Privy Council Office Government Directive on Regulating

Draft Report

Interdepartmental Workshop

September 8th, 2005



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1.0 WORKSHOP PURPOSE

The Regulatory Affairs Division of the Privy Council Office (PCO), with the support of TDV Global Inc., organized an Interdepartmental Workshop on the proposed draft Government Directive on Regulating (the Directive). The purpose of this workshop was to:

- Obtain views and feedback from the regulatory community on the Government Directive on Regulating;
- Identify implementation and capacity challenges and possible solutions;
- Provide advice to senior management on improving regulatory management; and
- A community building, learning and networking opportunity.

The workshop brought together approximately 150 working- and director-level officials (refer to **Annex F** for the list of participants) from across federal departments and agencies. Large departments and their smaller counterparts were asked to invite between 8-12 participants and 3-5 participants respectively. Each department selected and organized its own delegations. Participants were selected from across the regulatory lifecycle; from development, through implementation, compliance and review. Participants occupied a wide range of roles and positions, including program managers, policy analysts, inspectors, performance specialists, RIAS authors and economists.



2.0 KEY SPEAKERS

2.1 Welcome and Introduction (Mr. George Redling)

Mr. George Redling opened the retreat by welcoming all participants to the Interdepartmental Workshop on the Government Directive on Regulating. He indicated that it was encouraging to see so many members of the regulatory committee from across departments and across the country in attendance for this important step in the Smart Regulation Initiative. He explained that the current regulatory policy in Canada has guided the country over a number of years and that the challenge is now to improve regulatory governance in order to better serve Canadians in the years to come. As the attendees will have a large role to play in carrying out the new Directive, he pointed out that it is the reason why their participation is so important.

He explained that of the many responsibilities of the federal government, the one that affects the everyday lives of Canadian citizens in the most direct fashion is its responsibility for regulating – whether it be the safety of health products like medicines, to nutrition labeling so shoppers can make smart choices, or the quality of the natural environment, to name but a few. He expressed that good regulation is an enormous responsibility, one that is shared by all departments and agencies. He highlighted that Canadians have consistently indicated that they want a strong regulatory system that serves the public interest. The question being faced is how, as regulators, we provide the best protection and opportunities for Canadians at a time when the regulatory system is faced with pressures to evolve; not only to meet the changing needs of its citizens but also to ensure that the country does not fall behind other countries – economically, socially and environmentally.

He expressed that Smart Regulation is a comprehensive government-wide approach to improving regulation. The strategy exhibits three key areas of concurrent activities to:

- strengthen regulatory management;
- enhance regulatory cooperation; and
- achieve results in key sectors and thematic areas.

The focus of the workshop is on the first area of activity, promoting relevant discussion on:

- the new Directive;
- the supporting analytical frameworks, processes, tools and guides that will provide better guidance to departments on managing the life-cycle of regulation and conducting the required analysis;
- an enhanced PCO Challenge Function; and
- a regulatory community learning strategy.

In closing, he explained that all attendees, as regulators, had a critical role in moving policy into practice. It was highlighted that the objective of the workshop was to provide an opportunity for the Federal Community of Regulators to come together and provide relevant feedback on the Directive. These comments will be a key input to a draft to be submitted to public consultation in early October.

Once his opening address completed, Mr. Redling introduced Mr. Morris Rosenberg, the Champion of the Community of Federal Regulators and Deputy Minister of Health Canada. He highlighted salient points of Mr. Rosenberg's remarkable career and spoke highly of his knowledge and understanding of laws and regulations, as well as the challenges regulators face and address on a regular basis.



2.2 Delivering Results for Canadians: The Importance of the Regulatory Community (Mr. Morris Rosenberg)

Mr. Morris Rosenberg highlighted the importance of the regulatory framework and acknowledged the outstanding work that had been accomplished to date on the new Government Directive on Regulating.

He highlighted three lessons learned from Hurricane Katrina namely:

- the importance of government in taking care of the population's basic needs;
- the importance of the knowledge and experience of public servants; and
- the unfortunate fact that sometimes a crisis is required in order to learn the first two lessons.

A core responsibility of government is to ensure that the regulations it puts in place contribute to a safe and secure environment for the country and instil confidence in the public. He explained that it is important to ensure that systems, planning, appropriate training and instruments of regulation are modern and relevant. While regulatory failures, e.g., Katrina, Vioxx, Enron, etc., can be highly valuable in terms of bringing about positive changes in regulatory systems, they are often too high a price to pay in order to learn these lessons. Thus, it was suggested that change should be brought about when there is a need as opposed to a crisis. Mr Rosenberg also acknowledged that change needs to be supported by senior leadership at all levels (including political) as well as by the regulatory community.

By the same token, we are no longer regulating local markets but regulating in international markets, requiring international cooperation (e.g. cattle feed and the impact on global consumer confidence). He acknowledged that there is also a challenge surrounding the coordination and management of horizontal issues which transcend departments and jurisdictional boundaries, e.g., climate change. In addition, departments and agencies are being called upon to respond to increased public expectation that regulatory decision-making will be increasingly open and transparent, and that the government will be able to protect them (through the effective use of modern, appropriate regulatory instruments and approaches) when required, e.g., on an ongoing basis, but also during times of emergency/ emerging threats.

It is important therefore that the new policies, tools and processes coming about as a result of Smart Regulation implementation will be supported by a robust HR capability focused on skill development and judicious recruiting that reflects diversity, skills and abilities conducive to cross-disciplinary and crossorganizational work. In this regard, the Community of Federal Regulators is an important component of Smart Regulation implementation. He felt that support from this community could be provided in:

- Promoting learning and professional development;
- Ensuring that staff are equipped with the right tools, e.g., a mechanism to integrate social and ethical considerations into regulatory decision-making;
- Communicating to ensure public trust;
- Providing on-going feedback and dialogue; and
- Establishing communities of best practices.

