Policy Research Initiative | Projet de recherche sur les politiques

Canada-US Regulatory Co-operation
Charting a Path Forward

Interim Report

December 2004

PRI Project
North American Linkages

Canada

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Executive Summary

Within Canada, concern is mounting that the potential benefits of NAFTA are not being fully realized due, in part, to the different regulatory approaches of Canada and the United States. Extensive empirical research at the OECD clearly established direct linkages between domestic regulatory frameworks and the economic performance of member countries in terms of trade, investment, and productivity. For Canada, a small economy whose trade largely depends on a single giant neighbouring market, it is important to weigh the benefits and costs for industry, governments, and citizens of having regulatory differences with the United States.

This is recognized within the Government of Canada. Regulatory departments and agencies have been involved in regulatory co-operation with other jurisdictions on both bilateral and multilateral bases for years, with varying degrees of success. The final report of the External Advisory Committee on Smart Regulations (EACSR) made several recommendations regarding the need for the Government of Canada to enhance international regulatory co-operation, particularly between Canada and the United States, having argued that the public environment is now conducive to regulatory change.

The Policy Research Initiative (PRI) approached the issue of regulatory co-operation from three different yet complementary steps. The first was the review of several bilateral regulatory co-operative arrangements involving different countries, which confirmed that successful international regulatory co-operation:

- is based on a firm economic relationship;
- requires political commitment at the highest level; and
- necessitates time and sustained effort to build the necessary level of knowledge and mutual trust.

The second step was to review the literature and conduct empirical research on the potential impact of regulations and regulatory co-operation on economic performance. It became apparent that regulations could have a significant impact on productivity, competitiveness, trade flows, and both foreign and domestic investment. For example, OECD estimates suggest that a reduction in the level of economic burden of Canadian regulations to the level of the United States would substantially increase productivity growth. This is an important policy consideration within the context of Canada's lagging productivity performance relative to that of the United States, and the corresponding growing gap in living standards. In summary, PRI research indicates that:

- investment in Canada has been 40% higher than it would have been in the absence of the numerous regulatory reforms that have taken place in the past 25 years.
- If the decline in the level of burden of our regulatory system would have matched the decline observed in the US during this period, then investment could have been another 30% higher.

- further reform to bring the level of regulatory burden in Canada to that of the US could increase per capita income by some 2%.

The third step was the examination of specific sectors that could potentially benefit from regulatory co-operation and possible initiatives to move further down the path of co-operation. The area of new product approvals (i.e., drugs, pest control products, medical devices, new chemical entities) is regularly put forward as a promising candidate for greater regulatory co-operation, but progress has been slow. Many Canadian academics and industry groups encourage regulators to capitalize on the degree of confidence, familiarity, and close working relationships that have been well cultivated over the years, and move toward a greater degree of regulatory convergence between the two countries.

Using the academic literature as a guide, a basic empirical model of regulatory cost was developed and applied to the issue of regulatory product approvals. Results suggest the potential gains from faster regulatory decisions in Canada in the five sectors studied could lead to:

- an average annual increase in the present value of new product sales of 10.7 percent.
- annual gains of about 8 percent in present value of net income from new products.
- An increase in the average rates of return on new products of 4.8 percent.

To date, PRI's research has focused on the potential economic benefits to Canada of greater regulatory convergence with the United States. The underlying assumption is that many of these gains can be achieved without threatening existing levels of regulatory protection. Available evidence suggests that, in many cases, both the efficiency and effectiveness of our regulatory system could be improved through greater regulatory co-operation with the United States.

Most Canadian regulators recognize they are well positioned to take the next step to deliver on these potential gains. A number of key regulatory departments and agencies already have framework agreements (e.g., memoranda of understanding, mutual recognition agreements) in place, as well as less formal working arrangements with their American counterparts, that provide the basis for concrete action to bring the two regulatory systems more in step with each other. There is also mounting recognition by regulators that greater co-operation with the United States, whether through mutual agreements or unilateral action by Canada, will play an increasingly important role in improving efficiency and increasing Canadian regulatory quality and effectiveness.

Where concerns about pursuing regulatory co-operation persist, additional analysis should be undertaken to fully assess net benefits – through more detailed, rigourous analyses of the *incremental* costs and benefits of specific regulatory differences between Canada and the United States. Such analysis would provide the objective, evidence-based information that policy makers need to take actions that are in the best interests of Canadians.

Preliminary Observations and Conclusions

The research undertaken thus far by the PRI on regulatory co-operation suggests that Canadians stand to gain significantly from greater regulatory co-operation with the United States. These results and common sense dictate that Canada should look for ways to leverage the regulatory resources in other, more highly resourced countries, and focus its relatively limited resources on regulatory issues where it can nurture a comparative advantage or where potential risks to Canadians may be the greatest. In short, determine in which ways regulatory co-operation with the United States is in the best interests of all Canadians.

However, it must also be recognized that regulatory co-operation is a complex public venture with potential costs. Some argueco- that there can be benefits to maintaining distinct regulations if uniqueness is conducive to innovation or if tougher standards are justified on the basis of clear health and safety benefits for which Canadians are willing to pay a premium.

Overall, most observers would agree that when it comes to regulatory co-operation, each situation must be examined carefully to assess the net benefits from moving along the path of regulatory co-operation. However, research suggests options that could yield greater net benefits for Canadians. The challenge will be to persuade policy makers not to fall prey to protectionist thinking, whereby small insignificant regulatory differences are perceived as essential constituents of the Canadian identity and sovereignty. Rather, they need to focus on the larger picture, wherein broader net benefits can be realized for all Canadians.

The PRI's research suggests that a new policy strategy should be considered to accelerate progress on Canada-US regulatory co-operation. Given the potential net benefits of greater compatibility between Canadian and US regulations, federal regulators need to be actively encouraged to accelerate the pace of co-operation by applying the various tools available to them in a strategic, incremental fashion. In some cases, it may be in the best interests of Canadians to take unilateral steps to accept US outcomes, especially in areas of lower risk, and to focus limited resources where they will benefit Canadians most (e.g., areas of higher risk or emerging issues, or where Canada has a comparative advantage).

These issues were discussed by experts from academia, NGOs, industry, research institutions and government at a joint PRI and Social Sciences and Humanities Research Council (SSHRC) symposium held on October 29, 2004 in Ottawa. On balance, the following key observations and conclusions were reached at the symposium:

- There is a need to accelerate Canada-US regulatory co-operation.
- There is a need to focus on both the costs and benefits in selecting priority sectors for greater Canada-US regulatory co-operation.
- The political will to move forward exists; but a clear, practical plan is required.
- To be successful, any plan must be supported by a sound internal organizational framework based on prior experience, and provide a role for Parliamentarians.

Many of the themes discussed at the symposium were subsequently addressed in the "New Partnership" statement issued jointly by Prime Minister Paul Martin and US President George W. Bush on November 30th, 2004.

PRI's research will now turn to the important task of assessing specific strategies and options for deepening Canada-US regulatory co-operation, based on the themes that emerged from the symposium and the direction provided in the New Partnership statement.

1. Introduction

A recurring debate in Canada concerns whether policies should be targeted at reinforcing bilateral relations with the United States (the "second option") or whether Canada should put the emphasis on the diversification of its export markets and a more multilateral approach to international issues (the "third option"). This debate has been a constant in Canadian politics. Now, in the context of the 10th anniversary of NAFTA and the review of Canada's foreign and defence policies, this debate is at the forefront of the agenda.

One premise of the research is that it is not incompatible for Canada to be an active player both on the North American scene and on the multilateral stage. Indeed, to remain a meaningful economic actor in the current international economic context, Canada must maximize the potential benefits from an integrated North American market. It is illusory to believe Canada can be a competitive force in world markets if it cannot maximize its opportunities within the North American market. If Canadian firms and workers are able to hold their ground in markets close to home, then they will be in a position to succeed in international markets. However, the flip side of this argument does not hold.

Hence, one can dub the fourth option a policy approach for maximizing access to, and success in, the US market to provide the economic foundation to become a competitive force world markets.[1] This implies, among other initiatives, doing what is necessary to enhance the role of Canada as a gateway to the vast US market and improve the attractiveness of Canada as a location for foreign direct investment.

Looking at ways to reduce regulatory differences between Canada and the United States could eliminate some remaining obstacles to trade and enhance significantly the attractiveness of Canada as a gateway to the US market. Leveraging the vastly larger US regulatory resources and better co-ordinating regulatory approaches between Canada and the United States where it is in Canada's interests to do so, would go a long way in making Canadian firms more competitive in the US market, which is a prerequisite to international competitiveness, and in making Canada more attractive to foreign investors.

> In 2003, Canada-U.S. trade accounted for $570-billion.… Canada is stunningly, overwhelmingly dependent on just one market, the United States. Canada enjoys a huge bilateral trade surplus with the United States - $92 billion last year. It runs a trade deficit with all other major players: the European Union, Japan, China, Brazil, and Mexico. The net effect – surplus with the United States; deficit with everyone else – leaves Canada in surplus, courtesy of the U.S. market (Simpson, 2004).

There is considerable evidence and widespread conviction that NAFTA has generated substantial economic benefits for Canada. This has led to growing interest in strengthening existing ties and exploring options for realizing the Agreement's full potential and, in other quarters, for deepening existing ties and pursuing a more

encompassing “NAFTA-plus” arrangement (Fagan, 2004: A7). Canada’s regulatory regime is an integral part of this effort.

> The regulatory environment is a key factor in creating a climate conducive to enabling Canadian business activity, attracting investments to Canada, and facilitating North American and global trade. Because an economic space is defined and must be supported by a regulatory space, the quality and effectiveness of Canada's regulatory system have significant implications for our economic competitiveness (EACSR, 2004).

