

Objectives

It is overwhelmingly accepted that government regulation needs adaptation when technology evolves. Take genetic testing: the first genetic tests were pre-natal exams to detect genetic disorders in foetuses (Hudson et al. 2006). These non-intrusive tests were performed in a handful of clinics and laboratories to help couples decide whether they should consider testing that was more precise, but also more intrusive. While false-negative results were always a concern, the consequences of false-positives were minimal, mostly causing anxiety before more thorough tests were conducted. In most countries, governments opted for a light regulatory approach to oversee the validity of these genetic tests.

The information produced by the Human Genome Project accelerated the development of genetic tests, which are now conducted in a large number of clinics and laboratories for a wide array of medical decisions. For example, genetic testing has become a common tool in cancer treatment (Kolata 2016). While technological advances have expanded the field of application and the benefits of genetic testing, its risks have deeper implications than simple anxiety caused by false-positive pre-natal tests. Today, a false-positive test for a cancer patient can dangerously delay treatments or encourage unnecessary surgeries. The validity of the tests and their interpretation have thus become a serious concern, feeding into rational expectations that regulators will increase oversight of genetic testing.

As rational as regulatory adaptation might seem in this example, it is unlikely to occur straightforwardly, largely owing to information supply. When making decisions, regulators must rely on expert information, seemingly independent from political influence. Finding and selecting this expert information, however, is not a simple task. In the United States, information on genetic testing is eclectic, stemming from congressional committee hearings and various expert bodies of the executive branch. Therefore, regulators are often overwhelmed when trying to prioritize information and decide on adequate adaptations. The UK government tried to avoid this information overload trap in 1999 by creating the Human Genetics Commission (HGC), whose mandate was to draw from varied sources to provide unified advice for regulatory adaptation. The approach worked for a while, with HGC reports effectively informing regulatory adjustments. However, internal tensions over the credibility of various sources of information made it untenable in the longer term, and the HGC was disbanded in 2012. As seen in the American and British examples, informing regulatory adaptation is a difficult task; the main objective of this research proposal is to examine how Canadian regulators address this challenge.

While research on government regulations abounds in the United States and the United Kingdom, we know very little about regulation as a distinctive form of governmental activity in Canada. Canadian scholars have conducted informative case studies, but nothing comprehensive enough to tackle the big questions this project seeks to address. How do regulations change? Which expert information warrants these changes? Is this information likely to enable regulatory adaptations that are consistent with the evolution of scientific knowledge and technology? These questions are pressing, as technology and scientific knowledge are changing quickly, and not only in the field of genetic testing. With the arrival of self-driving cars, car safety regulations no longer suffice (Dwoskin and Fung 2016); regulations that protect private information need revising to keep up with the progress of big data and machine learning (Keats Citron 2016); and GMO regulations can easily be bypassed by biotechnology developers using new gene-editing technologies (Ledford 2016).

This project seeks to overcome a major obstacle to the study of Canadian regulations, one that might explain why the topic has remained understudied. The Canadian federal government releases a large quantity of information about its regulatory activities, but in formats ill-suited for research (Roberts 2006, chapter 9). For example, since 1986, all new regulations, as well as amendments to existing ones, have to come with a Regulatory Impact Analysis Statement (RIAS). RIAs provide surprisingly rich and

systematic information on the content and purpose of the regulatory changes, and on which experts were consulted. However, RIAs are published in the *Canada Gazette* along with a large amount of other information (government appointments, prizes, etc.). The systematic extraction of RIAs from the *Canada Gazette* presents a challenge to researchers, one that this project will surmount. Beyond producing new knowledge about regulatory adaptation to technological change, my objective is to pull relevant information on the federal government's regulatory activities from the mass of government documents available on-line and compile it into a dataset that is accessible to other researchers and interested publics.