Following this, Mr Rosenberg spoke about the importance of making sure that if regulators are going to be continue to be asked to make tough and innovative decisions, they need to be protected from legal recourse wherever possible. This is not to say that the government as a whole should be immune from scrutiny, but that individual public servants should be protected from being named in law suits provided that



they have acted with appropriate duty of care. Mr Rosenberg noted that staff across the CFR and in his department have identified the possibility of being held personally responsible for their decisions in the context of government action as having a significant impact on recruitment and retention of regulatory personnel; and that in his role as DM Champion of the CFR, he intends to explore the options related to employee immunity.

In conclusion, Mr. Rosenberg reiterated that the role of all attendees is very important in providing leadership and assistance in "getting it right". He highlighted that the Government Directive on Regulating is an important step in that direction and challenged the audience to identify what still needs to be improved in the GDR and to identify implementation challenges as early as possible.

2.3 Highlights of the Draft Government Directive on Regulating (Ms. Diane Labelle)

Ms. Diane Labelle pointed out that the Community of Federal Regulators is an essential element in the success of Smart Regulation and that the government is actively interested in listening to the advice of a multiplicity of experts and resources as to how best to move forward on Smart Regulation and the Government Directive on Regulating.

She highlighted that in the past years there have been a number of observations pertaining to regulation. In 2000, the Office of the Auditor General (OAG) reviewed federal health and safety regulations (but not the regulatory policy or the regulatory system per se), suggesting that the current regulatory policy has a strong economic focus and that the government needs to better identify and communicate federal priorities with regard to health and safety regulation. The OAG also recommended the need for stronger interdepartmental coordination for major health and safety regulations.

In 2002, the Organization for Economic Co-operation and Development (OECD) noted that Canada has a mature and well functioning system of regulatory governance, that regulatory reforms have contributed to Canada's good economic performance and that Canada should continue to sustain this momentum of reform. The OECD did note that Canada does need to take steps to ensure that regulation continues to support the government's overall policy agenda, including developing an approach for regulatory evaluation and review and emphasizing a stronger contribution from competition policy to regulatory management. In 2004, the External Advisory Committee on Smart Regulations (EACSR) conducted a thorough review of the federal regulation and provided the government with 40 recommendations dealing specifically on regulatory governance, including a recommendation to "give priority to developing a new federal regulatory policy."

It was explained that the Government Directive on Regulating is intended to:

- communicate to Canadians the federal government's commitment to protect health and safety and provide supportive conditions for an innovative economy;
- ensure Canadians have information and opportunities to participate in regulating;
- communicate to government officials their regulatory roles and responsibilities; and
- ensure that Ministers have the information necessary to make sound decisions.

Ms. Labelle pointed out that this will be accomplished through the promulgation of supporting analytical frameworks and guidance on how to fulfill directions (instrument of choice, public consultation, international regulatory cooperation, risk management, compliance, regulatory review) as well as Tools and Processes



(enhanced PCO challenge function, capacity assessment and learning strategy, renewed regulatory impact analysis statement, performance measurement and evaluation).

By the same token, it was highlighted that implementation would follow a lifecycle approach in order to create the conditions for departments and agencies to move forward on Smart Regulation and produce overall improvements to the regulatory management system.

The government would also proceed with sector improvements through the work of theme tables, including:

- Healthy Canada;
- Environmental Sustainability;
- Safety and Security;
- Innovation/Productivity and Business Environment; and
- Aboriginal Prosperity and Northern Development.

The lifecycle would comprise of the following activity areas:

- Analysis and Proposal Development
 - o consultation with Canadians;
 - o identification of the problem and risks;
 - o selection and assessment of regulatory responses; and
 - o assessment of the impact of proposed options.
- Implementation
 - o consultation with Canadians;
 - o compliance planning;
 - o implementation planning;
 - o financial and human resource allocation; and
 - o skills and training; and
- Evaluation and Review
 - o consultation with Canadians;
 - o performance measurement; and
 - o evaluation and review of regulation.

She then proceeded to highlight the accountabilities of respective Departments and Agencies in each of these areas.

In closing she explained the critical path forward and provided a high level overview of the input solicited from the attendees during the course of the day.



2.4 Implementing Right – Perspectives from Advocacy Groups, Industry and Academia (Guest Speakers)

Three guest speakers were invited to address the attendees as to their perspectives on implementing right.

M. Jacques St-Arnant (Option Consommateurs)

The first speaker, M. Jacques St-Amant of Option Consommateurs highlighted the role of Options Consommateurs. He discussed the increasing complexity of issues impacting on the regulatory framework; including globalization, technology, and an increasing range of cultures and views in society which impact on establishing consensus. He pointed out that when considering consultation on the Directive, there are a number of citizens that are functionally illiterate. Consultation should however be an ongoing process rather than a reaction to an impact assessment.

From a wider perspective, EACSR and similar initiatives have a broad understanding of "regulation", not simply in terms of legal and technical notions of regulation. It was observed that good regulation requires a smart regulatory strategy. He also pointed out that smart regulation requires smart diagnosis, and that requirements for consensus may paralyze regulatory activity, particularly when the data involved is not clear.

By the same token, there are a number of challenges associated with decisions increasingly driven by international agreements. On the cost-benefit front, he outlined that in the past, the cost of regulating had to be determined but not the benefits or cost of not regulating. These issues may need to be explored. He concluded his presentation by reviewing four case studies and reiterating the need for a broad approach to smart regulation, based upon smart diagnosis, involvement and proactive consultation.

Ms. Denise Dewar (CropLife Canada)

The second speaker, Ms. Dewar of CropLife Canada, provided her perspectives on smart regulation and the proposed Directive. She highlighted the need for effective consultation. It was pointed out that there was in effect a need for a communication policy, particularly in terms of standards and codes and that stewardship programs and the proliferation of best practices would also be beneficial. By the same token, she warned that "one size fits all" may not be the answer.