Many argue that the absence of a level playing field in the area of regulations, rules, and standards between Canada and the United States restricts the potential to reap the full benefits of membership in the North American economic space. More regulatory co-operation with the United States is one means to capture greater economic benefits while simultaneously safeguarding and improving the integrity of the regulatory system. This challenge has become central to Canada’s policy agenda since the implementation of the Canada-US Free Trade Agreement (FTA) in 1989 and the North American Free Trade Agreement (NAFTA) in 1994, and continues to dominate the developing 21st century policy agenda.

Targeting the United States as the key partner for regulatory co-operation does not mean lessening efforts invested in the pursuit of regulatory co-operation with other partners, through either bilateral agreements or more informal co-ordination. However, the existing linkages between Canada and the United States strongly suggest that Canada stands to gain the most from further regulatory co-operation with the United States.

This Report

The purpose of this interim report is to stimulate discussion of the potential for expanding regulatory co-operation between Canada and the United States, and the approaches available to Canada. The goal is to identify a more strategic and concerted approach to managing existing and future regulatory constraints with a view to maximizing the benefits arising from North American trade and investment opportunities.

2. What Is Regulatory Co-operation?

The OECD defines "regulatory co-operation" as the range of institutional and procedural frameworks within which national governments, sub-national governments, and the wider public can work together to build more integrated systems for rule making and implementation, subject to the constraints of democratic values such as accountability, openness, and sovereignty (OECD, 1994: 15).

Regulatory co-operation can be bilateral as between Canada and the United States, regional as among parties to NAFTA or the European Union (EU), or multilateral as among signatories to the World Trade Organization (WTO) agreement. Regulatory co-operation can also be unilateral, whereby one country acts to bring its regulatory approaches more in line with others, usually major trading partners.

Regulatory co-operation can take place at each stage in the act of regulating: at the early policy development stage, in designing or modifying enabling legislation, regulations, and standards and, perhaps most important, in the regulatory policies, practices, and procedures carried out every day in ongoing compliance and enforcement activities.

2.1 A Toolbox of Instruments

Regulatory co-operation has often been described as a continuum, ranging from the least formal approach, such as basic information sharing, to complete harmonization at the other end of the spectrum.

A more appropriate description would be a toolbox of practices that can be

> adapted to the needs and opportunities that present themselves in each specific situation. The choice of instrument will depend on the characteristics of the markets, the regulatory environment and technical infrastructure in the countries or regions concerned, the nature of the products, and the willingness on the part of industries and regulators to make use of such different instruments (CEC, 2001: 4).

Table 1 provides a brief overview of the tools available for regulatory co-operation. A more detailed description of these tools, examples where Canadian regulators have used them, and potential advantages and disadvantages of applying the tools in practice, are provided in Appendix I.

Table 1: Summary of Regulatory Co-operation Practices

Tool	Description	Example	Advantages	Disadvantages
Co-ordination				
Information Sharing	Exchanges of information and institutional experience through seminars, joint visits, audits, surveys, and information gathering. Commitment is key to successful co-operation.	December 2001 Minor Use Pesticide Workshop by Canadian Agri-Food Research Council; Information sharing between Fisheries and Oceans and the Federal Drug Administration, as well as between Environment Canada and the Environmental Protection Agency.	Potential for lower administrative and compliance costs; common understanding of best practices and mutual trust; early warning systems-risk management.	In the absence of clear goals or strategies, confidence-building can continue for years without achieving real outcomes; focus has generally been on regulatory differences rather than solutions.
Work Sharing	Approaches such as data sharing, research collaboration and parallel or joint reviews, often formalized in memoranda of understanding (MOU) between regulators.	Sharing of post-evaluation surveillance data; Health Canada's approach to distribution of new AIDS therapies; Canada-US Border Air Quality Agreement.	Fosters mutual understanding of regulatory rationale; facilitates risk detection; spreads the workload and for specialization of skills and protection of sovereign interests.	May be constrained by confidentiality requirements; does not address the shortage of regulatory resources faced by a small country like Canada.
International Standardization	Means of establishing international technical requirements, primarily on a voluntary basis.	International Standards Organization (ISO); International Electrotechnical Commisssion (IEC)	Contributes to increased global trade; unifies practices; provides a globally accepted reference; eliminates unnecessary divergences.	Membership can be ambiguous;; focus on existing technical practices.
Unilateral Co-ordination	A country may recognize another's assessment procedures as equivalent to its own, or align their regulations with those of another country.	Accept foreign approvals; foreign submission formats; test results; foreign summary data; and align regulatory standards	Reduces duplication of regulatory effort; can be a means to reduce product decision times; by definition, does not require mutual agreement with another country.	Can be complex, requiring detailed sectoral approaches; requires a high degree of trust, may be limited to areas of low risk only.
Mutual Recognition Agreements	Trading partners agree to recognize each other's standards as equivalent.	Canada and the EU on drugs and medical devices; Codex Alimentarius.	Can lead to better utilization of resources, reducing duplication of effort and increasing potential competitive advantage when partners share the costs of regulatory decision processes	By definition, requires co-operation of the other party, which may not be forthcoming. Also requires extensive trust and discussion, especially when changes occur in standards or regulations in either jurisdiction.

Harmonization	Establishment of common or identical rules by a group of authorities, with the intention that mandatory rules be identical.	The US Department of Agriculture and the Canadian Food Inspection Agency have harmonized some grade standards for fresh fruit and vegetables.	Rules are the same, enabling producers to adopt one process for all jurisdictions.	Can take longer than recognition of equivalence; harmonization may not always be a preferred option for non-technical reasons.

2.2 Experience in Applying These Tools

International Experiences

The PRI's examination of regulatory co-operation in four cases (within the EU, between Switzerland and the EU, between Australia and New Zealand, and between the EU and the United States) provides the following lessons for expanding Canada-US regulatory co-operation.[2]

Regulatory co-operation usually flows from pressures for further economic integration. In all four cases, the processes of regulatory co-operation came to fruition as a result of economic integration between major trading partners. Except for the US-EU experience, all parties made explicit reference to mutual recognition as the central mechanism to attain full trade liberalization. In the case of New Zealand and Australia, following the commitment to broad and deep integration, the two countries entered into an array of bilateral co-operative arrangements tailored to address issues in the targeted sector(s).

Australia-New Zealand, member countries of the EU, and the EU and Switzerland all moved beyond basic agreements aimed at increasing trade to regulatory co-operation, first in areas such as competition policy, transportation, and other areas of economic regulation, as well as food safety. Co-operation followed in more complex areas, such as social policy, policies involving sovereign interests, and the preservation of citizens' health and safety.

Regulatory co-operation takes time. All cases examined illustrate that regulatory co-operation is a complex process built on mutual trust. The countries in question all participated in trust-building exercises to establish a strong foundation for their relationships, and capitalized on this trust. This could best be achieved progressively as participating countries learn to rely on the regulation-setting process and the enforcement and compliance system of the other participants.

It is noteworthy that Canada and the United States have engaged in confidence-building exercises for many years now. The lesson from these international examples is that Canada and the United States can build on this foundation of trust to engage in concrete actions (i.e., mutual recognition and harmonization).

Political commitment is required. Political commitment is necessary to overcome implementation hurdles arising from agreements requiring internal co-operation between two or more organizations, when organizational mandates are incompatible, or

when sub-national governments share responsibility for delivering regulatory results. A strong political commitment can also help reconcile potentially conflicting national interests and international opportunities.

Canada-US Experience

Regulatory co-operation between Canada and the United States is not a new idea; it has existed in different forms and to various extents for decades.

The follwing observations are drawn from our review of research into the Canada-US experience:[3]

Canadian and US authorities work together successfully on many fronts. Common examples are the joint regulatory reviews of pesticides, new chemicals, and AIDS drugs. To date, the key benefit from regulatory collaboration has been a growth in knowledge, an understanding of each other's regulatory systems, and a general increase in mutual confidence.

Canada-US regulatory differences persist: The External Advisory Committee on Smart Regulations recently observed:

> Associations cited the lack of harmonization between Canadian and American regulations, approval processes, long wait times in Canada, and a "tyranny of small differences" between Canada and the US. A particular concern of firms is "accidental" differences – differences that occur not as a result of a deliberate policy choice but from slight variations in approach between jurisdictions that nonetheless have significant impact on business.

Both systems yield markedly similar regulatory outcomes. Despite socio-political and cultural differences, and the regulatory diversity that has built up over time between the two countries, Canada and the United States generally pursue similar regulatory outcomes, such as effective protection of security, health, safety, and the environment.

Empirical evidence suggests that relative costs of compliance are higher in Canada than in the United States.[4] Canadian businesses are generally concerned about two areas in particular:

- differences in the relative costs of compliance between Canada and the United States; and
- the opportunity costs imposed by regulatory differences between the two countries (i.e., cases where investment does not take place, products or services are not introduced to Canada, due to regulatory impediments).

Relative Costs of Compliance

Differences in regulatory requirements to get products approved or registered for the Canadian market impose additional costs on industries. Examples include the costs of additional testing for the Canadian market for pesticides products (specific Canadian field trials for residue, efficacy, and crop tolerance data) and for new chemicals (Canadian testing and volume tracking costs).

Differences in product standards between Canada and the United States can create impediments to domestic production (by shortening production runs to serve different markets or by diminishing the ability to promote products, secure investment, or service niche markets in Canada), and can impede the ability to export Canadian production to the United States, for example, differences in food product regulation (health claims, nutrition labelling, fortification) and differences in automobile standards (seat belt standards, daytime running lights).

