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VALGEN

GE^{3}LS in Brief

A Primer on Genomics, Ethics, Environment, Economics, Law and Society in the Biosciences

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Acronyms

AAAS	American Academy for the Advancement of Science
AAFC	Agriculture and Agri-Food Canada
ACRE	Advisory Committee on Releases into the Environment (UK)
ABC	Applied Genomics Research in Bioproducts or Crops
ABM	Agent Based Modeling
AHRC	Assisted Human Reproduction Canada
ATI	Aggregate Therapeutics Inc.
BC	British Columbia
BCCA	British Columbia Cancer Agency
BECCRR	Bio-Economy Center for Commercialization and Research
BERD	Business Enterprise Research and Development
BIO	Biotechnology Industry Organization (US)
BMCC	Biotechnology Ministerial Coordinating Committee
BSE	Bovine spongiform encephalopathy
CAFC	Court of Appeals for the Federal Circuit
CBAC	Canadian Biotechnology Advisory Committee
CBC	Canadian Broadcasting Corporation
CBD	Convention on Biological Diversity
CBS	Canadian Biotechnology Strategy
CCA	Council of Canadian Academies
CDSR	Cabinet Directive on Streamlining Regulation
CETA	Canada-European Union Comprehensive Economic and Trade Agreement
CECR	Centres of Excellence for Commercialization and Research
CFI	Canadian Foundation for Innovation
CFIA	Canadian Food Inspection Agency
CGIAR	Consultative Group on International Agricultural Research
CIHR	Canadian Institutes of Health Research
CIHR-TAAM	CIHR Team in Aboriginal Antidiabetic Medicines
CIPO	Canadian Intellectual Property Office
CIPP	Centre for Intellectual Property Policy
CLIMA	Center for Legumes in a Mediterranean Area
COP/MOP 7	Conference of the Parties serving as the meeting of the Parties for the CPB
CPB	Cartagena Protocol on Biosafety
CRIAQ	Consortium for Research and Innovation in Aerospace in Quebec
CSIRO	Commonwealth Science Institutes Research Organization (Australia)
CSR	Corporate social responsibility
CSTA	Council of Science and Technology Advisors
DNA	Deoxyribonucleic acid
DPD	Disaggregate policy Delphis
EFSA	European Food Safety Administration
ELSA	Ethics, Law and Society Aspects
ELSI	Ethics, Law and Society Implications
EPA	Environmental Protection Agency (US)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations

FDA	Food and Drug Administration (US)
FTO	Freedom to operate
GBN	Global Business Network
GM	Genetically modified
GDP	Gross domestic product
GE³LS	Genomics and its Ethical, Environmental, Economic, Legal and Social Aspects
GERD	Gross domestic expenditure on research and development
GHG	Greenhouse gas
GLIP	Grains Legume Integrative Project
GLP	Good laboratory practice
GMO	Genetically modified organism
GRASP	Genome Research on All Salmon Project
GRDC	Grains Research and Development Corporation
GRDI	Genomics Research and Development Initiative
HACCP	Hazard analysis critical control point
HQP	High quality personnel
IAD	Institutional Analysis Development
ICARDA	International Center for Agricultural Research in Dry Areas
ICRISAT	International Crop Research Institute for the Semi-Arid Tropics
ICT	Information and communication technologies
iGE³LS	Integrated GE³LS
IP	Intellectual property
IPM	Intellectual property management
IPR	Intellectual property right
IRD	Industrial research and development
IT	Information technologies
JSF	Jefferson Science Fellows
KM	Knowledge mobilization
MFP	Multifactor productivity
MII	Matching Investment Initiative
MIT	Massachusetts Institute of Technology
MOPOP	Manual of Patent Office Practice
MOSST	Ministry of State for Science and Technology
NBAB	Norwegian Biotechnology Advisory Board
NBAC	National Biotechnology Advisory Committee
NBS	National Biotechnology Strategy
NGO	Nongovernmental organization
NIH	National Institutes of Health
NIHR	National Institute for Health Research
NOC	Notice of compliance
NRC	National Research Council
NRTEE	National Round Table on Environment and the Economy
NSERC	Natural Sciences and Engineering Research Council of Canada
OECD	Organization for Economic Cooperation and Development
OHRI	Ottawa Health Research Institute
OPEC	Organization of the Petroleum Exporting Countries
PFS	Parliamentary Friends of Science
PIAF	Public Interest Accountability Framework
PIPRA	Public Intellectual Property Resource for Agriculture

PMPRB	Patented Medicine Prices Review Board
PNT	Plants with novel traits
PPM	Production and processing methods
PTO	Patent and Trademark Office (US)
RAF	Risk analysis framework
R&D	Research and development
SARS	Severe Acute Respiratory Syndrome
SCC	Science Council of Canada
SCC	Supreme Court of Canada
SCN	Stem Cell Network
SEC	Socio-economic considerations
SGC	Structural Genomics Consortium
SNA	Social network analysis
SPG	Saskatchewan Pulse Growers
SPS	Sanitary and Phytosanitary
SR&ED	Scientific Research and Experimental Development
SSHRC	Social Sciences and Humanities Research Council
STI	Science, technology and innovation
STIC	Science, Technology and Innovation Council
STM	Strategic Thinking Model
TRIPS	Trade-Related Aspects of Intellectual Property Rights (WTO)
TTO	Technology Transfer Office
PI	Principal Investigators
UK	United Kingdom
UN	United Nations
UNEP	United Nations Environment Programme
US	United States of America
USAID	US Agency for International Development
USD	US Dollars
VALGEN	Value Addition through Genomics and GE³LS
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WTP	Willingness to pay

Preface

As you will appreciate as you read this volume, it is a resource material rather than a how-to manual. It offers brief, concise and structured overtures to a wide range of old and new models, methods and metrics related to the governance of transformative technologies.

Given its reach, it is inconceivable that anyone could realistically construct this alone. We both 'stood on the shoulders of giants' and struck off in a wide array of ways to test new approaches.

We would like to acknowledge and thank all of the researchers who contributed to this work, whether they were investigators in the VALGEN team, collaborators or simply targets and correspondents for our output. In particular, we would like to acknowledge the critical role of Kari Doerksen, our anchor as Program Manager for VALGEN, Lisa Jategonkar and Nancy Carlson, two VALGEN staffers who did a lot to help shape this product, Wanda Phillips, who assembled the first draft, and Bethany Penn, who pulled this across the finish line.

We would like to thank Genome Canada for allowing us to reprint the content of a range of GPS Policy Briefs written by members of our research team. Those works stand the test of time and warrant new audiences.

We would like to thank our funding and research partners, including: Genome Canada, Genome Prairie, Genome Quebec, Genome BC and Genome Alberta; the Universities of Saskatchewan, Ottawa, Western Ontario, Edinburgh, Klyver, UBC, Econoving, Missouri and Chalmers; and the Canola Council of Canada and SRC Holdings Ltd.

Finally, we would like to remind our readers that while the Genome Canada investment in VALGEN ended, the network and work continues. Most of our investigators continue to collaborate, we own a trademark on our name and have maintained our website, VALGEN.ca.

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Introduction

Value Addition through Genomics and GE³LS (VALGEN), was launched 1 October 2009, as an international research network. VALGEN was designed to support groundbreaking research on social aspects of bioscience and biotechnology innovation.

Through the competition in Applied Genomics Research in Bioproducts or Crops (ABC) Genome Canada invested in 12 large-scale projects focused on applied genomics research in bioproducts and crops. The 12 projects had a total approved budget of C$112M. VALGEN, a four-year, $5.4M project was unique among these projects with its primary focus on ethical, environmental, economic, legal and social issues in genomics (GE^{3}LS). The project and network was managed by Genome Prairie and administered through the University of Saskatchewan.

Why VALGEN? Amidst the opportunities in applied genomics for bioproducts and crops, deep governance challenges exist. VALGEN responded to these challenges by assembling a team of researchers to study how Canada can benefit from applying genomic research to agriculture. Using current research methods in the social sciences, humanities and legal scholarship, VALGEN researchers examined three contexts from which barriers to innovation in agricultural biotechnology research and development arise: intellectual property management and technology transfer, regulation and governance, and democratic engagement.

- *Intellectual property and technology transfer* research concerns the use of legal tools like patents, copyright and trade secrets in combination with public policy, industrial structure and business strategy, and the effect on commercialization and use of new technologies and products.
- *Regulation and governance* research addresses increasingly complex systems of domestic and international regulation meshing, with varying outcomes, with private supply chains, and the identification of regulatory bottlenecks and blind spots.
- *Democratic engagement* research focuses on the need to engage the public early and often about the direction of scientific research and technological development, and to identify meaningful ways for Canadians to participate in decisions about how we choose to use new agricultural technologies and products.

VALGEN added value to the 11 GE³LS that were integrated in the ABC science-based projects through a number of mechanisms – formal networking, identification of overlaps, gaps and potential for synergies in the collective research activities of integrated GE³LS, communications, coordination of partnerships, and new researcher mobility programs. VALGEN furthered the reach of the ABC competition by spanning disciplines, institutions and other preexisting networks and collaborations to foster national and international collaboration and partnerships. Mobilizing knowledge in creative and effective ways was a chief priority of VALGEN.

Canadian prosperity depends on science and technology innovation. Bioproducts and crops research benefits from GE^{3}LS research and knowledge mobilization to guide scientific and technological creativity into beneficial, safe products and services welcomed by the public. VALGEN's research portfolio and value-adding activities provided insight into the social determinants of successful innovation.

This book is a compilation of some of the discovery and translational research conducted by the VALGEN team and their GE³LS partners across the ABC landscape.

Theme 1

Models, Methods and Metrics

The social sciences are possibly at a tipping point. The various disciplinary approaches to examining economic and social phenomena, including the development and use of science the technology, have relatively well articulated and refined models and methods and, in many cases, a compendium of metrics that provide a strong foundation for policy and decision making. Many of these approaches were designed for and work particularly well for studying discrete, simple economic and social phenomena. Sociologists of science assert that many of the achievements of the first scientific revolution flowed from curiosity-led research that emerged from traditional Mode 1 systems that are delimited and governed by discrete disciplines. This approach fit well with deductive, reductionist methods, where the problem space is sliced and diced into the smallest discrete units in order to poke, prod, describe and simulate the comparative static responses to different stimuli.

The challenge is that much of the scientific enterprise over the past generation has moved beyond the traditional, Mode 1 world, and now is more purposeful, with specific real-world problems motivating a diverse group of public, private, collective and academic actors to partner to define problems, to empower interdisciplinary teams of researchers and ultimately to take up and use the resulting products. The global biosciences have moved substantially towards this model, with diverse teams pursing a range of global challenges that offer significant opportunities for improved welfare and prosperity. It is difficult for any single discipline to offer much insight into the structure and impacts of these potentially transformative efforts. The response has been the willful construction of interdisciplinary ventures, with a range of social scientists and humanists working together, sometimes actually embedded as co-investigators inside the scientific and technological teams engaged in the discovery and commercialization process.

In the biosciences, this new mix of interdisciplinary problems and teams has been variously labelled in Canada as GE³LS (Genomics Ethics, Environment, Economics, Law and Society), in the US as ELSI (Ethics, Law and Society Implications) or in Europe ELSA (Ethics, Law and Society Aspects). This research space uses a heterodox mix of models and methods that attempt to capture the expansive, dynamic nature of these new research spaces. This section offers insight into a range of new models and methods the research world has developed, has beta-tested and is reducing to practice.

Critical Essay 1

New Methods for Science, Technology and Innovation Analysis

By: David Castle and Peter W.B. Phillips

Research activities in the VALGEN alliance followx a central principle: the alliance exists to add value to iGE³LS and genomics projects; it does not exist to supplant, or to replicate, existing research projects. With this principle in mind, VALGEN is governed by a decision-tree by which research activities are sorted into three main categories: triage of projects and research questions, problem-solving 'normal' research, and foresight research. Inasmuch as these three categories are differentiated types of research, they also represent the planned progression of the VALGEN alliance from a triage and alliance building exercise, to the execution of normal research, and finally to the completion of high-value, ambitious foresight research activities. As the decision tree indicates, there is a direct operational path from triage, to normal research, to foresight research. At the same time, the intent is for the VALGEN alliance to be a learning organization – one that transfers knowledge from one stage to the next, adding value each time, to focus on ABC GE³LS research questions that cut across iGE³LS and genomics projects, and to achieve high-level translation and mobilization of GE³LS research into practice.

There are three distinguishable theoretical and methodological challenges and opportunities to this program:

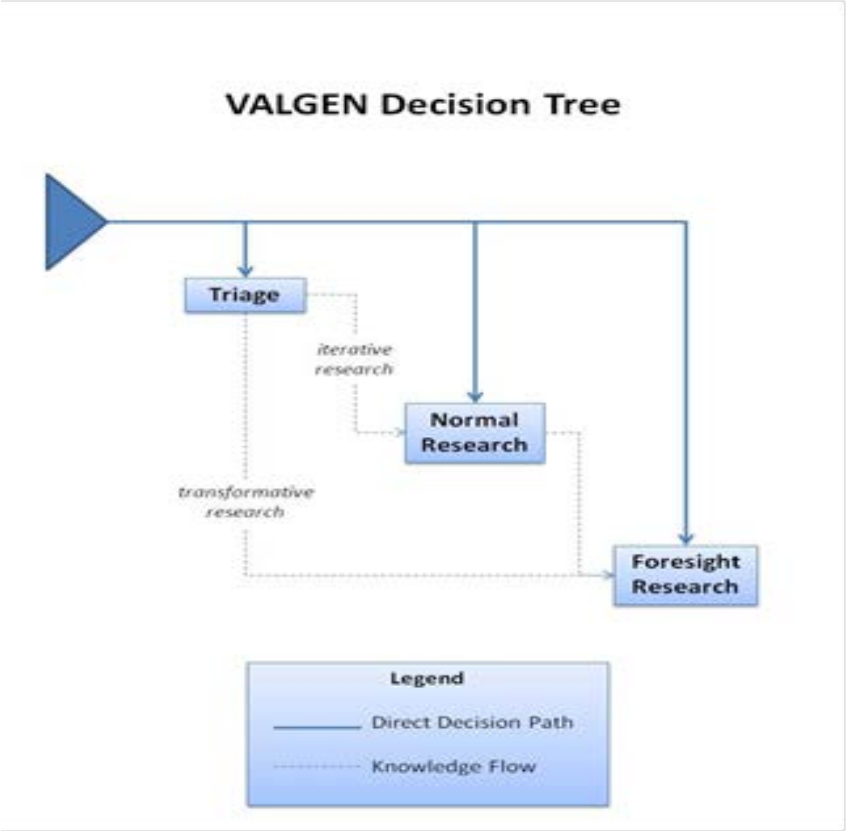

Figure 1

Priority setting and triage

VALGEN is a value-added research alliance dedicated to consolidating resources, setting priorities, eliminating redundancies and developing synergistic partnerships between iGE³LS projects. VALGEN will use a triage methodology adapted from the workflow management literature:

