes (such as SARS and BSE) illustrate well – will prove to be either relevant or enduring.

That said, it must be recognized that these present-day challenges have been severe and unrelenting – and there will be more of them. They are also very expensive, in terms of economic impacts. All of which means that Canada must re-examine, on an ongoing basis, the way it conducts the business of risk regulation. There *must be* a way forward,

in the sense of – at the very least – devising practical, real-life experiments in finding ways to achieve our collective objectives in health and environmental protection both more efficiently and more effectively.

The single most important caveat to be added here is, these are areas of great public sensitivity, in part because the public is aware of terrible tragedies – notably in the blood system and at Walkerton, Ontario – which are the direct outcome of *mistakes in regulatory policy and practice*.[4] In my view, the mistake that has been made so far in Canada, among those desirous of effecting changes in risk regulation, is to want to run before they have learned to walk. In other words, as indicated in the sections that follow, in some cases the proposed changes to established policy and practices have been far too sweeping and indiscriminate, having been based on either a superficial analysis – counting costs while ignoring benefits – or on an ignorance of the scope of the possible costs (human and economic) of the mistakes that have been made.

The appropriate course of action, in finding a way forward is to

> (a) identify a number of well-defined and limited areas of risk regulation where change might be desirable;
> (b) apply a robust methodology for comparative assessment;
> (c) design experiments *based on predicted outcomes*;
> (d) evaluate the results – under full public disclosure and transparency, and without ideological preconceptions – as to their degree of success or failure.

In the risk analysis literature of the last decade a huge amount of attention has been devoted to the issue of trust and credibility.[5] Anyone who works in this area, either as an academic analyst or as a practitioner in government or industry, ignores the dimension of public trust at his or her peril. In the general area of risk management, the

factor of public trust grows in importance with each passing year. Finding a viable way forward should be done with the objective of retaining public trust uppermost in mind.

B. Historical Overview: Risk and Regulation.

Seen from the angle of public policy, health and environmental risk regulation in Western democracies may be said to have begun with the episode of the "Broad Street pump."[6] In 1854 a physician, John Snow, investigating another in a series of cholera outbreaks in London, England, associated excess mortality with a specific source of contaminated water; his findings not only launched the discipline of epidemiology but also the practice of science-based public health strategies. The victories won since that time, especially in the control of infectious disease through sanitary measures and surveillance, are the enduring foundations for the entire edifice of risk management.

The later phases of risk regulation include: occupational health and safety regulation and workers' compensation schemes (late nineteenth and early twentieth century); consumer protection legislation (food, drugs, and product safety), dating from the first quarter of the twentieth century; and comprehensive environmental protection legislation, starting in the 1970s. In all these areas, of course, there is lively and ongoing debate about what works and what doesn't, and why.

Over a period of more that 150 years, therefore, modern society has constructed what may be called an "invisible shield" of protection for individuals and collectivities, embracing many and diverse types of risks. The major categories of protection include:

1. health and environmental risks;
2. markets, banking, insurance, finance, contracts, business practices;

3. regulation of labour and professions (medicine, law, accounting);
4. public safety and security (criminal code);
5. family life and child protection;
6. industrial standards (products, processes);
7. animal welfare.

The areas of life that are regulated or controlled include many aspects of individual and collective behaviour; tens of thousands of industrial and consumer products, processes, and services; workplaces; and thousands of specific chemicals, minerals, and metals, as well as biological agents (plants and pathogens).

There is a very broad variety of policy instruments through which these controls may be exercised, either through consensus or directive processes:

1. explicit statutory authority (police, public health);
2. regulation;
3. compensation for injury or accidental death;
4. voluntary standards (CSA, CGSB);
5. market-based instruments (taxes, incentives);
6. social-welfare support structures;
7. legal liability (class-action lawsuits);
8. insurance;
9. international conventions (Law of the Sea, etc.).
10. information dissemination.

