Protection and Precaution: Canadian Priorities for Federal Regulatory Policy

An NGO Position Paper on the proposed Government Directive on Regulating

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About CELA:

The Canadian Environmental Law Association (CELA) is a public interest group founded in 1970 to use and improve laws to protect the environment and conserve natural resources. Funded as a community legal clinic specializing in environmental law, CELA represents individuals and citizens' groups before trial and appellate courts and administrative tribunals on a wide variety of environmental issues. In addition to environmental litigation, CELA undertakes public education, community organization, and law reform activities.

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Hugh Benevides has worked in the field of environmental law and policy reform for 14 years, currently as research associate for the Canadian Environmental Law Association (CELA) in Toronto. Areas of particular interest include toxic substances regulation, environmental assessment, regulatory theory and democratic administration. Hugh coordinated CELA's submissions to the External Advisory Committee on Smart Regulation in 2003 and 2004. Hugh holds Bachelor of Arts (High Hons., Carleton) and Bachelor of Laws (Dalhousie) degrees, and is currently pursuing a Master of Laws degree at Osgoode Hall Law School, York University. The author acknowledges the contributions of representatives of environmental, health, labour and other citizens' groups in the preparation of this report.

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Introduction

In a parliamentary democracy the development and enforcement of a regulation, enabled by parent legislation, completes the linkage extending from Canadians, through their elected representatives, to the laws that are enacted in the legislature. In a democracy, Parliamentarians and Canadians alike should be able to see how this final link in the chain is completed.

Any government policy directed at the critical function of regulation-making should begin with a statement, in the clearest possible language, of the substantive purpose of such a policy. It should focus on ensuring that legislative objectives, delegated to regulatory instruments, are achieved. It should not erect inappropriate barriers to regulation.

Contrary to these basic requirements of a democracy, the current *Government of Canada Regulatory Policy*, like the proposed *Government Directive on Regulating* ("draft GD-R"), imposes significant obstacles to enacting regulations. The policy tends to thwart the intention of legislation rather than promote it.[1]

The signatories to this report recommend that the Government of Canada acknowledge the overall purpose of regulation as the protection of public goods, and that consistent with this purpose, that it open up the regulatory process to Canadians.

It includes a number of recommendations, in addition to the following proposals that non-governmental organizations have made over the past two and a half years in the context of so-called "smart regulation". These fundamental recommendations are repeated here because they form the necessary base for the federal regulatory system that Canadians expect:

- Effective regulations for protection of the public good must be made by authority of government, and backed by the force of law.

- In order to ensure protection of the public, the federal government must have the necessary involvement, capacity and ability to exercise its powers.

- Significant regulatory capacity and demonstrated willingness to enforce regulations are the primary motivators for regulatory compliance, and must be maintained by the Government of Canada.

  Regulation, defined to include public accountability features, has proven effective. Evidence suggests that actual regulation is more effective than mere threat of regulation, which in turn is more effective than mere ability to regulate. [2]

[1] John Jackson, Citizens' Network on Waste Management, Toronto public workshop on proposed GD-R (November 18, 2005).
[2] Canadian Environmental Law Association, *Submission to External Advisory on Smart Regulation* (CELA, April 2004), pp. 10, 11 and CELA's *Remarks to the EACSR* (July 21, 2004), p. 3.

Laws, and the regulations authorized by them, are meant to protect against potential negative effects and hazards, in order to prevent their being unleashed on the public and on the land, air and water. This protective role is a basic function of government, and it must be clear in any government's regulatory policy.

But throughout the "smart regulation" initiative – and indeed, in federal regulatory policy dating back at least twenty years – this public good protection imperative has been buried among and "balanced" against a number of other priorities, notably economic values like "competitiveness" and "economic efficiency". [3] In his 2000 report, the Auditor General of Canada recommended that the Government of Canada

> … should **explain to Canadians** and the government's regulatory and inspection community **its priorities for health and safety regulatory programs, particularly the balance that the government has reached** to protect Canadians and address budget, social, economic and trade objectives. The government should revise its regulatory policy and other policies to reflect this emphasis. [4]

The proposed GD-R, like the current *Regulatory Policy*, does not explain how this "balance" is to be reconciled. A mandatory **Precautionary Framework for Public Good Regulation** as proposed here would, on the other hand, clearly identify the priority of Canadians.

<u>Recommendation 1</u>: The organizations and individuals supporting this report continue[5] to assert, in keeping with the recommendations of the Auditor General in 2000,[6] that the Government of Canada must be explicit that the single priority of the regulatory system is public good protection.

> ***The purpose of regulation is protecting the public and public goods against threats to safety, health and the environment***. Another way of expressing this, which extends to economic regulation as well as social regulation, is that the ***purpose of regulation is to limit the negative effects and excesses of economic activity***.