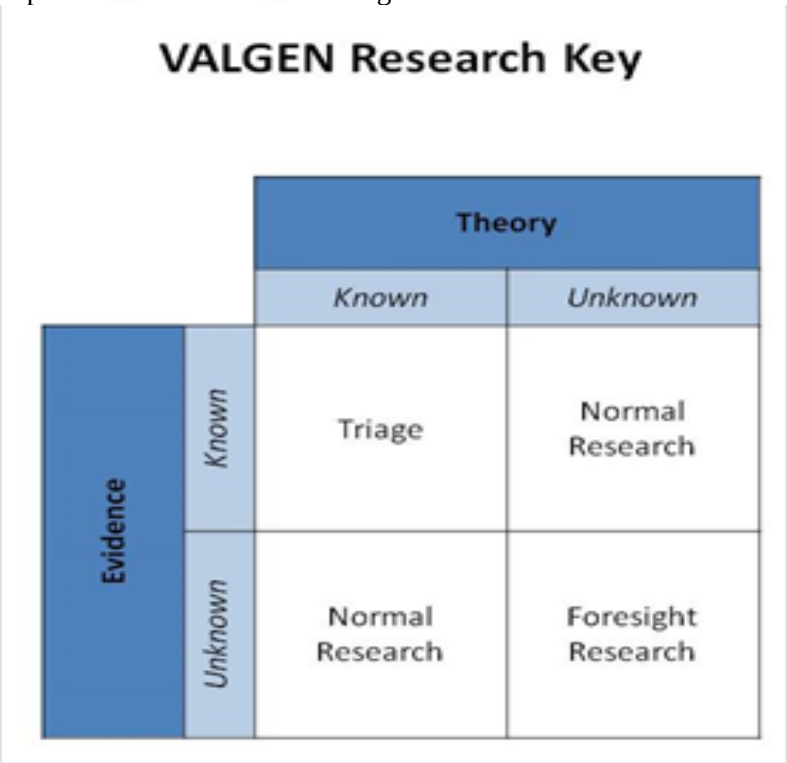

Figure 2

"Triage is the selection and prioritization of cases in the performance of a task, based upon easy-to-identify characteristics. (One example of triage is the fast lane in a supermarket, where cases are split into larger cases – cases that require a lot of work – and small cases – cases that require less work.) The objective of triage is to reduce average completion time" (van der Aalst and van Hee 2004, p. 255).

Triage is a method and, like all useful methods, its criteria can be specified. The first criterion is epistemic. VALGEN triage activities start with an epistemic matrix that sorts research questions into 'bins' of known and unknown theory and evidence. For research questions where the theory and evidence are known, or can be drawn from analogous cases, it is possible to triage the research activity by answering it directly, finding overlap or synergies with other, similar research projects. Situations involving gaps in either theoretical or empirical knowledge present puzzles for which known methodologies and conceptual frameworks apply. They are 'normal research' questions, in the sense defined by Kuhn (Kuhn 1962) as will be explained in detail below. An example of normal research would be research using known methodologies for public engagement on a new technology, such as bioproducts derived from lupins, for which there is no extant research or useful analogous research results. Research questions where there are gaps in both theory and evidence will require more sophisticated work than normal research in the formulation of hypotheses, development of appropriate research teams, consultation, and use of research methods. This foresight research requires the triage process and normal research as antecedents, discussed below. An example would be the preferred practices, policies and institutions for intellectual property management for bioproducts and crop biotechnology looking forward ten years.

A second criterion is 'granularity.' The anticipated 15 iGE³LS projects will address specific GE³LS issues in, for example, the development of crops with cold or drought tolerance or for biofuels. One GE³LS issue that is sure to arise in a research project focused on a transformation event is intellectual property management (IPM). An individual iGE³LS project addressing IPM issues tied to a specific technology, like drought tolerance,

is fine grain: it must have focused research questions related to drought tolerance traits in crops. Similarly, other iGE³LS projects may have fine grain IPM issues specific to the S&T project in which they are integrated. If the results of the scan of S&T and iGE³LS projects reveal the repetition of the same issue at similar levels of granularity, an opportunity to consolidate resources and develop synergistic partnerships presents itself. If the results of the scan show that there are gaps in iGE³LS projects, for example, on IPM questions, the VALGEN alliance can channel pooled resources to address the gap.

The third criterion is redundancy. VALGEN adds value to iGE³LS projects by identifying, through the initial scan, common research questions arising in several projects. Even with adequate capacity and competence for each iGE³LS project to address common issues in, for example, democratic engagement of the public about comparable biotechnology, it is not in anyone's interest, certainly not the taxpayer's, to have multiple, parallel projects researching roughly the same question. Hence, VALGEN provides an alliance-based mechanism for synthesizing iGE³LS research efforts, to achieve greater efficiencies, larger scales and synergistic outcomes.

The fourth criterion distinguishes between iterative and transformative research. Iterative change tends to be the result of modest, discrete problem-solving research. It usually involves marginal adjustments to an applied technology or end product. The resulting technologies and products are often substitutes or complements for existing technologies, and can be easily adapted and assimilated in our production systems, by existing commercial actors, by our regulatory systems and, ultimately by consumers. As a result, iterative research tends to deliver relatively self-limiting end-use solutions and their effects are frequently short-lived. In contrast, transformative general-purpose technological changes involve up-stream inventions that open up a wide array of new production, consumption, political and cultural opportunities. Transformative research often involves challenges to our accepted concepts, technologies, products and organizational structures, with effects spanning decades if not centuries. Our governance systems are simply ill prepared and poorly structured to deal with these changes. While transformations may or may not have significant social or cultural roots, they almost by definition have social impact. Finally, it would appear that as they get going, they tend to precipitate debate, discourse and conflict. While the rate, scale and scope of the change will vary depending on whether the technology involves small, iterative adjustments or poses large, transformative modifications, the challenge remains the same. Institutions need to respond and to adapt to the new circumstances (6 2001; Phillips 2007).

Table 1

Triage Methods Summary	
Triage Criterion	*Description*
Epistemic	Where a problem's theory and data are known and a solution can be easily reached, research resources can be moved to normal or foresight research.
Granularity	iGE³LS projects focus on fine grain problems based on particular S&T projects; the VALGEN alliance adds value to GE³LS research at a higher level of generalizations.
Redundancy	Overlapping research activities can be consolidated with an eye to finding synergies in multiple research programs.
Iterative vs. Transformative	Iterative research often poses GE³LS questions that can be easily triaged into normal research projects, whereas transformative research typically involves foresight research.

Problem-solving research

Problem-solving science involves areas where theories or evidence may be lacking. In this domain, new models, methods and metrics are required to gain a better understanding of the choices we are making now. This work will focus on three foundational issues related to applied genomics for bioproducts and crops: intellectual property management policies and strategies; regulation and governance of genomics based innovations; and democratic governance of risky science.

This area of research might be viewed as a 'sweet spot' for research because it addresses tangible problems with practicable approaches – it is do-able with predictable successes. In this domain, we may have some theory but need to gather appropriate evidence. Similarly, we may have some anecdotal or experimental data that needs buttressing with theoretical advances. In both cases, there is a need to bridge from what is anticipated or known. This will inevitably involve developing new models, methods and metrics.

Recent experience suggests that GE³LS research is neither a straightforward research program nor lacking in emerging, unanticipated challenges because Canada's innovation landscape is constantly in flux. While genomics research has expanded, governance mechanisms have not kept pace (for example, in the case of plant molecular farming). New GE³LS tools and methods are needed to support governance without impeding social and commercial uptake.

Recognizing this need, this theme is structured to build interdisciplinary teams focusing disciplinary components of GE³LS research on development and investigation of models, methods and metrics for improved coordination and governance of genomics innovation.

- Models: There is no certainty in Canada or elsewhere regarding which models of coordination and governance are most effective in advancing genomics innovation. Several approaches that assess and encourage social acceptance and use can be found. Similarly, a range of public, private and collective models of innovation governance exist in the literature. Mostly, these differ along disciplinary lines, according to different interpretations of the actors, their motivations, relationships and normal practices. Projects to develop models will be challenged to extend disciplinarily based work into interdisciplinary explorations, and apply the resulting models to genomics research. Various models used in other research contexts will be adapted, tested, and incorporated into new models related to the social acceptance, adoption, uptake and governance of genomics. The work of the Intellectual Property Modeling Group at the Centre for Intellectual Property Policy is a significant step in this direction (CIPP 2008) and sets an appropriate benchmark for the scope and duration of potential projects. Given the complexity of the Canadian system, it might be tempting to seek out general models to capture the complexities of the system in a realistic, if coarse grain, of analysis. It is unclear if simpler models will do justice to the complexities of the system, and alternative theories and models must be responsive to the changing political-economic and socio-cultural context. It appears more realistic to search for models that work with, not against, complexity and draw from broad framings of the innovation process. Cross-disciplinary approaches can be found, for example, in complexity and chaos theory (Herbert 2005), new concepts and approaches to distributed governance in a global system and various formal and less formal simulation and evaluation models (e.g. small-world game of life models, currently used in evolutionary biology). Similarly, a variety of consultation and communication models can be adapted for assessing social acceptability of genomics technologies. Citizens' preferences can also be elicited by simulations of voting and market situations through innovative experimental approaches. These models appeal to and bridge theoretical concepts from sociology, psychology and economics. These and other conceptual innovations offer an opportunity to link traditional theoretical structures and approaches into a more complete (and complex) assessment of the innovation process and the constraints and limitations that affect this process.
- Methods: Conceptions of the opportunities and trade-offs associated with genomics investments are reflected in processes for governing innovation. Standard performance indicators can deliver useful information about how effectively closed-system technical problems have been solved, but they have little to say about how science and technology perform in a social context. New methods that provide this composite appraisal will allow Canadians to tackle challenging questions about the opportunities, constraints and governance of innovation. A number of emerging methods offer interesting prospects for combination with widely used qualitative methodologies such as focus groups and case studies. Social network analysis (SNA), for example, uses graph and number theory to provide for visualization and empirical descriptions of network dynamics. SNA can be adapted to track and define more clearly the often-overlooked social steps in knowledge translation involved for successful innovation. This research will begin by identifying perspectives of civil society organizations and other important stakeholder groups and how these map on to or help to shape policy development. Similarly, there are efforts to develop

experimental methods to assess social acceptability and potential social constraints for particular innovations and the basis of individual's decision making regarding acceptance of these. There is much scope to extend these methods, initially in small-group contexts and then potentially to large-group formats, that may give a stronger basis for inference and a higher level of statistical confidence.

- Metrics: The current narrow set of metrics for the assessment of innovation and the resulting social and economic benefits from genomics research (i.e. HQP, publications, patents and spinoffs) is incomplete and often misleading. This is the case despite the extensive work of Statistics Canada and the impact of the Frascati and Oslo Manuals of the Organization for Economic Co-operation and Development. These measures simply define the tip of the innovation iceberg – most of the critical processes, outcomes and impacts are uncharacterized and ignored. The methods and models that need to be developed and tested must ultimately be grounded in measures that better capture social causes and effects of innovation. The advent of boundary crossing science and technology that destabilizes the regulatory environment, together with awareness of the far-reaching social and environmental effects of innovation, increases the demand for meaningful measures of innovation. Customary measures of innovation are inadequate to meet the need.

Forecasting and foresighting

Anticipating the impact of ABC research, invention and innovation is difficult, but it is not simply guesswork or crystal ball gazing. While it is impossible to 'pick the winners' at the start of a research program, once a research program is underway it is possible to make predictions about the probable areas, and kinds of impact, innovations will have. Technology assessment techniques, such as those used by the widely lauded but now defunct U.S. Office of Technology Assessment, or the integrated technology assessment models used in the European Union, for example, by the European Commission Joint Research Centre Institute for Prospective Technology Assessment, aid in the identification of emerging technologies. Technology assessment tools are an aid to planning and decision-making because they predict what will be in the pipeline, when it may emerge, and the impact the technology might have.

The VALGEN research team recognizes that, in addition to the need for technology assessment, additional foresight is highly desirable to understand the interaction of innovations with the marketplace, regulators and the public. Innovation in ABC science and technology will create new products and services destined for trade and commerce and these will raise issues about the management of intellectual property, regulation and governance, and democratic engagement. Increasingly, scientists are opting for data sharing agreements built on open source frameworks that operate somewhat antithetically to university, government and private sector preoccupations with patents. Uncertainty in systems of regulation and governance will arise when science-based approvals of products and services cannot be completed because of a lack of data or the absence of entire protocols for establishing hazards, and pathways and frequency of exposure. New products and services can also engender public debate about the merits and desirability of ABC innovation.

Two formalized foresight methodologies will be used to grapple with situations in which there is a paucity of data and theory about ABC innovations. Foresight research will build upon the 'normal' research described in this proposal, to the extent that wisdom can be drawn from past lessons learned (European Environment Agency 2001) and from analogous cases involving uncertainty. Formal methods are needed, however, to fully anticipate the implications for government, industry, universities and the public. Consequently, VALGEN will use Trochim-style concept mapping to develop structured concept maps for evaluating and planning responses to ABC innovations (Trochim 1989). The Trochim method is a multi-step process in which participants respond to a particular conceptualization of a problem or plan by generating statements in response. These are represented in a graphical concept map using multi-dimensional scaling and cluster analysis, and the map is then given a rigorous interpretation. In the final stage, the map can be used for planning, either directly, or as an input into other processes such as the scenario building method.

Developed as a formal system in response to Shell's market position jeopardized by the environmental movement and the emergence of OPEC in the 1970s, scenario building methodology has since been used extensively as an aid to decision making in private and public sectors. The method is particularly useful in the foresight research proposed by VALGEN because it imagines a 'client,' such as the Government of Canada, with a defined objective in the near future (such as improved IP management, regulation, governance or

democratic engagement with respect to ABC). The scenario method involves the identification of drivers of a change in a system, categorized by importance and uncertainties involved. These are used to form matrices of options for action, from which potential scenarios of the future are developed (Sharpe and van der Heijde 2007). The candidate scenarios can then be tested as thought-experiments, analyzed and compared. When scenarios are built, they represent future states and the potentials for action. The 'time signature' can be reversed through a back-casting exercise in which the steps necessary to reach the targets in the scenario are 'reverse-engineered.' Scenarios are thus powerful tools for decision-making (Fahey and Randall 1998).