As can be seen, domestic regulation *per se* is only one of a number of instruments, perhaps not even the most important one, for risk regulation in the broad sense. What this list also indicates is that regulation is a part of a large and dynamic structure of social institutions in the modern state. Because all these instruments are part of an

interconnected whole, changes to any important part of the risk regulation framework can have unintended or spillover effects, which ought to be taken into consideration.

C. The Risk-based Approach.[7]

There is clearly an imperative to explain what meaning we assign to risk for the purposes of managing risk. Kaplan and Garrick proposed that risk is a multi-dimensional entity comprising the answers to three questions:

- What can go wrong?
- How likely is it?
- What are the consequences?

The answers to these questions effectively amount to an assessment of risk.[8]

Risk situations form part of a seamless continuity bounded by *what is known with a reasonable degree of certainty*, on one side, and *the sphere of the (currently) unknown*, on the other. A risky situation as such is one that is expressed as a range of probabilities, within which there are one or more aspects of uncertainty, low or high:

What is (now) known	***What is "at risk"***	***What is (now) unknown***
Basic chemical, physical, and biological processes, theoretically described and /or experimentally validated	**Probable outcomes:** High ⟷ Low Uncertainties Low ⟷ High	Undiscovered or unvalidated chemical, physical, and biological processes / relations

This is a continuum, not an array of three independent categories. At the border where the category of the known shades into that of the "at risk," a physical process has been described and validated: A single particle of alpha radiation *can* initiate the long

process resulting in a fully-developed case of lung cancer, by causing unrepaired genetic damage in a single cell of lung tissue in an organism. (In other words, this is a well-characterized hazard.)

Now, let us say, we encounter the case of a person who *may have been* exposed – with a high degree of probability – to some amount of alpha radiation. What cannot be known, but only estimated (with varying degrees of uncertainty), is the probability that this particular person will go on to develop lung cancer. We can reduce, but not eliminate, some of these uncertainties if we know something about the genetic variability of the whole population, the genetic profile of the individual in question, and the relationship between genetic variation and the toxic dose of alpha radiation. But some uncertainties will always remain, because that is the very essence of risk itself.

On the other side of this border, "what is (now) unknown," reside the basic physical, chemical, and biological processes which remain undiscovered at present. For example, before 1984 the existence of the so-called "prion particle" (an infectious protein) was not known, and therefore the risk of prion disease, such as contracting the neurological disorder known as Creutzfeldt-Jakob Disease from transmission of infected tissue, could not even be estimated, as it now can be.[9] Since the process of scientific discovery is ongoing, we can expect that in the future a continuous stream of entirely new risks (or risk factors) will be uncovered and characterized – and that existing risk factors will be re-evaluated through new studies. But in all of the risk characterizations some uncertainties will remain, because uncertainty is an integral part of risk itself.

There are a number of problematic areas for public policy choices within the risk-based approach. One that requires careful attention is known as *risk-risk tradeoffs.* An

important study was published on this subject some years ago, Jonathan Wiener and John Graham's *Risk vs. Risk*.[10] I will summarize some of their main points here:

1. Virtually all decisions taken to reduce health and environmental risks (called the "target risk") involve some kind of tradeoffs whereby other ("countervailing") risks are affected; it is advisable to make a dedicated effort to assess whether those tradeoffs are *advantageous* or *disadvantageous* (i.e., whether they result in clear net benefits once the offsetting impacts are taken into account).

2. There are many reasons why the need for these comparative assessments is rarely recognized, and why disadvantageous tradeoffs occur, the most significant of which are jurisdictional divides between both levels of governments as well as between the many separate agencies at senior levels of government. Another important reason is that some "voices" among social interests are much more influential than others, in lobbying both governments and industry and in monopolizing public attention; this too can be a source of disadvantageous tradeoffs.