Opportunity Costs

Impediments to timely market access causing concern in a number of economic sectors include the perceived delay in product approvals for the Canadian market. For industry, regulatory decision times directly affect time to market which, in turn, affects the ability to earn a return on investment in product development (for successful products and the investment in research on unsuccessful products). While this issue has been highlighted for many years, there is surprisingly little in the way of quantitative estimates of the actual economic implications of regulatory delays. Section 4 of this report addresses this issue.

Impediments to investment, trade, and innovation can result from regulation, directly and indirectly. The OECD observed that foreign ownership controls in Canadian telecommunications, airline, and banking industries restrict competition and investment (OECD, 2003: 12). Other regulations can indirectly affect the level, type, and location of investment when they are perceived to impose undue compliance costs, opportunity costs, and market access delays.[5] For example, regulation of intellectual property in Canada has been cited as an impediment to investment and innovation in biotechnology.[6]

Regulatory Federalism Issues

Canada and the United States have long regulated a broad range of economic and social activities. As federations, both countries have the added issue of sharing regulatory responsibilities with their provinces/states. How they manage this shared responsibility determines what their regulatory environment looks like, how well it functions, and whether the policy aims of one level of government undermines or complements the regulatory efforts of another (PRI, 2003a).

Small Country Disadvantage

The United States devotes about 10 times as many resources to regulatory activities as does Canada. However, in many instances, the volume of regulatory activity required in both jurisdictions is similar (number of regulated products and services), and is a function of several factors, such as the global marketplace and the demand by Canadians for access to the same products as their US neighbours. The result is that, generally, the US regulatory system has more regulators conducting an equivalent or more rigorous examination, within a shorter period of time.[7] This latter point is sometimes a major concern for Canadian consumers and one that cuts across a number of sectors.

Policy Preferences

Canadian regulations reflect policy preferences, which can differ from those of American counterparts and complicate the potential for regulatory convergence. For example, the federal government's commitment to bilingualism is integral to life in Canada, and this makes complete harmonization impossible in a number of areas, especially labelling requirements.

Legal Systems

Approaches to regulation in the United States tend to emphasize informed consent, consistent with reliance on tort liability as a complementary regulatory tool. Canada tends to place more weight on the informed opinions of government officials, rather than placing the onus entirely on the courts. Furthermore, access to information legislation and other regulatory or legal constraints regarding private/corporate information can pose challenges to information sharing with other countries.

3. Why Pursue Greater Regulatory Co-operation with the United States?

3.1 Key to Canada's Regulatory Reform Agenda

Regulations are a key tool of economic and social governance. In reviewing Canadian regulatory reform, the OECD noted that the quality of Canada's regulatory governance and its continued efforts to improve its regulations contribute to Canada's success in terms of both economic performance and the achievement of social goals. The importance of a nation's regulations to the well-being of its citizens is beyond debate.

However, bad regulations do occur. They result from unnecessary intervention, use of regulations as technical barriers to trade, lack of co-ordination of regulations among important economic partners, poor implementation mechanisms of good regulations, or more stringent regulations than are needed to achieve the regulatory objectives. They alter the incentives structure in the economy in a perverse manner, with a consequent welfare loss.

Concerns about the economic effects of regulations have been prominent on the government regulatory agenda since 1978. A consistent theme throughout this period of regulatory reform has been that good theoretical and practical reasons exist to pursue regulatory co-operation. For example:

- Many critical problems can be solved only by working together, particularly in areas, such as environmental protection, nuclear materials control, and matters within the purview of international financial institutions.

- Markets, production, and financing are becoming global. Barriers to participation in the world economy would lower Canada's standard of living.

In 1992, the requirement to pursue regulatory co-operation became entrenched in the regulatory policy of the Government of Canada, which stipulates that all regulatory agencies must co-ordinate their work with other governments, and adhere to international agreements, such as NAFTA and the General Agreement on Tariffs and Trade (GATT).[8] Article 714 of NAFTA establishes the goal of "equivalence" in the regulations of trading parties.

> **Article 714: Equivalence**
> 1. Without reducing the level of protection of human, animal or plant life or health, the Parties shall, to the greatest extent practicable and in accordance with this Section, pursue equivalence of their respective sanitary and phytosanitary measures.

The regulatory policy also establishes that the negative impacts on the capacity of the economy to generate wealth and employment must be minimized, and that limited resources available to government must be used where they do the most good.

One challenge is the concern that deepening Canadian collaboration with the United States will negatively affect achievement of regulatory objectives and that enhanced co-operation is being pursued in the name of economic gain, at the expense of regulatory safeguards (security, health, safety and environmental protections, and social/political values). If there were closer co-operation with the United States, would these protections be negatively affected? Or, is it possible to achieve greater economic benefits without sacrificing core regulatory objectives?[9] The overarching objective under the Government of Canada Regulatory Policy (PCO, 1999) is to maximize ***net*** benefits to Canadians. Within this central policy construct, the key question regarding enhanced regulatory co-operation with the United States is whether it can be a means to deliver greater *net* benefits to Canadians.

3.2 Regulatory Co-operation Is Smart Regulation

To reap the benefits associated with more effective regulatory approaches, the Government of Canada created the Executive Advisory Committee on Smart Regulation (EACSR) in 2002. The EACSR defines smart regulation as the ability to protect environmental and social benefits while simultaneously promoting conditions for a highly competitive and productive market, as well as the development of regulations that are more responsive to developments in science, technology, and international markets.

The EACSR chose to include regulatory co-operation as a component to a smart regulation approach. According to the EACSR, the goal of regulatory co-operation is to secure social and environmental benefits while simultaneously enhancing economic performance. "While exercising leadership is important, the government must be strategic and use resources for the maximum benefit of the Canadian public interest" (EACSR, 2004:24).

The EACSR also places priority on regulatory co-operation with the United States.

> North America should be the primary and immediate focus of the federal government's international regulatory co-operation efforts. (EACSR, 2004:22)

The EASCR observes that Canada faces two significant challenges in improving regulatory performance and economic competitiveness within the North American context.

- Canada and the United States both maintain parallel regulatory structures, frameworks, and institutions across almost all areas of regulatory activity. In many cases, these parallel regulatory structures and institutions reflect a convergence in policy objectives and regulatory procedures as well as high levels of co-operation. However, much of their work often overlaps, particularly in light of the fact that North America is a single, integrated market. These parallel, duplicative procedures can result in higher costs for governments and businesses in Canada.

- In spite of a high degree of regulatory co-operation and convergence, regulatory differences still exist across the NAFTA partners, especially with the United States. Some variations arise from differences in policy objectives, as for example is the case regarding Canada's commitment to the Kyoto Protocol, but many arise from differences in regulatory methods, procedural requirements, and decision-making processes. Many have questioned the benefits of these differences compared to their cost. More importantly, the cumulative impact of regulatory differences often results in higher cost structures for companies and higher prices and less choice for consumers. Much can be gained, therefore, by exploring ways and means in which such differences can be bridged or their impact ameliorated.

3.3 Economic Realities

In recent years, the persistence of productivity and income gaps between Canada and the United States reinforced the issue of whether part of that gap could be attributed to more restrictive regulations in Canada. This partly originated from research showing that regulations contributed significantly to the productivity slowdown in the United States in the 1970s, as well as more recent research pointing to strong, almost always negative links between economic performance and the burden of regulations. Evidence from cross-country studies also suggests country differences in regulatory regimes partly explain international differences in economic performance (Ndayisenga, 2004:9).

Canada's proximity and extensive trade links to the world's largest economic power, the United States, have made Canada a forerunner in the development and management of regulations in a globalized world. These factors have influenced recent developments in the Canadian regulatory system, including Canada-US regulatory co-operation in various economic sectors (Centre for Trade Policy and Law, 2004). To the extent that regulations have an impact on a country's international competitiveness through productivity, investment, or research and development, it is the efficiency and efficacy of its regulatory regime, relative to its major trading partners, that matters most. In the case of Canada, a persistent gap in the burden of regulations relative to the United States will result in the erosion of Canada's competitiveness in the US market.

As summarized in an article by Ndayisenga (2004) in the June 2004 issue of *Horizons*, the PRI examined research by a number of leading academics and pursued its own research into the broad economic impacts of regulations. Ndayisenga used a recently developed OECD database on regulatory indicators to assess the extent of convergence in the burden of regulations between Canada and the United States.[10] He found that Canada's regulatory regime, even with reform, has been more constraining on the economy than that of the United States. The gap, which was highest in the early 1980's, had narrowed in the mid and late '80's, but has exhibited an increase since 1991. As well, the literature reviewed points to a negative and statistically significant relationship between restrictive regulations and various economic performance measures including investment, innovation, productivity, and productivity growth. However, the magnitude of the effects varies from sector to sector, and from study to study.

In another recent study, Ndayisenga and Downs followed this line of research, and estimated the impact of regulations on Canada's standard of living as measured by per capita income (Ndayisenga and André Downs, 2004). They found that under various specifications, regulatory restrictiveness proxied by the OECD regulatory index is invariably statistically significant, negative, and relatively stable in the various specifications.[11] Their results showed that an increase of one percent in the regulatory index decreases per capita income by 0.12 percent to 0.16 percent, depending on the model used. Using these estimates, they calculated that per capita income in Canada would have been up to two percent higher had there been a total regulatory convergence (equality of OECD regulatory restrictiveness indices) between Canada and the United States.

Using the average OECD estimate of the impact of regulations on the investment rate (investment/capital stock), the PRI calculated that, if Canada had had the same degree of regulatory restrictiveness as the United States from 1976 to 1998, there would have been an average increase in investment of about US$1 billion per year. If Canada's regulatory regime had changed at the same pace as that of the United States, total investment in the Canadian economy would have been higher by about US$400 million per year, on average. In other words, Canada could have had an average of 30 percent more investment per year than what it actually had over the period.