On behalf of CropLife, she explained that innovation is the driver for growth in agriculture and Canada's competitiveness. Canada is facing increasing competition from other countries with strong agricultural sectors whereas Canada's farm income has reached historic lows. Canada maintains a small domestic market and is thus highly dependent on agricultural trade and exports. In the past, Canada's agricultural sector has been competitive as a result of the ability to adopt new technologies and adapt more rapidly than competitors. One of the reasons for this is due to the effectiveness of the regulatory system. While this provided an advantage in the past, it is felt that this advantage is slipping away.

She highlighted that the agri-food industry, by and large, is very supportive of the work of the proposed renewal and is a firm believer that Smart Regulation is the key to a competitive agri-food future for Canada. She explained that the position of CropLife is reflected broadly in the legislature, with all political parties



supporting regulations that are both smart and that enable innovation in Canadian agriculture based on effectiveness, cost-efficiency, timeliness, transparency, accountability and performance with a distinct focus on health, safety and the environment. She was pleased that the current forum is in fact taking a proactive stance in this area. She reiterated support for a continued focus on science-based risk assessments and noted that it is important to ensure that the cost of regulations remain proportional to the cost of the problem being solved.

Dr. Paul Thomas (University of Manitoba)

The last speaker, Dr. Paul Thomas, explained that sound regulation is critical to the faith of the Canadian citizenry in their government. As such, he felt that regulation can be viewed as a microcosm of the government. He regarded the implementation of regulation as a process whereby policy ideas translate into actual practices.

Until the early 1970s, the academic literature presumed that implementation was a relatively straightforward, unproblematic step in the policy process in which the administrative apparatus executed the declared policies of government. Studies revealed there is often slippage between policy intentions and policy results, with implementation issues identified as a big part of the explanation for the gap.

The focus in most academic studies has been in explaining the so-called "implementation gap": the distance between the original design of policies and programs and what happens in practice. In other words, the academic orientation is mainly concerned with failure, describing what doesn't work and why, as opposed to prescribing how things could be made to work better. He explained that there is little or no advice on what dimensions or factors of the environment are important to the process of implementation.

He nonetheless suggested that, at the outset of policy development, there should be an implementation plan focusing on:

- the soundness, clarity and consistency of policy intentions;
- the authority, resources and capabilities of the implementing agency;
- the extent of agreement among the relevant stakeholders on the goals and means to achieve policy goals;
- the incentives and disincentives for cooperation among various participants; and
- the potential impacts of both the immediate and the wider context of short-term developments and long-terms trends.

He expressed that "good" regulatory processes must:

- be consistent with law, based upon sound analysis and best available knowledge;
- encourage collaboration, flexibility and learning;
- be committed to fairness, due process and neutrality;
- promote transparency, accountability and responsiveness;
- emphasize efficiency, effectiveness and timeliness; and
- be legitimate in terms of both procedure (how regulations are adopted and assessed) and substance (be consistent with widely held values).

Before concluding his presentation, Dr. Thomas pointed out that regulation is where government is the most visible.



2.5 Implementation Considerations for the Government Directive on Regulating (Mr. Benoit Turcotte)

Mr. Benoit Turcotte provided a PowerPoint overview of Smart Regulation Implementation Considerations. He initially focused on the characteristics of the strengthened PCO Challenge Function outlining the recent improvements in areas of an interim challenge checklist, instrument of choice training within PCO as well as the Working Group on enhancing the PCO challenge function. He explained that the next steps would focus on ensuring adherence to Smart Regulation principles and frameworks as they are implemented, identifying MCs with regulatory implications (and updating the MC writing guide) and improving PCO capacity.

From a Triage perspective, he explained that effort and analysis devoted to regulatory initiatives needs to be commensurate with the scope and impact of the problem and that three categories of significance have been identified.

From an implementation perspective, he observed that the framework will be a work-in progress expected to be subjected to review through ongoing collaboration. He highlighted the characteristics and importance of the revised Regulatory Impact Analysis Statement (RIAS) as well as its possible three point structure (Description, Impact Analysis and Implementation).

From a challenge perspective, Mr. Turcotte pointed to the requirement of building internal Regulatory Affairs Division capacity within PCO, providing departments and key stakeholders with adequate time to prepare, and consolidating and updating existing guides, manuals and online tools.



3.0 BREAKOUT SESSIONS

Three breakout sessions were held at different times throughout the workshop, addressing different elements of the proposed Government Directive on Regulating:

- 1. Directive Section: Our Commitment to Canadians;
- 2. Directive Sections: Accountabilities of Departments and Agencies; and
- 3. Implementation Needs and Measuring the Success of the Directive.

The workshop attendees, representing 27 different organizations, were proportionally allocated to four breakout groups and subsequently into five subgroups each in order to allow for in-depth discussion.

The following section illustrates the highlights of the feedback generated in each of the breakout sessions. This information was captured for reporting back in plenary at the conclusion of the workshop. More detailed observations of the subgroups were also captured for each breakout session and are attached separately in **Annexes B**, **C and D**, respectively. The presentation utilized in the plenary that summarizes the breakout session findings is attached in **Annex E**.

3.1 Breakout Session 1: Our Commitment to Canadians

The first breakout session was focused on the section of the Directive entitled "Our Commitment to Canadians", which all subgroups reviewed. They were asked: "Does the section titled "Our Commitment to Canadians" convey accurately the intent and policy direction for the Government of Canada?"

Attendees were required to structure their analysis according to the following prompts:

- What would you keep?
- What would you modify?
- What would you delete?