3. *Inadvertent risk transfers* are one of the most serious consequences of failing to assess risk/risk tradeoffs. For example, in a publicly-funded health care system, insufficient attention to children's health programs (and in Canada, especially for aboriginal children) can result in vastly increased incidence of illness and medical costs in later life – as well as premature morbidity – for individuals at special risk. Or, the public may be unaware that a process of "downloading" responsibility from one level of government to another may represent an unarticulated risk transfer – as happened in Ontario during the 1990s in the case of drinking water protection.

4. When the need for risk/risk tradeoffs is clearly recognized, carefully assessed, and competently communicated to the public, risk managers are doing their job. For example, Canadian Blood Services has had to undertake these tradeoffs, imposing a donor deferral program in parts of Canada to control the risk of spreading West Nile virus infection (thereby exacerbating the risk of inadequate supply of blood for medical treatment).[11] In my opinion they have assessed and communicated the need for these tradeoffs competently.

5. Proposed solutions to the serious problem of disadvantageous tradeoffs tend to focus on various strategies for centralizing risk management, by a combination of administrative changes (central agency control), judicial oversight (this applies only to the U.S. system), and greater reliance on international institutions.

6. My own assessment: There is a serious issue here that should be addressed. In terms of the Canadian governance system, by far the best option for introducing changes lies in establishing some form of central agency oversight (an "Office of Integrated Risk Management") in both federal and provincial governments. This Office would be charged with (1) developing and applying protocols for (a) identifying when risk/risk tradeoffs are occurring and (b) assessing whether they are either advantageous or disadvantageous, and (2) communicating effectively the methods and results both to risk managers and the public, so that social learning in this area can be advanced. This forms *Recommendation 1* in my paper.

D. Regulatory Burden and Regulatory Efficiency.

1. The Concept of "Regulatory Burden."

In Canada this concept has been promoted largely by the Fraser Institute, notably in a report entitled "Canada's Regulatory Burden," issued in 2001.[12] The wording chosen for the concept is itself provocative, and almost certainly was designed to be so. However, it was the mode of exposition chosen by the authors that is probably responsible for the limited attention bestowed on the report since its publication. The contention is that the direct costs of regulation (expenditures by federal and provincial governments) amounted to $5.2 billion in 2001; at the same time, the indirect economic costs of regulation to Canadians – in the form of costs of compliance born by firms – was $103 billion.

These are substantial sums, to be sure. What one needs to know, however, is the other side of the coin – namely, the benefits derived by Canadians from these expenditures. The Fraser Institute report acknowledges that such benefits do exist (such as law enforcement), but immediately adds: "It is beyond the scope of this study to measure the benefits of regulation." For all we know, therefore, this level of expenditure (assuming that it is correctly tabulated) may be a genuine bargain, in that it might yield – if we did the appropriate calculation – a level of benefits considerably in excess of

these costs. What is the value of the high degree of public safety and security we Canadians enjoy, for example? Whatever the answer might be, this one-sided analysis focusing on the costs of regulation alone, even assuming they are fairly tabulated, sheds no light whatsoever on either the efficiency or the efficacy of Canada's existing regulatory structures.

2. "Regulatory Efficiency."

This notion became part of what can only be described as a curious episode in the field of public administration in Canada. Very few Canadians had even encountered the concept before having it sprung on them in the title of a proposed piece of federal legislation, Bill C-62, tabled for first reading in 1994, presented as part of one of many different incarnations of a federal "innovation agenda." Both the bill itself, as well as the manner of its birth, elicited a strenuous response, little of which was favourable. The bill died on the order paper in 1995 and was never re-introduced.[13]

Todd Weiler, a lawyer who worked on the bill as a consultant with the Regulatory Affairs Office of Treasury Board Secretariat, provided in 1995 one of the few rationales for it that can still be accessed today: "Far from representing an assault on the rule of law, *Bill C-62*, *The Regulatory Efficiency Act*, is really a process-oriented bill designed to improve the way in which Canada regulates risk."[14] (The first part of his sentence gives some indication of its reception.) He wrote:

> Compliance plans – the meat of the bill – would be proposed by a regulated party in order to vary the prescriptive details of an existing, designated regulation. In this way, the regulation and its purpose – some form of risk reduction – remain of general application, but the means of compliance would be varied to suit different regulatory environments. Presented with a proposed compliance plan, the regulator would be under a duty to listen to and consider the party's ideas for an alternative to the existing regulation.