Interpretation of econometric results is subject to an important qualification. As currently measured, the per capita income or productivity does not account fully for all the public goods and services produced by regulations. That is, what is captured by various studies is not the total net effect (benefits-costs). Rather, the estimates merely measure the cost in terms of lost per capita income or productivity attributable to the level of restrictiveness of regulations or the way the regulations are designed or implemented. Efforts to pursue regulatory reform in Canada and around the world strongly suggest that regulations could be better designed to achieve the same objectives. To the extent that this is true, the econometric results discussed above are a measure of what can be potentially gained by regulatory convergence.

What Can Be Learned?

Both a broad literature review and Canada-specific estimates on the economic effects of regulations contain useful lessons. First, the bulk of the evidence shows a statistically significant relationship between regulations and economic performance measures including productivity, investment, and income per capita. Second, there are clear economic benefits to regulatory convergence between Canada and the United States. Whether these economic benefits represent net benefits to Canadians has not been measured. Third, there is an important regulatory data gap, which hampers research on the impact of regulations on economic performance. Yet, this type of data will become increasingly important in informing the policy process and evaluating regulatory outcomes for a number of reasons.

- With increased incomes and the emergence of novel industries, comes more demand for regulations (health, safety, environment).

- With the elimination of tariffs as protectionist instruments, countries are likely to resort to less transparent measures, such as regulations, to shield themselves against international competition.

- Increased competition in international markets and for foreign direct investment demands that Canada's regulations take into account the regulatory frameworks of its main trading partners, particularly those of the United States.

- For a trading country such as Canada, it is the efficiency and the efficacy of its regulatory regime relative to its major trading partners that matter most. One approach to increase the competitiveness of Canada's regulatory regime is regulatory co-operation with selected trading partners.

3.4 Who Gains?

Who would benefit from the types of gains estimated by the PRI and others? According to basic economic theory, reductions in regulatory cost can benefit businesses, citizens, and the government.[12]

Gains to Canadian Businesses

Basic micro-economic theory suggests reductions in regulatory cost can shift marginal cost curves for firms which, depending on various market conditions (e.g., market power of the firm, demand elasticities), can increase the producer surplus. The EASCR observes that Canadian businesses benefit, because they can adopt one approach/platform across multiple jurisdictions, and the number of country-specific regulations with which they must comply decreases. This reduces costs, and enables them to realize and capitalize on manufacturing and research and development efficiencies.

Gains to Canadians

Micro-economic theory also suggests that regulatory co-operation can increase the consumer surplus and social welfare. The EACSR observes that Canadian citizens can benefit from regulatory co-operation, because they have access to a wider number and higher quality of products within a shorter delay. They also gain from the outcomes of better regulatory decisions resulting from an international pooling of expertise.

Gains to the Canadian Government

Regulatory co-operation can lead to more effective and efficient allocation of resources within government. For example, as discussed by Griller in the June 2004 issue of *Horizons*, regulatory co-operation can enable regulators to redeploy scarce resources to areas of highest risk for Canadians and to tackle emerging challenges. The Auditor General agrees. In her March 2004 report (OAG, 2004: 18), she observed that regulatory co-operation can increase efficiency and reduce regulatory burden by focusing on "those activities that are high priorities and establish international relationships that allow it to benefit from the efforts of other jurisdictions for those activities that are lower priorities." Governments also gain in that regulatory co-operation allows for greater pooling of scientific and technical expertise, and access to the latest and best knowledge, enabling them to become more effective regulators and decision makers.

4. Measuring Potential Economic Gains at the Sector Level

A summary of findings from an analysis by the PRI of the potential economic gains from enhanced regulatory co-operation for specific sectors follows. Using the academic literature as a guide, Blair (2004a) developed a basic cash flow model and then applied the model to the issue of regulatory product approvals (for human drugs, veterinary drugs, pest control products, and new chemical substances). Preliminary estimates at the product level were then used to derive sector-level estimates, accompanied by a discussion of potential indirect and induced effects. The model is general, but can be applied to assess a range of policy options and how they affect private sector investment decisions.

The estimates derived from the model are principally direct impacts on firms at the product or service level. In most instances, the types of indirect impacts that could accrue from various scenarios of Canada-US regulatory co-operation are discussed, but are not estimated. For this reason, the quantitative estimates likely underestimate the potential economic gains.

4.1 Basic Cash Flow Model

The cash flow model developed in Blair (2004a) has a long tradition in the literature. Heller (1995) developed quantitative estimates of the impact of regulatory approval times using discounted cash flow scenarios for commercializing biotechnology products in Canada and the United States. Heller found that the profitability of drug firms is most seriously affected by protracted delays in regulatory approval. Heller estimated that if regulatory approval delays were reduced by two years, it would improve the rate of return on investments by drug firms by at least 5.5 percentage points.

More recently, DiMasi (2002) studied a sample of 68 randomly selected investigational drugs from 10 pharmaceutical firms to determine the effects of shorter development and regulatory review times on capitalized costs for the drug industry. DiMasi found that a 50 percent reduction in regulatory review times would reduce capitalized costs by 7.6 percent.

Schwartz (2003) also developed a model to estimate the financial impacts of product approval delays at the firm level. While Schwartz based his work on the pharmaceutical industry, he noted that the model could be used to evaluate the effects of regulatory delays on net present value for any product approval process.

Grabowski et al (2002) developed a rate of return model to examine the worldwide returns on research and development for drugs introduced into the US market. The study assessed the impact of changes in various model parameters (margins, tax rates, sales profiles, cost of capital, and regulatory review times) on after tax cash flows, research and development costs, net present value, and internal rates of return.

Cash flow modelling has also been used in regulatory impact analysis in the United States. The EPA Office of Pollution Prevention and Toxics developed a cash flow model to assess the impacts of regulations on biotechnology products in 1997 (EPA, 1997).

The basic cash flow model underlying these studies is shown below.

$$PV = \int_{t0}^{T} [CF_t]\, e^{-rt}\, dt,$$
$$\text{where } CF_t = -RD_t - M_t + Rev_t - TX_t$$

where
t_o = beginning of the product life cycle
T = end of the product life cycle
CF_t = Cash flow at time t
RD_t = Research and development expenditures at time t
M_t = Production and marketing cost at time t
Rev_t = Revenues at time t
TX_t = taxes at time t

Blair (2004a) refined and added to this basic cash flow model to allow greater focus on specific regulatory parameters identified as key issues in Section 2 of this report, namely Canadian regulatory costs and regulatory decision times. Some model parameters were also refined to reflect Canadian business realities.

Figure 1: Stylized Cash Flow Scenario for a Regulated Product

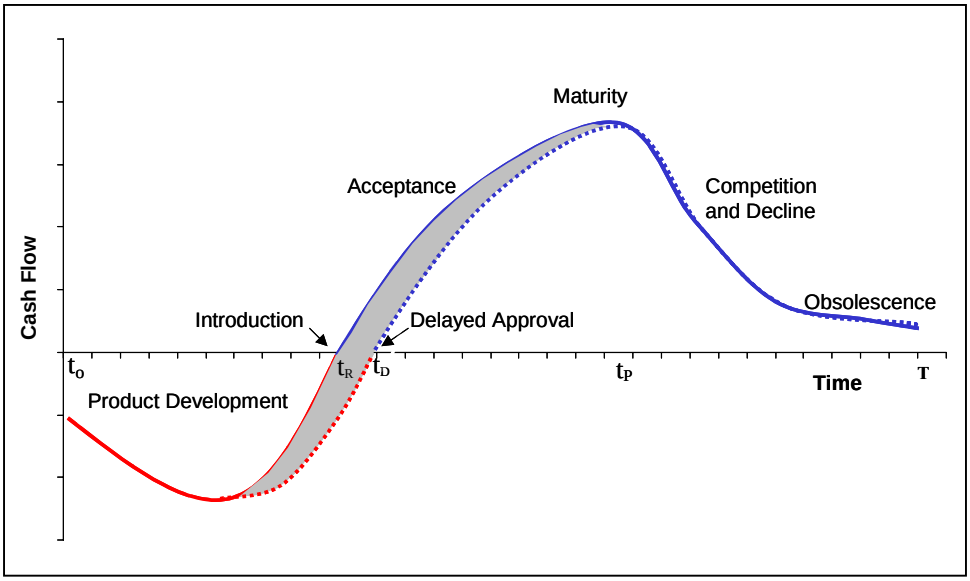

Figure 1 depicts life-cycle cash flows for a regulated product (in this case, with market entry restrictions via patent protection). The shaded area represents the change in cash flow resulting from faster regulatory decisions.

The literature observes that while there are no "typical" product life cycles, sales generally increase through product introduction, acceptance, and maturity. As the product reaches maturity and encounters competition (in this scenario, competition

from generic drugs), the sales curve falls dramatically for the original product. This effect can be somewhat mitigated by market segmentation by the market leader. Eventually, obsolescence results in sales volumes falling, and the product begins its final decline.

4.2 Applying the Model to Regulated Products

The model was then applied to estimate the economic consequences of enhanced regulatory co-operation with the United States. A number of co-operative tools can and have been applied in Canada, as discussed in Section 2 of this report. For example, what if conditional approvals were granted in Canada for products based on US approvals? Such an approach could have two economic effects: reduce regulatory decision times for products entering the Canadian market and potentially reduce up-front compliance costs for industry.[13]

This section summarizes results for a number of Canadian market sectors using various product development and market life-cycle scenarios to assess the direct, indirect, and induced effects that might be anticipated as a result of selected approaches to increased regulatory co-operation with the United States. Results for each sector, including summary industry sector statistics, a discussion of the current Canada-US regulatory environment and issues, and detailed estimates of the potential economic gains from enhanced regulatory co-operation with the United States are contained in a separate research paper (Blair, 2004a), available on request.