[3] A stated "principle" of the 1986 regulatory policy, for example, was that government should "regulate smarter." [OECD, "Regulatory Reform in Canada: Government Capacity to Assure High Quality Regulation" (OECD, 2002), p. 11.] Then, as now, the "smart" language was allowed to stand in for a potentially deregulatory agenda.

[4] Chapter 24, *2000 Report of the Auditor General of Canada*, "Federal Health and Safety Regulatory Programs", paragraph 24.94.

[5] See "Letter from CELA and 45 other[s]" (July 2004) and "Letter to Rt. Hon. Paul Martin" (October 2004), both at http://www.cela.ca/coreprograms/detail.shtml?x=2017.

[6] "… there is a need for the government to clarify the priorities of the regulatory policy for health and safety regulatory programs and clarify the balance it has reached to protect Canadians and address costs and other objectives …". 2000 *Report of the Auditor General*, chapter 24, at para. 24.86.

Purpose of Regulation: Protection and Precaution

While regulations may be made for a wide range of different *particular* purposes, a purpose *common* to all of them is the protection of public goods from some unwanted impact of economic activity. This is true whether the regulation is intended

- to allow a fair and level playing-field for actors wishing to engage in the economic activity in question (in this category, *in addition* to ensuring fairness among participants, the government's role is to ensure the public is neither cheated nor put at risk);

- to control the number of entrants to, or the mode of exit from that economic activity so that the public is protected, for example, from a company's unfair business practices, or from the consequences of the company's insolvency; or

- to protect the public and the environment from some negative externality – such as environmental, health, or safety hazards – generated by the economic activity.

Recommendation 2: **The regulatory policy should begin with an overarching policy direction that regulation is always intended to achieve the same purpose: the protection of public goods from undesired impacts of economic activity**.[7] **Further, the policy should make explicit that regulation is the preferred instrument choice over non-regulatory approaches.**

The Canadian public puts a priority on regulatory protection, not promotion

Public opinion is firmly behind the protection priority.

Canadians consistently indicate their expectation that regulation be used to protect public goods. According to focus group research conducted by Health Canada on "smart regulation", Canadians' strongest substantive reasons for regulatory review are to "improve safety" and "enhance fairness".[8] In addition:

- "Most [Canadians] think about regulation on a case-by-case, issue-by-issue basis. In particular, many associate regulation principally with the protection of the health and safety of Canadians."

[7] An overarching purpose for the regulatory policy (as opposed to "balancing" a number of potentially conflicting objectives against each other) is not unprecedented: the 1992 version "adopted the over-arching regulatory objective of "maximizing net benefit for Canadians": OECD, *Reviews of Regulatory Reform: Canada: Maintaining Leadership Through Innovation* (Paris: OECD, 2002), at 32 and 55.

[8] See "Arguments in Favour of the Smart Regulation Initiative" in The Strategic Counsel, *A Presentation to the Government of Canada Inter-Departmental Group on Smart Regulation (Findings from Focus Group Research – Final Report)* (overhead deck, December 2004), p. 13.

See also Canadian Environmental Law Association, *Submission to External Advisory Committee on Smart Regulation* (April 2004), footnotes 7-9 and supporting text (pp. 3-4), at http://www.cela.ca/publications/cardfile.shtml?x=1879.

- "It is generally understood that regulations are in place in order to protect "the public interest", … [which is] broadly defined as protecting [the] health and safety of Canadians."

- When prompted by "a series of arguments in support of a "Smart Regulatory" initiative, … the population health and safety benefits [stemming from a review of the regulatory framework] were most salient by comparison to economic impacts."

- Among all possible alternatives, "Participants spontaneously highlighted the following values/principles as key pillars: Safety comes first. Participants referred to safety both in terms of their personal health as well as environmental safety. [This notion of safety came first ahead of all other considerations, including the promotion of economic growth and competitiveness.]… Notably, a number of participants placed considerable emphasis on the ethical or moral dimensions of regulatory policy." [9]

The Auditor General has also recognized that citizens clearly support health and safety over economic considerations in the areas of health and the environment. In his 2000 Report, he criticized government regulatory policy for failing to indicate clearly the relative priorities of health, environmental and economic factors:

> Health Canada's 1999 National Consultations Summary Report found that Canadians believe that 'health and safety must take precedence over economic and other considerations.' However, the government's regulatory policy contains potentially conflicting requirements. The policy requires that costs and economic objectives be considered when developing and implementing regulatory programs. In our view, there is a need for the government to clarify the priorities of the regulatory policy for health and safety regulatory programs and clarify the balance it has reached to protect Canadians[,] and address costs and other objectives. *Our concern for priorities of these programs stems from the emphasis on economic considerations in the regulatory policy …* [10]