The concept behind the bill, at least in this formulation of its intent, was a distinction between means and ends, specifically, between a regulatory objective (in risk reduction) and the range of instrumentalities available to achieve it. This concept survives in the idea of smart regulation, as we shall see. The rest of Bill C-62 perished without a trace.

3. Voluntary Instruments and the "Optimal Policy Mix."

The so-called "CEPA review" process – the renewal of the *Canadian Environmental Protection Act,* 1988 – took, incredibly, six years (1993-9).[15] Although the final result was an act pretty much like its predecessor, the review period had witnessed an extensive discussion of policy instruments, particularly the notion of "voluntary instruments" as a mechanism for regulatory compliance. One reason for this was the existence of an actual case of a voluntary (more precisely: "proactive") initiative, undertaken by the Canadian chemical industry, known as "ARET" – the "accelerated reduction and elimination of toxic substances."[16]

A broader conception, known as the "optimal policy mix," emerged out of these discussions; the Conference Board of Canada sponsored a multi-year project on this theme.[17] Its overall thrust can be summarized as follows:

1. develop environmental objective/policy goal (end);
2. select policy instruments (means); and
3. evaluate impacts of alternatives and select preferred approach.

In the Conference Board document policy instruments ("means") include the following:

a) regulatory (bans, limits, standards);
b) economic (taxes, depreciation, tradable permits);
c) voluntary, non-regulatory (negotiated agreements, voluntary codes);
d) information (technical assistance, public information campaigns).

These were presented in the form of a menu, arranged along a continuum, with "formal structures" (equivalent to command-and-control measures) on one end and "informal structures" (equivalent to "flexible, voluntary" measures), on the other.[18] As we shall see, the core concepts developed in this phase of the risk regulation discussion are carried over intact into the concept of smart regulation.

E. The Concepts of Smart Regulation and Risk Regulation Regimes.

The most detailed study ever written on smart regulation will be found in the volume published in 1998 by Neil Gunningham and Peter Grabosky, *Smart Regulation: Designing Environmental Policy.*[19] One notes immediately its self-imposed limitation, namely, to environmental policy; thus it does not provide coverage for the broader domain discussed in this paper – health and environmental risk management. Nevertheless, it provides the only systematic thinking published to date on the concept of smart regulation itself. In the "Introduction" we read (p. 4):

> The central argument will be that, in the majority of circumstances, the use of multiple rather than single policy instruments, and a broader range of regulatory actors, will produce better regulation. Further, that this will allow the implementation of complementary combinations of instruments and participants tailored to meet the imperatives of specific environmental issues. By implication, this means a far more imaginative, flexible, and pluralistic approach to environmental regulation that has so far been adopted in most jurisdictions: the essence of "smart" regulation.

The authors also endorse the concept of "optimal policy mix" (pp. 25-31).

One can see immediately the congruence between this perspective and the earlier Canadian discussion (section D.3 above). What both do is first, to explicitly set aside the evaluation of regulatory objectives; second, to focus on the efficacy of the policy instrument mix in reaching those objectives; third, to endorse the idea of a flexible mix

of instruments as the "optimal" path to the achieving such objectives. They adopt the economists' terms of "efficiency" and "effectiveness" for seeking optimality:[20]

> By efficiency is meant the static aspects (i.e., what levels of administrative costs are associated with the instruments) and the dynamic ones (e.g., to what extent will the various instruments induce technological innovation or diffusion). By effectiveness is meant the degree to which the determined environmental objectives are achieved through the use of certain instruments.