4.3 Overview of Empirical Results

Table 2 summarizes results from the PRI's preliminary empirical research into potential gains for five regulated product sectors.

Table 2: Potential Gains from Regulatory Co-operation

	Human drugs	Veterinary Drugs	Medical Devices	Pest Control Products	New Chemical Substances	Total
Sector Statistics (2003)[14]						
Market Size	$14 billion	$500 million	$4.0 billion	$1.1 billion	$13.4 billion	$33.0
R&D	$1 billion	$25 million (est.)	$53 million	$2 million	$42 million	$1.1
Employment	27,000	Sector specific statistics not available	17,000	550	13,900	58,540
Contribution to GDP	$5 billion		$930 million	$206 million	$3.4 billion	$9.5
US share of imports to Canada	47%		60%	97%	61%	55%
US share of exports from Canada	80%		76%	70%	73%	76%
Estimated Annual Present Value Gains						
Change in Net Income from New Products	6.6%	18%	**	9.9%	122%	$139 million* (8.2%)
Change in the Value of New Product Sales	10.5%	11.3%	**	8.5%	39%	$1.05 billion* (10.7%)
Change in the RoR for New Products	4.2%	12.2%	**	4.2%	54.2%	4.8%*

* Sales-weighted average
** To be completed

The domestic market for the five sectors exceeded $30 billion in 2003, contributing about $10 billion to GDP. In all cases, the United States dominates Canadian export and import markets for products in these sectors.

Potential annual gains in the present value of sales for new products based on the application of the cash flow model averaged over $1 billion, or an average 10.7 percent increase. By this we mean that, based on various scenarios of reduced regulatory decision times and costs for industry, the present value of their sales over the life-span of a basket of new products normally introduced in one year would be about 10% higher on average than the current present value. It is important to note that this does not imply increased sales, but rather reflects the time-value of faster market access and lower regulatory costs.

In terms of net income, annual gains were estimated to be 8 percent in the present value of net income from the basket of new products normally introduced in one year.

Average rates of return on new products were estimated to increase by an average of 4.8 percent, ranging from 4.4 percent to 5.3 percent.

How such gains at the industry level translate into gains for Canadians and the federal government is difficult to quantify directly. Micro-economic theory suggests any decrease in marginal costs for firms, resulting from increased regulatory co-operation, increases the consumer surplus and social welfare to some degree. Examples include greater product choice and lower prices.

Other social benefits can accrue from faster access to new products. A number of empirical studies have been done on the connection between increased sales and investment in selected industrial sectors and estimated increases in health benefits, decreases in health expenditures, and improvements in quality of life for citizens.

Assumptions and Limitations of the Analysis

Cash flow models have the advantage of capturing potential benefits to business, by modeling the flow of hard costs (e.g., research and development costs, production and marketing costs, and regulatory costs) as well as the potential opportunity costs, risks, and uncertainty of investments. A cash flow analysis better captures the dynamic nature of investment decisions and a full range of the financial considerations of businesses.

However, all models are limited by underlying assumptions and data availability. These limitations are discussed below:

- The cash flow analysis summarized here provides estimates of the time-value of money impacts of faster approvals and lower compliance costs. Potential increased risks to consumers or loss of regulatory protections from faster approvals were not estimated. Also, transactions costs (e.g., additional regulatory resources required to implement greater regulatory co-operation) were not estimated.
- The analysis is based on synthetic scenarios of R&D and market size from the academic literature, not observed Canadian-specific data.
- The cash flow model is a closed, static model: it assumes no other policy or economic changes (e.g., tax incentives, exchange rate fluctuations, etc.) and does not include dynamic effects such as potential increases in investment and higher rates of product introduction due to improved financial returns in Canada. Based on anecdotal evidence from industry, the hypothesis was put forward that faster decisions and lower regulatory costs would make more products financially viable in the Canadian market and increase the number of new products introduced in Canada each year. However, this effect has not been estimated empirically.
- Estimates of potential indirect and induced effects on the Canadian economy are incomplete. One reason is that in three of the four sectors examined, the extent to which sales of new products drive overall sales growth could not be determined. This measure is needed to assess the induced effects on the

economy. Only in the case of human drugs were indirect and induced effects estimated. A summary of these results is presented in Table 3.

Table 3: Estimated Sector-Wide Effects for Human Drugs

	6-Month Faster Approvals	12-Month Faster Approvals
Indirect Effects		
Annual increase in industry R&D investment	$20 million	$40 million
Annual increase in rate of new product introduction	Not estimated	Not estimated
Induced Effects		
Increase in GDP	$134 million	$268 million
Employment impacts	2,340	4,680
Societal benefits	Not estimated	

- Other societal benefits are discussed, but not estimated empirically. In the case of drug approvals, a number of academic studies were cited which suggest that faster drug approvals could lead to decreased spending on other health care (e.g., hospital spending) coupled with long-term benefits to the health of Canadians (as measured by decreased morbidity, mortality, and improved quality of life).

  For example, Lichtenberg (2002) conducted an econometric investigation of the contribution of pharmaceutical innovation to mortality reduction and growth in lifetime per capita income. Results showed a highly significant positive relationship across diseases between life expectancy and rates of introduction of new drugs.

  Overall, estimates from the literature suggest that faster drug approvals in Canada could:

  - Lead to savings in other areas of health care by the provinces. For example, Lichtenberg (2002) found that that new drugs lead to a reduction in non-drug expenditures at a rate 7.2 times as much as they increase drug expenditure;
  - Generate long-term health benefits. For example, MedTap (2003) provides estimates from a number of recent studies of the value of expenditures in health care in the US. These analyses suggest that each additional dollar spent on health care in the past 20 years has produced health gains worth $2.40 to $3.00.
  - Generate societal returns on research and development. For example, a major study of returns to investment in health care found that overall, annual societal rates of return lie between 1 and 5 times R&D expenditures (Australian Society for Medical Research, 2003).

- The analysis assumes that greater regulatory co-operation on product approvals could reduce Canadian decision times and regulatory costs. However, the extent

to which regulatory co-operation will speed decision making and reduce costs will be a function of case-by-case issues:

- the nature of risks for future product submissions;
- the average depth of information required for submissions, and the nature of the required monitoring and controls;
- the extent to which firms would voluntarily conduct certain activities, such as a field test or clinical trial monitoring, if not required to do so by the regulator;
- the number and cost of multiple testing requirements needed during a single product development program;
- uncertainties about industry growth; and
- the number and types of exemptions from specific requirements.

Despite these limitations, preliminary assessment shows that if greater regulatory co-operation with the United States led to faster regulatory decisions and reduced costs, positive net benefits would accrue to Canadians.

5. Policy Considerations

Preliminary analysis presented in this report suggests there could be positive gains in net benefits to Canadians from further regulatory co-operation with the United States. And the benefits are not only efficiency gains. Regulatory co-operation with the United States can be an important vehicle for improving the quality and effectiveness of Canada's regulatory system. The implication is clear; it would be unwise not to target the United States as the primary candidate for regulatory co-operation.

5.1 Observations from Research to Date

Regulators have been involved in co-operative efforts for years, but many question what has actually been accomplished in making Canadian and US regulatory regimes more compatible. Despite an impressive record of regulatory reform in Canada, and a clear policy commitment to regulatory co-operation, it is very difficult to assess the effectiveness of regulatory co-operation to date. Efforts across the system appear disjointed, unco-ordinated, and lack a coherent strategy. For example, when should regulators try to lead or influence the United States versus converging with them? What are the measures of success in this area? What are the specific goals? Regulators are looking for direction on these issues from within their departments, from central agencies, and from Parliament.

More could be done. International experience suggests that regulatory co-operation takes time. Canada and the United States have been building trust and confidence for decades, and a high degree of knowledge, understanding, and mutual confidence exists between Canadian and US authorities. It is time to capitalize on this experience.

Again, international experiences also suggest political commitment is a necessary condition for successful and meaningful regulatory co-operation. To secure such commitment, politicians and policy makers need better information on where greatest potential gains could occur and what the real risks are.

Clearly, departments have already made significant inroads; but the research suggests more could be done to capitalize on this experience. Also, regulatory co-operation (and in some cases unilateral action) can help overcome Canada's small country disadvantage by capitalizing on the regulatory resources of the United States and others, and lead to a more efficient and effective allocation of both private and public resources in Canada.

Many Canadians feel strongly about issues affecting their regulatory programs. From sovereignty concerns to languages and legal systems, from health management to product safety, these and a myriad of other values that Canadians prize, are all factors in any debate about regulatory co-operation. A discussion follows of some of these issues as they influence the debate about building regulatory co-operation with the United States.

One key obstacle in pursuing regulatory co-operation is the debate over the implications for national sovereignty. The issue often raised is the need to be careful when examining actions that might limit sovereignty, that civil society has concerns about specific co-operative arrangements if the benefits of restricting sovereignty remain unclear.

In some respects, this debate can be viewed as more definitional than real. Is the debate over regulatory sovereignty confusing Canada's right to make sovereign decisions with the process and evidence used to make final, sovereign decisions? This important distinction seems to get lost in the debate.

The implication for regulatory co-operation is twofold. First, there may be much greater scope for co-ordinating Canada's regulatory efforts with the United States in ways to better inform those regulatory decisions, without threatening Canada's right to make sovereign decisions. Examples include harmonizing regulatory submission formats, accepting common testing protocols, and making use of summary data and decision documents from the United States.