Unlike the Auditor General's report, other "advice" relied upon by the federal Cabinet and the Privy Council Office (PCO) clearly accentuates economic objectives with very little emphasis on specific public good protection. Meaningful context is badly lacking in the various Organization for Economic Cooperation and Development (OECD) documents relied upon by PCO as providing guidance for the GD-R. [11]

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[9] The Strategic Counsel, "Arguments …", at pp. 15-16. See also submission to PCO by Dr. Tim Lambert emphasising the need for a focus on justice rather than net benefit, available at http://www.regulation.gc.ca/default.asp?Language=E&Page=smartregint&sub=subbusngo&doc=busngo_e.htm.

[10] Chapter 24, *2000 Report of the Auditor General of Canada*, "Federal Health and Safety Regulatory Programs", at paras. 24.86-24.87 [emphasis added].

[11] See "*The government's reliance on particular sources of "advice" in re-shaping the Regulatory Policy raises questions about accountability"*, below.

Protection requires precaution

The proposed GD-R (like the current Regulatory Policy) reflects government's tendency to concentrate on "managing issues" and "mitigating risk", [12] rather than concentrating on preventing harm posed by threats to humans and the environment.

While contemporary corporate management favours risk-based practices, a more appropriate perspective for government *regulatory* programs would emphasise "precaution." [13] A more precautionary approach would emphasize Canadians' expectation that regulation be used to protect public goods such as health, safety and the environment.

During the public consultations, Privy Council Office officials heard consistently from Canadians that they want government to err on the side of caution rather than competitiveness. However, PCO also heard familiar objections to precaution, for example that it requires proponents to "prove the complete absence of risk." Such irresponsible and disingenuous interpretations of precaution should be dismissed once and for all. Precautionary approaches do require fundamental shifts, but not away from science, and not imposing impossible hurdles before proponents. Instead, the necessary shift will favour the independent assessment of scientific evidence, and shifts in the weighting of evidence, toward more rigorous consideration of a full range of alternatives to technological responses to hazards. [14]

The following response to the objection that "the Precautionary Principle is about values, not science", demonstrates the nature of the necessary shift in thinking:

> The oft-heard critique that the precautionary principle abandons science to simply put forward a value of zero risk is rendered moot by San Francisco's simple statement that application of the Precautionary Principle will involve "careful assessment of available alternatives using the best available science." All reasonably foreseeable costs should be considered, "even if such costs are not reflected in the initial price." Moreover, "As new scientific data become available, the City will review its decisions and make adjustments when warranted." [15]

To the credit of the drafters, the draft GD-R attempts to embrace aspects of this approach. For example, the notion of a life-cycle approach to regulations may have merit, as long as the allocation of resources does not compromise the capacity of regulatory bodies to implement existing regulations, or create a chill against new regulations.

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[12] See for example Section B of the draft GD-R.
[13] See, for example, the Environment Code for the City and County of San Francisco. "The Code begins with a policy statement that recognizes the Precautionary Principle as the guiding model for future legislation." http://www.sfenvironment.com/aboutus/innovative/pp/
[14] See, for example, T. McClenaghan and H. Benevides "Implementing Precaution: An NGO Response to the Government of Canada's Discussion Document" (Canadian Environmental Law Association, 2002).
[15] Mary O'Brien, "Critiques of the Precautionary Principle" in *Rachel's Environment and Health Weekly* (December 5, 2003), at http://www.sfenvironment.com/articles_pr/2003/article/120503.htm.

However, the draft GD-R is unduly constrained by the assumption in other federal government policies that the precautionary approach is a "distinctive approach within risk management", to be used only in situations of "significant uncertainty".

While risk assessment is a necessary part of decision-making, the submission of the Canadian Labour Congress points out its limitations:

> …the mistake is to apply the process without qualification to environmental health regulations, where the project is deeply compromised by the paucity of data on exposure … and by the unknown effects of a multiplicity of confounding factors. …
> [E]ach stage [of the risk assessment] is vulnerable to a compounded error – a sure sign that the risk *assessment* exists only in name. …
> [T]he scientific integrity of regulations can be maintained without the exclusive reliance on risk assessment. [16]

The new San Francisco *Environment Code* and its "Precautionary Principle Policy Statement" [17] (unlike the Government of Canada's *Framework for the Application of Precaution in Decision-Making About Risk* [18]), uses clear language emphasizing:

- the need to be proactive to prevent, not merely manage, hazard and risk;
- the importance of measures ensuring transparency in decision-making; and
- the role of alternatives assessment,

as features of precautionary approaches.