Critical Essay 2

Science and Innovation Policy for the 21st century: Shaping the Dialogue

By: Peter WB Phillips and Peggy Schmeiser

Generating, developing and applying science and innovation to benefit humanity at local and global levels has never been more important and challenging for decision-makers in the public, private and civil sectors. Keeping in mind that scientific discovery may be a necessary condition for change, it is seldom sufficient for economic development. Innovation involves the application and use of both old and new science and technology in new ways. Making that system work is a challenge no country has completely solved.

Canada's federal government recently stated that innovation is "essential in shaping our future." Moreover, it recognizes that this country "needs an inclusive plan to foster a confident nation of innovators—one that is globally competitive in promoting research [and] translating ideas into new products and services" (Government of Canada 2016a). Strategies like Canada's new Innovation Agenda (2016b) will undoubtedly support the pursuit and implementation of new measures that strive to make good on ambitious government promises "to build Canada as a global centre for innovation" (2016a). However, reaching that goal involves dealing with complexities and imbalances that may render many policies, initiatives and instruments ineffective or in some cases counterproductive, leading to unequal distribution of benefits and risks for diverse communities across the innovation spectrum. Thus, new thinking is required about the drivers and tools underpinning current approaches to science and innovation policy.

Current innovation challenges

The idea that science can be put to work in solving pressing public policy challenges is embraced by think tanks, governments, universities and industry. In many ways, the history of Canada is a story of scientific progress driving socio-economic development. Governments invested heavily in adapting, adopting and tweaking the best transportation technologies to open the country, in developing new crop varieties to grow in Western Canada's harsh climate, working with industry to address challenges in the management and use of our forests, fisheries, mineral deposits and oil fields, and driving the development of long-distance telephony, anchored on satellite systems, to link us for the 21st century. Science (and government) have been central to all of these achievements (Doern, Phillips and Castle 2016).

Canada, more than most countries, has had a strong supply-push model of scientifically driven technological change and economic development. This remains true even today. The OECD reports that the public sector, universities and not-for-profit foundations combined contribute about 47 percent of the resources and undertake about half of the nation's research. While some of that money is notionally directed to specific targets, much of that funding is unfocused compared with programs in other countries; governments in Canada direct much of their support either through the higher education sector where the commercial application is not specified or to firms as ex post subsidies for research expenditures (STIC 2015).

Science and innovation in the 21st century is characterized by at least three dominant trends (Phillips 2007). First, the science underlying the modern economy is far more diffuse and distributed than in the past. Small teams of motivated individuals were at the core of the waves of technological change over the past 150 years. Those teams could draw from a relatively stable stock of global scientific knowledge and use that to solve discrete problems that constrained our national economy. Now science is both global and dynamic. Jinha (2010) estimated that between the first formalized journal article in 1665 and 2009, the world had collectively published about 50 million articles and was adding approximately 1.5 million articles a year to that stock. At that rate, the stock of knowledge would approximately double by 2033. Second, global science has been amplified by global markets, where consumers and suppliers aggressively compete to be the first to exploit new innovations. The result is that those few new ideas that are introduced are often rapidly and widely adopted. Those that are adopted are often not the best or most inventive, but rather the first to match with needs in the marketplace. Third, the market—represented by consumers, governments buying on behalf of individuals, firms producing finished consumer goods and the broader social community—is becoming much more engaged and demanding. Isolated, supply-driven innovations risk missing the mark of what citizens and consumers want or

will tolerate. At the extreme, consumer-led innovation is completely disconnected from the underlying scientific enterprise.

The main impact of this accelerating world is that the gains from successful technological change are concentrating in specific sectors, markets, locales and firms. Rogers (2003) characterized the world as one where innovations go through a normalization process, with early adapters testing and validating the value of an innovation, before widespread adoption occurs. In such a world, benefits are distributed across and along the supply chain to both early and late adopters. With the acceleration and integration of the scientific and innovative system, we are seeing new distributions of impacts and outcomes, with far more of the benefit being captured by leading innovators and the average participant gaining less in total. These winner-take-all events challenge our standard assumption that investment in science will lead to widespread prosperity. The quintessential example of this is the internet, where a handful of oligopolies (i.e. Amazon, Google, Facebook, Netflix, Disney, Alibaba and Tencent) dominate the choice architecture for most on-line consumers, thereby earning the bulk of the on-line profits (Economist 2017).

Disconnects in the generation and utilization of new ideas is equally problematic and bringing the fruits of science to markets has never been more difficult. The most recent state of the nation report from Canada's Science Technology and Innovation Council concluded that "Canada's most profound and urgent ST&I challenge lies in increasing the number of firms that embrace and effectively manage innovation as a competitiveness and growth strategy" (STIC 2015). Although "higher education institutions also play a vital role in developing and advancing knowledge and its application", there are uphill battles within the academic research environment that can stifle innovation processes (STIC 2015). Researchers in single disciplines are limited in their capacity to fully address and resolve the large-scale oft-called "wicked" problems of adaptation and adoption in this complex, dynamic world. As one recent study at four universities observed, more must be done to facilitate and enable collaboration across the sciences, social sciences and humanities if we are to bring about the sorts of comprehensive and effective solutions needed to address large-scale challenges (Schmeiser *et* al. 2015). Moreover, research conducted in isolation from other disciplines and modes of thinking carries the risk of generating innovations that disrupt current practices and modes of thinking, creating conflict that either mobilizes or disenfranchises divergent geographic or social populations, including northern and First Nations communities. While there may be winners from such disruptive events, the costs of transition for many are often higher than they need to be.

Towards an effective science and innovation policy research agenda

This new context of global innovation requires a more effective policy tool kit. The policy system since the end of the Second World War has aspired to evidence-based policy making, where objectively-based problems are framed through the public choice lens and adjudicated by rational (or at least 'boundedly-rational') decision makers (Simon 1991). More recently there is a move to characterize and study policy in the context of evidence-informed policy making, where causal stories frame problems subjectively in the context of the social system (Stone 1989) and decision making involves 'muddling through' (Lindbloom 1957).

Deductive, reductionist approaches that rely on argumentation and basic presuppositions evolved to contribute to evidence-based policy making but are no longer adequate. The traditional public choice framing assumes largely autonomous actors independently make rational choices yielding outcomes that deliver impacts that fit a bell-curve distribution. All our models assume this. In some ways, the development of the risk analysis framework and the adoption of cost-benefit analysis as core filters to assess individual projects and discrete policies reflect this model of policymaking.

The emergence of complexity confounds that. We now can observe a range of lumpy market and policy spaces, where new integrated market structures or densely packed socio-economic subsystems make judgments in the face of profound uncertainty. Decisions from these types of systems are subject to significant asymmetries and network effects, with the potential for emergent, non-linear outcomes. Innovation is one policy space where we see profound complexity—most transformative events, such as the internet or mobile devices, develop in unexpected ways, disrupting both the proponents themselves and government policy systems (Phillips 2007). Assuming we know where technology will take us often leads to stranded public investments and wasted effort. Where these conditions hold, our conventional modeling and analysis lead to biased and inconsistent

conclusions, which would lead governments to make poor policy choices. These circumstances, along with current concerns regarding the questionable authority of science – including the so-called "reproducibility crisis" (CBC Radio 2016) and loss of trust in "expertise" (Nichols 2017) necessitate an expanded tool kit to develop and implement policies that are seen as appropriate and palatable.

This challenge to policy analysis is not unique to the science and innovation space. Nevertheless, the science and innovation policy space engages with all aspects of the new policy paradigm, making it a good place to do exploratory and comparative analysis within and beyond the different issues and tools. A new policy research agenda must necessarily address three discrete but interrelated aspects of governance: strategic assessment, public engagement, and decision-making.

First, we need to work to reframe how we assess and judge prospective and emergent scientific advancements and technological or organizational innovations. Assessment begins well before we know of the applications. Whereas in the past the federal government used to be the lead, setting national priorities and providing the lion's share of funding, the space is increasingly occupied by other funding entities. Foundations, new arms-length granting agencies, universities and private firms are testing a set of new structures to accelerate science, technology and innovation, including conditional grants, networked multidisciplinary projects, clusters, partnerships, big science infrastructure, and institutes, centres and open innovation spaces. These systems have proliferated with little evaluation of their system effects. There is a need for new diagnostic, design and evaluation tools. There has been significant work already on the impact of different decision criteria (e.g. scientific novelty, commercial viability, economic impact, sunk costs, environmental sustainability, safety, risk, uncertainty and ethics) on both the nature and flow of selection decisions. Theory and evidence suggests that when ill-defined or nebulous criteria are added to decision systems, objective evidence is less important than the structure of the decision space and the personal views of the decision makers. This is especially true when people argue from different starting points, or when evidence is agglomerated without consideration of the respective importance for the different variables.

Given that less than 1% of funded projects deliver technologies or products that find success in the market place, research design, selection and evaluation warrant more consideration. We need to test to determine whether research management decisions—including the decisions by researchers to collaborate and apply, the panels to adjudicate, and funders to allocate funds to portfolios of investments—are appropriately structured, tasked and normalized to handle risk framing and uncertainty. Poorly designed systems are more likely to generate intuitive choices based on weak evidence that leads to risk aversion, anchoring on familiar or immediate opportunities and overall sub-optimal activity (Kahneman 2002). A range of new approaches, including institutional and network analysis, case studies, agent-based models, and behavioural experiments, offer ways to test for the impacts of different structures, rules, process and criteria on assessment.
Second, citizens and consumers are no longer content to be the compliant markets for new technologies and their products. People from all walks of life are seeking, sometimes demanding, a greater role in defining the goals and methods of research and innovation. Governments everywhere have taken up the challenge but generally have not found mechanisms that improve the 'fit' of science, technology and innovation into the social space.

Governments have constructed a wide range of processes to engage people (Rowe and Frewer 2005) but there is limited evidence that these efforts have improved public acceptance or government decisions (Phillips 2012). Ultimately, engagement, uptake and use of new technologies is an individual choice, but the social context for the decision can at times be critical to the outcome. Perceptions of costs, benefits, tolerances for risk or uncertainties, and values and interests, in particular, are factors in our personal choices, but are fundamentally influenced by the communities and social networks in which we live and work (Thaler and Sunstein 2008). Most citizen and consumer assessments interrogate the individual to discover the personal calculus one goes through in making a decision related to adopting new production technologies or consuming novel products. There is prima facie evidence that communities, citizens and consumers are less influenced by objective evidence of personal cost and benefit and are more driven by causal stories and the opinions of others. When people are challenged to deal with conflicting opinions, especially about fundamentally uncertain phenomena, they often revert to biases, heuristics and conventions. We need to delve further into the cognitive and social foundations

that drive citizen and consumer opinions (e.g. by region, socio-economic type or psychographic attitudes/beliefs) and to examine the structures designed to aggregate and target their preferences.

Third, we need a new tool kit to design, structure and audit decision making itself. There are a number of opportunities to populate the research toolkit. We could examine the role of key organizations that frame decision sets (Guston, 2001, calls them boundary organizations). Using behavioural experiments, we can assess how the number and types of variables affects choice. Finally, we can test to see how people made decisions that involve sunk costs and uncertain future costs and benefits. Applying these approaches to real decisions in the science and innovation policy space will enable us to assess how to ensure evidence is appropriately considered and used in complex decisions.

There is significant work already done describing and critiquing the goals, structures and outputs of regulatory and policy systems, but little that critically models or assesses the internal decision-making structures and processes and their impact on choices. The rising cost and increased time for review for some classes of technology is unambiguously altering investment strategies and priorities (Phillips 2016). Specific policies and mechanisms have become flashpoints about the benefits and risks of developing disruptive technologies. New crop varieties, pipelines, energy developments, new mines and new drugs have all faced long, uncertain and costly reviews and significant social conflict. Decisions can be and are skewed by ideological positions and political wrangling in legislative processes, by precedent-setting interpretations of rules during administrative and judicial proceedings, and by inadequately supported and complex government review processes. The risk analysis framework, in particular, has framed risk as hazard mitigation, which often truncates consideration of benefits and tends to skew risk dialogues and decisions to discussions of harm avoidance. This approach has arguably minimized errors of commission, but at the expense of errors of omission, as safe and efficacious innovations are delayed or erroneously rejected. A range of therapeutic drugs, genetically modified crops and animals, energy production technologies and industrial chemicals have passed all the objective tests for safety in many OECD countries yet await final approval to be used. Understanding how perceptions about risks, benefits and uncertainties are shaped and how specific decision events are structured offers an opportunity to contribute to science-based, evidence-informed policy and regulation.

There is a real opportunity to use, build and advance a set of theories and methods to assess the relative role of ideas, decision architecture and human cognitive capacity in regulatory and policy decisions arenas that make decisions about which science, technologies and innovations we will pursue and utilize. Understanding the roles of stakeholders, both as individuals and in purposeful organizations (especially those operating at the boundaries of science, policy and regulation), what they view as evidence and how they use evidence to frame problems, assemble options and make choices within decision-making structures, is fundamental to identifying opportunities for improving governance.

The policy imperative

The emergence of a knowledge-driven, scientifically based global innovation system fundamentally challenges the Canadian and global policy system. Complex systems operate differently and deliver profoundly different outputs. The policy and regulatory system can no longer solely rely on our old models, methods and metrics. The basic task for policy scholars and practitioners is to develop and adapt a set of tools that will assist society to optimize the use of the full suite of technologies our research community is generating. Our long-term health and prosperity depend on this mission. Science and innovation policy in Canada offer a unique opportunity to develop and test a range of new models and methods of strategic assessment, meaningful citizen engagement and thoughtful decision making in order to strengthen our evidence-informed policy system.

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Policy Brief 1

Relationship Building: A Key Social Convention for Researchers

Event

Researchers working on GE³LS – the ethical, environmental, economic, legal and social issues associated with genomics research – are a highly diverse group. They are also fragmented and dispersed, often working in isolation from one another according to their institutional, geographical and disciplinary setting. Tracking GE³LS researchers' networks and knowledge exchanges within them is consequently difficult. Social network analysis (SNA) provides a useful way of identifying and characterizing the complex and dynamic interactions and exchanges that occur among researchers.

Significance

Social network analysis is a powerful tool for explaining variances in social behavior, institutional dynamics and resources and can also be used to evaluate the socio-economic outcomes of GE³LS and scientific research.

Analysis

Where academic disciplines, public and private sectors and geopolitical boundaries overlap, traditional approaches for evaluating performance and outcomes of research networks may no longer effective. GE³LS research on agriculture and agro-industrial products is located in the 'fuzzy' territory of academic inter-disciplinarily and is often a collaboration and exchange with the public and private sectors. How GE³LS researchers construct their research community through networking and knowledge exchange remains an important research question one with implications for knowledge mobilization of GE³LS and science and technology research.