The second point is broader. Is Canadian sovereignty "protected" through individual decisions by regulatory officers, or is sovereignty "exercised" through informed policy decisions and directions implemented by ministers and Parliament? Granatstein (2003) and others argue the latter: that Canada's sovereignty is exercised through strategic policy decisions. These would include decisions such as furthering regulatory co-operation with the United States.

Finally, regulators have been co-operating at many levels with their US counterparts for years. There has been very little public concern over potential loss of sovereignty on arrangements to date.

The issue of preserving Canadian values and identity is also central to the debate on Canada's regulatory diversity. However, there is no one monolithic Canadian identity to which all Canadians ascribe. The American reality is similar. There are, inter alia, geographic, ethnic, socio-economic, and cultural characteristics, on which people base their values.[15] These can play a large role in discussions on increasing regulatory co-operation. For example, the Interdepartmental Task Group on Regulatory Co-operation (2003) observed that convergence in some sectors would be limited by differences in legal and political systems, and social values (e.g., Canadian mores, values, and behaviour patterns).

Thus far, much of the debate surrounding regulatory co-operation appears to have been driven by the desire to maintain strong Canadian values in regulations. However, the literature analyzing the real differences in values between Canada and the United States suggests "the differences between Canadian and US values may be more technical than substantial" (Boucher, 2004: 46). Polling analysis indicates that most values differ between the two countries by percentage points, not in direction.

Some would argue that regulators in most countries demonstrate what Freud referred to as "the narcissism of small differences" (Boucher, 2004: 42). To date, the focus in regulatory co-operation has been on negotiation surrounding detailed differences between regulatory systems (e.g., compliance and enforcement activities, conformity assessment processes, technical standards, data testing protocols, submission formats), rather than capitalizing on the similarities (i.e., equivalent goals and outcomes). Recent public overtures from the FDA are one example of this phenomenon. As part of the debate being waged on Internet pharmacy sales from Canada to the United States, the FDA raised concerns about the safety of Canadian-approved drugs – ignoring the fact that most "Canadian" drugs sold through Internet pharmacies are *exactly* the same drugs (manufactured at the same sites worldwide) that are approved and sold in the United States.[16]

To move forward on regulatory co-operation, the focus must shift from struggling over minor differences to recognizing major similarities. Where processes must remain distinct and reflective of specific Canadian interests, the goal should be to recognize acceptable regulatory outcomes of other competent jurisdictions through regulatory co-operation.

Regulatory co-operation must address both the existing stock of regulations and the development of new regulations. For the current stock of regulations, deeper co-operation with the United States could be a means to address unnecessarily burdensome differences between the two regimes. In some cases, this may entail unilateral action by Canada to make regulatory requirements more compatible with those of the United States. Questions that need to be addressed include what incentives exist for the United States to enter bilateral agreements with Canada? When are negotiated solutions possible, and when should unilateral Canadian regulatory actions be pursued?

For future regulations, more co-operation can help to avoid creation of new differences, especially in emerging areas, such as regulation of nanotechnology (EACSR, 2004: 89; Roco, 2001). More regulatory co-operation in these emerging areas would also provide

Canada with greater influence through shared decision-making, and a leadership role in those areas where Canada may have a comparative advantage in knowledge and expertise.

One challenge in international regulatory co-operation is withto deal with both economic and social imperatives. There is concern that changes to how Canada regulates will negatively affect achievement of regulatory objectives in the health, safety, and environmental areas, and that enhanced co-operation is pursued in the name of economic gain, at the expense of regulatory benefits (i.e., protection of health, safety, and security, and social/political values).

Some argue that protection of health, safety, and the environment is at stake, and should be the primary (only) consideration of policy makers. Canada's regulatory system is designed to ensure safety and efficacy of products and services, and protection of the environment. Would changes in the regulatory approach, through more co-operation and collaboration with the United States negatively affect these protections?

The empirical evidence suggests many of these concerns are unfounded. For example, in Harris (2003), Nancy Olewiler examined empirical evidence concerning "race to the bottom" arguments (i.e., economic integration leads governments to reduce the stringency of their regulation until the lowest common denominator prevails, or they pass regulations they have no intention of enforcing). In environmental regulation as a result of more economic integration, Olewiler found no support for a race to the bottom. Similarly, Industry Canada, in research done in 2002, observed "no evidence from the case studies that regulatory co-operation impairs the protection of health, safety and the environment. Furthermore, it appears that this co-operation fosters numerous benefits…" (Industry Canada, 2002). Recent analysis by Copeland and Taylor (2004: 67) supports these views. They observed "little convincing evidence to support the pollution haven hypothesis."

While empirical evidence suggests regulatory co-operation does not lead to an erosion of regulatory standards, it is important that any approach to regulatory co-operation not be perceived as a threat to regulatory benefits in Canada. Economic and social goals are not necessarily at odds when considering greater regulatory co-operation with the United States. The overall policy objective of the Government of Canada (PCO, 1999) is not to place primacy on one goal over the other, but to consider both and to maximize the net benefit to Canadians by minimizing the economic costs required to achieve social imperatives (i.e., the regulatory protections Canadians demand).

A great deal of effort has been expended on the process rather than on outcomes. Canadian regulators have invested many years of effort and considerable resources in building confidence with their US counterparts in the two regulatory systems. However, much of the effort has focused on the details of how Canada carries out compliance and enforcement activities (e.g., conformity assessment processes, technical standards, data testing protocols, submission formats). There has been much less focus on the actual regulatory outcomes (i.e., measurable levels of health, safety, and environmental protections). isIt is usually agreed that, despite socio-political and cultural differences,

and the regulatory diversity that has often built up over time between nations, developed nations are generally after the same regulatory outcomes: effective protection of security, health, safety, and the environment. In this context, any marginal differences in the details of Canada's regulatory systems must be carefully questioned.

Federal departments need an organizational framework for managing regulatory cooperation. In March 2004, the Auditor General of Canada observed, "There is only limited guidance from the Canadian government on which models of international regulatory co-operation are the most efficient and effective and the most socially acceptable to Canadians." At a recent symposium on Canada-US regulatory cooperation, senior federal officials agreed and pointed to numerous other challenges in managing regulatory cooperation such as the sheer complexity of regulatory matters, the lack of rigorous analysis of costs and benefits of maintaining regulatory differences from the US, and the potential costs of negotiating and implementing cooperative arrangements. Regulators also noted that regulatory cooperation is not a unique or ultimate solution to market access issues.

Experts at the symposium concluded that a sound internal organizational framework was required to deal with these challenges. The framework should provide guidance on institutional arrangements, processes, public transparency and accountability, and other tools required to implement deeper Canada-US regulatory cooperation. One senior official recommended an internal process whereby departments would start with the US regulations, in terms of standards and expected outcomes, and deviate only where clearly justified by information and analysis. Another expert suggested following the Smart Border agreement model, with risk-based principles supported by specific actions with timelines. Others pointed to the North American Commission for Environmental Cooperation and the Great Lakes Agreement as sound institutional models to emulate (Purchase, 2004).

Any regulatory co-operation carries risks and uncertainty. Observers and practitioners both inside and outside of government will question the approach and intent. The rationale, risks, and benefits for change must be explained and understood. A recent report of the Auditor General of Canada observed "it can be difficult to get consensus among all players because each jurisdiction defines risk differently, has its own priorities for managing risk, and uses different approaches and standards for managing those risks." (Canada, OAG 2004:18)

Public perception of risk can affect the perceived scope for collaboration. In areas where the perceived risks are low, harmonization and mutual recognition may be easier to achieve. In situations where the perceived risk is high, public pressure may favour case-by-case decision-making in Canada.

Also, in many health and safety areas, knowledge is uncertain. Uncertainty requires exercising political judgment, and the factors affecting Canadian and American decisions are often different.

Finally, the costs associated with entrenched approaches to policy and the potential benefits of more co-operation between governments must be made known to the public. Technical demonstration of mutual benefit may not always be sufficient; the public must see that intergovernmental co-operation is in the public interest.

6. Charting a Path Forward

6.1 Elements of a Strategy

> Government commitments to co-operation must be more than words – actions matter most. Governments must recognize that implementation will not take care of itself (PCO, 1993: 9).

Stating that regulatory co-operation is a government priority is a start, but it is not enough to bring about results. Canada needs to develop a strategy to advance its interests as a small country with relatively few regulatory resources. Regulatory co-operation (and in some cases unilateral action) can help to overcome this small country disadvantage by leveraging greater use of the regulatory resources of the United States and other countries to Canada's advantage, and lead to a more efficient and effective allocation of resources.

A strategy is required to take more concrete and focused actions to eliminate unnecessary differences between Canadian and US regulations. Elements of a government strategy to move beyond words to more substantive results from greater Canada-US regulatory co-operation have been proposed by the EACSR in their recent report on Smart Regulation.

The federal government should work to:

- achieve compatible standards and regulation in areas that would enhance the efficiency of the Canadian economy and provide high levels of protection for human health and the environment;
- eliminate small regulatory differences and reduce regulatory impediments to an integrated North American market;
- move toward single review and approval of products and services for all jurisdictions in North America; and
- put in place integrated regulatory processes to support key integrated North American industries (e.g. energy, agriculture, food) and provide more effective responses to threats to human and animal health and the environment (EACSR, 2004:22).

The empirical evidence presented in this paper suggests that greater net benefits could accrue to Canadians from implementation of these EACSR recommendations.

Accelerating Canada-US Regulatory Co-operation

How should regulators be encouraged to secure these benefits for Canadians? Regulators have already done much of the legwork to enhance regulatory co-operation with the United States. Knowledge and understanding of the regulatory systems in each country have grown over the past decade, and valuable experience has been gained in

applying various co-operative tools with the United States and other partners around the world. The stage appears to be set to make real progress now.