Thus, the greater integration of precaution into regulatory science and decision-making does not amount to abandoning science. Instead, it would encourage the consideration, development and application of more holistic, environmentally- and health-based alternative measures for "well-being", "growth" and "progress". It would also encourage and facilitate the kind of precautionary regulation characterized by the Canadian Labour Congress's Pollution Prevention Planning proposal. [19]

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[16] Canadian Labour Congress Department of Health, Safety and Environment, "Preliminary Comments by the CLC on the Development of a Government Directive on Regulating" (CLC, July 2005), p. 7 [emphasis added]. Available at http://www.regulation.gc.ca/default.asp?Language=E&Page=smartregint&sub=subbusngo&doc=busngo_e.htm.

[17] http://www.amlegal.com/nxt/gateway.dll/California/environsf/chapter1precautionaryprinciplepolicystat?fn=altmain-nf.htm$f=templates$3.0.

[18] http://www.pco-bcp.gc.ca/default.asp?Language=E&page=publications&sub=precaution&doc=precaution_e.htm

[19] See CLC, "Preliminary Comments …", pp. 8-10.

Recommendation 3: **Instead of proceeding further with the current *Government Directive on Regulating*, a government-wide *Risk Management Framework*, a policy on *International Regulatory Cooperation*, and other policies and directives currently under development, the Cabinet should:**

- **instruct departments and agencies of the Government of Canada to place a priority on implementing precaution within their legislative contexts;**
- **in open consultation with these departments and the public, order the development of a Precautionary Framework for Government Regulation, emphasizing legislative duties, anticipatory action, transparency, alternatives assessment, full-cost accounting, and a participatory decision-making process. This framework would replace the *Regulatory Policy* [20] and other policies, existing or in development, dealing with risk and precaution; and**
- **order the review of all initiatives undertaken under the "smart regulation" banner, on the basis of the new precautionary framework.**

Transparency and accountability: ensuring compliance with the overarching purpose

Regulation-making is a government function of fundamental importance that Parliamentarians delegate, by definition, to the executive branch.

The great volume of both existing and needed regulation make openness more important, not less relevant. Parliamentarians have a role in vetting regulatory decisions that flow from regulatory legislation. New ways of fulfilling this role (beyond the current function of the Standing Joint Committee for the Scrutiny of Regulations) need to be explored as part of any regulatory reform exercise.

Citizens need to see greater openness in government decision-making, rather than further concentration of decision-making power in the Prime Minister's Office and in other central agencies. Parliament is one (but not the only) proper forum for considering not only legislation, but also major policy proposals before they are implemented. A major policy like the proposed GD-R should be discussed in the House of Commons and in parliamentary committees whose mandates include tracking regulatory departments and agencies.

A greater role for Parliament in discussing such fundamental policies would also enhance Canadians' respect for Parliament. Recent extension of the "statutory disallowance procedure" to all federal regulations, [21] making regulators more accountable to Parliament, is just a beginning.

[20] For an example, see the San Francisco policy statement, which can be found at http://www.amlegal.com/nxt/gateway.dll/California/environsf/chapter1precautionaryprinciplepolicystat?fn=altmain-nf.htm$f=templates$3.0.

[21] *An Act to amend the Statutory Instruments Act*, S.C. 2003.

Just as the Auditor General recommended that the "balance" sought in the regulatory policy should be "clarified", other policy and regulatory decisions should be announced at the proposal stage, and debated thoroughly, both publicly and in the House of Commons before being adopted. This applies to major policy decisions, such as a new regulatory policy.

Recommendation 4: **Major policy decisions, such as a new regulatory policy, should be announced at the proposal stage and debated thoroughly, both publicly and in the House of Commons, before being adopted.**

The objective of closer scrutiny of regulatory decisions, by Parliament and the public, requires adoption by the Government of Canada of a mandatory regulatory policy, with public good protection as the overall purpose.

Mandatoriness can be achieved in two ways. First, all aspects of the regulatory process must be opened up to parliamentary and public scrutiny, as suggested elsewhere in this document.

Second, the regulatory policy must be given the legal status necessary to make it enforceable. A submission (from a former Director of Regulatory and International Affairs in the Food Directorate, Health Protection Branch of Health Canada) to PCO, during the summer 2005 consultation on the GD-R, underscored the low profile of the current policy:

> One of my colleagues recently asked a group of about 15 federal regulators if they were familiar with the Government of Canada Regulatory Policy. Only three regulators acknowledged any familiarity with the policy and even those tended to dismiss it. [22]

Similarly, in reviewing the *Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, the Commissioner of the Environment and Sustainable Development wrote,

> We found major gaps in how the directive is being applied. A number of the 12 departments we examined have put in place few of the basic management systems needed to comply with the directive. The three departments we evaluated in detail have conducted few strategic environmental assessments in the years we examined (2000, 2001, and 2002), and their completeness varies. [23]

The pattern is clear: despite any assurances that policies constituting the "internal law" of government will be enforced and complied with, the very nature of such policies is that they are neither enforceable, nor enforced.