The following major elements were identified:

What Should Be Kept:		
There was overall support for the direction of this Section. Some concern was raised with respect to the		
audience of the document, with suggestion for separate documents for separate audiences (i.e.		
Canadian public, federal regulatory personnel)		
What Should Be Modified:		
Audience:		
 Need to clarify the identity of the audience and orient accordingly; 		
Language:		
 Need for definition of key terms employed, such as "public interest", "evidence"; 		
 Inclusion of a glossary could help define these terms in the proper context; 		
• Requirement of clear articulation of "overall benefit" approach vs. "net benefit" approach;		
Broad statements decrease the specificity of the commitment and could promote the setting of		
standards which cannot be realistically met;		
Need Increased Emphasis on:		
Importance of informed decision-making;		
niperative of method decision matrix,		

• Promoting and protecting Canadian identity and values;



- Balancing:
 - o economic, social and environmental factors;
 - o national and international science and obligations;
 - need to qualify the commitment to evidence-based decision making and a risk / precautionary approach;
 - o responsiveness and inclusiveness (e.g. crisis situations);
 - o efficient and effective processes and demonstrating accountability to Canadians;

Requested Inclusion of:

- an Applications Section that helps define the Scope of the Directive, including:
 - o Regulation;
 - o Legislation; and
 - o Processes.
- References to:
 - o issues concerning the Aboriginal peoples;
 - o domestic trade in addition to international trade;
 - o domestic and international benchmarks;
 - o the requirement for responsiveness to changes in science and stakeholder needs; and
 - o the requirement for timeliness.

What Should Be Deleted	
 No specific items were requested to be deleted with respect to this section. 	

For additional material developed by the subgroups explores the topic in more detail see Annex B.

3.2 Breakout Session 2: Accountabilities of Departments and Agencies

The second breakout session was focused on the sections of the Directive entitled "Accountabilities of Departments and Agencies". Within the groupings, the five subgroups were asked to review different sections which comprised the entirety of the subject matter content dealing with accountabilities.

They were asked: "Does the section on "Accountabilities of Departments and Agencies" help departments achieve the government's commitment to Canadians? How can we better integrate "accountability" into the Government Directive and ensure that it has "teeth"? Is intent clearly articulated and is the direction easily understood? Can it be implemented?"

Participants were again asked to orient their responses according to the following prompts:

- What would you keep?
- What would you modify?
- What would you delete?



The following major elements were identified:

Should Be Kept:
from specific observations identified below, the remaining content of the sections dealing with
ntabilities was well-supported;
Should Be Modified:
, Consultations and Problem Identification:
Some situations may not warrant full consultations;
Dialogue and consultation may be required on "potential" regulatory issues, in order to determine
whether regulatory solutions are required or not;
Language considerations remain important, e.g., what are the implications of the term, "full and
fair" consultation opportunities?;
There remains a need for flexibility and balance between the need to consult and the need for
urgency, while maintaining accountability and scrutiny;
A better definition of interdepartmental consultation is required;
Guidance is required on ethical considerations and public perceptions;
Consultations section requires a reference to aboriginal peoples;
ing and Assessing Regulatory Options:
Need for incorporation of ethical considerations with due recognition of the fact that social /
ethical impacts can be difficult to measure;
Triage concept required for assessing social and environmental impacts;
Requirement for better links between policy background and regulatory proposal
review/challenge function;
Requirement for balance between prescription/level of detail and flexibility;
Concern with respect to the potential usage of "[only] when merited by specific Canadian
circumstances" with respect to international regulatory cooperation;
More emphasis on strengthening coordination across GoC (Theme Tables and Community of
Federal Regulators);
Demonstrating compliance with the Directive – Regulatory Process Management Standards
ensures consistency;
Strengthening the language ("are EXPECTED to") could promote accountability;
Requirements for international regulatory cooperation is too rigorous, e.g. what if international
standards don't exist or the international regime is of lower quality?;
French version includes an additional paragraph in which the usage of "unique" is overly strong;
ng and Measuring Performance:
Reference to RIAS is required;
Ensure language is consistent between sections and with RIAS;
Accurate performance measurement can be difficult if regulatory policy implementation
responsibilities are shared or handled by another department or P/T government;
ting to Central Agencies
Enforcement reference required in order to outline the consequences for departments and
agencies that do not comply;
Changing government priorities cause difficulties in planning an agenda over multiple years;
Role of Parliament is not reflected in the document;
Privy Council Office
• Requirement to address PCO's delicate role in acting as both collaborator and adjudicator;



o Concern as to whether the authority of the PCO is sufficient for its expanded role;

- Department of Justice Canada
 - Preference for wording of previous Directives with respect to the responsibilities and authority of the Department of Justice with respect to its role in the development of regulation.

What Should Be Deleted

In light of the observations above a number of statements will need to be deleted and recrafted.

For more detailed material developed by the subgroups see Annex C.

3.3 Breakout Session 3: Implementation Needs and Measuring the Success of the Directive

The third breakout session was focused on implementation and assessing performance associated with the Directive. Participants were asked to discuss "implementation needs and measuring the success of the Directive" in their breakout groups.

Participants were asked to structure their commentary according to the following questions:

- What skills and training do you need to implement the Government Directive on Regulating successfully?
- How does the Regulatory Impact Analysis Statement need to change to reflect the new expectations in the Government Directive?
- How does the PCO Challenge Function need to change to reflect the new expectations in the Government Directive?
- What other tools, guides and processes are needed for successful implementation?

The following major elements were identified:

Skills and Training Required for Implementation:

- Knowledge-based needs:
 - o Economic and Cost-Benefit Analysis capacity;
 - o Environmental Assessment capabilities;
 - Ongoing tracking of the international regulatory regime;
 - o Availability of the instrument of choice;
 - o Performance measurement for social impacts;
- Skill-based needs:
 - o Inter-disciplinary team building for policy development;
 - o Increasingly complex and topical types of consultations;
- Determination of the suitability of applying a generalized training structure or a centres of expertise model;
- Explicit account of the roles and responsibilities of other government departments; and
- Provision of senior management training with respect to Smart Regulation.