In this respect, GE³LS research represents a newly organized research paradigm immune to analyses focused on input-output models viewed as mere sums of parts. Linear models of GE³LS research and knowledge mobilization conceal the complex and typically unpredictable nature of relationships and patterns of network development and knowledge creation and mobilization. The Mode 2 knowledge-intensive, multi-disciplinary, multi-institutional and geographically dispersed network that comprises GE³LS research is better interpreted as a loosely organized system. The GE³LS research network operates as an ecosystem, with a structure and function affected by a complex blend of externalities, driven by human behavior and choice.

GE³LS can be construed as a social network where, as Kauffman (1993) suggests, knowledge outputs are necessary inputs for network expansion. Various types of knowledge are brought together to create new (and new types of) knowledge, thus sustaining or expanding the network and its output. SNA identifies patterns of interaction of individuals, actors or institutions, as well as knowledge flows within a network. It shows how knowledge intensive work is done or can illustrate complex communication channels within a network. As a tool for analysis, SNA views actors and actions as interdependent units. It acknowledges that relational ties between agents provide channels for transfer or flow of resources and can also create opportunities or constraints on individual action. SNA can help to identify boundary spanners, gatekeepers, knowledge bottlenecks and, most importantly, can identify under and over-utilized individuals, organizations or resources. SNA is a tool that enables VALGEN to:

- Understand how science and social science is governed in a complex, multi-disciplinary environment;
- Identify gaps and opportunities for linkages in and amongst actors within the network, and;
- Launch longitudinal studies of VALGEN's impact on science/social science research communities.

Conclusion

Social network analysis is an indispensable method by which networks of researchers and their knowledge mobilization efforts can be characterized. SNA allows VALGEN to fine-tune its three-theme research portfolio, enables the calibration of value-adding activities to maximize impact on GE³LS and scientific research communities.

Policy Brief 2

The Delphi Method and its Application to Genomics and GE³LS

Event

The Delphi method is a survey-based technique that is used to solicit thoughts and judgments on a specific question or issue from a carefully selected, knowledgeable group of participants. The Delphi method is being used in the context of applied genomics for bioproducts and crops (ABC) to identify issues and trends in science and integrated GE³LS.

Significance

Not all research questions have answers that can be sourced from existing literature, much of which is generated by individuals or small groups using methods established for specific forms of publication or knowledge transfer. In cases where a research question calls for group input, but resources constrain opportunities for meetings group dynamics or the contentiousness of a topic suggest that a face-to-face meeting may not be desirable, alternative methods must be sought. The Delphi method can be used to create a forum of exchange to remotely, and anonymously, conduct a structured and focused dialogue. Delphis can be used to generate new ideas, as well as identify and prioritize issues.

Analysis

Developed by the RAND Corporation, in the 1950s, as a means of technological forecasting, the Delphi method has become a widely accepted and validated means of soliciting the opinions and judgments from a group of experts. While there is no strict methodology that governs this research method, there are three essential characteristics common to all Delphi surveys.

The first is its iterative nature. Successive rounds of the survey, modified each time, are administered over a defined time-span, ranging anywhere from days to years. Thus, the Delphi is a process that allows time for reflection, analysis, and development of ideas, similar to other deliberative methods in the social sciences.

The second is feedback to participants. After each round, participants receive the results from the previous round before completing the next survey. Participants have the opportunity to see what their peers are saying, and may change, or defend their position accordingly. The reflexivity of the Delphi assists in the creation of a collective perspective, rather than the views of individuals, particularly in situations where the Delphi is being conducted to generate a consensus.

The third characteristic is anonymity. By eliminating personal identifiers from responses before they are shared with the group, participants are free to express their thoughts and opinions openly without concerning themselves with power hierarchies and social dynamics that might arise at a face-to-face meeting. Additionally, the anonymous nature of a Delphi prevents certain participants from dominating the conversation, and others suppressing their opinions.

Policy Delphis are used to identify and priorities for policy development and strategies for implementing activities. Policy Delphis strive for convergence on a set of options or priorities are called consensus Delphis. They can be contrasted with disaggregate policy Delphis (DPD) which are not intended to generate a consensus or be a mechanism for decision-making. Instead, DPDs raise options and justifications for action, but prioritizing options is deferred to later processes. The ABC projects are highly diverse, yet have common trajectories and demands placed on them. VALGEN researchers are deploying a multi-year DPD to facilitate dialogue across projects and between scientists and GE³LS researchers to learn more about project goals, activities and constraints, especially those relating to GE³LS integration into science.

Conclusion

The outcome of the DPD is knowledge about the ABC domain otherwise inaccessible by other research methods. Equipped with this knowledge, GE³LS and science researchers, with the assistance of the VALGEN researchers, can initiate activities to maximize synergies, close gaps, and avoid pitfalls, thereby adding value to ABC research.

Policy Brief 3

Institutional Analysis Development (IAD) Framework

Event

Research on agricultural biotechnology and genomics of the kind supported through the Genome Canada ABC competition strives for transformative innovations that create significant regulatory challenges. How rules influence outcomes and how actors within the system respond to those outcomes in response to transformative technological innovation is generally not well understood, but promising new analytical frameworks are emerging. One that is proving useful is the Institutional Analysis and Development (IAD) framework developed by Nobel Laureate Elinor Ostrom. The IAD framework offers a flexible, multi-purpose model to examine how rules (institutions) and aspects of the physical and cultural world interact to shape outcomes in different governance systems and organizations.

Significance

The IAD framework is considered a rational choice, an institutionalist approach, drawing on systems and public choice theory. Rather than assume a universal rational actor model, the IAD instead views actors as operating under bounded rationality. While actor interests and motivations are assumed to remain relatively constant and salient, imperfect information, misperceptions and mistakes can yield sub-optimal outcomes and behaviors. Thus, the development and structure of the institutional system is essential to explaining and predicting outcomes.

Analysis

The IAD framework consists of a series of interactive variables that together make up a complex system that produces outcomes. There is a common understanding among actors on a range of exogenous variables, such as rules, attributes of the community and relevant biophysical characteristics. These variables interact in an action arena, which consists of actors and an action situation. The system leads to an outcome.

While many social sciences posit such an arena, it is often characterized as a black box in which policy inputs are converted into policy outputs. The IAD, in contrast, seeks to deconstruct the system and test the interface between institutions and actors. The framework explicitly assumes that actors engage in ongoing evaluations of actions and outcomes, through a range of feedback loops and learning processes that determine the ultimate outcomes.

The IAD framework provides scholars with a common language to use in analyses of institutional dynamics. It also recognizes the important role that interactions among actors play in outcomes, while accounting for the influences that both formal and informal rules have on system outcomes. The IAD framework continues to evolve to include issues of power distribution, the norms of fairness in the community and how humans order their behaviors on a sub-conscious level. These issues are critical to understanding how people and systems make choices about fundamentally uncertain opportunities, such as presented by transformative technologies like genomics and biotechnology. There are numerous challenges to regulating ABCs – including horizontal connections through mutual recognition agreements and knowledge exchange. The IAD can help trace the ways information is circulated through feedback loops, while providing a useful method for unpacking operations within the regulatory system. It can be used to enhance learning and identify inefficiencies within the system.

Conclusion

The IAD framework has been informatively applied to a variety of research areas including urban public services, the international aid regime and forestry governance. A flexible model, it can be used effectively to explore the dynamics between institutions, rules, actors and policy outcomes. It accounts for the complexity of interactions that exist in decision-making systems while acknowledging that change can occur at any point in the system, which can influence the subsequent behavior of the system itself. In short, it is one available way to assess and understand the nature of complex, learning, dynamic systems.

Policy Brief 4

Scenario Methods for the Governance of ABC Technologies

Event

Uncertainties associated with the research, development and regulation of new crop genomics, bioproducts and related services creates significant governance challenges. Foresight methods, especially scenarios, are being developed by the public sector to validate normative underpinnings of governance options in strategic planning exercises.

Significance

Scenario methods have been used for nearly three decades in private sector energy strategies, but their adoption by the public sector and in large-scale research projects like VALGEN is new.

Analysis

Foresight methodology is in general based on the idea that the future is not yet determined and that a myriad of factors will interact to shape it. With this accommodating starting point, foresight applies to nearly any problem or context important enough to seek ways to bring about desirable outcomes and lessen undesirable futures. Shaping the future is an activity based partly on facts as they are known now or reasonably predicted, but it is also a creative act of envisioning alternative pathways. Used strategically, foresight prepares one for different possible futures, enabling one to anticipate and react in the present. The foresight method best suited to this undertaking is the development of scenarios.

Developed as a formal system in response to Shell's market position jeopardized by the environmental movement and the emergence of OPEC in the 1970s, scenario building methodology has since been used extensively as an aid to decision-making in the private and public sectors. In recent years, governments have also begun to use scenarios and there has been a surge in the literature of practice guidelines to conduct scenario exercises. In the past two years, Health Canada, Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency have used foresight and scenario methods.

Many different scenarios methods exist, but the most common one that has emerged is the use of the matrix model in scenarios workshops. In workshops, carefully selected participants are led through a brainstorming situation to identify all possible drivers of change. These are factors, trends or situations that would drive future possible states. Once a list of potential drivers has been brainstormed, they are discussed and analyzed to determine which two carry the highest degree of impact and uncertainty. These are then used as two axes to form a four-quadrant matrix from which potential scenarios are derived. The candidate scenarios can then be tested, analysed and compared via thought-experiments. When scenarios are developed, they represent future states and the potential for action. The 'time signature' can be reversed through a back-casting exercise in which the steps necessary to reach the targets in the scenario are reverse-engineered. By creating scenarios based on drivers and trends that are uncertain, the process does not need to make an explicit value judgment about which scenarios are preferable to others.

Conclusion

The scenarios method is particularly useful for addressing challenges in the governance of agro-industrial biotechnology because it shapes possible futures from present uncertainties and captures these in an action-oriented matrix which enable one to 'back cast' to initial steps. The public sector, facing governance challenges associated with research, development and regulation, is finding scenarios effective in strategic planning. VALGEN researchers have participated in recent public sector planning exercises and will be conducting a series of scenarios workshops along the lines of the three research themes in VALGEN.

Policy Brief 5

Foresight Scenarios, Theory and Drivers of Change

Event

Foresight scenarios are based on user-selected drivers of change that comprise the axes of a four-quadrant model. The characterization of drivers, and how they are selected, lack a theoretical basis in foresight literature (Bishop, Hines and Collins 2007).

Significance

The normative and epistemological underpinnings of foresight methods are under-theorised, and more has been written about foresight practice than theory for two reasons. First, foresight studies arose mainly out of work done in, or associated with, the military and large corporations whose work is kept secret. Second, because foresight is tied to the practices of individuals and institutions, and is meant to change them, theoretical development has lagged behind the advancement of practice. Because driver selection is a key step in scenario development, better theoretical justification of the method of selection and criteria for drivers could yield more robust, and defensible, foresight scenarios.

Analysis

The scenario method arose from work of Herman Kahn in the 1950s and 60s and was later developed by Pierre Wack of the Royal Dutch Shell Company and popularised by Peter Schwartz in the 1970s. It is now known as the four-quadrant model or the Global Business Network (GBN) model, and is the most common scenario method. The scenario method involves brainstorming a list of factors that will drive future change, and then selecting the top two factors with the greatest level of uncertainty that promise to have the greatest impact. The two drivers are then used to create two axes, representing a spectrum of possibility with the two poles representing different extreme outcomes. Since the two axes intersect, the result is a two-by-two square, or four possible future states, each representing a different possible reality.

With respect to process of driver selection, the foresight scenario method has been criticized for its inability to adequately consider the uncertainty of the future using only two dimensions. In fact, the reasoning and justification as to why only two drivers of change are selected to form the foundation of the scenarios has been gravely overlooked in the literature. While there are suggestions that using two drivers only was made to simplify the process and make it easier for participants to understand, there appears to be no methodological basis for this decision, only a logistical one.

With respect to the drivers themselves, little has been written about the epistemological and normative underpinnings of the drivers. Selecting drivers of change with the highest level of uncertainty compels participants to explore futures at the limits of their knowledge, while drivers of change about which more is known can be integrated directly into the scenarios. This would seem to defy a criterion of verifiability associated with strategic planning, but no immediate paradox arises in foresight studies. Because risk mitigation implies anticipating and controlling for the unknown, and since foresight scenarios are conceptions of preferred futures, uncertainty is at the forefront of scenarios. Nevertheless, drivers are not well characterised in terms of epistemic criteria including typologies of uncertainty or systems of inductive logic. Equally, the underlying norms are not well characterised and the lack of explicit ethical theory opens scenarios to being expressions of preferences only. Also, poorly understood is whether drivers need to be necessary or sufficient causes in scenario development, and whether the difference constitutes a selection criterion.

Conclusion

Foresight scenarios are powerful tools to conceive of, and plan for, desired futures amidst uncertainty. Their power is diminished, however, by under-developed theory about the underpinnings of driver selection. Scenarios that are more robust can be created with better epistemological and normative justification of driver selection and number. Additionally, driver selection criteria partly address concerns that scenarios can be gamed by driver choice.

Policy Brief 6

Advocacy Hyperlinked: Using a Webcrawler for Managing Issues

Event

Non-governmental organizations (NGOs) and social movement actors are becoming more connected through 'advocacy networks' (Keck and Sikkink 1998) that leverage resources and information on the Web in an effort to influence policy and public opinion.

Significance

The complexities of some issues (e.g. *terminator technology* and *synthetic biology*) involve a number of key stakeholders from government, the private sector, non-government organizations and consumer interest groups resulting in a proliferation of information sources, all of whom, to a greater or lesser degree, rely upon the Internet to disseminate information. Therefore, understanding online behavior becomes important in understanding how to manage controversy and communication strategies around specific issues.

Analysis

Web tools, such as IssueCrawler, offer an automated way in which a user can observe online networks. IssueCrawler offers a method for making "politics of association visible, analyzable, and comparable" (McNally 2005). It has the capacity to highlight exchanges on the Internet related to specific issues such as *terminator technology* or *synthetic biology* (Ryan 2010). The IssueCrawler program is comprised of crawlers, databases, analytical engines and visualization modules (Rogers 2008) to generate node lists, actor rankings and links of a given issue network. The program also offers a set of 'allied tools' which permits users to more fully (and qualitatively) analyze a given Internet-based network or issue. The tools can be used to geographically or abstractly map a social network and it can be used to conduct impact assessment (event mapping) or changes in actor rankings over time.