[22] Barry L. Smith, letter to George Redling (June 20, 2005), p. 3.
[23] Chapter 4, "Assessing the Environmental Impact of Policies, Plans, and Programs" in Report of the Commissioner of the Environment and Sustainable Development (2004), p. 1.

A regulatory policy with a single, clear public purpose, namely the protection of public goods, would facilitate the enactment of fair, sound regulations. Regulatory departments must have the capacity necessary for the implementation and enforcement of such regulations. Their responsibilities must not be diluted by conflicting roles such as the promotion of industry or the competitiveness of Canada's economy. Promotional functions are not to be confused with the central regulatory function of protecting public goods.

By contrast to the public good protection purpose, enhanced economic competitiveness, "efficiency" and timeliness of regulatory functions may be coincidental *effects* of regulatory functions, but they should not be considered central *objectives*. The purpose of protecting public goods through regulation can only be achieved if it is the overarching, undiluted purpose.

The temptation to pursue economic goals ahead of, or as a means of achieving the public good protection purpose, will always be strong, with pressure coming from industry leaders and other governments. But bending to this pressure will invariably compromise the latter. [24]

Most important, a policy clearly rooted in such a public purpose must be both enforced, and seen to be enforced. Without mechanisms for ensuring accountability for a regulatory policy, the policy lacks the imprimatur of democracy.

> ***The obstacles and barriers to enacting sound, enforceable federal regulations*** that exist in current federal regulatory processes are significant, and ***constitute a serious contribution to the democratic deficit***. ***The Government Directive on Regulating (GD-R) currently proposed by the Government of Canada would intensify this threat.***

The government's reliance on particular sources of "advice" in re-shaping the Regulatory Policy raises questions about accountability

Of all the sources of advice on which the Privy Council Office bases the policy direction of the GD-R, only the Auditor General's report bears the mark of a parliamentary officer. The others, which include an advisory committee and the Organisation for Economic Cooperation and Development,[25] fail to address adequately the context of specific public

[24] See for example, Janice Graham, "Smart Regulation: Will the government's strategy work?" in 173 *Canadian Medical Association Journal* 12 (December 6, 2005), p. 1469. Dr. Graham notes the lack of proper deliberation on "smart regulation", and questions "… the ability of the private sector to cooperate effectively in the regulatory process": "For example, … the pharmaceutical industry … invariably lobbies for deregulation policies that would allow it to quickly get its new patented products to market" (p. 1470).
[25] External Advisory Committee on Smart Regulation, *Smart Regulation: A Regulatory Strategy for Canada* (2004), and at least three different reports by the OECD on Canadian regulatory reform published in 2002. Highlights of the 2002 OECD and 2004 EACSR reports mentioned at page 6 of PCO's overhead

good protection regimes. Where such regimes *are* addressed, these contexts are balanced against and consequently, buried by a series of other items that in some cases are "values" that compete directly with public good protection, and in other cases are means of governing, such as the exhortation to government officials to "facilitate timeliness [and] efficiency" when regulating, mistaken for public ends. [26]

Not surprisingly, the EACSR report reflected its narrow membership:

> "Eight of the 10 committee members had either extensive corporate experience or work experience as management consultants. Remarkably, one member is the managing director of an international consulting firm that proudly advertises privatization, deregulation and liberalization as the pillars of its business." [27]

The OECD regulatory reform programme focuses particularly on strengthening "market openness and competition, and [reducing] regulatory burdens" [28] and tends to neglect specific regulatory contexts, in part because of a particular focus on "horizontal" and "whole-of-government" aspects of regulatory systems:

> "Isolated efforts cannot take the place of a coherent, whole-of-government approach to create a regulatory environment favourable to the creation and growth of firms, productivity gains, competition, investment and international trade." [29]

Such approaches tend to weaken the influence of regulatory departments that, compared to central agencies, are more likely to have the scientific expertise, the legislative obligations, and the will to implement regulatory objectives.

Of all the sources relied upon, only the Auditor General report makes the necessary connections between Canadians (not corporate "persons" and their lobbyists) and regulations.

A constellation of guidance documents

Other features of the regulatory system present further obstacles to transparency. For example, the existence of a constellation of interrelated policies and guidelines clouds the role and quality of implementation of the *Regulatory Policy*.

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deck titled "Public Workshops on the GD-R" focus on regulatory process, rather than on the context and objectives of particular regulatory regimes. The Auditor General's report, by contrast, takes explicit account of the purposes of health, safety and environmental legislation.

