Friday, March 27, 2009

Critical Conversation

EVENT SUMMARY

A Critical Conversation

on the Regulation of Known Unknowns

Co-hosted by:

Regulatory Affairs Sector, Treasury Board of Canada Secretariat

and

Regulatory Governance Initiative
School of Public Policy and Administration, Carleton University

April 2009

SUMMARY OF SPEAKER PRESENTATIONS

1. Introductory Remarks by Dr. Susan Phillips

Director, School of Public Policy and Administration, Carleton University

Dr. Susan Phillips welcomed event participants to the Critical Conversation on behalf of the Carleton University School of Public Policy and Administration (SPPA). She also provided an overview of the intent of Critical Conversations and of Carleton University's Regulatory Governance Initiative.

Critical Conversations aim to contribute to more informed debate and better, evidence-based policy and regulation. They bring together people with different perspectives, experiences and responsibilities – people who are leaders and bold thinkers in their respective fields, but who are not often in the same room together. Dr. Phillips noted that a good deal of time and effort goes into selecting the right mix of participants and thoughtful and audacious presenters, but also stressed that the experience and ideas expressed during the roundtable discussions were at least as important as the speaker presentations.

With respect to the choice of topic, i.e. the so-called "known unknowns" in regulation, Dr. Phillips noted the intent of the day's workshop was to address the hard choices associated with known unknowns in instances where regulatory attention is required but where the ideal course of action is not clear. She noted that the March 27, 2009 workshop would focus on three areas of regulation: nanotechnology, biofuels, and the financial sector. While quite disparate in their specifics, the intent of focusing on three sectors is to draw out lessons regarding regulatory governance and management – about choices of regulatory instruments, institutional design, how to govern and manage the process – that might be common across these areas, and that can be of practical use to regulatory communities.

Finally, Dr. Phillips welcomed Mr. Michael Presley from the Treasury Board Secretariat to say a few words of introduction on behalf of the event co-sponsors (on behalf of Mr. George Redling, who was regrettably unable to attend the event due to illness).

2. Introductory Remarks by Mr. Michael Presley

Executive Director, Regulatory Affairs Division, Treasury Board of Canada Secretariat

Mr. Michael Presley welcomed event participants on behalf of the Regulatory Affairs Division of the Treasury Board of Canada Secretariat, event co-sponsors with the Carleton School of Public Policy and Administration.

Mr. Presley noted that he was very pleased to read the discussion paper authored by Dr. Robert Slater that had been circulated in advance of the event to all participants. He noted that the themes contained within this paper resonated with Treasury Board, and also noted that he was struck by the similarity between references to unknowns in this discussion paper and management instructions given to new Managers entering the Public Service. Mr. Presley noted that the concerns associated with organizational practice are very relevant to regulatory matters. He spoke of the consequences of late decision making, and the challenge of taking bold action in the absence of a visible crisis. He noted that staff turnover in the public sector is a particular challenge of regulatory governance. Finally, he noted that he and the Treasury Board of Canada Secretariat looked forward to a continued partnership with Carleton University.

3. Presentation by Dr. Frank Milne

Bank of Montreal Professor in Economics and Finance at Queen's University and Special Advisor (2008-2009) to the Bank of Canada

Dr. Frank Milne noted that giving an overview of financial sector regulation (and mistakes that had been made in regulating new financial instruments that had led to the current financial crisis) in 15 minutes was akin to "giving an Executive Summary of the Bible".

He noted that those interested in further detail could refer to a July 2008 commentary that Dr. Milne wrote for the C.D. Howe Institute titled *Anatomy of the Credit Crisis: The Role of Faulty Risk Management Systems* (paper available online at the following link: http://cdhowe.org/pdf/commentary_269.pdf).

Here are a few key messages drawn from Dr. Milne's remarks:

- Private sector response to financial sector regulation is a very important topic.
- We have to look past this short-term economic crisis, and resist the urge to let it influence the end game too much; we should not try to "regulate corpses".
- With respect to the current financial crisis, we "don't fully understand all the bits yet", and there are a lots of theories and ideas floating around. A general consensus is that we'd like to do better in the future.
- The current financial crisis stems in part from underestimating the risk associated with new financial instruments (i.e. short-term paper that was being used to invest in the long-term through mortgages, etc...).
- The issue of systemic risk is incredibly important – however, a few years ago, it was difficult to get people to discuss this issue. Systemic risk is an externality that runs throughout and around the entire banking system. Nowadays, systemic risk is a hot topic in financial regulation.
- Referring to comparisons made between Taleb's Black Swan Theory of unexpected rare events and the current financial crisis, Dr. Milne stressed that the current economic crisis was not a black swan. There were lots of people warning about the risks in advance of the crisis, but these signals (or "outliers", as described in Dr. Slater's discussion paper) were not being heard (or were perhaps being ignored).
- Dr. Milne referred to a cartoon of a herd of sheep moving toward the edge of a cliff, with one lone sheep heading in the opposite direction saying "Excusez-moi, excusez-moi, excusez-moi" – and likened this cartoon sheep to certain analysts and academics who warned of the risks.
- One important lesson coming out of the current economic crisis is that we didn't have a lot of information regarding the risks associated with certain new financial instruments; this is due to the fact that these assets were under-regulated.
- In the context of financial regulation, macro-economic or "top-down" models may at times be too crude; Dr. Milne stated that we need to think very, very carefully about some of the macro models.
- Dr. Milne also stressed that the task of pulling risk models apart is a large component of risk management in the financial sector; it is the role of risk managers to look very carefully at available models and to critique their validity.
- Speaking of the Canadian banking system, Dr. Milne posited that the fact that Canada has a small number of large banks (rather than a multitude of small banks as in other jurisdictions) offers a comparative advantage, in that this makes it a bit easier for regulators to track the banking system.
- Dr. Milne spoke of the international aspects of banking regulation. One challenge for regulators is how best to address international products, i.e. how do we track the products / stuff that comes from outside a jurisdiction?

- Dr. Milne noted that although we hear a lot about current problems in the US in the Canadian press, it turns out that the UK's problems are at least as serious (or worse) than in the US. People in Eastern Europe are also very worried about potential fall-out from the current crisis.
- An event participant asked Dr. Milne about claims in the press that here in Canada, financial regulators "got it right" and that we are therefore better off today as a result. The participant worried that such claims could feed complacency, and asked for Dr. Milne's views about whether regulators "got it right" or rather, did regulators get lucky?
  Dr. Milne replied that we should worry about being too complacent – we might think that everything is fine right now, but he cautioned that things could change (you never know). In Dr. Milne's view, as Canadians we have a tendency to be prudent; we should be equally prudent about saying that everything's okay – we could end up looking silly if things should change.

4. Presentation by Mr. Claude-André Lachance

Vice-President, Government Affairs at Dow Canada Inc. and former Member of Parliament (1974-1984)

March 27, 2009, the date of the workshop, was Mr. Lachance's last day in his position as Vice-President Government Affairs for Dow Chemical, as he was retiring at the end of the day. The organizers would like to sincerely thank Mr. Lachance for having dedicated such a large portion of his last day on the job to this event.

From an industry perspective, Mr. Lachance noted that the regulatory process must deal with the following questions or issues:

1) Is a product safe?
   - He noted that this is a process issue in many respects, and that a lack of data or facts is a fact in and of itself.

2) How best to manage externalities?
   - Mr. Lachance stressed the need for scope in regulation.

3) What is the legitimacy of regulatory outcomes?
   - It was noted that this is a question of regulatory governance.

Mr. Lachance noted a paradox which he has observed in his years of experience with regulation (mainly around toxics regulation), which is that as we get more knowledge, we actually seem to know less.

Mr. Lachance noted that things have become more complex for regulators as detection methods have become increasingly sophisticated. He asked the question: how do you regulate single molecule aspects associated with toxic exposures? Thus, a significant challenge of regulatory governance / risk management becomes one of "managing boundary conditions" – in other words, stuff that is at the margins, where knowledge is uncertain or fragmented.

Referring to the oft-cited Donald Rumsfeld quote about known unknowns ("*as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns — the ones we don't know we don't know*"), Mr. Lachance stated that in his opinion there should be a 4th category added: Things we THINK we know, but we really DON'T know.

With respect to policy development and regulatory action around the topic of climate change, Mr. Lachance posited that policy makers seemed to be suffering from a "collective amnesia", whereby they forgot to follow proper policy development frameworks and to properly frame the issue or issues. Instead, policy makers skipped directly into "solution mode".

Mr. Lachance also cautioned that we must be careful not to force the regulatory system to do what it's not intended or supposed to do – which is to define the scope. This should be part of a proper policy development process. He also noted the need to incentivize innovation in Canada.

Referring to the "New Directions Group", an Industry / NGO collaborative effort around biotechnology, Mr. Lachance noted that this was an example of a useful partnership. Dealing with a past example of biotechnology regulation, Mr. Lachance noted that the best evidence available suggested that 80-90% of the products of biotechnology were found to be adequately managed by existing risk assessment frameworks. For the remaining 10-20%, there were potential ethical, social, and even reproductive issues associated with these products; it was this minority of products which were the topic of the most debate around risk.