In other words, *"smart" means, essentially, (a) having a wide range of policy instruments available for use, (b) being flexible in choosing various mixes, depending on specific situations, and (c) being able to evaluate the comparative efficiency and effectiveness of different instruments objectively and fairly.*

It may be objected at once that this conception of smart regulation can appear to be trivial. However, in my opinion this is not the case. For one thing, the definition italicized above reflects a measured approach to the task of changing regulatory structures, rather than one driven by ideological perspectives.[21] Thus Gunningham and Grabosky emphasize (p. 6), for example, the point that the "critique of command and control legislation can be seriously overstated." Second, just having a wide range of policy instruments available for use is no trivial task. The Government of Canada, for example, has carried on endless discussions about how to design, create, and manage markets for tradable emissions permits, but so far has failed to actually do anything along these lines. And European governments, led by the Dutch, have spent considerable time and effort in designing an appropriately robust legal framework for negotiated compliance agreements between government and industry, whereas in Canada ours are still too unstructured.[22] Thus *Recommendation 2* in this report: The Government of Canada needs to create and implement a well-designed set of wider policy instruments for risk regulation.

Third, without a credible methodology in place for the evaluation of the key criteria (efficiency and effectiveness), we are unable to make defensible judgments about optimal policy mixes for realizing specific objectives. Advocating the changing of regulatory structures in the absence of such a methodology is a case of the blind leading the blind. Needless to say, given the degree of controversy which can be, and has been, elicited by discussions about changing regulatory approaches, this methodology must have a high degree of transparency and public disclosure. Thus *Recommendation 3* in this report: A credible and transparent methodology for assessing the comparative efficiency and effectiveness of policy instruments for risk regulation should be developed forthwith.

The volume by Gunningham and Grabosky is a long and dense text, with detailed chapters on "varieties of regulatory instruments" and "instrument mixes," as well as elaborate case studies of certain industry sectors (chemicals, agriculture). These chapters cannot be summarized here; suffice it to say that a close examination of this text is a prerequisite for anyone who wishes to take up the challenges posed by the first two recommendations. A second study, published in 2001, *The Government of Risk: Understanding Risk Regulation Regimes,* is less directly useful for these purposes, but is still worthy of study and application in this same context.[23]

F. The Legacy of Regulatory Failure: Blood and Walkerton.

To restate here the basic premises of this paper: First, the fundamental objectives of Canada's risk regulation regime, for the management of health and environmental risks, is not in question: Canadians expect a high level of protection from risks to health and the environment, and they expect major institutions (governments and business) to

collaborate effectively in delivering such protection. Second, given the sheer size and complexity of our risk regulation regime in Canada, as well as its importance and sensitivity to our citizens, the condition of our contemporary risk regulation regime needs to be intensively examined, on an ongoing basis. Third, given the length of its history and evolution, our risk regulation regime most certainly can be improved, in terms of efficiency and effectiveness – but only if a fully transparent methodology for the comparative evaluation of instruments is designed and implemented.

Canadians are well aware that public policy and regulatory choices made by both governments and industry can lead to catastrophic regulatory failure. The two most serious cases of such failure in living memory are those of the blood system and the protection of drinking water in Ontario. With respect to the first, the detailed review conducted by Mr. Justice Horace Krever, and reported in his three-volume study in 1997, revealed massive fault lines in the existing risk regulation regime for blood safety, due to (among other things) gaps between the responsibilities of various parties, namely the federal government, the blood products industry, and the Canadian Red Cross.[24] Incredibly, the nature of some of those fault lines, which extent back in time to 1981, are still being revealed.[25]

In the case of the tragedy at Walkerton, Ontario, where seven deaths and hundreds of serious injuries resulted from failures to control *E. coli* contamination in drinking water in May 2000, the inquiry conducted by Mr. Justice Dennis O'Connor identified specific policy and program choices in the Ministry of Environment's risk regulation regime that played a determining role in bringing about this tragedy. These program choices affected, among other things, the policy instrument mix though which drinking water protection was supposed to be delivered.[26]

In general, for the whole range of risk regulation regimes in Canada (for environmental and health risks), Canadians do enjoy a comparatively high level of protection. However, they are keenly aware that these regimes have a certain fragility and may be compromised, inadvertently, through changes in policy choices and the instrument mix.