[26] Proposed GD-R p. 2, final bullet.

[27] Graham, "Smart Regulation …" at 1469. (See http://www.regulatoryreform.com/Guillotine.htm for information about the "Regulatory Guillotine™" programme that the EACSR member's firm promotes to countries wishing to reform their regulatory regimes.)

[28] OECD, *OECD Guiding Principles for Regulatory Quality and Performance* (OECD, 2005), p. 1.

[29] OECD, *OECD Guiding Principles for Regulatory Quality and Performance* (OECD, 2005), p. 1.

The relative importance of the various policies, guidelines and directives (Which are mandatory? Which are merely advisory in nature?) must be made clear both to regulatory agents and to the public, in order to give confidence that public good protection is indeed the first priority of regulatory systems. Even the OECD has noted the lack of clarity:

> [O]ne criticism of the Canadian approach may indeed be that it is too comprehensive, in the sense that drafters are subject to a larger number of quality criteria and procedural requirements than can reasonably be understood and implemented. For example, the Privy Council Office Web site lists a total of 16 publications, with seven relating to different requirements of the *Regulatory Policy* such as cost benefit analysis, compliance strategies, [and] writing a RIA statement.
>
> The question of whether regulators can be expected to assimilate all of this material effectively necessarily arises. Moreover, there may be issues in terms of the ability of the centre of government itself to keep up to date with this range of material. [30]

Unlike laws and regulations, the "internal law" of policies, directives and guidelines including the regulatory policy, is unenforceable. This weak system of accountability to the public contributes immeasurably to a "democratic deficit".

Improving openness for greater accountability

The regulatory process must be designed so that any Canadian, including parliamentarians, may look inside the process and see, whenever they wish, how decisions are made.

The current use of public consultation (often held after a decision has been made to regulate or not to regulate), and the notice of proposed and final regulatory decisions through *Canada Gazette* publication including the Regulatory Impact Analysis Statements (RIAS), are important but <u>minimal</u> procedures.

Despite the shortcomings, the RIAS can demonstrate (after the fact) how the regulatory system is prone to abuse by vested interests. One RIAS provides examples of serious accountability and transparency problems that can occur under the current regulatory policy.

We learn from this RIAS that:

[30] Organisation for Economic Co-Operation and Development, *OECD Reviews of Regulatory Reform: Regulatory Reform in Canada: Government Capacity to Assure High Quality Regulation* (OECD, 2002), pp. 21-22.

- A regulatory function (government testing to ensure a veterinary drug's minimal "compliance with safety for humans") is confused with a "service", [31] and the manufacturer or other applicant making a submission is referred to as a "client" or "service recipient."

- As a result of the federal government's cost recovery policies, funding of the veterinary drug programme depends directly on the revenues of manufacturers, which in turn requires that the programme provide a greater number of "services". "In anticipation of revenue from fees, parliamentary appropriations for the Veterinary Drugs Program (VDP) have been reduced by $1.2 million for 1996-97." [32]

- An alternative to user fees, namely a levy on veterinary drug sales as used in Australia, is "not feasible under current cost recovery policies",[33] and "The implication of [the chosen cost recovery] approach is that funding for the VDP has become a joint responsibility of government and industry." [34]

- The RIAS describes at length "who pays for what", further distracting the government from its responsibilities to ensure the safety, health and environmental characteristics of veterinary drugs.

- Despite government policies "requiring" consultation with the public, the RIAS describes an "open and transparent consultation process" involving only industry "stakeholders." [35]

- Not surprisingly, the RIAS reflects the outcome of the consultations as including the imposition by industry on government of "strong conditions … if industry is to continue to support the Canadian VDP." [36]

The story told by this RIAS calls to mind the advice of Justice Krever, that

> "The relationship between a regulator and the regulated…must never become one in which the regulator loses sight of the principle that it regulates only in the public interest and not in the interest of the regulated. The regulator must develop its own expertise and not rely on that of the regulated." [37]

Serious issues of conflicts of interest created by cost recovery policies has also been raised by the Auditor General, who reported that:

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[31] "Regulatory Impact Analysis Statement" for *Veterinary Drug Evaluation Fees Regulations* (SOR/96-143, 12 March 1996) in Canada Gazette Part II, Vol. 130, No. 6, pp. 1109-1119.
[32] RIAS, p. 1110.
[33] RIAS, p. 1113.
[34] RIAS, p. 1114.
[35] RIAS, p. 1115.
[36] RIAS, p. 1117-1118.
[37] Justice Horace Krever, Report of the Commission of Inquiry on the Blood System in Canada (Canada, 1997), p. 995.