Referring to new methodologies, where regulators are currently assessing the need for new regulatory systems or alterations of the current system, Mr. Lachance referred to the example of molecular pharming (the use of plants to "grow" and thereafter purify pharmaceutical products). In this particular example, Mr. Lachance noted that the new technology might actually offer advantages versus existing industrial processes.

Mr. Lachance stated that he felt what was really needed in the regulation of emerging technologies was a "Pre-Process" that would allow for the determination in advance of regulatory streams. Three possible streams noted were:

1) The traditional risk management / risk assessment track;
2) A more negotiative track, whereby stakeholders interact with regulators to frame solutions; or
3) Removing a particular issue entirely from the regulatory stream.

Referring to the "unknown", Mr. Lachance emphasized that while knowledge is good, we also need to be realistic. Science will never be able to provide absolute answers to all of our questions, and regulators need to keep this in mind.

Mr. Lachance stated that where precaution is concerned, it's often appropriate to be cautious, but that it is inappropriate to use the "precautionary principle" as a trump card.

On the topic of "outliers" as outlined in Dr. Slater's discussion paper, Mr. Lachance stated that the issue is not just one of hearing such signals. Rather, we need to be able to both RECEIVE signals as well as to DECODE them.

We should also be mindful to ask ourselves whether we are asking the regulatory process to do what it's not designed to do.

5. Presentation by Dr. Jo Anne Shatkin

Managing Director, CLF Ventures Inc., Boston, MA, USA
and Author of the Book *Nanotechnology: Health and Environmental Risks*

Dr. Shatkin stated that, with respect to the regulation of nanotechnology, there remain a number of risks, or unknowns, at this time. The small size of nanomaterials raises concerns about potential adverse effects, but it remains unclear whether the unique properties of engineered nanoscale materials might adversely impact upon human health or the environment. Safe levels have not yet been determined, and given the state of current knowledge, it is not possible to generalize about potential effects.

Another risk or unknown is that we are not yet sure how best to measure nanomaterials – as such, characterization remains a big source of uncertainty at this time. We are also not yet sure which nanomaterials will be the big market drivers.

Nanotechnology also presents opportunities. Proactive measures could produce real benefits, and we are able to learn from previous examples of regulating new chemicals and biotechnology. However, we also have the opportunity to address some concerns over nanotechnology "by design" – for example, we could employ "green" chemistry / risk analysis in product design.

From the perspective of non-governmental organizations (NGOs), Dr. Shatkin stated that NGOs are very aware of nanotechnology. Nanotechnology is the "next big wave" for environmental NGOs (among others), and well organized NGO campaigns could contribute to negative public perceptions of nanotechnology, as could low public trust in governments' and industry's capacity to protect public health and the environment.

In the US, there are already several petitions that have been filed with the US Food and Drug Administration and Environmental Protection Agency dealing with the regulation of nanotechnology. Dr. Shatkin warned that if we are not more proactive about the regulation of nanotechnology, then we run the risk that case law (as a result of such petitions) could be the primary driver of policy development in this area.

Dr. Shatkin outlined the following important elements for regulatory governance approaches to nanotechnology:

- A sound research strategy;
- Intra- and inter-agency / governmental collaboration and cooperation;
- Meaningful involvement of stakeholders;
- Surveillance;
- Adequate human resources;
- Adaptive/incremental approaches to regulation, building from case-by-case evaluations by increasing knowledge through experience; and
- A life cycle approach to risk analysis, which considers worker, consumer and environmental risks, not just ingredients.

For nanotechnology, Dr. Shatkin stressed the importance of adaptive / incremental approaches to regulation, and outlined a few of the models that have been proposed to date, including her own model of life cycle risk assessment (LCRA) and a partnership between DuPont and Environmental Defense (the "Nano Risk Framework"). Dr. Shatkin stressed that in her opinion, a life cycle approach to risk analysis for nanotechnology will be critical.

6. Roundtable Discussions

The event facilitator Dr. Marc Saner, Director of Research with the Regulatory Governance Initiative at Carleton University, thanked the presenters and explained the roundtable exercise.

Event participants had been pre-assigned to one of eight different roundtables. At each table, a Chair had also already been designated. Each roundtable was asked to debate a different question; these questions were based on the discussion paper by Dr. Bob Slater.

Each table was encouraged to have a free and unfettered discussion lasting approximately one half hour on the question which had been previously assigned to them. Chairs were instructed to distil from these discussions the "top three" answers to the question (e.g. approaches, guiding principles, "best practices", recommendations, etc...). These answers were captured on flipcharts by members from each table.