G. Contemporary Challenges: SARS and BSE.

Only brief mention of these two cases will be made here, for the purpose of indicating that Canada still today experiences shortfalls in its risk regulation regimes – shortfalls that can have, in addition to their human casualties, huge economic costs. In the case of SARS, a disease causing a relatively few cases of serious illness and death brought about, as well, enormous collateral damage to Ontario's health care system (closure of hospitals and cancellation of essential surgery), about $1 billion in excess health care costs, and perhaps as much as $2 billion in direct economic costs.[27] Clearly our infectious diseases surveillance system was not ready for this novel virus, even though expert forecasts of new and emerging infectious diseases, originating elsewhere in the world, have been made for some time already.

In the case of BSE, the discovery of a single case of mad cow disease has cost the Canadian economy in excess of $3 billion as of September 2003 (the costs are still rising). Analysis has shown that there was a serious policy failure in the risk regulation regime: Whereas the probabilistic risk assessment ought to have predicted the non-zero chance of a small number of cases of BSE occurring in Canada, Canadian regulators asserted that the risk was "negligible," implying that no case would occur. (The risk assessment would show also a vanishingly small probability of any human cases of nvCJD occurring as a result of having a small number of BSE cases in Canadian cattle herds.) They also implemented a policy of shutting Canada's borders to other countries which

had even a single case of BSE in their cattle herds. Policy choices on animal feed and disease surveillance also were inadequate to control the risk of BSE.[28]

In principle, it might be said, a robust system of risk forecasting might have predicted the likelihood of both of these occurrences – and enabled us to make changes in the inadequate risk regulation regimes *before* the incidents of SARS and BSE occurred. These changes, if they had proven to be correct responses to the actual risks, and had they been carried out in a timely fashion, might have reduced, perhaps considerably, the subsequent human and economic costs. However, a robust system of risk forecasting must be carried out in a central agency of government, because it has to be insulated from the commitments of departments to their existing choices of risk regulation regimes. Thus *Recommendation 4* in this report: The federal government should design and implement a robust method of risk forecasting, to be housed in a central agency.

H. A Way Forward.

In Canada and elsewhere national risk regulation regimes change all the time, and so it is never a question of whether or not change is necessary. The following types of changes occur as a matter of course in such regimes:

1. entire new domains of social life may be either brought into, or taken out of, regulation regimes (firearms; abortion; marijuana possession);
2. existing regimes may be altered with respect to an increase or decrease in the degree of control ("stringency") – in terms of penalties, for example (tobacco use, marijuana possession);
3. alterations in the policy instrument mix;

4. decisions to adhere or not to international conventions (Kyoto Protocol, International Criminal Court);
5. impacts of budgetary allocations;[29]
6. availability of avenues of redress for citizens (class-action lawsuits);
7. changes in democratic institutions for participation, access, etc.

Some of these changes are the result of explicit choices, for reasons articulated in the policy process; some are intended but implicit; some are inadvertent; and some may be purely accidental consequences of unrelated choices.

The purpose of moving towards smart regulation is to bring a higher degree of awareness, explicit design, and coherence to the process of change in risk regulation regimes. The element of awareness refers to reflection on both what is happening in Canadian society generally, and what is happening in the changing international scene which has a bearing on our situation.

For example, in risk regulation these days, there is far more activity occurring in international institutions than there used to be. To mention only food safety and animal health regulation as an example, there are very new institutions recently created in the European Union (now the world's largest economic bloc), the European Food Safety Authority and related national agencies, as well as very active agendas at multi-national bodies (the Codex Alimentarius Commission, FAO, WHO, OIE, etc.). The issues addressed by these bodies are international in scope, and thus there is a pressing need to develop modes of higher integration and coordination – while acknowledging, of course, that disputes between nations on these matters will not disappear anytime soon.