Some key observations on our exploration of online issue networks include: 1) networks appear to grow over time with more stakeholders becoming involved; 2) key actors appear to dominate these issue networks over time; 3) events and news issues arise which prompt advocacy organizations to shift activities into other areas and often push new stakeholders into more central positions; 4) issues generate sub-issues, often lead by one-off, even temporary, organizations or stakeholders; and 5) despite the 'virtual' nature of these networks, lead advocacy stakeholders are geographically clustered around government-based centres (e.g. Ottawa and Washington).

Despite promising utility, the value of web crawling depends on how the research method is developed and employed. Upfront understanding of the scale and scope of stakeholders involved and the timing of analysis is critical. Social network analysis, institutional analysis or in-depth interviews or case studies can be used to enhance results.

Conclusion

Advocacy activity is alive and strong, particularly in the anti-technology realm. However, the impact of such organizations is not yet clear. Given the ubiquitous role that the Internet plays in advocacy strategies, it is useful to explore the structure of networks or coalitions of actors through online or hyperlinked connections in order to understand better those networks. Methods to do so must be triangulated, multifaceted and strategically implemented.

Policy Brief 7

The Practice of Foresight Scenarios in Canada

Event

In the past five years in Canada, foresight has emerged as a prominent tool in futures analysis. Government agencies, such as the Canadian Food Inspection Agency (CFIA) and Agriculture and Agri-Food Canada (AAFC), have undertaken several foresight events on a wide range of topics including agriculture, bio-economy, and animal and plant health. Reports summarizing these events offer the opportunity to undertake an assessment of Canadian foresight practices.

Significance

Foresight is a well-established practice in several countries including Japan, Germany, United Kingdom and the United States. In contrast, the practice of foresight has only recently gained popularity in Canada. Recent Canadian foresight events offer an opportunity for critical appraisal of how foresight is being performed in Canada.

Analysis

In the past five years, approximately twenty foresight exercises have been undertaken in the life sciences in Canada (Foresight Canada 2012). Eleven of these foresight initiatives have released detailed reports available to the public, either online or by contacting the event sponsor directly. These reports have been analyzed to identify commonalities, themes, and differences in foresight methodologies (Demian 2012).

Each event followed a different methodology. This observation is consistent with literature describing foresight methods as flexible and wide-ranging, and subject to choice about which methods are to be used depending on factors relating to the purpose of the event and resources for it (Popper 2008). Six of the reported eleven events used a form of scenario development.

Each event had a complex design and idiosyncratic use of scenario methods, raising several queries for consideration:

1. *The number and criteria for participant selection*: The number of participants varied from 10 to 100, with an average of 60 participants. Although many of the reports indicate that relevant stakeholders with expertise participated in the exercise, the selection criteria were not mentioned.
2. *Participant preparedness:* Nine of the eleven reports did not indicate if the participants were given information in preparation for the exercise.
3. *The selection and characterization of drivers of change*: None of the reports provides specific details in how the drivers are chosen, and no report explored in detail the role of uncertainties in foresight scenarios.

Conclusion

An overview of Canadian foresight events indicates that scenario development has emerged as a common foresight technique. In Canada, the development and use of scenarios is relatively under-theorized, especially in comparison to other national science policy planning processes. Concerns also arise regarding the lack of rigorous and well-documented methodologies being associated with these foresight exercises. The lack of explicit theoretical underpinnings and demonstrated practical rigor may put the validity of the output of these foresight exercises as explorations of potential futures into question. The potential outcome is that foresight, and scenarios in particular, come to be regarded in Canada as methods by which current policies are validated, rather than being the intended ‘strategic conversation (van der Heijden 2005) about the future. A loss in confidence in an approach to developing strategic plans for public policy in the life sciences would be a detriment to Canadian policy planning processes.

Policy Brief 8

Assessing the Quality of Foresight Scenarios

Event

Foresight scenarios guide strategic decision making, and should not be mistaken for predictive forecasts about the future. This important distinction raises the question about how one evaluates the quality of foresight scenarios. Statistical methods can be used to evaluate the robustness of predictive forecasts, and predictions can be validated retrospectively by comparing predicted with actual events. Comparable methods for evaluating or validating foresight scenarios do not exist, however, leaving a gap in practice and methodology.

Significance

Scenarios are used to guide strategic decision-making, and a natural consideration is whether decisions informed by scenarios are based in good evidence and judgment. The gap in practice and methodology for assessing scenarios raises questions about the warrant for their use in strategic planning, and alerts practitioners and theorists to the need for an evaluative process to underpin continuous improvement of foresight theory and practice.

Analysis

In the literature on foresight scenarios five factors have been suggested as the basis for assessing the quality of foresight scenarios:

1. *Plausibility*: A scenario must be plausible, which is to say that it can be distinguished on the basis of its likelihood from the broader range of possible scenarios, or from the narrower range of scenarios that are preferred purely on normative grounds (Ratcliffe 2000; Shoemaker 1997)
2. *Consistency*: A scenario must be internally consistent such that no aspects of the scenario are contradictory (ibid).
3. *Challenging*: A scenario must challenge current assumptions and beliefs about the future, not merely conform to them, (Ratcliffe 2000) and scenarios may in this respect be interesting and perhaps surprising (Stout 1998).
4. *Differentiated*: A good scenario exercise results in multiple scenarios being formed, generally four. These scenarios ought to be distinct from one another, rather than being simple variations on a theme (Ratcliffe 2000; Shoemaker 1997).
5. *Credible*: A good scenario is based on, but not reducible to, a set of facts that have been, or can be, verified (Stout 1998).

Although there is an emerging consensus on the characteristics required to create a good scenario, there remains a gap in the literature on assessment of these elements. There is further work to be done in linking these factors with various expectations of scenarios as, for example, a heuristic for a type of conversation, a sense-making exercise, or a strategic planning or decision-making process. That is, criteria that are 'internal' to the scenarios need to be linked in practice and theory to the reasons that motivate undertaking scenarios in the first place. Not only would this linking bring about greater methodological coherence to foresight scenarios, it would also provide practitioners with evaluative cues as they develop scenarios. It would also reassure scenario participants that the results are not just-so stories, but have qualities to evaluate and associated methods supported in theory and practice.

Conclusion

It is essential that researchers, policy makers, and other stakeholders who intend to rely on scenario building exercises, are basing their decisions and judgments on effective and useful scenarios. However, there is still a gap in the literature as to both what makes a good scenario, and how a scenario ought to be evaluated. Without this issue being addressed, foresight practitioners and researchers are at risk for investing valuable time, energy, and resources into questionable, and potentially ineffective, scenarios.

Policy Brief 9

Social Capital, Innovation and Large-Scale Projects

Event

'Large-scale' research models constitute a key feature in innovation policy today. Since 1997, more than C$3 billion of federal funds have been channeled to key research organizations that pursue large-scale partnerships and networking models. These efforts have been widespread, including as the ISTP Program (Industry Canada) and a range of network and partnership grants at CIHR, NSERC, SSHRC, CFI and Genome Canada (GC).

Significance

Large-scale projects are promoted in the hopes that network effects will accelerate research and generate downstream benefits to researchers, funders and the economy. There is compelling theory but limited evidence that public funding directed towards large-scale innovation projects strengthens outcomes.

Analysis

In 2009, Genome Canada invested C$112 million in 12 large-scale projects in the Applied Bio-products and Crops (ABC) Competition. A recent study by Sharma (2012) examined the impact of these investments by investigating the role of social capital in the structuring of those projects. The successful projects in the ABC competition incorporate essentials of large-scale team formation. Funded investigators (scientists and GE^{3}LS experts) exhibit a range of network relationships that draw on links to local, regional, national and global capacities. The absolute and relative relational position of 139 investigators in the ABC community and their background social capital was assessed using Social Network Analysis. The study examined ties during 2000-2009 for each ABC investigator to quantify the pre-existing social capital they brought to the ABC competition and its impact on their relative success in the program. Four specific sources of social capital were considered: shared disciplinary backgrounds (based on the ISI Web of Science categorization of peer-reviewed publications); physical co-location (based on location of primary employment in the previous 10 years); prior engagement through peer-reviewed grants (based on a review of 10 years of grants awarded by CIHR, NSERC, SSHRC, CFI, and GC); and prior co-publication (based on an ISI search of all published works in the past 10 years). Each factor was measured and relationally assessed through SNA tools to identify the degree of social capital exhibited. Then the personal outcomes of each investigator in the ABC competition were correlated to each of the social metrics, to determine any statistical connections. Each source of social capital is hypothesized in the literature to facilitate large-scale project team interaction and generate both current and future advantages for individual researchers and program outcomes.

This study drew four conclusions from the analysis. First, social capital produced via disciplinary ties negatively impacted the ability to generate future financing; large-scale projects in the Genome Canada competition favored and rewarded cross-disciplinary ties over in-field relationships. Second, co-location of investigators in institutions, which might be assumed to facilitate real-time communications, failed to differentially generate financial rewards for investigators. Third, investigators who span networks funded by research grants generate greater follow-on research funding. Fourth, co-publication, the most intensive type of relationship examined, provides the greatest financial success. Engagement through research grants and co-publication offers the highest returns to the investigators and is a stronger measure of overall research success.

Conclusion

For investigators (and one might infer for granting agencies), maximum benefits appear to accrue in large-scale innovation projects that: have minimal requirements for co-location/real time interactions; encourage hybridization across disciplines; and facilitate cross-disciplinary exchanges through personnel mobility, knowledge production and partner research grants. Public funding for projects supporting co-publication opportunities and partnered research awards, such as Genome Canada programming, appear to offer a positive way to sustain research and innovation.

Policy Brief 10

Citation Analysis and the Evolution of Collaborative R&D

Event

A longitudinal citation analysis on AAFC peer-reviewed canola research papers published 1986–2007 in five-year intervals demonstrates how structural changes to the industrial organization of the financing of canola research and development (R&D) are mirrored in the changes to the citation rates of AAFC papers relative to a global average of 1.0 per paper. Specifically, when AAFC was the primary funder of canola R&D, the AAFC citation rate was greater than the global average. As cutbacks to this funding facilitated a transition to private "fee for service" research, relative AAFC citation rates plummeted in a reflection of the desire for corporate confidentiality. Eventually, over the long-term, the cutbacks in AAFC funding facilitated the requirement of collaborative funding arrangements with producer public-private partnerships (P3s) using innovative financing strategies, in turn generating a discernible increase in relative AAFC citation rates.

Significance

Theory suggests that the production of knowledge has transitioned from a vertically structured process involving homogenous organizations in the pursuit of theoretical knowledge to a horizontally structured process involving heterogeneous partners in a collaborative and problem-focused environment (Gibbons *et* al. 1994). The Triple Helix Theory suggests that economic growth is dependent upon developing knowledge in an environment characterized by collaboration between the public, private, and university sectors (Etzkowitz, H. 2008). Common to both perspectives is the requirement for a structure or process that connects disparate partners.

Analysis

In the interval between 1986 and 1990, a period when AAFC was the primary funder and organizer of canola R&D, (then a one-dimensional process), its relative citation was 1.22. During the 1991–1996 and 1997–2002 intervals the AAFC relative citation rate declined to .85 then to .66 respectively. The decline reflected changes in structure and process in the funding of AAFC research, ensuing from government cutbacks and simultaneous privatization of the canola R&D process. The fee-for-service research, which had become a two-dimensional process, became the focus. During the 2003–2007 interval, the citation rate increased to 1.11 as result of three inter-related factors: collaborative R&D funding, the use of new funding mechanisms — the AAFC Matching Investment Initiative (MII), a funding mechanism that links private needs and financing with public capabilities and money — and the rise in producer-governed P3s that use crop levies to finance canola R&D, all synonymous with a three-dimensional process. A negative binomial regression logarithmic likelihood model was used to isolate the effects of the three variables of interest. A statistically significant relationship exists between the use of three or four funding partners and increasing citation rates. Specifically, using three, four, or more funding partners doubles the likelihood of a paper being cited.

Conclusion

From a policy perspective, there are four items of interest. First, as suggested by theory, R&D is now a three-dimensional process, as the rise in the use of levy funding from producer governed P3s demonstrates. Second, government has transitioned from being the manager of R&D to a facilitator of such as the use of MII indicates. Third, confirming theory, collaboration does enhance the development of new knowledge as demonstrated by the regression analysis. Fourth, citation analysis provides a robust analytical tool that can compare the relative citation counts of institutions to global averages to identify emerging trends and document the flow of knowledge.

Policy Brief 11

Meta-analysis: A New Instrument in the Regulatory Assessment Toolkit

Event

The Canada-US Regulatory Cooperation Council, the Canada-EU Comprehensive Economic and Trade Agreement (CETA) and the US-EU Transatlantic Trade and Investment Partnership have all identified regulatory harmonization as a key objective, including for food. The wide array of estimates of the cost of regulatory compliance for new crop technologies, including GM crops, is driving this. Drawing the appropriate lessons from the numbers requires new tools.

Significance

In the context of agricultural biotechnology, more than 70 estimates of costs of regulatory approval have been developed for 16 countries involving a dozen crop species and more than 10 different genetic constructs. Industry and academics have calculated the cost of compliance with plant biotechnology regulations for a single trait in a single market could be between US$73,000 and US$14.8 million (Phillips and Williams 2013) while full market approval (i.e. approval to cultivate in two major producing nations and permission to import in five key markets) could be US$35 million (Phillips and McDougall 2011).

Analysis

Meta-analysis, or the analysis of analyses, is one tool for extracting meaning from conflicting estimates (Hedges and Olkin 1985). Executive Order 12866 on Economic Analysis of Federal Regulations offers a cautious endorsement for meta-analysis as a tool for combining data from a number of different studies to re-estimate the impact of key drivers and thereby improve confidence in the estimates (Office of Management and Budget 1996). The basic approach is to aggregate research findings statistically and calculate a set of explicit or implicit weights for the key factors underlying the estimates. The traditional approach to assessing competing evidence involves narrative reviews and statistical summaries (i.e. means, variances) of a selection of studies. Meta-analysis involves selecting a set of studies that use comparable methodologies, identifying a set of 'moderator variables' (such as the method, timing, location, specific assumptions and tools used) and running a regression to assess the impact of the moderators on the variable of interest. The goal is to combine the results of a number of separate studies to generate weighted averages of moderator effects on the results.

The practice of meta-analysis has already been developed and applied to several aspects of biotechnology management, such as estimating the value of a statistical life (for risk analysis), assessing willingness to pay for GM food (relevant to trade conflicts over labeling) and weighing the returns to research (useful for research managers).