Context

One stream of literature that will be useful in this research prescribes “planned adaptive regulation”—that is, administrative procedures whereby regulations can be aligned with technological change within a reasonable timeframe (Eichler et al. 2015; McCray, Oye, and Petersen 2010). This project shares with this literature the definition of regulatory adaptation as decisions about government regulations, which can add to, discard or replace existing rules. This project, however, does not share the normative underpinning of the literature on planned adaptive regulation, which assumes that gaps between regulations and technological/scientific knowledge are anomalies that always need to be addressed through regulatory adaptation. Related complaints about the failure of regulators to adapt regulations to emerging technologies and scientific advances are reminiscent of a cybernetic ideal (e.g. Nature editorial 2016). Academic knowledge on cognitive limitations (Simon 1957) and on the nexus between values and facts (Douglas and Wildavsky 1982) raise serious doubts about the use of cybernetics in regulatory adaptation. Nevertheless, we learn from planned adaptive regulations (as well as from cybernetics) that expert information is key to regulatory change. A regulatory adaptation motivated by political pressure only—that is, an adaptation that ignores expert information—risks serious failures, especially in technical sectors. The selection of expert information sources by regulators, however, is problematic (Weible 2008). That is precisely the problem this project seeks to illuminate, and the literature on experts and public policy will be particularly useful in defining a working hypothesis.

Early scholarly literature on experts and public policy was concerned with technocracy and the use of expert reasoning for political decision-making (e.g. Akin 1977). Later work on experts and public policy focused on policy processes that allow for the exercise of power by a narrow elite of expert scientists (Jasanoff 1990), as well as on the difficulties arising from relying on experts to guide policy decisions (Harrison 1991; Brunner and Ascher 1992; Jasanoff 2003; Collingridge and Reeve 1986; Weible and Sabatier 2009; Montpetit 2011). These difficulties range from the lack of democratic accountability of experts and their internal disagreements to the moving boundary between the political and scientific spheres. The literature further suggests that difficulties do not arise only from the experts themselves, but also from policy-makers' demands for scientific guidance. The timing of political decisions does not often leave scientists sufficient time to produce credible knowledge; policy-makers often prefer expert knowledge that confirms rather than challenges their prior beliefs; policy-makers demand clarity and simple messages while scientists prefer complexity and acknowledgement of uncertainty (Sarkki et al. 2014).

These observations coincide with an opening of policy processes to a wider diversity of experts, even to so-called “expert citizens” (Li and Marsh 2008). Scholars from both Europe and North America have witnessed a democratization of expertise and the implosion of policy monopolies once held by a narrow set of experts (Beck 1992; Radaelli 2002; Maasen and Weingart 2005; Montpetit and Rouillard 2008). This literature on experts and public policy suggests that over time, regulators have started to draw information from increasingly eclectic sources of expertise.

Baumgartner and Jones (2015) contend that eclectic information arises from what they call “entropic search.” Entropic search, they argue, informs problem-relevance; they contrast this type of search with the narrower “expert search”, which informs problem-understanding and assesses the solution’s impact. Each type of search faces its own distinctive sets of problems. While expert-search facilitates the implementation of a solution, it also prioritizes a single dimension of an issue, potentially ignoring serious problems in other dimensions. In contrast, entropic search attends to several dimensions of an issue and it is therefore less likely to overlook problems. However, entropic search can overwhelm decision-makers, who have difficulty prioritizing and deciding on policy solutions. In the absence of decisions, policy stagnation prevails and eclectic information about problems in the policy environment accumulates until change becomes so compelling that policy-makers overreact. Entropic searches thus encourage both insufficient and excessive reactions to problems, instead of encouraging reactions that are proportional to the severity of the problems.

Transposing this reasoning to regulatory adaptation, I expect a lot of over- and under-adaptation in response to technological/scientific change, and few proportional adaptations. This expectation arises not only from Baumgartner and Jone’s (2015) *Politics of Information*, but also from the difficulty in maintaining narrow expert searches in today’s context of expertise democratization. My general working hypothesis in this project is therefore that the more entropic the information provided to regulators, the more likely they are to over- and under-adapt regulations.