But more generally, for many health and environmental risks, where a strong expert scientific consensus is required to underpin credible risk assessments, a higher level of

integration for national bodies within international assessment organizations must be achieved.[30] One thinks of prescription drug and toxic chemicals evaluation, for example, substances in common use around the world which could be evaluated for safety using international panels. Thus *Recommendation 5:* Canada should be in the forefront – as it has been in the case of IPCC – of a drive to create additional, credible international institutions for undertaking the scientific assessments necessary in risk regulation regimes.

And finally, *Recommendation 6:* At the domestic level, Canada should undertake specific, "controlled" experiments – in a small number of key domains – for improving the efficiency and effectiveness of its own overall risk regulation regime. (By controlled experiment I mean a proposal for change which specifies in detail and in advance the desired outcomes as well as the method of evaluation.) As indicated above, one of the reasons for the failure of earlier initiatives along these lines has been the tendency to propose sweeping changes on the basis of rudimentary analyses. Unless this tendency is discouraged, citizens will resist those initiatives – as they have done. A new approach is needed, consisting of the following steps:

1. develop a credible and transparent methodology for the comparative assessment of efficiency and effectiveness in policy instruments;

2. choose a small number of specific cases, where changes are thought to be desirable, and specify the desired outcomes of the proposed changes;

3. conduct the experiment and evaluate it fairly, including the use of independent third-party experts drawn from both within and outside Canada;

4. fine-tune the methodology and reapply it to new cases.

One might choose the "change cases" for the first round through a consensus exercise involving a number of federal departments and managed by a central agency.

Endnotes.

[1] About the author: William Leiss is a Fellow and former President (1999-2001) of the Royal Society of Canada. He is author, collaborator or editor of twelve books, including *In the Chamber of Risks: Understanding Risk Controversies* (2001), *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication* (co-authored with Douglas Powell, 1997) and *Risk and Responsibility*, 1994 (all from McGill-Queen's University Press). Over a period of twenty years he has worked extensively in an advisory capacity with industry and with Canadian federal and provincial government departments in the area of risk communication, risk management, public consultation, and multi-stakeholder consensus-building processes. He has been an advisor on issues dealing with pesticides, toxic chemicals (chlorine, dioxins, and others), tobacco, prescription drugs, radio-frequency fields, genetic engineering, , and others. He was a member of the Senior Advisory Panel for the Walkerton Inquiry (2000-2002) and in 2000 was Chair of the Task Force on Public Participation for Canadian Blood Services. See: http://www.leiss.ca

[2] United States, "Executive Order: Regulatory Planning and Review" (September 1993), online at: http://www.elaw.org/resources/text.asp?id=1995; Peter Grabosky & J. Braithwaite, "Business Regulation and Australia's Future" (1993) – http://www.aic.gov.au/publications/lcj/business/

[3] http://www2.itssti.hc-sc.gc.ca/HPCB/Policy/LegislativeRenewal.nsf/WebHome/575087A768EAEFD185256D3A0058E5D6?opendocument&L=E&. An indicator of the intense controversy which any proposed changes to regulatory structures can elicit can be seen in the recent reaction to this document by a group called the Canadian Health Coalition, available online at http://www.healthcoalition.ca/, where one can also find the text of an article by André Picard, "Health law may protect Ottawa," *The Globe and Mail,* 10 November 2003, p. A4.

[4] These mistakes include making changes to the existing regime that were precipitous and thoughtless, and made without having in place a mechanism for the prediction of expected outcomes. See below, Section F.

[5] The most recent article is W. Poortinga and N. Pidgeon, "Exploring the dimensionality of trust in risk regulation," *Risk Analysis,* vol. 23, no. 5 (October 2003): 961-972, which includes references to many other studies on this theme.

[6] http://www.epidemiology.tulane.edu/broad_street.htm

[7] Excerpts from William Leiss, "The Risk-based approach to long-term management of high-level nuclear waste in Canada," prepared at the request of the Nuclear Waste Management Organization (http://www.nwmo.ca).