> … the government's policy on cost recovery to fund regulatory efforts may be creating a potential conflict between the public interest and the interest of private organizations that are paying fees to help fund regulatory programs. For example, … [t]he Auditor General told the [House of Commons Standing Committee on Finance, during its study of cost recovery] that "as there is a greater dependency on fee recovery, a client-provider relationship could be established, and in some areas that may not be entirely healthy." He indicated that there is a need for direction on how to avoid potential conflict of interest. [38]

The advice of the Expert Panel on the Future of Food Biotechnology[39] in terms of greater public access to the results of scientific assessments, and the need for greater government capacity to conduct them, also reinforces the recommendations here on the need for a strong federal regulatory system, independent of economic interests.

A more deliberative democracy requires processes that include more fulsome public consideration of alternatives *before* policy directions are determined.

Current modes of encouraging transparency must be enhanced considerably to allow this to happen, and to ensure that access to decisions is not limited to those with a pecuniary interest in the outcome, and to those having the most resources for influencing decision-makers.

A central reason for improving transparency is to discipline the regulatory system to a public check on the quality of regulations before they are finalized, and to ensure that the priority is placed on public good regulation, not on private interests.

To date, the approach for motivating compliance with the *Regulatory Policy* has been to position responsibility for regulatory policy in either the Treasury Board Secretariat (along with a decentralized, self-regulation approach to compliance, originally embodied in the Regulatory Process Management Standards) or, alternatively, with the PCO. [40]

The performance of this "challenge function" by a central agency can increase the concentration of power in the system. From the point of view of health and safety regulation, the centralised challenge function poses a further, significant barrier to the ability of science and other experts in regulatory departments to design and implement effective regulations. [41]

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[38] 2000 *Report of the Auditor General*, chapter 24, paragraph 24.90.

[39] Expert Panel on the Future of Food Biotechnology, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (Royal Society of Canada, 2001).

[40] "Mechanisms to promote regulatory reform within the public administration". Section 2.2 in OECD, *OECD Reviews of Regulatory Reform. Regulatory Reform in Canada: Government Capacity to Assure High Quality Regulation* (OECD, 2002), pp. 23-28.

[41] Other systemic barriers – in addition to procedural barriers listed elsewhere – include insufficient capacity in regulatory departments, the muzzling of scientists, and the creeping domination, within individual departments and legislative schemes, of economic considerations over protective considerations.

Instrument Choice

The meaning of regulation

The notion of regulation has different meanings, to different people, in different contexts. In order to discuss the context for a government policy on regulating, we first establish two main categories of regulation.

> "Regulation, in its broadest sense, is a principle, rule or condition that governs the behaviour of citizens and enterprises ... to achieve public policy objectives. Regulation protects our health, safety and the environment and it plays a role in virtually every aspect of our lives: the products and services we use, the medication we consume, and the food we eat." [42]

A regulation in its narrower sense means the single policy instrument that a government will use when it wants to ensure that legislated public policy objectives are met, while respecting democracy and the rule of law.[43] The main reason for the choice of regulation as the preferred instrument of government policy is that economic actors cite the presence of regulation as the strongest source of motivation for complying with government policy.[44] Other, additional policy instruments may be used to *complement* regulation, but should not be considered as *replacements* for regulation.

Despite the proven effectiveness of regulations, both the current regulatory policy and the proposed GD-R introduce biases against the use of regulations, in favour of non-regulatory alternatives, by requiring elaborate risk-benefit assessments for proposed regulatory measures that they do not require for other instruments, such as voluntary measures. The specifications for the risk assessments to be conducted compel regulatory agencies to ask questions that underscore the potential costs of regulations, rather than instrument-neutral questions. In this way, the regulatory policy mobilizes biases against regulations by attaching significant transaction and analytical costs to their selection and use, relative to other instruments. The emphasis on avoiding these costs, in both the existing policy and in the proposed GD-R, is likely to lead to the selection of non-optimal instruments in order to avoid these costs, thereby preventing selecting the most appropriate combination of instruments.

Nothing in this report should be interpreted as lessening the determination of public interest groups to continue applying pressure to strengthen the public good protection aspects of the relevant regulatory laws and institutions.

[42] Government of Canada, "Regulatory Reform in Canada, Backgrounder [to release of *Smart Regulations Report on Actions and Plans: Fall 2005 Update*]" (October 2005)

[43] This narrower sense of "regulation" is consistent with the technical definition in the *Statutory Instruments Act*.

[44] See for example, Canadian Environmental Law Association, *Submission to External Advisory on Smart Regulation* (CELA, April 2004), pp. 3, 11.