Following the roundtable discussion, each Chair was given the opportunity to report back on the outcomes of their discussions to the full group. The outcomes of the roundtable discussion, as summarized on flipcharts provided to each roundtable, are summarized below.

Participants were also given the opportunity to vote on the answers to each question. Participants were each given 8 blue stickers (one per question) and 2 red stickers. The blue stickers allowed them to select their preferred answer from among the "top three" listed on each flipchart. The red stickers could be used to "veto" from among the outlined answers. Numbers of votes in favour of each response are noted in brackets following each answer.

The questions asked of each table, outcomes of the roundtable discussion and results of the voting exercise are summarized below.

ROUNDTABLE DISCUSSIONS: OUTCOMES AND RESULTS

Table 1: INSTITUTIONAL DESIGN (Chair: Benoit Turcotte)

When regulating "known unknowns", what are the implications for institutional design (including governance arrangements and resource needs)?

Answers by Roundtable 1:	**Number of Votes**
1. Greater collaboration and pooling of resources between institutions and jurisdictions.	**6 votes**
2. Appropriate training of regulators (more emphasis)—more sharing of expertise between public and private sector.	**5 votes**
3. More public input into reviews and assessments of products, substances and drugs, etc.	**2 votes**
4. Higher prominence/importance given to research into areas of "public good" issues and leveraging expertise in universities.	**5 votes**
* Increased use of pilots to gauge social acceptance of new approaches to managing risks.	**3 votes**

Table 2: STAKEHOLDERS (Chair: Claude-André Lachance)

When and how should stakeholders be determined and engaged?

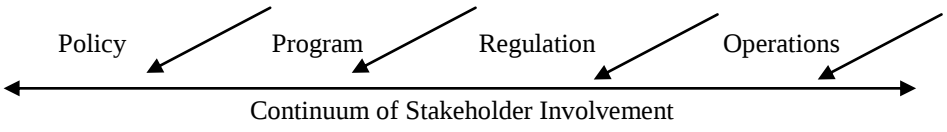
Answers by Roundtable 2:	**Number of Votes**
1. 	**4 votes**
2. Stakeholders need to "contribute" (scientific; facts; societal values; challenge function) during regulatory phase.	**3 votes + 1 red**
3. All institutions have "bias" (scientific; institutional; client); stakeholders can contribute to "identify" and "clarify" bias.	**7 votes**

Table 3: PREPAREDNESS (Chair: Richard Paton)

How do we improve regulatory preparedness during calm times and how do we deal with predicted low probability / high impact events?

Answers by Roundtable 3:	Number of Votes
1. Build structure in organization specifically responsible for foresight and analysis.	**4 votes + 1 red**
2. This structure needs legitimacy and is plugged into senior management (speaks truth to power).	**1 vote**
3. This foresight structure would: • do routine environmental scans; • stress test risk scenarios; • ensure policy/regulatory tool kit is routinely updated; • the implementation of the findings from the above work would be institutionalized.	**12 votes**

Table 4: EVIDENCE-BASED DECISION-MAKING (Chair: Alan Nymark)

How do we make sure we are up-to-date on international knowledge and how to communicate successfully at the interface between science and policy?

Roundtable 4 noted that they took issue with the original question (they felt this was primarily an issue of how to manoeuvre at the interface of science and policy), and reframed the question as follows:

	Number of Votes
International Knowledge:	
1. fundamental	**0 votes**
2. incentives	**3 votes**
3. peer review protocol (global)	**3 votes**
Science ⟷ Policy	
1. soft science – hard decisions	**4 votes**
2. competitive ideas – vigorous + transparent	
3. dialogue is recursive	

The Chair noted that current incentives are wrong, which is an issue. In addition, we are not recognizing the value of ongoing, vigorous, recursive dialogue between the scientific and policy communities.

Table 5: EMERGING TECHNOLOGIES (Chair: George Greene)

What strategies should be used to put in place regulatory regimes associated with new technologies (or from a new application of an existing technology)?

Answers by Roundtable 5:	**Number of Votes**
1. Define problem and determine public perception and interest →Who initiates? / participates? / how?	**9 votes**
2. Timing vis-à-vis the innovation cycle	**2 votes**
3. Is regulation needed? If so what type?	**0 votes**
4. Role of different parties	**0 votes**

Table 6: DEALING WITH OUTLIERS (Chair: Susan Fletcher)

How can we improve our capabilities to recognize "outlier" risks that merit attention (early or unorthodox warnings that may later turn out to be correct)?