A recent meta-analysis of 49 comparative estimates of the costs of regulating a GM crop showed that the type of trait (herbicide tolerance or insect resistance) had no measurable effect on the cost, that events designed for non-food applications were significantly less costly to regulate, that ex-ante forecasts were unambiguously more conservative than ex-post calculations and that regulatory compliance in exporting countries is more expensive than in importing countries.[1] This offers more nuanced meaning than the simple aggregate cost of compliance.

Conclusion

Carefully constructed meta-analyses offer increased explanatory power of the cost drivers and settle controversies arising from conflicting claims. These types of analysis offer an attractive new form of evidence that can and should be part of the management of regulatory policy.

Policy Brief 12

Agent-based Modeling: A New Instrument in the Policy Toolkit

Event

In Paris on 23 June 2011, U.S. Agriculture Secretary Tom Vislack acclaimed that the G-20 Agricultural Ministers had reached "an historic union of resolve in combating the pressing challenges of hunger … committed to increasing agricultural production through use of improved practices and technologies and a commitment to new and expanded research and development." Given the diffuse and complex nature of hunger, models that assume all actors have common motivations may at times deliver weak insights into policy outcomes, especially when major or abrupt change is considered. Agent-based modeling (ABM) offers a new tool for assessing the impact of heterogeneous actors on policy outputs and outcomes.

Significance

The G-20 agenda is being driven by results from a number of demographic, econometric and climate change models (e.g. AgLink used by OECD and FAO), all of which rely on a strict set of behavioural and statistical assumptions (e.g. linearity, homogeneity and a range of data rules). The difficulty is that food plays a role in many contexts, including basic survival, cultural norms, economics, trade, and social systems. Choices within and across these contexts are often not consistent across all individuals; nor are an individual's preferences about a specific option consistent in the context of those varied motivations. This complexity poses a serious risk that projections based on traditional policy models will be flawed. One plausible result might be that planned investments in agriculture may generate unexpected and unwanted outcomes.

Analysis

ABMs describe a system from the perspective of its constituent units. This is an important departure from the common theoretical norm in policy modeling that society is hierarchically organized and that institutions and norms shape individual behavior from the top down (Macy and Willer 2002). ABM starts at the bottom, defining the system as a collective of semi-autonomous individuals ('agents') making decisions in the context of some landscape that presents threats or opportunities. In these models, agents are given simple rules to govern their decision-making and then motivated to interact with other agents in response to a specific environment (or in the context of a changing environment, such as increasing scarcity or abundance of resources). Local interactions among agents generate learning, called 'adaptive behaviors,' which, when aggregated at a system level, can reveal unexpected, macro-phenomena (called 'emergence').

While ABM was first applied to modeling complexity in the natural environment, it is now being applied to a range of public policy areas, such as land-use management, public health, water allocation and the dynamics of research systems. ABM neither depends on nor needs any of the restrictive assumptions of other modeling techniques, such as linearity, homogeneity, statistical normality and stationarity (Bankes 2002). The ability to use individual data, rather than aggregate data, offers unique opportunities for understanding how real people might respond to real contexts and circumstances; even when individual data is scarce, hypothetical data can be used to construct the rules and assess alternatives.

While ABMS can be used to forecast or predict outcomes, models can also be constructed to explain a phenomenon, guide data collection, discover new questions, illuminate uncertainties and dynamics, demonstrate trade-offs, challenge theory, and open new opportunities for policy dialogue (Epstein 2008).

Conclusion

The central place of agents within ABM offers deep insight into how individual preferences, motivations for behavior and relationships affect actions and outcomes. Moreover, ABM is well suited for exploring interdisciplinary insights, as most models integrate different aspects of society, economics, demography, epidemiology, sociology, and policy.

Policy Brief 13

Literature Assessment Using the Delphi Method

Event

A large body of literature exists to assess the advent and impacts of agricultural biotechnology. An upcoming publication from Edward Elgar compiles a collection of some of the most influential journal articles in the field (Smyth, Phillips and Castle, forthcoming). There are a variety of methods that can be used to put together a research collection; an expert opinion process was chosen for this book and was carried out through a series of Delphi surveys.

Significance

The editors of a recent research collection used a Delphi process to solicit expert opinions and identify the most significant articles in the field of agriculture, biotechnology and development. Three survey rounds provided anonymous feedback, and each was used to develop the subsequent survey. Participants were able to assess the results of each survey by following up in subsequent rounds. Such a research collection not only delivers a compilation of important contributions to the field, but also an insight into the values and viewpoints of leading researchers. Further analysis assessed the opinions of the editors and the social network connections between the authors of the chosen articles.

Analysis

The Delphi process was comprised of three main survey rounds along with analysis by the editors throughout. Before the first survey was developed, the editors compiled a list of topics and themes related to biotechnology, agriculture and development and a list of experts in the field that could be contacted to participate in the Delphi. The first survey then asked the participants to identify additional themes that could be highlighted in the research collection, as well as other experts that could be contacted to participate.

After the first survey, the editors converged on 19 potential topics and themes for the volume. The second survey process asked participants to nominate key articles and identify to which thematic area the citation relates. The third survey provided a list of 421 articles, from which the respondents were asked to select the 40 articles they consider the most important to biotechnology, agriculture and development. After the voting was complete, the top 51 articles (based on votes cast) were identified and compiled into a list to be included in the research collection. The entire process was carried out over a seven-month period and received input from over 50 leading scholars in the field.

A social network analysis of the co-authorship ties between the authors of the selected articles revealed that most fall into a series of clusters around their specific area of expertise. Because the surveys were anonymous, and participants were not aware of who provided the other responses, the clusters of the selected authors are not necessarily related to the social networks of the survey respondents. The nature of the clusters is an important result of the Delphi process, as it lays out a knowledge network of the leading scholars in the field and the themes that tie their research together.

Conclusion

Using the Delphi method to develop this research collection of key publications was an innovative means of engaging a network of scholars to paint a picture of the current state and future directions in a research field. The process resulted in a few surprises regarding the themes that were chosen and those that did not show up in the final selection of articles. This method revealed a strong concern for the evaluation of the impacts of biotechnology and the policy response to development challenges. On the other hand, consumer theory and technical assessment of biotechnology were two themes that had been identified as early priorities but did not get voted into the collection.

Theme 2
Intellectual Property Management and Technology Transfer

The global scientific enterprise has changed fundamentally in recent years. The traditional view, propounded by Robert Merton, is that science is characterized by communal, universal, disinterested efforts motivated by organized skepticism (aka Merton's CUDOS). This parsimonious model is incorrect, or at least incomplete, in one key respect. In the current era, the reality is that most fields in science operate more like clubs than isolated ventures, that scientists are passionately interested, and that a large portion of scientific discovery is profoundly purposeful, in that it is designed to find answers and provide solutions to problems that can then be used to do something. The motivation for much of this effort is to solve real problems and the preferred means of translating discoveries into use in the market.

Economists for a long time have remarked that the market requires scarcity to function. Universal, communal knowledge does not fit well into the world. Hence, most of the discussion about how we can motivate and mobilize knowledge to improve the lot of humankind is framed about how we incentivize organizations and people to do what is right or best in the long run. Intellectual property management and technology transfer then are the answer.

The GE³LS community has spent a significant amount of time and energy exploring if, how, where, when and why different IP systems might advance the appropriate research efforts. This section reviews the key approaches that have been developed and adapted to use.

Critical Essay 1

Intellectual Property Management: Policy Issues and Options

By Jeremy De Beer, Richard Gold and Mauricio Guaranga

Creating and implementing an effective science and technology strategy requires not only the right natural and social sciences research priorities, but also appropriate regulatory and governance choices, legal frameworks, competition policies, venture capital and business practices, education systems and much more. These will help scientific and technological research make a difference in solving major policy challenges such as food security, environmental sustainability, population health and economic growth.

One ingredient in the policy mix is intellectual property. This brief outlines the role that managing intellectual property can play in encouraging collaboration and partnership between research institutions, business, government and civil society. Elsewhere we and many others have addressed, and must continue to address, different aspects of innovation systems. We focus here on intellectual property not because it is the only or even the most important issue, but because it is one piece of a larger puzzle with which policymakers are struggling. While the right intellectual property policies and practices cannot, by themselves, catalyze innovation – other factors are equally if not more important – the wrong policies and practices can impede it.

The Issue

The latest report card from the Conference Board of Canada gives Canada a "D" on innovation, influenced by, among other things, low scores for Canadians' share of world patents, patents by population and cross-border trademarks (Conference Board of Canada 2010). In part because of such reports, much public discussion has assumed the characterization of Canada's existing intellectual property framework as weak. Canada must provide higher levels, even "the world's strongest" levels, of intellectual property protection, it is said, or risk losing investment in research and development, especially in the biotechnology industry (Canadian Council of Chief Executives; Coalition for Action on Innovation in Canada 2010). Others claim, to the contrary, that Canada already overprotects intellectual property rights to the detriment of the world's poor in accessing essential medicines (Canada HIV/AIDS Legal Network 2011).

Discussing the relative strength or weakness of intellectual property protection in these ways, particularly given the very limited empirical basis for such opinions, distracts attention from concrete strategies to achieve the instrumental purposes of intellectual property policy or risks missing the broader policy picture (Gold 2000; Gold *et* al. 2008; de Beer 2008; Gold *et* al. 2009). Rather than extending a discourse that focuses on weak or strong rights, analysis should consider whether the intellectual property system is effective in achieving policy priorities (Patry 2009; Corbin 2010).

To repeat, intellectual property is one factor among many that influence direct investment, technology transfer and innovation systems (Maskus 1998; Phillips 2007; Castle 2009; Gold *et* al. 2008). However, some commentators such as Corbin (2010) suggest that shifting the analysis from innovation to intellectual property has the benefit of operationalizing broad concepts into "practical, unambiguous economic components" that are "potentially monetizable," and offers the "seductive practicality of being able to count outputs." Although focusing on intellectual property outputs may be convenient, it is inherently risky, especially if the analysis depends on limited or inadequate metrics. For instance, the Conference Board of Canada (2010) recommends that policymakers "ensure incentives are in place to encourage more patenting of inventions at home, as well as more strategic patenting of inventions from elsewhere." This advice fails, among other things, to appreciate that more patents will not necessarily cause more innovation, productivity or growth, and could possibly cause fewer by flooding the system with weak claims or incremental variations and potentially encouraging anti-competitive practices (Jaffe and Lerner 2006; Bessen and Meurer 2008).

What matters for science and technology innovation far more than counting outputs is leveraging the intellectual property system to better mobilize knowledge within a global economy. This more modern analytical paradigm stresses sharing and collaboration, not only the pursuit of protection (Gold *et* al. 2008). Moreover, it puts intellectual property in the context of increasingly distributed regulatory and governance systems that involve a dispersion of power over a wide variety of actors and groups (Phillips 2008). This

paradigm is based on transdisciplinary understandings about the history of innovation (Johnson 2010), flowing information to solve problems (von Hippel 1994) and social production through networks of collaborators (Benkler 2006). For example, the Organization for Economic Cooperation and Development (OECD)'s guidelines for licensing genetic inventions (OECD 2006) and its new "Innovation Strategy" depend less on protecting intellectual assets than facilitating "knowledge networks and markets" (OECD 2010). Such networks and markets involve deep interdependencies within the triple helix of innovation: university, industry and government (Etzkowitz 2008).

To benefit from new modes of production and innovation given the social, cultural, economic and technological realities of the 21st century, we need better legal strategies for managing intellectual property (de Beer 2008). This brief addresses the strategic options for policymakers – including especially research funding agencies, national and sub-national governmental departments, public sector institutional administrators and, to a lesser extent, private sector industrial partners. While policymakers are a diverse group, the nature of the information in this brief makes it a useful foundation for more specific discussions tailored to particular constituencies. It is not intended as policy advice, and does not advocate for any particular solution to the complex problems of intellectual property management. The objective is to synthesize ideas and proposals, and provoke critical reflection on available options.

The Context

In considering strategic policy options, there are several facets of the intellectual property system to consider. The legislative framework is one. During the past decade, the subject matter and scope of patent protection has been at the forefront of debates about science, technology and intellectual property. The Supreme Court of Canada decisions in Harvard College v. Canada (2002), which interpreted the Patent Act to exclude higher life forms from protection, and Monsanto v. Schmeiser (2004), which effectively reversed course by broadly interpreting patent claims over genes and cells, were focal points for these debates in Canada. Such issues were in play, however, even before the much earlier American case of Diamond v. Chakrabarty (1980). The most current controversies about intellectual property in genomics involve ongoing litigation over the validity of gene patents such as those held by Myriad Genetics (Association for Molecular Pathology v. USPTO, 2011) and their enforceability in the agricultural biotechnology industry (Organic Seed Growers v. Monsanto 2011). While those matters are undoubtedly important, they may not be the highest priority issues for Canadian policymakers for at least three related reasons.

First, questions concerning the patentability of higher life forms, genes or gene sequences, and similar topics are extraordinarily sensitive, controversial and often politicized. Legislative or regulatory reform may be difficult or impossible in this current political context; gaps in the legal framework are inevitable. Second, constructive ambiguities will always be subject to interpretation by the institutions enforcing intellectual property rights, as happened in Harvard College v. Canada (2002) and Monsanto v. Schmeiser (2004), and is happening now in patent enforcement disputes in Canada (de Beer and Andrews 2009) and the cases going forward in the United States. Third, despite threats about moving capital elsewhere, biotechnology researchers and firms have adapted to Canada's framework without any legislative reform. Of course, Canada should comply with its obligations to the rest of the world, reflected in instruments like the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD) to name just two, but the fact is that Canada's approach is mostly consistent with the international intellectual property governance framework. These obligations allow for a range of policy and practical options for intellectual property management and this flexibility can be used to craft appropriate, context-specific solutions.

Consequently, policymakers' attention is probably best directed toward more practical issues on which they can have real impact: Managing intellectual property in ways that facilitate innovation within the existing legislative framework.

Legal – Policy Background

Patents provide exclusive rights to make, use and sell inventions that are new (novel), not obvious (inventive) and useful (capable of industrial application), normally for 20 years from the date of an application for protection. Inventions can be products or processes, or improvements to products or processes, in any field

of technology. Trade secrets draw on general private law to prevent those to whom information has been disclosed from either using it or revealing it to others, for as long as the information remains secret. Although long considered a poor cousin to patents, which provide more extensive rights, plant breeders' rights protect plant varieties in a complementary manner. Copyrights provide exclusive rights to copy, transmit, distribute or adapt original expression, generally for at least 50 years and often longer. Automatically protected expression can include among other things written outputs, computer code and in some cases compilations of data or other materials. Trademarks provide exclusive rights to use distinctive marks that identify goods or services. Others cannot use such marks to create confusion in the market for as long as the mark remains distinctive.