[8] S. Kaplan & B.J. Garrick, "On the quantitative definition of risk," *Risk Analysis*, 1 (1981): 11-27; S. Kaplan, "The words of risk analysis," *Risk Analysis*, 17 (1997): 407-417; O. Renn, "Concepts of

Risk: A Classification," in: S. Krimsky & D. Golding (eds.), *Social Theories of Risk* (Westport, CT: Praeger, 1992), 53-79.

[9] R. M. Ridley & H. F. Baker, *Fatal Protein* (Oxford University Press, 1998).

[10] Jonathan Baert Wiener and John D. Graham, *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment* (Cambridge, Mass.: Harvard University Press, 1995).

[11]http://www.bloodservices.ca/centreapps/internet/uw_v502_mainengine.nsf/web/87E5F16FC7398A4385256C53004D32DC?OpenDocument

[12] http://www.fraserinstitute.ca/admin/books/files/aug-forum.pdf

[13] One of the reasons, surely, is the poor choice of label; the bill's authors would have been wiser to baptize it the "regulatory effectiveness act."

[14] Todd Jeffrey Weiler, "The Straight Goods on Federal Regulatory Reform," *Government Information in Canada/Information gouvernementale au Canada*, Vol. 2, no. 2.3 (fall, 1995). <URL:http://www.usask.ca/library/gic/v2n2/weiler.html>

[15] For the story see W. Leiss, "The CEPA Soap Opera," chapter 8 of *In the Chamber of Risks: Understanding Risk Controversies* (Montréal: McGill-Queen's University Press, 2001).

[16] *In the Chamber of Risks*, chapter 9, "Voluntary Instruments."

[17]http://www.mineralresourcesforum.org/workshops/regulators/2002/docs/Optimal%20Policy%20Mix2002.pdf

[18] For an alternative view see *In the Chamber of Risks*, p. 240.

[19] Oxford Socio-Legal Studies, Oxford: Clarendon Press.

[20] H. Opschoor *et al., Economic Incentives and Environmental Policies* (1994), cited by Gunningham & Grabosky, page 27. Note that they do not refer to "cost-effectiveness."

[21] Gunningham & Grabosky (page 24) advocate "a pragmatic approach to regulatory design, where government is relatively unencumbered by the ideological baggage of the regulation versus deregulation debate…."

[22] For these two cases see *In the Chamber of Risks*, pp. 171-2, 221-2 and the references cited.

[23] The authors are Christopher Hood, Henry Rothstein, and Robert Baldwin; the publisher is Oxford University Press.

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[24] http://www.hc-sc.gc.ca/english/protection/krever/ and http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/FAQKrever?OpenDocument. See also André Picard, *The Gift of Death* (Toronto: HarperCollins, 1997).

[25] André Picard, "Blood officials knew in '81 of hep-C test, memos show," *The Globe and Mail*, 12 November 2003, p. A1.

[26] http://www.attorneygeneral.jus.gov.on.ca/english/about/pubs/walkerton/part1/. See pp. 23ff of the *Summary* of Part One. A unique feature of this inquiry was that Justice O'Connor's terms of reference specifically directed him to identify whether government policy choices played a role in the origins of this tragedy; he answered in the affirmative.

[27] See "Learning from SARS," report (June 2003) to Health Canada by a commission chaired by David Naylor: http://www.hc-sc.gc.ca/english/protection/warnings/sars/learning.html

[28] W. Leiss, "Finally, the penny drops: BSE risk in Canada" (July 2003), online at: http://www.leiss.ca/chronicles/125

[29] Justice O'Connor specifically identified budgetary changes as a factor in the weakening of Ontario's risk regulation regime for drinking water protection: *Summary,* Part One, pp. 34-5.

[30] The model for this development is IPCC, the Intergovernmental Panel on Climate Change, the largest group of distinguished scientific experts ever assembled to address a major risk issue.