Answers by Roundtable 6:	**Number of Votes**
1. Governance a. Institutionalize capacity to recognize outliers (e.g. through "futures" units & emerging contaminants units) b. Integrate decision-making between relevant departments.	**8 votes**
2. Seek out diverse perspectives e.g. from NGOs, private citizens, academic scientists, etc.	**4 votes + 1 red**
3. Develop criteria to screen outliers – e.g. whether B > PS a. Balance burden of taking precautions against probability & severity of harm b. Manage risk holistically.	**2 votes**

Table 7: THE RIGHT SCOPE (Chair: Hélène Quesnel)

How should one go about selecting the scope of cost-benefit assessments and risk management decisions – how do we decide what to include, what to leave out and how far into the future to plan?

Answers by Roundtable 7:	**Number of Votes**
1. Be ready to re-examine real issue: a. First step – may be more precise risk b. Broaden out risk assessment to cover multi-disciplinary lens.	**6 votes** **8 votes**
2. A. Be ready to revisit decision over and over again as circumstances change New information can change scope, thus judgement.	(Not displayed during voting)
B. Communication of dilemma on scope. e.g. Tylenol – we don't know what is risk / we are pulling product. Scope: your health / your confidence.	(Not displayed during voting)

Table 8: TRANSSECTORAL LEARNING (Chair: Richard French)

Is it worthwhile trying to learn from the experiences of other sectors?
If so, how? If not, why not?

Answers by Roundtable 8:	**Number of Votes**
1. Transectoral learning: Important but not reflected in behaviour or financial or institutional support	**2 votes**
2. Potential sources of learning 1) CFR 2) Career rotation 3) Academia: research and training 4) Civil society 5) International collaboration	**9 votes total**
3. Regulation at university program • Regulatory law & policy • Ind. Organization & reg. econ. • Science, technology & risk	**0 votes**

FINAL COMMENTARIES

7. Commentary by Mr. Dan Gardner

Columnist with the Ottawa Citizen
Author of the Book *Risk: The Science and Politics of Fear*

On the topic of uncertainty, Mr. Dan Gardner commented that our mind rebels against uncertainty, and that certainty sells. Thus, in situations of systems uncertainty (such as the current global economic crisis), people get very uncomfortable; this, he said, is a psychological phenomenon.

Mr. Gardner described himself as a recent "psychology convert". He noted the applicability of psychology to the day's discussions and "What could be more fundamental to the business of regulation than psychology". One psychological theme that he noted to be particularly relevant was that of "Bias-Bias".

According to Mr. Gardner, the phenomenon applies when you explain the concept of psychological biases to people. Armed with the knowledge of psychological bias, people have a tendency to overestimate the extent to which other peoples' thoughts are biases while simultaneously discounted the possibility that one's own thoughts could be biased. Mr. Gardner noted this phenomenon was at least equally applicable to senior decision makers.

Faulty risk perception is another psychological theme. Mr. Gardner posited that we cannot explain what happened recently on Wall Street without touching on psychology. The mentality may have been one of "everybody's doing it, so it must be a good idea", where the full extent of the risks being incurred was not appreciated. This is the herd mentality, much like the sheep cartoon described earlier by Dr. Frank Milne.

8. Commentary by Dr. Robert Slater

Adjunct Professor, School of Public Policy and Administration, Carleton University

Dr. Robert Slater praised the diversity of views and spirit of open collaboration and discussion associated with the day's proceedings. He noted that, in hindsight, he wished that he had participated in more such events in the past.

Dr. Slater authored the draft discussion paper that had been circulated to all event participants in advance of the Critical Conversation. Input from participants on the discussion paper was welcomed prior to Friday, April 3rd, 2009. Following the event, Dr. Slater would refine the paper, and it would be published as the third in the series of Regulatory Governance Briefs produced by the Regulatory Governance Initiative.

ACKNOWLEDGEMENTS

We gratefully acknowledge the support and financial contribution by the Treasury Board of Canada Secretariat, and in particular Benoit Turcotte, Executive Director of the Centre of Regulatory Expertise (CORE), who provided intellectual vision and other contributions throughout the process.

The hard work of Kimmie Huang, Special Projects Administrator for the Carleton University School of Public Policy and Administration, and Alin Charrière, Master's Student, were also essential to the success of this event.

The Regulatory Governance Initiative

The Regulatory Governance Initiative (RGI) at Carleton University builds on the proven track record of Carleton's School of Public Policy and Administration to develop regulatory capacity and competence through research, education, and dialogue. Its scope is regulatory policy, governance, and management. Its approach is holistic and problem-driven. The RGI assembles expertise from the humanities, social and natural sciences as needed. For most projects, practitioners in the private, public and nonprofit sectors collaborate with scholars from the RGI network.

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