The potential gains for Canadians characterized in this report, while not definitive, strongly suggest there are positive net benefits in taking action to make Canada's regulatory regimes more compatible with the United States.

To inform decision makers, additional analysis should focus on *what* net benefits can be achieved by taking specific actions to eliminate unnecessary differences between Canadian and US regulations. Of greatest value would be detailed, rigourous analyses of the *incremental* costs and benefits of specific differences in regulatory approach in Canada, by sector. Such analysis would provide an objective, evidence-based starting point for the work of sector SWAT teams, as proposed by the EACSR.

Many observers believe real progress in this area has not been achieved, and prescribe an all-inclusive or macro-policy solution. For example, some argue for a single overarching approach that will bring the United States to the table as an equal partner to negotiate mutual agreement on regulatory convergence (e.g., broad brush Canada-US mutual recognition agreement) using security issues to leverage US interest. Others point to the development of new bilateral institutions as the best mechanism for greater success.

No one-solution approach can be deduced from research into this issue. Rather, a more inductive policy approach would appear to hold the greatest promise. Such an approach would involve implementing a policy strategy that places priority on capturing the gains from greater regulatory co-operation with the United States at the individual regulatory program level as well as at the level of specific regulatory requirements within programs.

And, based on the potential gains examined in this report, achievement of tangible results needs to be accelerated. Regulators should be encouraged not to wait for the United States to co-operate where Canada could gain from unilateral action, and to take action at every stage of regulating. Lessons learned and best practices from these incremental steps should be shared among regulatory officials, and successes in making Canadian regulations more compatible with the United States should be recognized, celebrated, and rewarded.

6.2 A Final Word

A joint Policy Research Initiative and Social Sciences and Humanities Research Council symposium on Canada-US Regulatory Co-operation was held on October 29, 2004 in Ottawa.[17] The purpose of the symposium was to discuss the key issues arising from a preliminary version of this Interim Report. Presentations by the Smart Regulations Implementation Strategy, the PRI, Agriculture and Agri-Food Canada and Health Canada, led to rich discussions and contributions from all participants.

At the end of the day, the discussions focused on how to move forward on this policy agenda with a clear, practical, and above all, politically achievable strategy. On balance, key observations and conclusions from the discussion can be summarized as follows:

- There is a strong case for increasing Canada-US or North American regulatory co-operation.
- The political will to move forward exists, but a clear, practical plan is required.
- The plan should focus on selected priority sectors, taking account of both costs and benefits as well as current best practices.
- The plan must be supported by sound internal organizational and decision making structures, and provide a role for parliamentarians.

These conclusions appear consistent with the direction of the "New Partnership" statement issued jointly by Prime Minister Paul Martin and US President George W. Bush on November 30th, 2004.[18]

PRI's research will now turn to the important task of assessing specific strategies and options for deepening Canada-US regulatory co-operation, based on the themes that emerged from the symposium and the direction provided in the New Partnership statement.

Appendix I: The Regulatory Co-operation Toolbox

Co-ordination

Information

Information sharing involves exchanges of information and institutional experience on specific requirements for sectors or product categories through seminars, training sessions, joint visits, audits, surveys, and information gathering. It can occur as a result of an informal understanding between regulators or it may involve formal arrangements, such as guidelines, memoranda of understanding, or agreements. The level of commitment by participating regulators, however, is key to their successful implementation, as these arrangements are not usually legally binding.

Examples

- The Minor Use Pesticide Workshop conducted in December 2001 by the Canadian Agri-Food Research Council brought together Canadian, US, and other international regulators and industry groups, and led to a significant improvement in the co-ordination of Canada-US regulatory efforts for minor use pesticides.

- Many Canadian regulators rely heavily on the United States for basic research data, because of the greater resources available to their US counterparts. For example, the Chemicals Evaluation Division of Environment Canada uses data sets made available to them by the US Environmental Protection Agency (EPA) that are much larger than their own, because of the higher volumes and wider range of chemicals used in the larger US economy.

- The US and Canadian food inspection agencies share information to prevent unsafe food, particularly meat and poultry, from entering their respective countries. Similarly, regional offices of the Department of Fisheries and Oceans Canada and the US FDA share information, as do Health Canada and the FDA (Bredahl and Holleran, 1997). The Four Corners Arrangement (EPA, 2004) is another example of this type of co-operation between Canada and the United States. This initiative allows for completed EPA assessments to be available to the Canadian government, and vice versa. After consideration of an EPA assessment, Environment Canada may either add the substance to Canada's Non-Domestic Substances List or accept a portion of the information for use in the assessment.

Advantages

Information sharing represents a relatively low-cost entry stage of regulatory co-operation. It allows those with specific regulatory experience and expertise to benchmark their regulatory practices against other jurisdictions, and to establish a common understanding of the basic principles of good ways to regulate, such as exchanging information on trade issues, transparency in programs, clarity of rules, fitting the regulatory approach to the objective of the regulation, and the like. The identification of good regulatory practices can also lead to regulatory transparency and enhanced market access. Information sharing has the potential to reduce compliance

and administrative costs, serve as an early warning system, build mutual trust, and even serve as a stepping-stone for more structured co-operation.

Disadvantages

In the absence of clear goals or strategies, information gathering and confidence building can continue for years without real progress towards higher levels of collaboration. Without strong political commitment and policy direction, such exercises also tend to focus on identifying differences between regulatory systems, rather than solutions. Considerable time and resources can be invested in these exercises without taking further concrete steps toward increased convergence between regulatory systems.

Work Sharing

Work sharing approaches include data sharing, research collaboration, and parallel or joint reviews. Such arrangements are often formalized through memoranda of understanding (MOU) between the regulators. Direct co-operation at the working level can be used to facilitate sharing of information and reducing workloads. Scientists can pool information and resources and share conclusions, but final approval decisions remain the responsibility of each country's regulatory authority.

Examples

- Sharing post-evaluation surveillance data is an excellent method of international work sharing since most regulating agencies appear to be willing to share information on safety and efficacy once products, such as drugs and medical devices, have been approved. It is important to understand that post-evaluation surveillance is key to effective risk management. Pre-market evaluations of safety and efficacy are based on relatively limited experience with clinical trials. Recognizing this, where products appear to represent breakthroughs or substantial improvements in medical diagnosis or treatment, there are clear benefits to expediting market access and using enhanced post-marketing surveillance to monitor problems. This is the approach Health Canada has used in the past to get new therapies to AIDS patients in a timelier manner.

- Canada and the United States announced in January 2003 a border air quality agreement, which sets out a commitment to develop joint air quality pilot projects, and will serve as a platform to encourage continued innovation in border air quality management. One pilot project will be a joint Canada-US analysis of the feasibility of emissions trading of NOx and SO2, to improve ambient air quality in both countries.

Advantages

Work sharing results in a better mutual understanding of the thinking of regulators in partner countries and facilitates the early identification of problem areas and emerging issues, allowing a more timely and proactive action. It has been of greatest value in areas where risk is high, real, or perceived (e.g., law enforcement and high-risk products). In the latter case, scientists pool information and resources and share conclusions, but have the flexibility to make final approval decisions on their own. Such

an approach spreads the workload and takes advantage of specialized knowledge, but preserves the sovereign right of nations to decide (PCO, 1992).

Disadvantages

This kind of partnership may be constrained by the need to respect the confidentiality of proprietary information. However, such constraints may be overcome through agreement with the regulated party or by making an evaluator in one country an employee of the regulating agency of another. This approach also does not address the shortage of resources that a small country like Canada can devote to regulatory decisions. Some industry groups have indicated a reluctance to participate in joint-review programs where it may threaten to slow their access to the US market.

International Standardization

International standardization has become important as a means of establishing technical requirements at the international level, in principle for voluntary application. The classical international standards bodies – the International Electrotechnical Commission (IEC) and International Standards Organization (ISO) – have been in use for many years, and are well established internationally.

Advantages

International standardization can lead to a single solution agreed across the global economy that can contribute to increased trade, unify technical practices, provide a globally accepted reference, eliminate divergent though equally valid solutions, and allow for greater competition among different products.

Disadvantages

Organizations that draw up technical specifications for international use, such as the International Electrotechnical Commission, International Standards Organization, International Telecommunication Union, Organization for Economic Co-operation and Development, and the United Nations Economic Commission for Europe, among many others have proliferated. Membership in these organizations varies (governments, standards bodies, industry federations, or even individual commercial enterprises), and it is not clear that each follows basic principles for the development of international standards. Additionally, there is the difficulty in establishing timely responses to regulatory needs. The international standardization process can be slow (typically four or five years from proposal to publication), and priorities do not always appear to be set by the needs of international trade. There is no established mechanism by which governments can call on the international standards bodies (as distinct from intergovernmental bodies) to draw up international standards that can then be used in support of a common regulatory structure. And, general standards tend to enshrine existing technical practice.

Unilateral Co-ordination

Information and work sharing can provide the level of confidence required to allow regulators to take unilateral steps to co-ordinate their regulatory approaches with another jurisdiction. For example, a country may choose to recognize another country's technical and conformity assessment procedures as equivalent to its own, or align its regulations with those of another country.

The most extreme form of unilateral co-ordination is recognition of equivalence, whereby a country accepts that imported products that meet the applicable technical requirements of the exporting country are placed on its market as if they met its own applicable technical requirements. Recognition of conformity assessment is another form of equivalence, whereby one country accepts that the process of another country to assess whether a product or service conforms to technical requirements is equivalent to its own process.

Together, recognition of conformity assessment and equivalence of technical regulations ensures that a product can comply with only one set of technical requirements and can be tested and assessed only once, by the public or private conformity assessment bodies that are recognized in both countries.