Recommended Changes to RIAS:

• RIAS and the Directive:



 Inconsistencies in language between the RIAS and the Directive should be corrected; Guidance: PCO should produce an improved RIAS writer's guide to help departments address the new expectations and the requirements of the challenge function; PCO should update their website in order to make all RIAS-relevant information and documentation easily available in one location; Experts in this area (e.g. TB, PCO, Canada Gazette) should be identified for consultation: A background section included to provide additional context; Usage of 'problem definition' implies that regulations are uniquely required to address problems, which is often not the case; Policy objectives should be identified better: A social impact section should be added to better situate the case for regulation; and Potential performance indicators should be identified in the RIAS to provide insight into future assessment of the implemented regulation. Recommended Changes to the PCO Challenge Function PCO involvement must be early in the regulation development process; Smart Regulation Policy checklist should be shared with departments with guidance from PCO on how it is to be applied; Clarification required of how PCO will possess the subject matter expertise required to assess highly technical regulations; PCO internal communications should be emphasized so as to encourage information transfer between different individuals who could be addressing the same regulation (e.g. MC analyst, regulatory analyst) Accountability – clear identification of the responsible party is required should a regulation not conform to the Directive; Additional Tools, Guides and Processes Required Contact lists of individuals from rele		• The RIAS should be included in some fashion in the Directive itself;		
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Form more detail material developed by the subgroups see Annex D.



ANNEX A Agenda

Government Directive on Regulating: Interdepartmental Workshop September 8th, 2005

Crowne Plaza – International Ballroom A

Purpose:

To obtain views and feedback from the regulatory community on the Government Directive on Regulating, identify implementation and capacity challenges and possible solutions, provide advice to senior management on improving regulatory management, and provide a community building, learning and networking opportunity.

0830 Coffee and Muffins

0900	Opening Comments – Delivering on Regulation: A Community Approach	George Redling, Assistant Smart Secretary to Cabinet, PCO
	Agenda, Norms, Logistics	Facilitator
0915	Delivering Results for Canadians: The Importance of the Regulatory Community	Morris Rosenberg, DM Health Canada and Champion of the Community of Federal Regulators
0935	Highlights of the DRAFT Government Directive on Regulating	Diane Labelle, A/Director of Operations, PCO
1000	Breakout Session #1 - Government Directive: "Our Commitment to Canadians"	Facilitators (x4)
HEALTH BREAK (1050 – 1110)		
1110	Breakout Session #2 - Government Directive: "Accountabilities of Departments and Agencies"	Facilitators (x4)
<i>LUNCH</i> (1210 – 1300 hrs)		



1300	Implementing right!: (Perspectives from Advocacy Groups, Industry, and academia)	Jacques St-Amant, Option Consommateurs Denise Dewar, Executive Director, Plant Biotechnology Croplife Canada Paul Thomas, University of Manitoba	
1345	Presentation of Implementation Considerations for the Government Directive on Regulating	Ben Turcotte, Coordinator, Cabinet Committee Operations, Regulatory Affairs Division, PCO	
1410	Breakout Session #3 - Implementation Needs and Measuring Success of the Directive	Facilitators (x4)	
HEALTH BREAK (1505 – 1520)			
1520	Plenary Session – Review of what was heard during 3 Breakout Sessions	Regulatory Working Group Leads (x4)	
1625	Next Steps & Concluding Remarks	Diane Labelle, A/Director of Operations, PCO	

ADJOURNMENT OF INTERDEPARTMENTAL WORKSHOP (1630)



ANNEX B DETAILED COMMENTS FROM BREAKOUT SESSION # 1

"Government Directive: Our Commitment to Canadians"

Breakout Session 1: Our Commitment to Canadians		
Does the section titled "Our Commitment to Canadians" convey accurately the intent and policy direction for the Government of Canada?		
What would you keep?What would you modify?What would you delete?		
Table 1 – Our Commitment (page 2) Table 2 – Our Commitment (page 2)	Table 3 – Our Commitment (page 2) Table 4 – Our Commitment (page 2)	

What would you keep?

Overall content seems fine

What would you modify?

- Need to define the scope of the document.
- Is it about responsiveness of the regulatory system or is it about transparency & openness? A little muddled.
- Who is the audience?
- Overall need 2 documents (One: internal policy, the other communication tool for Canadians)
- What is regulation?
- Stronger intro clarify need
- Overall benefit vs net benefit?
- Public interest social/heritage needs to be included
- What does greatest overall benefit mean?
- Better define "overall benefits"
- Make glossary/lexicon more explicit
- What is regulatory authority" Need more upfront clarity.
- More clear language on what exactly be done
- Earlier policy was more clear
- Too jargon driven
- Demonstrate accountability to Canadians. No need to tell "how to be accountable to Canadians.
- Is it about responsiveness of the regulatory system or is it about transparency & openness? A little muddled.
- Respond in a timely manner to changes in science, stakeholder needs, health & safety
- More clearly identity need for balance among economic, social & environmental interests
- Ensure transparency/responsibility
- "Protect & enable \rightarrow 1st principle.
- Adapt performance based, so that regulations can comply more effectively.
- Timeliness or regulation \$ making process/lifecycle, responsiveness is different from transparency