Patents tend to dominate intellectual property debates around science and technology policy, but patents are not the only, nor necessarily the most important, intellectual property right to consider. Patents may be relevant for the underlying science and technology: research tools, diagnostic tests, modified genes and chemical or biological compounds. Copyrights, however, affect the accessibility of equally important bioinformatics software, scientific publications, original compilations of data, and possibly even synthetic DNA sequences. Trademarks are used for branding genomics research enterprises or particular technologies. A holistic view of all forms of intellectual property rights, and classic tangible property rights over biological materials (de Beer 2005), is especially important in areas such as synthetic biology, which lies at the confluence of information technology and biotechnology.

Most public and private sector organizations involved with genomics are generally aware of the importance of these intellectual property issues. The challenge for policymakers is to help build further awareness and, more importantly, translate awareness into coherent intellectual property management policies that effectively and efficiently facilitate continuous circulation of knowledge.

Policymakers recently began hearing opinions that the legal tactics of the open source software movement can do that best, by providing a partial solution to the social and economic problems that intellectual property can cause for biotechnology (Joly 2007). While more empirical work is needed, research does suggest that in some cases "thickets" of overlapping intellectual property rights can make it impossible to negotiate the right to actually make or sell anything (Shapiro 2001). Similarly, a "tragedy of the anti-commons," in which many independent rights result in "gridlock," may threaten the circulation of knowledge or impede the discovery or distribution of valuable technologies (Heller and Eisenberg 1998; Heller 1998; Heller 2008). While some are of the view that stronger rights will best overcome these problems (Kieff 2011), the broad consensus is that developing clear pathways to partnership offers a better solution (OECD 2010). The question, then, is how best to facilitate collaborative partnerships and exploit networked knowledge (Phillips 2005).

Policy Options

Option 1: Acquisition toward commercialization

Since – or perhaps because of – the United States Supreme Court decision in Diamond v. Chakrabarty permitting patents for "anything under the sun that is made by man," and the American Bayh-Dole Act permitting universities to hold patents arising from federally funded research, a culture of intellectual property acquisitiveness has arisen in the field of genomics. This culture of acquisitiveness in both private and public sector organizations is most apparent through the expectations placed upon technology transfer offices and the metrics used to evaluate their success. Bubela and Caulfield (2010) report evidence that technology transfer offices are increasingly pressured to advance and implement the commercialization agenda of the organization to which they belong, especially in the life sciences, and are rewarded for obtaining patents, granting licenses and creating spin-offs. Smyth (2011) describes a variety of policy measures in Canada that have contributed to the expectation that research institutions should acquire intellectual property rights in order to commercialize them.

This model rests on a simple view of innovation: Researchers disclose promising inventions to technology transfer offices, technology transfer offices evaluate and protect the commercially promising ones, industrial partners or affiliated spin-offs acquire rights to the intellectual property, normally on undisclosed terms, and technology transfer offices occasionally receive royalties or remuneration for commercialized research. Inverted

from industry's perspective, the process looks similar: research is essentially out sourced to academic partners that are sometimes given use or royalty rights to new technologies in exchange for their services (Weigelt 2009).

In implementing this model, the vast majority of technology transfer offices at best either break even or lose money for the institutions involved. In addition, they are not effectively stimulating research productivity or innovation. Smyth's (2011) analysis of Canadian data from 1998 to 2008 shows that while the total investment in university research has increased sevenfold, the proportion of patents actively licensed by universities is declining, and the number of spinoffs has fallen to half what it was a decade ago. Intellectual property management costs of technology transfer offices are nearly equal to the licensing revenues they generate, and more concerning, costs are trending upward – particularly in respect of litigation – while revenues are relatively flat. These data likely understate the problem, as they fail to account for the probable increases in costs of enforcement over the entire life cycle of organizations' intellectual property portfolios. Also, they do not account for other rights holders' potential anti-competitive uses of intellectual property portfolios, or the transaction, licensing and other costs that are likely to increase in the future, as the intellectual property landscape becomes more crowded, in part because of these institutions' own policies and practices.

This disappointing picture may be partly attributable to the metrics being used for evaluation. In addition, the model fails to recognize that innovation is messy, circular and dispersed (von Hippel 2005). Innovation occurs in networks, not lines (OECD 2010). The actual or perceived shortcomings of the acquisition model might also reflect the possibility that innovation coming from research institutions may simply lack sufficient economic value to make commercialization worthwhile. The lack of success might therefore be attributable to unattractive innovation rather than inappropriate intellectual property management. Nevertheless, this strategy seems especially ill suited for mobilizing innovation with high social, but not necessarily commercial, potential.

Not all current efforts at intellectual property management in genomics research are without merit and never achieve positive outcomes. Universities, governments and companies have made considerable investments in establishing technology transfer and liaison offices. The resulting qualified personnel and institutional relationships are likely to be integral to any intellectual property management strategy, whether based on acquisitiveness and commercialization or any of the other options presented in this brief. They are often in the best position to see opportunities to develop networks, despite being hampered by policies, metrics and funding models that prevent them from taking full advantage of their knowledge.

To improve the existing, dominant model, policymakers could consider two possibilities. One is to reformulate technology transfer offices' mandates to be more consistent with institutional missions and employ evaluation metrics that account for academic, societal, economic, political and financial impacts more holistically. The University of British Columbia's industry liaison office has led this effort by developing new metrics (Bubela and Caulfield 2010) but has only had funding to assess its work once. Another possibility is to increase the efficiency of operations by using new tools for licensing the intellectual property portfolios that technology transfer offices are encouraged to acquire. For instance, the OECD Working Party on Biotechnology (2010) describes why model agreements might help to simplify licensing transactions by eliminating the need to negotiate all but the most contentious issues. It cites the success of the "Lambert Toolkit," a set of model agreements developed in the United Kingdom by representatives from academia, government and large and small companies in order to reduce the financial and human resources required to negotiate intellectual property agreements. The University of Glasgow has similarly simplified its technology transfer processes through a dedicated online portal that clearly lists "Easy Access IP" available for free as well as "Commercial Deals" for licensing and co-development.

Option 2: Free-revealing to build the public domain

One reason for disappointing financial returns on investment in acquisition-oriented intellectual property management strategies is the significant expense of acquiring and enforcing rights, especially patents. These costs can be entirely eliminated by choosing to forego any intellectual property protection, instead freely revealing knowledge and technology directly into the public domain.

There is a possibility of confusion in differentiating this approach from other putatively "open" models of intellectual property management. The open source approach taken by some software developers, the Creative Commons system of licensing copyright protected works and several examples of open source biotechnology

described below all depend, fundamentally, on acquiring intellectual property protection. The novelty of such open source systems is that intellectual property is then licensed to require rather than restrict access to the protected content or technology. The free-revealing approach is distinct because it sidesteps the intellectual property system altogether. It not only involves foregoing intellectual property rights; it also develops strong community norms that ensure what is publicly revealed not be appropriated by others.

Perhaps the best example of an unrestricted public domain model of intellectual property management is the Structural Genomics Consortium. Its access policy prohibits affiliated scientists or collaborators to seek patents that would grant exclusive rights over its research outputs, and encourages funders from government, industry or civil society to similarly forego patent rights. Unlike some other models that use the intellectual property system itself, through licences, to enforce such conditions, the Structural Genomics Consortium relies on a combination of contracts and social norms such as trust. The organization's non-proprietary philosophy is a key reason cited for its success (Edwards 2008; Edwards *et* al. 2009; Weigelt 2009).

A good illustration of an intellectual property management model on the border between the public domain and open source is PLoS, the Public Library of Science. While everything published in its repository is publicly available free, some copyright restrictions still apply. Specifically, content remains copyright-protected and is licensed on one of the standard terms of the Creative Commons system, which permits use and reuse on the condition of attribution of source and authorship. Sage Bionetworks, a nonprofit biomedical research organization, takes a similar approach to providing data, tools, analysis and models.

While the orthodox approach rests upon acquisition and commercialization of intellectual property, Boyle (2008) argues: "'the opposite of property' is a concept that is much more important when we come to the world of ideas, information, expression, and invention. We want a lot of material to be in the public domain, material that can be spread without property rights." Rai and Boyle (2007) apply this principle in the specific context of synthetic biology, and in the process explore tensions among different ways to create openness, including both public domain and open source models. As a promising example of the public domain model, they mention the Registry of Standard Biological Parts created by the Massachusetts Institute of Technology (MIT), which indexes biological parts, offers assembly services to construct parts, devices and systems, and could grow into a repository of information and specifications to facilitate synthetic biology. Such public disclosure makes the parts and trivial improvements unpatentable by others.

Free revealing may in some cases, however, leave open the possibility that others will attempt to acquire intellectual property rights over public domain knowledge or technologies. Therefore, some organizations, such as the British Columbia Cancer Agency (BCCA), seek patents for defensive reasons -- to guarantee freedom to operate for themselves and their constituencies.

Option 3: Open collaborative licensing

Recognizing that current models of technology transfer have proved less successful than desired, and pursuing the ethos of publicly accessible science, a number of organizations have begun to experiment with middle ground models of intellectual property management. These models rely on intellectual property protection, but leverage protection to implement creative licensing practices that encourage co-operation and facilitate collaboration.

Their common feature is that they help to facilitate multilateral intellectual property transactions, either through the creation of centralized or decentralized structures. The OECD Working Party on Biotechnology (2010) explains how in centralized systems, like a patent pool, an agent (a rights holder or third party) bundles intellectual property rights and provides standard licences covering that bundle, while in decentralized systems, like a clearinghouse, an agent merely provides a mechanism through which rights holders and licencees can efficiently interact.

Historically, agreements among patent holders to bundle rights in a pool have been controversial for their potential anti-competitive impacts; similar issues about their misuse have been raised around open source biotechnology (Feldman 2004). Such concerns are alleviated when patent pools are used to develop common technological standards for an industry, but that context is more applicable to information and communications technologies than biotechnologies.

Biotechnology patents pools (or ponds, as some call them) have been most used so far by social entrepreneurs for philanthropic purposes. In the case of the Medicines Patent Pool, for example, a partnership has formed under the auspices of UNITAID to provide a "one-stop shop" for clearing patent rights related to antiretroviral medicines for treating HIV (Gold *et* al. 2007; Childs 2010; Bermudez and Hoen 2010). Similarly, the OECD Working Party on Biotechnology (2010) describes the important steps taken by Syngenta, in partnership with the researchers who genetically modified rice to produce β -carotene (provitamin A), to establish the Golden Rice Humanitarian Board with authority to license a large number of patents for free to subsistence farmers. (That Golden Rice has, despite this licence, still not achieved its promise because of regulatory barriers related to the deployment of genetically modified organisms reinforces the point that intellectual property management is simply one of many issues in translating genomics into practical impacts.)

Some commentators have highlighted the potential of patent pools in the field of gene-based diagnostic testing (Ebersole, Guthrie and Goldstein 2005; Verbeure *et* al. 2006), but nearly ten years of discussions about a pool to deal with patents around the severe acute respiratory syndrome (SARS) corona virus genome have so far failed to yield a tangible outcome, although this may be simply because SARS has not reappeared (Simon *et* al. 2005; Correa 2009). It remains to be seen whether these models can work successfully outside of the humanitarian context, where there are fewer incentives for firms to voluntarily pool intellectual property rights with other organizations. Clearinghouses, on the other hand, have had some modest success despite relying on non-financial incentives for participation. Van Zimmeren's (2009) conceptual typology of clearinghouses includes some that provide only access to intellectual property information and some that also aim to facilitate use through standard licensing or royalty collection.

Probably the most famous example of a clearinghouse is Cambia, a non-profit institute creating new technologies, tools and paradigms that enable innovation in agricultural biotechnologies through biological open source, or BiOS (Jefferson 2006; Berthels 2009). Its "Patent Lens" project and the related "Initiative for Open Innovation" provide cyber-infrastructure to access key legal, scientific, technical and business data. Another good illustration of an intellectual property rights clearinghouse is the Public Intellectual Property Resource for Agriculture (PIPRA), which supports the broad application of agricultural biotechnologies developed in public and non-profit institutions (Bennet and Boettiger 2009). Such tools are especially valuable for creating and modeling best practices (Krattiger *et* al. 2009), and useful in the context of intellectual property landscaping -- a key part of effective and efficient intellectual property management (Lewensohn and Gold 2011).

Clearinghouses and other open source licensing models for tools and materials, not just information, have proven more difficult to sustain. The BioBricks Foundation is one example of an enterprise making biological parts available through open source style licences. Cambia attempted to do so with a "TransBacter" plant transformation system to bypass the patent-stacked Agrobacterium-mediated gene transfer technology, and "Diversity Array Technology" to analyze genomes (Berthels 2009). Intellectual property rights related to DArT are currently being licensed by a privately held company on non-exclusive and reportedly fair and equitable terms that the technology's proprietors describe as open source (Kilian 2009).

One of the major challenges in even considering the possibilities of open source models is the lack of consensus around a precise definition or even conceptual framework for analysis. Promising work is emerging from the management research on open innovation in general (Dahlander and Gann 2010) and analyses of open source biotechnology and genomics (Hope 2008; Van Overwalle 2009; Joly 2010). However, there are still major gulfs in the discourse and framing of concepts like openness and accessibility (compare, for example, Chesbrough (2005) with Kapczynski and Krikorian (2010)).

For Jefferson (2006), the key features of the open source model include full disclosure of enabling information and accessibility of technologies, and legal mechanisms that confer permissive rights as well as responsibilities to "share alike," i.e. licence improvements or subsequent innovations back to the source community. In the most thorough analysis of open source biotechnology to date, Hope (2008) elaborates on the general objectives of open source, which are enforcing intellectual property protection to avoid opportunistic exploitation, granting standard licences that permit competition and technological improvements or "forks," and often, but not always, imposing on licencees' reciprocal obligations to share their improvements on similar terms.

The core challenge with these models explains Hope, is to create relatively standard licences that can accommodate the complexity and variety of biotechnology transfer agreements, yet remain faithful to the underlying logic of open source. We would add another key issue, which is identifying a viable business model to profit from substantial capital investments in scientific and technological research. Without economic sustainability, open source models are unlikely to enter the mainstream. Whether these challenges can be overcome remains an open theoretical and practical question.

Practical Application and Considerations

In very general terms, policy option #1 directly or indirectly encourages acquisition and commercialization of all possible intellectual property rights. Policy option #2, on the other hand, favours no intellectual property protection, supporting strong norm development to ensure a vibrant public domain. Policy option #3 promotes the acquisition of some intellectual property protection, but does so to facilitate collaboration rather than (or in the process of) exclusive rights to commercialization. While there is an understandable, perhaps inevitable, instinct to gravitate toward this middle ground in the search for consensus, the theoretical and practical considerations discussed in this brief suggest that one or the other more clear-cut management strategies in many cases may be more efficient and effective.