The reasons for not relying more on the scholarly literature on government regulation to inform this project’s working hypothesis need a brief explanation. Much of the existing literature was produced by economists looking into regulations as a means to overcome market failures (Atkinson and Tietenberg 1991) or as costs to industry (Ryan 2012; Helm 2006). But political scientists have also produced important work on regulations, examining the differences in national regulatory styles (Vogel 1981), studying long-term shifts in risk aversion reflected in regulatory approaches (Vogel 2002), analysing private regulation (Cashore et al. 2007), examining disjunctions in sectoral regulatory regimes within a single country (Hood, Rothstein, and Baldwin 2001), categorizing varieties of regulatory capitalism (Levi-Faur 2006), or looking into regulatory discourses in times of crisis (Lodge and Wegrich 2011). I rely on some of this literature in the methods section of this proposal, but it was of little help in defining a working hypothesis about short-term regulatory adaptation in a changing technological environment. A seemingly relevant stream of literature is one that promotes the concept of “responsive regulations,” which calls for the involvement of stakeholders and a flexible attitude on the part of regulators (Ayres and Braithwaite 1995; Grabosky 2013). While this project might contribute indirectly to scholarly debates on these matters, the main concern in this literature is compliance with rules (Nielsen and Parker 2009; Decker 2007; Baldwin and Black 2008), a somewhat distant concern from this proposal’s focus on information feeding into regulatory adaptation.

Methods

Policy scholars have defined regulations in a variety of ways (Koop and Lodge 2015). Here I rely on the definition provided by the government of Canada:

Regulations are a form of law, often referred to as delegated or subordinate legislation. Like Acts, they have binding legal effect and usually state rules that apply generally, rather than to specific persons or situations. However, regulations are not made by Parliament. Rather, they are made by persons or bodies to whom Parliament has delegated the authority to make them, such as the Governor in Council, a Minister or an administrative agency (Canada and Privy Council Office 2001, 176).

Although Acts of Parliament attract more attention, regulations account for a huge part of the federal government's activities. In 1998, it was estimated that the federal government had some 3000 regulations, together comprising over 30,000 pages of documents. These figures compare to about 450 federal statutes comprising some 13,000 pages. Every year, about 1000 regulatory proposals, including orders-in-council, are submitted to cabinet for consideration, versus 80 bills studied by Parliament (Canada and Department of Justice 1998, 3). Unsurprisingly, analysts have often suggested that to understand government activity, it is not enough to study budgets and Acts of Parliament; regulations must also be included as objects of analysis (Hood 1983). And yet Canadian scholars studying government activities tend to overlook regulatory activities. Most studies of regulations in Canada are case studies looking at sources of influence or regulatory impacts for particular groups or economic sectors (e.g. Montpetit 2005).

Centered on the issue of regulatory adaptation, this project examines new regulations, as well as amendments to existing ones. It also includes the most important category of orders-in-council (Category A), which also contribute to regulatory adaptation (Canada, Privy Council Office, and Treasury Board Secretariat 2013, 3). These orders-in-council possess the attributes of a regulation, although they are adopted through a less stringent process, often in response to emergency situations. The government discusses new regulations, amendments to existing ones, and orders-in-council every week, making regulatory decisions in all policy sectors in cycles of just a few years. In fact, it is part of the government's regulation management strategy to encourage regular reviews of all regulations, notably to keep up with techno-scientific change (Canada 2012). Covering a period of 18 years, this project embraces the entire range of regulatory activity of the Government of Canada.

The Government of Canada is required by law to publish a wide range of information about new regulations, amendments to existing ones and orders-in-council. The process whereby regulations are made and amended in Canada is governed by the *Statutory Instruments Act*, which requires them to be pre-published in Part I of the *Canada Gazette* before adoption. Moreover, since 1986, all new regulations and amendments to existing regulations have been required by law to be pre-published with a Regulatory Impact Assessment Statement (RIAS). Regulatory impact assessments have been promoted globally since the 1980s to make sure that regulators take into account the impact of their decisions on business (OECD 2009), but in Canada, RIAs have become far more significant. Although not formally part of the regulations, judges use them to inform their decisions in technical domains (Houle 2006). Owing to the fact that they must be written in plain language, RIAs provide a "layman's guide" to the regulation (Salembier and Bernhardt 2002, 15). More importantly for this project, RIAs systematically describe the intended change. They explain its objective and rationale, present the alternatives that have been considered, summarize a cost-benefit analysis, address issues of coordination with provincial governments and describe the stakeholder consultations that were conducted. In other words, RIAs inform both the nature of the regulatory adaptation and the input that went into it. Category A orders-in-councils are not accompanied by a RIAS, but they do come with a plain-language explanation in Part I of the *Canada Gazette*. Note that there are far fewer orders-in-council than there are regulation proposals and amendments.