- Not just international also domestic
- Add guidance for timeliness (crisis response or emerging issues)
- Promoting identity/protecting Canadians
- Add promote and protect Canadian values...
- Demonstrate accountability to Canadians No need to tell "how = be accountable to Canadians.
- Build in more responsibility terminology such as: "enhance"? "A responsive regulatory system".
- Keep statement short to avoid capturing specific issues of the time but to make them applicable to issues over time.
- Is there a hierarchy of principles or are they all equal?
- Serving public interest should be the priority
- Timeliness" (e.g., emergency) : include in list of guiding principles as new bullet
- Line 40 strengthen intro to add purpose of directive -accountability!!
- Careful with bolding
- Instilling vs. strengthening terminology should be consistent
- Add international
- What is scope of regulatory authority? Is it full range?
- Line 42 What is scope? Our entire regulatory authority (regulations, standards etc) or just regulation making? As written most of the document seems to focus on just regulation making but first paragraph refers to general regulatory authority
- Line 42 add international organizations
- Line 43 sustain is in effect status quo. Sustained environment too "static"
- Line 43: "...and taking into account social, environmental, economic aspects"
- A suggestion would be to make each statement more direct & effective by using a verb only e.g. "instill", "serve", "support" etc.
- Some are NOT principles: more in the context of goal or objective. The principles listed are more like objectives.
- Line 55 More clarity required to the word fair
- Bullet #3:
 - o Domestic trade missing
 - Recognition of integrated/complex regulation making process & need to make it less complex
- Line 58 Based on "available" evidence what do we do in cases of incomplete evidence, do we need to
 incorporate the idea of risk-based decision-making? Evidence based decision. Where is the risk? Need to
 be explicit to Canadians. (Best available knowledge & science), making informed decision based on the
 best available knowledge in Canada & worldwide. Ensure consistency between qualifier (best available
 evidence) and line 168 (describe scientific and empirical evidence). Move "best available" to before
 evidence. How do we define "best" available knowledge?
- Bullet 4 Move up to before bullet 3
- Bullet 4 & bullet 2 should be combined
- Bullet 4:
 - Delete the word "evidence" (legalistic term)
 - o Change: what about precautionary principle?
- Bullet #6:
 - o Does test speak to Canadians?
 - o Accountability?
 - o Not necessarily understood by public
 - o Nothing a bout communication/transparency
 - Link bullet 6 to bullet 1
 - Bullet #6: Resources Is it government or more broad?
 - Line 66 add "key" before regulation



- Line 67: new bullet "Focusing human and financial..."
- Quality should also be in terms of protection of the environment
- 7th bullet add inclusive

What would you delete?

No specific comments received



ANNEX C DETAILED COMMENTS FROM BREAKOUT SESSION # 2

Breakout Session 2: Accountabilities of Departments and Agencies

Does the section on "Accountabilities of Departments and Agencies" help departments achieve the government's commitment to Canadians?

Do we have the right expectations and responsibilities for departments and agencies to assist ministerial decision-making and improve regulatory management?

- What would you keep?
- What would you modify?
- What would you delete?

Is intent clearly articulated and is the direction easily understood? How can we ensure that the government Directive has "teeth"?

Please note the allocation of sections for which detailed comments are sought:

Table 1 – Sections I. a, b and c (pages 2-4)	Table 3 – Sections I. f and g (pages 7-9)
Table 2 – Sections I. d and e (pages 4-7)	Table 4 – Sections II, III and IV (pages 9-11)

What would you keep?

• Overall content requires modifications but with few deletions

What would you modify?

Section I (a & b)

- Add Section VI to section II because identifying & allocating resources is critical to ability to execute.
- Switch order of section (a) & (b) to identify problem <u>before</u> consultation (as distinct from on going dialogue)
- 5 ways used to describe info (need to more consistent)
- Some situations do not warrant full consultation. Need flexibility.
- What is regulation?
- Find another term: not "problem" suggested issues or opportunities. Addressed only through regulation"? Other means also
- Where does the Directive start lifecycle?
- Apply principles to Legislation
- Not all decisions made by Minister (some already legislated by Parliament)
- Consultation with OGDs is required. Consultations to what level? Better definition of "full & fair" consultation is required
- Cabinet Directive on law making overlap
- Directive does not cover policy makers or other approach to changing law.
- Line 76 "Scope." remove title
- Scope line 88 90 is the scope. The rest does not belong. Better definition of scope. Does it encompass instrument of choice? Scope too broad. Some reg. Changes are single (better reference to triage)



Line 94: Add "potential" Regulatory Line 96: Delete "regulatory", analyze social, economic, environmental ٠ "Expected", "Ensure", "128", " to do our best" not well defined • Line 118 – 120, consultation pays, analysis and linkage (full opportunity too far) Line 140: define "significant" • Line 139 – 145 loses the current 75 day notification requirements for regulations affecting trade as • spelled out in Annex A of the current regulatory policy. Line 168 – 169 suggest leave out ethical/redundant Line 172 – 176 is confusing, 175 has no specifies • Section II (c & d) Where appropriate" or "subject to"...somewhere in section II (C) e.g. health and safety • o gender issues o environmental o economic (perhaps) Add a reference to implementation and compliance as a consideration Incorporation of ethical considerations is required Process guide tool needed What do we do in interim? • Debate on the default approach of what is out there • Dealing at the policy stage - include regulators at that point • Lines 192 - 195 Throughout section "risk" – in safety? (social safety) or economic as well? o Ignores expectation for government action to deal with an "issue" vs. "risk" (i.e. sport fishing) Line 199 – 207 – no mention of harmonization. "Equivalent" refers to tech requirement but does 0 not address conformity Lines 201 – 204: o Need clarity to put into practice so that "performance standard" can be understood by the regulator and regulated o Also, what about role of self-regulation, voluntary compliance Lines 205 – 251, eliminate. "Cooperate" not just accept. Line 211 – need to strengthen commitment to this. Horizontal accountability Line 211 more horizontal connecting 209: "Assessing Opportunity" • Too passive, needs more active voice o Jurisdictional issues: how/what to do about them? • Need flexibility: (i.e.) (1) When necessary (2) Telecom is clear fed jurisdiction Line 251 "only" not appropriate use OECD recommendations to use domestic unless have reason to adopt another. Line 251 – recommend OECD document on regulatory cooperation IRC – demanding! o "unique" is too strong • A lot of work in French o Is the word "ethics" needed? Lines 259-262. Assessing Impact of proposed options Ethical impacts need to be assessed o Appropriate mix of instruments vs. gualified mix? Assessing impacts at what stage of lifecycle o Early Cost Benefit Analysis for Regulatory Impact Analysis Talk to affected parties early on - e.g. cost to industry applicability of rule of law; "graduated" 0



regulations

- o Health risk e.g. West Nile
- o No assessment cost too high
- o Too focused on trade
- o CBA of public health & safety
- o Fast track/expedite
- o By pass Gazette
- Line 286 291 are in the French version only, not in English version
- Line 268, big burden. Introduce triage concept cross-ref guide? Burden introduce triage concept early in the document
- Line 307 320 not accurate characterization and does not promote int'l collaboration.
- 337 353 Cost Benefit Analysis
 - o Need guidance/direction on taking into account "abstract" or unquantifiable benefits
 - o Bias towards international trade versus Canadians domestic requirements
 - o "International requirements maintained" / treaty/ obligations