Accept Foreign Approvals

Where recognition of equivalence and conformity assessment procedures exist, it is possible to take the next step, which is acceptance of foreign approvals. Canadian regulators could then focus on developing areas of particular expertise (e.g., on specific emerging technologies in biotechnology or on particular therapeutic classes of health products that would directly benefit their citizens) and use that expertise as a lever to attract investment. This approach can be supplemented with other controls, such as random audits to satisfy regulators and the public that standards were being maintained in the foreign jurisdiction.

However, there are steps along the way toward recognition of equivalence and conformity assessment.

Accept Foreign Submission Formats

Formats for the submission of test data to a regulatory authority can either ease or deter entry to the domestic market. In general, harmonizing formats for the submission of test data with Canada's major trading partners is the best route to minimize direct submission costs and costs due to time lost in preparing special documentation.

Accept Test Results

One tool available to Canadian regulators is to accept test results from the United States in the areas where regulators have a high degree of confidence in the US process. This is the "tested once" principle. It provides the opportunity for a reduction in compliance costs, shorter decision times, as well as attracting direct investment and/or improving consumer choice.

Accept Foreign Summary Data

This allows regulators to focus on a foreign reviewer's summary data rather than a company's complete submission. In most cases, summary data from another competent jurisdiction can serve as an aid to the reviewers. Capturing the thinking of other regulators makes it easier to identify problem areas and quickly grasp the key issues under investigation. Accessing summaries provides a means of increasing efficiency by reducing the learning curve of evaluators, which is especially important in relatively new areas like biotechnology.

Alignment of Regulatory Standards

Canada has new emission standards in place for on-road vehicles and engines that align with US standards, generally recognized as the most stringent national standards in the world. By aligning Canadian and US standards, the regulations achieve their objectives with minimum cost and impact to the Canadian automotive industry.

Advantages

In many cases, the approaches outlined above will reduce duplication of regulatory effort. This can allow a relatively small country like Canada to capitalize on the expertise of other competent jurisdictions, such as the United States, reducing costs for both the regulator and the regulated community. By reducing duplication in regulatory effort, regulators may be able to reduce product decision times, which is an area of concern across a number of industry sectors.

Disadvantages

Alignment can be a complex process that must be done in detail, sector by sector. Also, any substantial revision or updating (e.g., to take account of technical progress) is likely to make a new determination and recognition of equivalence necessary. The process requires a high degree of trust, and there is a potential that reliance on other jurisdictions could erode domestic regulators' level of expertise over time.

Mutual Recognition

Mutual recognition occurs when trading partners agree to recognize each other's regulatory requirements as equivalent. Comprehensive mutual recognition agreements imply coverage of both technical requirements as well as conformity assessment procedures. Where the regulation in each country has the same regulatory objective as that in the other, and the two sets of regulations fulfill this objective, the authorities can agree to regard them as equivalent.

Mutual recognition agreements exist between Canada and the European Community (EC) for two health industry sectors – drugs and medical devices. The agreement for drugs establishes mutual recognition of each country's drug manufacturing licensing program based on good manufacturing practices (GMP). A manufacturing licence confirms that a company meets GMP in the production of a drug and that the plant has passed inspection by a recognized agency. It should be noted that this agreement, and the many others either existing or under development with Switzerland, Norway, Iceland, Liechtenstein, Australia, New Zealand, Japan, and the United States, do not address issues that directly impact on the speed of the decision process in Canada.

Other international forums exist to develop mutual recognition of approaches to human health assessment through international discussions (Codex Alimentarius, the OECD, and the Biosafety Protocol). However, the work of these forums often has been slow, stalled in confidence- building exercises.

Advantages

Mutual recognition agreements can lead to better use of resources, reducing duplication of effort and increasing potential competitive advantage when partners share the costs of approval processes. For example, mutual recognition can lead to shorter periods for market introduction of products at a lower cost, facilitate the development of new export markets for Canadian industry, reduce costs associated with the import/export of products, improve economies of scale, increase consumer choice, and support productivity growth of industry.

Disadvantages

By definition, mutual recognition requires the co-operation of the other party – co-operation that may not be forthcoming. Extensive trust between parties is an important precursor to mutual recognition agreements, and extensive discussion is required when changes occur in standards or regulations in either jurisdiction.

Harmonization

Harmonization is the most rigorous and formal strategy, which involves drawing up common or identical rules by a group of authorities, with the intention that the mandatory rules governing a product or service shall be the same among them. To be effective, harmonization also requires partners to recognize the enforcement and compliance systems of other countries. This model normally entails modification of domestic regulations, which is not always easily achieved, because this may require the adoption of new or amended legislation by domestic political institutions.

Advantages

Harmonization makes it clear that the rules are the same, and a supplier placing a product on the market can be confident that the same rules are applicable whatever the jurisdiction. Where harmonization is considered feasible, it is generally seen as a better tool than equivalence. Where technical regulations differ radically, particularly in terms of the objectives they seek to achieve, it is likely that a determination of equivalence will not be possible and that harmonization will prove unfeasible.

Disadvantages

Harmonization risks being a longer process than recognition of equivalence. Moreover, there may be non-technical reasons why harmonization is not an option, where equivalence would help achieve a very similar result in terms of trade facilitation.

Notes

[1] This is an oversimplification of the "Fourth Option" concept. In "Economic Regions in North America," Pierre-Paul Proulx (2004: 36) observed:

> The joint participation of Canadian and American firms in the same cross-border or trans-border cluster can result in improved performance for both Canadian and American firms vis-à-vis offshore firms. This can be seen as a new element of a potential fourth trade option for Canada (i.e., diversification through cluster-based North American integration).

Regulatory convergence/compatibility is key to facilitating North American cluster development, as described by Proulx.

[2] This section summarizes research from the PRI (2003c).

[3] The PRI has reviewed research by various groups such as the OECD, the External Advisory Committee on Smart Regulations, the Innovations Strategy, the Public Policy Forum, reports of the Auditor General of Canada, industry submissions to parliamentary committees, the Centre for Trade Policy and Law, and through informal discussions with regulatory departments and industry representatives.

[4] Hopkins (1992) and Winston (1993) estimated that the United States spends only about seven to eight percent of its GDP on regulatory compliance activities. Mihlar (1996) estimated that Canada spends 12 percent of its GDP on regulatory compliance.

[5] Jarvis (1998) provided perhaps the best insight into this issue. He argued that due to the new reality of global market conditions, driven by the speed of technological change, the portability of the capital, and economies of scale, competition for investment has shifted from company-to-company competition to competition between nations and within global corporate ownership structures.

[6] Research by the Canadian Biotechnology Advisory Committee suggests

> Canada has an international reputation for being unwilling to live up to its international obligations with respect to patent protection; companies find it difficult to convince head offices to invest in research and development in Canada because patent policies appear to be unfair; and Canada may be sending an indirect message to foreign investors and affiliates that biotechnology, and therefore investments, are not well protected in this country (CBAC, 2001: 15).

[7] For example, Rawson (2002) found that the number of personnel in Canada is two to 3.5 times that in Australia, the United Kingdom and Sweden, but less than 10% of that in the US. Because Sweden, the United Kingdom and the US all have significantly shorter review and approval times than Australia and Canada, the number of review staff does not appear to be a direct major determinant of the timeliness of an agency's review and approval performance. (Rawson 2002: 73-78)

[8] These agreements establish specific goals with respect to regulatory co-operation. For example, Article 708 of the Canada-US Free Trade Agreement establishes the goal "to harmonize their respective technical regulatory requirements and inspection procedures, taking into account appropriate international standards, or, where harmonization is not feasible, to make equivalent their respective technical regulatory requirements and inspection procedures."

[9] Industry Canada's paper *International Regulatory Co-operation* (2002: 23) observed, "there is no evidence from the case studies that regulatory co-operation impairs the protection of health, safety and the environment. Furthermore, it appears that this co-operation fosters numerous benefits.…"

[10] Ndayisenga and Downs (2004). In the study, two regulatory regimes are said to converge when they impose a similar economic burden on the respective economies. That is, they equally restrict economic activity in the countries or regions of interest.

[11] Economic burden is proxied by the restrictiveness index defined by the OECD. The OECD employs a regulatory "restrictiveness" index to study the economic impacts of regulations across OECD member countries. It should be noted that less "restrictive" regulations does not mean less "effective" regulations. A lower restrictiveness index does not mean that regulatory protections are lower. Rather, the level of restrictiveness is a measure of the extent to which intended regulatory outcomes (effectiveness) are achieved with the least burden on the economy (efficiency). For more information on the concept of regulatory restrictiveness, please see Ndayisenga, 2004.

[12] For a discussion of the direct, indirect, and induced effects of regulatory cost at the firm level, and how reductions in regulatory cost can lead to increases in consumer and producer surplus, and increases in social welfare (as measured by reductions in dead weight loss to the economy), please see Blair (2004a).

[13] For a discussion of these issues, see Griller (2004) and Rawson et al. (2000).

[14] Sector statistics are from Statistics Canada (2004).

[15] The PRI has been studying Canadian and American values as part of its Cross-Border Regions project. The main research hypothesis and preliminary empirical findings suggest that some Canadian mores, values, and behaviour patterns may be more regional than national in nature, and these value regions may also extend across the Canada-US border. More detailed results, expected in the coming months, could help to inform policy makers on the justification for establishing unique Canadian regulations based on the concept of unique Canadian values.

[16] Interview with Dr. Marcia Angell, former executive editor of *The New England Journal of Medicine* (CBS News, 2004).

[17] For a complete summary of the Symposium, see Purchase, 2004.

[18] Canada (2004). Joint statement by Canada and the United States on common security, common prosperity: A new partnership in North America

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