Beginning with Part I of the *Canada Gazette*, I will assemble a dataset that will inform regulatory adaptation. Archived in good quality electronic format since 1998, the *Canada Gazette* covers 18 years of regulatory activity by the federal government (more if we include the paper format), and yet to my knowledge, it has never been subjected to systematic analysis. Each line in the dataset will correspond to a new regulation, a regulatory amendment or a Category A order-in-council. For example, on February 15, 2014, the government pre-published an amendment to the Food and Drugs Regulations, authorized under the *Food and Drugs Act*. The corresponding RIAS presents the issue in the following terms:

“Recent events of food-borne illness derived from mechanically tenderized beef (MTB) have underscored the need for consistent and enhanced food labelling.” The RIAS further describes the amendment as “a requirement that all MTB sold in Canada be labelled clearly with information that it has been mechanically tenderized and safe cooking instructions.” While the cost-benefit analysis indicates a net benefit, it also acknowledges “a one-time compliance cost, estimated to be \$114,700,” to industry. In other words, the RIAS clearly indicates that this amendment provides for more, not less rule (more below about how such information can be coded into variables). As with all RIAS, this one clearly presents the information that supports the regulatory amendment. It speaks of a health risk assessment produced by Health Canada that “showed a fivefold increase in risk from MTB products when compared to intact cuts of beef.” It justifies the requirement to put cooking instructions on labels from “new scientific research specific to MTB that supports new cooking recommendations to achieve better protection.” Lastly, the RIAS explains that prior to its announcement, the regulatory amendment was the object of consultations. It mentions four meetings with named stakeholders, including the Canadian Meat Council and the Retail Council of Canada. The opposition of some of these groups to the amendment is underlined. In addition to key stakeholders, the participation of “academic experts from the University of Manitoba, Alberta and British Columbia” were mentioned at one of the meetings, while “meat and microbiology experts” were mentioned in two others. In addition to the health risk assessment, input from various interest groups and experts obviously went into this amendment.

As illustrated by this example, the RIAS contain the information needed to test this project’s hypothesis (including controls). To ensure the validity of this information, it will be crossed-checked using searches in *Reports on Plans and Priorities* that regulatory agencies are required to submit to parliament once a year, and in communication reports that the *Lobbying Act* requires of any interest group communicating with public office holders, notably for the purpose of influencing a regulatory amendment or a new regulation. Part II of the *Canada Gazette* will also be used to verify that the cabinet finally approved the amendment or new regulation. After organising the RIAS (and the explanations of the orders-in-council) into string variables, a codebook will be prepared. While it is useful to know that a risk analysis informed the mandatory labelling of MTB products in the above example, this project is after more general patterns, such as the frequency of regulatory adjustments stemming from a risk estimate as opposed to other types of expert information. The codebook will enable to categorize and measure Canadian regulatory activity and to analyze adaptation as a function of expert information that went into it, while controlling for consulted groups and other variables.