Section II (e & f)

- Incorporation of ethical considerations
 - o Tools to guide us
 - What to do in meantime
 - o Policy first
- Do departments have regulatory agendas?
- What kind of mechanism will be available
- Much of guidance should be geared to policy development process: MC/legislation (primary) at regulatory development stage may be too late
- Section to be added: enforcement
- Definition of compliance
- Section (f) should be better integrated
- "Law systems" → move to role of DoJ
- Planning for implementation should come before planning for compliance
- Overall how is this "smarter" than existing
- Are "compliance plans" the same as "compliance strategies
- RIAS needs to be written, to be understood
- Use adhere & ensure to satisfy international community
- Regulations are only part of evaluation process
- Use terms (mechanism) like regulatory
- Agenda need to formalize
 - Regulatory agenda, implementation plan, terminologies (will these be forthcoming?)
- Lines 314 320 Move paragraph at and insert after line 309
- Line 360 call it consultation, By the same token is this consultation does this mean capture in RIAS?
- Lines 360-362 are too wordy
- Line 368, to be reviewed: is it in right section?
- Line 376, more clarity is required
- Line 437 accessible & needs to say should be written to be understood
- Line 374 use compliance plus/strategies?
- Line 383 384 statement has no content

Section III

• Poor use of terms agenda, plan etc



- Change "expected to" \rightarrow does, "ensure" \rightarrow something else No consequence to non action, vagueness need incentive for agenda/plan, use comprehensive • Need editing and formatting • Plan vs. agenda \rightarrow report on plan • Delete "expected to", mixed message with responsible Teeth: what happens if you don't plan? Repercussion not clear o Allow departments to be vague. How to prevent departments from circumventing o What is really needed / intended? Add to intro: statement indicated that PCO & departments have different & complementary roles • Line 444, whole section should be deleted Line 448 – add reference to time frame Section IV Cannot "ensure" • "PCO is responsible for" (generally in doc) • Need to be clear what PCO will see • Line 459 - remove "sufficient" • • Line 463 – remove "to better" Line 467 – delete "policy &" • Line 467, remove policy as the regulatory • Line 483, Quality of RIAS vs. of the submission • • Line 486 – 486, too subjective Line 492, benchmarks where appropriate • Section V Line 511 – "tools" what are they? Use different word/explain (e.g. guidelines, standards, checklists. • Crown liability) Line 514 - Advice not usually given on "performance standards" what is it? What does it mean? Delete • (not a DoJ responsibility) or explain • Line 528 – TB "advises" seems top-down. Use "works with"... for resource management TBS responsible for coordination of process of reporting – Not for reporting , • • Not clear what it meant • How does TBS role relate to regulatory activity? • Line 534 – TBS not responsible for reporting. Also explain overall TBS responsibilities. What would you delete? Line 93: Delete: "dialogue" • (Int'l) from 439 • Line 251 – eliminate: o Incorporation by reference o Goes too far
 - Line 383 384, just a statement?



ANNEX D DETAILED COMMENTS FROM BREAKOUT SESSION # 3

Breakout Session 3: Implementation Needs

What does the federal regulatory community need to implement the Government Directive successfully?

- What skills and training do you need to implement the Government Directive successfully?
- How does the Regulatory Impact Analysis Statement need to change to reflect the new expectations in the Government Directive?
- How does the PCO Challenge Function need to change to reflect the new expectations in the Government Directive?
- What other tools, guides or processes are needed for successful implementation?

Q1: Skills and Training Required for Implementation:

Due to broader approach in the Directive, more specific & broad skill sets required (e.g., economist). Important new skills that are required to implement the Directive include:

- Analytical capacity
 - o Multi-disciplinary groups of specialists
 - How to collect & integrate information (on what other countries are doing for example)
- Communication oral & written(language skills)
- Consultative skills, including how to hold consultations
- Change management
- Economists / cost benefit analysis
 - o Knowledge econometrics
 - o Costing guides
- Project management \rightarrow leadership/organizational
- Interpersonal capacity to work with others

Specialized knowledge/experts are required in environmental assessment, values and ethics, performance measurement, international trade impact

New skill requirements should be tailored to meet departmental requirements / approach (HR issues collide):

- o Certification of a basic level of knowledge, then
- o Successive specialize levels Economic /Social /Environmental
- o Minimum levels for Education /Personal Development

New skill sets can be advanced through the provision of training such as:

- Consultations skills/guidelines/training
- In depth community knowledge, including communities of practice chat rooms (with passwords)
- F/P/T/M considerations
- Language
- Cultural sensitivity (aboriginal groups)
- Understanding the role of Parliament
- Understanding of the roles of science in analysis/risk analysis & regulations (e.g., consistency, precautionary principle, etc)



- Understanding the Regulatory place in the legislative process
 - o REGS 101: Policy development, MCs, Regulatory Drafting
- International trade (TBT/SPS)
- CBA / impact assessment (Benefit/cost analysis, minimal (basic) training in economy (econometric))
- Performance measurement training
- Instrument of choices (mix)
- How to effectively integrate information (store, manage etc...)