For example, the proposed GD-R requires regulators to do the following (italics have been added to illustrate how difficult, even impossible, and value-laden is the language used, and how it imposes the burden of answering sometimes unanswerable questions):

- demonstrate that the regulatory response will *not unduly affect* areas that it was not designed to address [lines 230-231]
- make use of voluntary consensus-based standards or guides when they *adequately fulfil* intended policy objectives [lines 241-242] [45]

- *consider accepting as equivalent* the technical regulations and conformity assessment procedures of other countries, *even if different, provided they achieve the intended regulatory objective* … [293-295]

- *minimize* the aggregate and *unintended impacts of regulation on Canadians and the economy* [312-313]

- *[limit] the number of specific Canadian regulatory requirements … to instances* where they are *merited by specific Canadian circumstances* and when they *result over time in the greatest overall benefit to Canadians*; and [identify] the rationale for [the proposed] approach, particularly when specific Canadian requirements are proposed [364-368]

- Departments and agencies are also responsible for *minimizing the adverse impacts of regulation on the capacity of the economy and the environment to generate wealth* and employment for Canadians, and for demonstrating that *no unnecessary regulatory burden will be imposed* on Canadians and businesses [428-431]
- *Limit the administrative burden* and *impose the least possible cost* on Canadians and business … [436-437]

- [choose] the option that (i) results over time in the *benefits justifying the costs* … and (ii) that helps *focus … resources where they will do the most good* [449-451]
- identify and … *quantify the benefits and costs* to Canadians, business and government … [458-459]

- *weigh the benefits against their costs* and use this weighting to rank the options … [465-466]

Cost-benefit analysis, in particular, has long been controversial for a variety of reasons, including its presumption that public goods can and should be valuated on the same scale as economic costs. It can also displace important public policy objectives. For example, if the policy goal is to reduce air pollution, the use of cost-benefit analysis at the instrument choice stage can suggest that the initial costs of policy implementation are too high

[45] Note that legislative purposes are not distinguished here from policy objectives, which may not have a legislative (that is, parliamentary-approved) basis.

relative to significant benefits later, with the result of the original policy action being rejected entirely and the problem continuing.

While the focus of the current *Regulatory Policy*, like the proposed GD-R, is limited to the regulation-making process, because of its biases against conventional regulations, it may actually encourage the enactment of fewer, and weaker, regulations.

These hurdles should therefore be removed from federal regulatory policy.
Recommendation 5: **The Precautionary Framework for Government Regulation should encourage the speedy enactment of regulations (along with other, complementary instruments) that are appropriate to address threats to public goods.**

In addition, both the current regulatory policy and the proposed GD-R unaccountably emphasize trade agreements ahead of Canada's obligations pursuant to other, equally binding, international agreements.

The Way Ahead

Rather than implementing a new regulatory process now, the Government of Canada needs to convene a national debate on the barriers to public transparency and involvement created when, for example, norms such as Cabinet secrecy are invoked to outweigh the need to protect public goods.

Recommendation 6: **Parliamentary committees responsible for tracking the regulatory activities of key regulatory departments, must be involved in the development of the GD-R, before the GD-R is finalized and sent to Cabinet for approval**.

Summary of Recommendations

Recommendation 1: **The organizations and individuals supporting this report continue to assert, in keeping with the recommendations of the Auditor General in 2000, that the Government of Canada must be explicit that the single priority of the regulatory system is public good protection.**

Recommendation 2: **The regulatory policy should begin with an overarching policy direction that regulation is always intended to achieve the same purpose: the protection of public goods from undesired impacts of economic activity. Further, the policy should make explicit that regulation is the preferred instrument choice over non-regulatory approaches.**

Recommendation 3: **Instead of proceeding further with the current *Government Directive on Regulating*, a government-wide *Risk Management Framework*, a policy on *International Regulatory Cooperation*, and other policies and directives currently under development, the Cabinet should:**

- **instruct departments and agencies of the Government of Canada to place a priority on implementing precaution within their legislative contexts;**
- **in open consultation with these departments and the public, order the development of a Precautionary Framework for Government Regulation, emphasizing legislative duties, anticipatory action, transparency, alternatives assessment, full-cost accounting, and a participatory decision-making process. This framework would replace the *Regulatory Policy* and other policies, existing or in development, dealing with risk and precaution; and**
- **order the review of all initiatives undertaken under the "smart regulation" banner, on the basis of the new precautionary framework.**

Recommendation 4: **Major policy decisions, such as a new regulatory policy, should be announced at the proposal stage and debated thoroughly, both publicly and in the House of Commons, before being adopted.**

Recommendation 5: **The Precautionary Framework for Government Regulation should encourage the speedy enactment of regulations (along with other, complementary instruments) that are appropriate to address threats to public goods.**

***Recommendation 6*: Parliamentary committees responsible for tracking the regulatory activities of key regulatory departments, must be involved in the development of the GD-R, before the GD-R is finalized and sent to Cabinet for approval**.