Scholars such as Baumgartner and Jones (2015; 2004; Baumgartner et al. 2009) have stayed away from developing direct measures of insufficient, excessive and proportional policy reactions, comparing instead the frequency of government activities in different policy sectors and time periods, and identifying correlations with different patterns of information search. In their analyses, they use frequency of change as a proxy: excessive adaptations are most likely to occur in sectors where frequencies are highest; where they are lowest, insufficient adaption is the logical inference. I intend to use a similar strategy, using topic codes developed in Baumgartner and Jone’s comparative agendas project to compare the frequency of regulatory adaptation by sector over time. The advantages to this strategy are twofold: firstly, topic codes will help identify sectors of regulation that are absent from the regulation agenda and that are therefore not being adapted at all; and secondly, they will cast light on variations that stem from known distinctions in sectoral logics (Levi-Faur 2006; Hood, Rothstein, and Baldwin 2001). Information search varies from sector to sector and if this project’s hypothesis is correct, regulatory adaptation will vary as well. While this strategy will not allow us ascertain whether a regulatory adaptation is an over- or an under-reaction (although gaps with technological advances could be investigated on a case-by-case basis), it will show whether the sectors where changes are more and less frequent are also the sectors where information search is most entropic.

Beyond enabling sector comparisons, the information contained in an RIAS will allow for the development other proxies to estimate regulatory adaptation. Looking at regulatory change, Knill et al. (2012) provide for measurement of variations in regulatory density and intensity. Density is the difference between the number of instrument adoptions and the number of abolitions, while intensity measures increases and decreases in instrument strictness. While sector codes remain useful in making these calculations, they require coding at the level of regulatory change for instrument adoption and abolition, as well as for strictness. To measure strictness, Al-Ubaydli and McLaughlin (2015) suggest text analysis, a method that I plan to adapt to my own purpose. Perhaps even better than frequency of adaptation, measures of intensity, density and strictness will allow us to make prudent inferences about excessive and insufficient regulatory adaptation. In addition, Swedlow et al. (2009) have developed a method to study risk regulations organized around questions (e.g. How is the regulated risk defined? Who regulates the risk? What regulatory instrument is used? etc.). Some of the new regulations and amendments pre-published in the *Canada Gazette* will not be risk regulations, but many will be, and the questions put forward by Swedlow et al. (2009) will be useful to reveal patterns of adaptation for this particular type of regulation. Together, these measures and categories help overcome the “dependent variable problem,” which too frequently prevents the comparative analysis of regulatory change (Howlett and Cashore 2009). The codebook will provide for the faithful application of these measures, enabling their use in international comparisons. The dataset will be made public on a website.

In the past seven years, I have gained considerable experience in both manual and automatic content analysis of various kinds of documents (Montpetit and Foucault 2012; Montpetit, Lachapelle, and Harvey 2016; Montpetit 2016). I intend for this project to reach another level, contributing methodological advancements to content analysis. The project will begin with handwork: collecting the RIAS, coding their content and using other sources for validation. This handwork will not only produce data, it will also serve to automatize the production of these data in the future. RIAS have a systematically structured format and are available on a high-quality electronic support platform, enabling the development of a web crawling tool. A web crawling tool is a program that provides a computer with the necessary instructions to collect systematically relevant information from the vast amount of information available on the web. RIAS are buried among the mass of information contained in the *Canada Gazette*; a web crawling tool could automatically extract the text needed for this project. The information needed for the validation of the RIAS is just as systematically structured; web crawling can also be used for this purpose. Al-Ubaydli and McLaughlin (2015) measure regulatory strictness using automatic text analysis. Not only will I adapt their algorithm, I plan on developing my own to measure other aspects of regulatory adaptation, such as intensity. Hand-coding will be instrumental in developing these tools, but by the end of this project, it will no longer be necessary, as the tools will be able to automatically update the dataset long after the project is over. In addition to my own experience, I will be able to count on the technical support of the Centre de recherche interuniversitaire sur la science et la technologie (CIRST) for the development of the web crawling and automatic text analysis tools. My hope is that this dataset will become the most important source of comprehensive information on Canadian regulatory activities.

In countries with governments that value technological innovation as much as they value citizen safety and environmental protection, developing appropriate regulations ought to be a priority. However, satisfactory regulatory adaptation is difficult to achieve, if only because regulators are often torn about which expert information to rely on in making decisions. Very little knowledge of this problem exists in Canada; this project will fill the gap by drawing from the wealth of online information on the regulatory activities of the federal government.