Q2: Recommended Changes to RIAS:

Current RIAS headings & proposed headings OK (only new thing is background previously covered in description). Potential avenues for making changes to the RIAS include:

- Instead of "alternatives" have a section on "instrument" of choice
- Instead of "benefits & costs" → "impact analysis"
- Need to add to implementation:
 - o Alternative, mix of instruments
 - o Performance management
 - o Sustainable development
 - o Continuous improvement
- Defining problem definition to include:
 - o Risk analysis
 - o Policy objectives

There is strong support for one stop shop guidance manual housing all info/guidance needed by departments & agencies. Suggest perhaps centers of expertise that are well identified to departments for T reasury Board/Privy Council Office issued, so if departments have questions they know who to go to. RIAS is also a tool to increase Govt. transparency

The RIAS writers guide should be redone to reflect new expectations in terms of analytical requirements and to be able to help departments to meet new challenge function. New items include:

- o Other tools (guidance)
- o Guidelines to include competition analysis.
- o Guidance on social/ethical dimension (definitions)
- o Business impact administrative burden
- How to better capture qualitative benefits (e.g. social) = guidance

The current focus of the RIAS remains economic. Cost benefit analysis is often difficult – the additional dimension of social impact analysis will be even more difficult. Social analysis also impacts on the consultation section:

- o New skills will be required
- o Need to ask the right questions

Flexibility must be maintained, especially if the Triage system is to remain effective. Flexibility would include not all of the RIAS needing to contain all categories. As well, the RIAS needs to be clearer: examples use visuals graphics. A standardized form that is used across the Internet would be helpful.

Q3: Recommended Changes to the Privy Council Office Challenge Function

Privy Council Office should question regulatory proposals that have:

- Other departmental initiatives
- International obligations
- Jurisdictional issues
- National vs. regional issue: instrument choice

Regulatory needs should then be immediately discussed with Privy Council Office to mobilize these proposals.



Different standards and due diligence should be applied for low, medium, high RIAS,

The PCO Challenge Function should be earlier, just after Triage. It is a good idea to submit a draft RIAS to PCO when it goes to the Department of Justice.

There are PCO capacity (Full Time Equivalents) challenges that limits there ability to provide an effective challenge function. As well the PCO challenger needs to be knowledgeable in the area/section. PCO should look at organizing analytical staff differently (specialize in compliance, etc).

Key suggestions for change include:

- Sharing the interim checklist
- Ensuring that the final approach should not be checklist
- Providing more of a guidance role
- Implementing a pool of specialized resources
- Being able to measure the impact of tools on litigation

Q4: Additional Tools, Guides and Processes Required

Range of products will be required for different people throughout the process

- Training for interpretation of Directive
 - o Updated RIAS writers guide
 - o Glossary of terms
 - o Standard of evidence
 - What are departments / agencies are required to provide to PCO/process
 - Guides training in:
 - o Ethics
 - o Performance indicators/measurement
 - o Risk analysis, benefit/cost analysis and social impact analysis
- Availability of key resources
 - o Analysts
 - o Horizontal coordinators.
 - o International regulatory cooperation
- Synthesizing of existing information and condensing into one guide and linking skills/training to guides/tools
- Use of an automated tools
 - o Electronic bulletin board internal to government
 - o A website with all documents related to regulation
 - o PCO hotline
 - o On-line tutorial with drop-down menus and flow charts
 - Network/forums/courses for interdepartmental staff working with regulations to share info/lesson learned/best practices, etc
- Provision of contact list with areas of responsibilities (e.g. theme table membership, etc.) and a roster of experts (analysts), including access to expertise in international community
- Consultation guidelines/mechanisms including additional process step for:
 - o Inter-departmental meetings (same as for MCs)
 - For high and significant regulations.
- Lessons learned including:
 - o Pilot studies thru entire process, including with stakeholders (reaction, focus groups)
 - o Post mortems of good/bad examples



ANNEX E PRESENTATION FROM PLENARY SESSION



The Government Directive on Regulating

Interdepartmental Workshop

September 8, 2005

Plenary Session – What We Heard in the Breakout Sessions

Canada













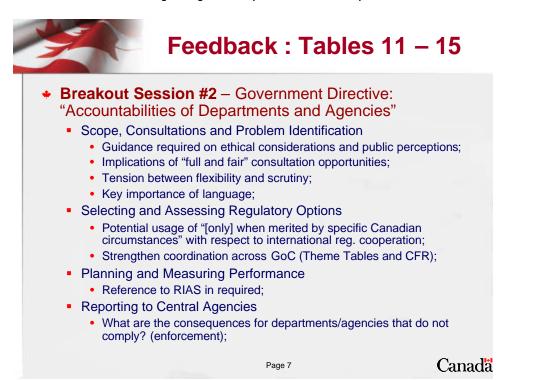


Feedback : Tables 16 – 20

Breakout Session #2 – Government Directive: "Accountabilities of Departments and Agencies"
Scope, Consultations and Problem Identification
Some situations do not warrant full consultations;
Flexibility is needed;
Selecting and Assessing Regulatory Options
Incorporation of ethical considerations;
Triage concept to assessing social and environmental impacts;
Requirement for better links between policy background and regulatory proposal review/challenge function;
Balance between prescription/level of detail and flexibility;

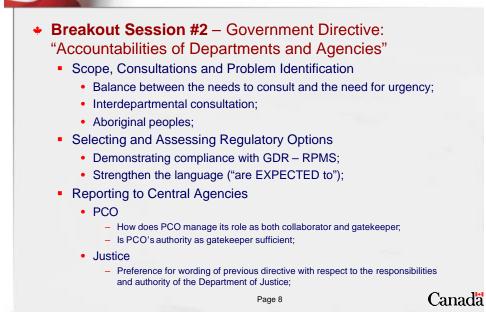
Canada







Feedback : Tables 6 – 10









Feedback

- Breakout Session #3 Implementation Needs and Measuring Success of the Directive
 - What skills and training do you need to implement the Government Directive successfully?
 - How does the Regulatory Impact Analysis Statement need to change to reflect the new expectations in the Government Directive?
 - How does the PCO Challenge Function need to change to reflect the new expectations in the Government Directive?
 - What other tools, guides or processes are needed for successful implementation?

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Canada



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September 8, 2005

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