It is important to realize that an increased focus on enriching the public domain does not ignore the importance of commercialization; it simply puts responsibility for pursuing and measuring that outcome on other actors in the innovation system. For example, the Structural Genomics Consortium builds the public domain for precompetitive research, in effect pushing the role of intellectual property rights further down the supply chain of commercializable science and technology. Conversely, the acquisition toward commercialization model is not meant to devalue the dissemination of knowledge. It is based on the good faith belief that the pursuit and use of intellectual property rights is an effective means to that end. For example, the requisite disclosure of innovations through patents creates an almost immediately accessible body of technical literature that anyone may rely upon, initially subject to the legal rights of the patentee but eventually for free.

Delineating the boundaries of control over innovation is not merely a matter of timing, either in terms of the stage in the innovation process at which intellectual property becomes important, or the duration of the term of intellectual property protection. It also depends upon other factors, such as the nature of the research (basic or applied) or the source of funding (public or private). Not least among other factors are issues of race and culture (Amani and Coombe 2005). In particular, the traditional knowledge of indigenous and local communities – including Aboriginal Peoples of Canada – has been conceptualized outside of the intellectual property system. A team of researchers working on Aboriginal anti-diabetic medicines is working to put principles of prior informed consent, joint or collective ownership, access and benefit sharing, and stewardship and responsibility into practice (CIHR-TAAM, n.d.). There is, however, an interesting but unexplored parallel between the values underlying indigenous perspectives on control of knowledge and the principles animating open source communities.

Despite the illustrations provided, it is unlikely that any single intellectual property management strategy would or should be applied rigidly within or across organizations. There is no need for policy-makers to choose only one of these options because they are not mutually exclusive, despite their convenient presentation in this brief as distinct. Degrees of openness can be characterized on a continuum reflecting the porosity of boundaries separating public and private rights, and the emphasis on osmosis between them. Moreover, different resources at different stages of development in different industries in different places involving different collaborators and different intellectual property rights can be managed using a mixture of approaches. Perhaps most importantly, the appropriate blend of intellectual property management models will depend on the essential nature of the commercial or non-commercial value to be created and shared among stakeholders.

At present, key policies of certain organizations are not neutral toward intellectual property management strategies. For example, most granting agencies' implicit or explicit criteria for evaluating and funding research proposals normatively establish the acquisition and commercialization of intellectual property as a prescriptive requirement, particularly as an expected economic benefit of the funded project. They tend not to encourage outside-the-box thinking or experimentation. While institutional cultures can be difficult to change, serious consideration should be given to the appropriateness of such policies in light of policymakers' objectives for

financial and non-financial returns on investments and the instrumental purposes of managing intellectual property. Intellectual property's functions should be to create knowledge networks and markets that facilitate access to and use of knowledge, provide incentives to invest in knowledge creation and dissemination ensure equitable distribution of commercial and social benefits and take account of the broader needs of stakeholder communities.

Policymakers have a key role to play in articulating the overarching principles that drive an organization's intellectual property policy. While the details can and should be left to those actually designing and implementing a particular intellectual property management scheme, statements of principle, effective funding mechanisms and training programs provide starting points for discussions and negotiations between actors.

Future Research Questions

As stated earlier in this brief, we have provided a general synthesis and concise valuation of various intellectual property management models, and an overview of some practical considerations for policymakers. Obviously, much more could be said about all of these issues. We believe that three points in particular warrant attention in the immediate future. First, we have identified the need to determine more precisely which actors could or should take responsibility for action. Who, specifically, are the policymakers best positioned to address each of the many distinct issues highlighted in this brief? Second, there is a need to establish a forum in which such actors can convene to consider the instrumental purposes of intellectual property and the specific tools available to actors for influencing management strategies. How can policy makers best make a difference? Third, if there is experimentation with new management models, it will be necessary to develop and test new metrics to measure the success of these models based on their objectives.

What might such evaluation mechanisms look like? Underlying these points is the need for further research exploring the conceptual and practical challenges associated with each of the intellectual property management models we have introduced. Here, we have provided a starting point for further study of such issues. Moreover, this brief on intellectual property management has, by necessity addressed only one of many issues relevant to science and technology innovation policy. That is not because we intend to overstate the importance of intellectual property, but is simply because other research in the past and future has addressed and will address other key issues, including consent and privacy, science and technology entrepreneurship, regulation and governance and much more.

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Critical Essay 2

On the Effectiveness of the Current Intellectual Property Regime in Canada

By E. Richard Gold

The primary issue facing Canada is not how to reform our patent laws – which are world class – but how to enable our institutions – Canadian Intellectual Property Office (CIPO) and courts – to better update our laws and how to reorient our investments away from subsidies toward the support of collaborations and partnerships.

I work extensively with public and private sector decision-makers around the world on patent law and policy and am considered a leading international and independent expert on patents and innovation. I have been a frequent expert providing advice to the World Intellectual Property Organization, the Organization for Economic Cooperation and Development, the World Health Organization, UNITAID and both Canadian federal and provincial governments. I have also worked with university technology transfer organizations in Canada and the US, have provided policy advice to members of the US House and Senate and will be participating in a high-level, intensive, summer course on intellectual property in France this summer. Additionally, I have participated in judicial training on patent law in the US, Canada and France. Through these experiences, I have gained insight into what makes innovation work and how Canadian patent law compares and contrasts with that in the US, European countries and elsewhere.

The overwhelming conclusion of anyone who seriously examines the patent system is that patent policy is based more on myth than on substance. It is only in the last 10-20 years or so that we have had any significant empirical study of patents and innovation. Most of what passes for fact – both for and against patents – is ideology, not fact. Empirical knowledge remains limited, but clearly shows that the role of intellectual property within innovation systems is far more complex than the simplistic assertions by industry and NGOs alike that too often dominate debate.

My goal in this brief is to present an overview of what we know about the role of patents in innovation and to point to promising avenues to strengthen the Canadian innovation system.

To start, here is a summary of what we know about how the Canadian patent system works:

1. Patents constitute only one policy tool among others – e.g. product regulation, competition law, tax policy, research grants, university infrastructure support, and, especially in health care, monopsonist purchasing – within the innovation system. Among all these tools, it is seldom the most important and in many industries, such as the food industry, not relevant.
2. Canada is in full compliance with all its international obligations. While certain industries, primarily those in music, film, software and pharmaceuticals, would like Canada to increase certain aspects of its intellectual property laws, Canada has no obligation under international law to do so. In many respects, Canada's patent laws are more generous to patent holders (tests for patentability, reasons to invalidate a patent, scope of patent rights, longer data-exclusivity, availability of accounting for profits, and so on) and in very few areas less generous (e.g., patent term extension) than those of the US.
3. Except in those few fields in which Canada represents a major market (e.g. snowmobiles), Canadian patents provide little to no incentive effect on innovation in Canada. Patents in the US and other major markets (for pharmaceuticals, the EU and Japan) provide whatever incentive effects that patents provide. Meanwhile, Canadian patents represent a cost to Canadian innovators since they must acquire licenses to be able to produce and market their improvements in Canada.
4. Patents have little effect on invention – the creation of a new idea – and much more on innovation: bringing together all the pieces to put a new product or service on the market.
5. It is rarely the case that a single patent underlies a new innovation. Much more frequently, the innovation touches on not only a number of patents, but trademarks, trade secrets and other intellectual property rights.
6. Patents are double-edge swords. On the one hand, they provide firms with a basis upon which to raise money to invest in the process of bringing the new product and service to market. On the other, it represents a cost to those same firms to the extent that they must negotiate with others who hold relevant

patent rights and represents a cost to those wishing to build on an existing patented platform to create something new. Who wins and who loses depends on industry, size of enterprise and strategy. Patents have caused significant concern in the IT field in particular.

7. The bio-pharmaceutical industry has not been kind to Canada. The industry only briefly met its promises to increase spending on R&D in Canada to about half of the OECD level in return for increased patent protection. The vast majority of that spending was in clinical trials that has little lasting impact on Canada's innovation capacity. We are now back to the levels of investment seen in the 1980s, with decreases in store with the closing of the research facilities of both Merck and Astra Zeneca in Montreal. Most Canadian biotechnology companies survive on government largesse.
8. Universities are sites of invention, not innovation. University researchers gain insight from working with industry. While this also raises conflict-of-interest concerns, overall university health researchers who work with industrial partners have more publications in better journals. While university-industry linkages are important to Canadian innovation, they too often are bogged down in misguided attempts by universities to extract direct financing from industry. Globally, universities either break even or lose money on technology transfer to industry. This does not mean that technology transfer is working: it is simply that it should be considered a part of knowledge translation and not of funding. Canadian universities however, are measured both internally and by governments based on revenues generated from technology transfer. UBC has been a leader in aligning its technology transfer procedures with the University's role in education and research
9. Evidence is mounting, but is not yet conclusive, that collaborations increase innovation. This involves sharing of knowledge including knowledge protected by patents. The OECD's 2010 Innovation Strategy introduced the concept of Knowledge Networks and Markets that aimed at facilitating the sharing and dissemination of knowledge between private and public sector actors. Strategies include the use of patent-free zones, patents broadly licensed at low cost and a few closely held and traded patents. We have successful examples of these strategies in Canada. The Structural Genomics Consortium (SGC), which brings together public funding, philanthropy and private sector funding, has created a patent and IP-free zone to create a base of knowledge to accelerate pharmaceutical innovation. The Consortium for Research and Innovation in Aerospace in Quebec (CRIAQ), made up of universities and industry, allows members to fully share and use any innovation coming out of the consortium while third parties are charged a licence fee.
10. The fact that Canada has no uniform policy with respect to whether universities or researchers own the intellectual property developed at the university has had no negative consequences on Canada. After investigating the issue for years, the technology transfer community has concluded that neither university-owned nor researcher-owned policies are superior to the other.
11. In certain areas, such as patentable subject-matter, non-obviousness, utility and exhaustion, Canadian patent law is falling out of sync with that of the US and Europe. In all of these areas, the US and Europe have sought thoughtful balances of interests between rights-holders, users and other innovators while Canadian law has remained unclear or has been stuck in out-of-date formulations. Revising Canadian law on these matters would bring Canada into line with comparator countries and bring clarity to Canadian researchers, innovators and patent-holders.
12. Canada pays among the highest pharmaceutical prices in the world. Effectively, the mechanism that the Patented Medicine Prices Review Board (PMPRB) uses to set maximum prices ensures that Canadians pay the second or third highest prices in the world. Further, the maximum price set by the PMPRB becomes the minimum price for the products in Canada. In addition, unlike the Pharmaceutical Price Regulation Scheme in the UK, PMPRB pricing does not consider value for money or investments in national R&D. The result is an additional strain on health care budgets as compared to comparator countries without any innovation benefits.
13. Canada's Access to Medicines Regimes has been invoked only once, with very poor reviews. The current system is the most bureaucratic of all IP-related laws. At the same time, it is unclear whether an improved regime will actually further access to medicines as Canada is not a natural source of generic

pharmaceutical products in most least-developed countries. Funding of the purchase of generics from elsewhere is likely to be more effective.

14. Counterfeiting is trademark problem, not a patent problem. If the product, for example, a pharmaceutical, is not what it purports to be, it is not, by definition, a patent infringement. On the other hand, if the product is what it purports to be, there are ample remedies within Canadian patent law to sue the counterfeiter. More importantly, the sale of the product would violate regulations guaranteeing the health and safety of Canadians and be punishable under those laws. Thus, the link between counterfeiting and patents has no factual basis.

There are three general conclusions that arise out of the above: 1) that there is little justification to enhance the powers and rights of Canadian patent holders; 2) that Canada invest the institutions best placed to elucidate patent law – CIPO and the courts – with the capacity to do so; and 3) that the federal and provincial governments transfer resources from subsidizing industry to supporting Canadian partnerships by financing the purchase of key Canadian and international patent rights in priority technology areas that can be licensed out to partners who agree to invest in Canada..

No Justification to Expand Patent Rights

On the first point – that there is little justification for granting more rights to holders of Canadian patents– there is no empirical evidence supporting the view that further increases in patent-holder rights will provide any benefits to the Canadian innovation system or the national economy. It may be that Canada decides, in a free trade agreement, to accept losses to the Canadian innovation system in return for concessions elsewhere, but there is no evidence to suggest that greater rights will do anything but harm the Canadian innovation system. This is particularly true since Canadian patents provide more benefits to foreign firms selling in Canada than to domestic firms selling internationally. Increasing Canadian patent holder rights – without securing greater rights for Canadian firms abroad – will do nothing to help Canadian enterprises. On the other hand, resisting changes to increased patent holder rights will assist Canadian firms in keeping their costs low.

Enhancing Institutional Decision-Makers

On the second point – that patent reform is best accomplished through greater reliance on CIPO and the courts – the international trend has been, with a few exceptions, to update patent law through non-legislative means. For example, the Supreme Court of the United States has introduced important limitations on patent rights in areas such as non-obviousness, claim construction, exhaustion and patentable subject matter through litigation rather than through legislative reform. Patent reform in the United has been limited and has concentrated on changing to a first to file system (as in Canada) and allowing for greater opposition rights (greater than those in Canada). Given unintended consequences of formal reform – Canada's Notice of Compliance (NOC) Regulations provide an excellent example of where the reforms only caused more confusion and litigation – Canada would be better off investing non-legislative bodies with the power to make incremental changes to the patent system.

While Industry Canada certainly has played a role in patent policy, it does so largely in the shadows rather than in active engagement with creative and user communities. For examples, despite several reports calling for reform of the patent system by governmental bodies dating back to 2002, Industry Canada has yet to respond. Industry Canada's role in Canada's Access to Medicines Regimes, amending the NOC Regulations and creating data protection laws have all been shrouded in secrecy. The Department has not shared its rationale for changes nor the content of its recommendations. Even access to information requests have been resisted. This is not to criticize Industry Canada but simply to point out that, in the dynamic environment in which innovation takes place and in which communication of policy is as important as the policy itself, Industry Canada is ill-placed to reform Canada's patent regime.

Both CIPO and the courts offer better prospects as being the loci of reform. Changes are needed, however, to enable both bodies to carry out their roles.

The Federal Court of Appeal's 2011 decision in The Commissioner of Patents v. Amazon.com Inc. removed any policy-making authority from CIPO. In that case, the Commissioner of Patents had consulted on the wisdom

of allowing patents on business methods under Canadian law and, following that consultation, declined to grant such a patent to Amazon.com. The Federal Court of Appeal held that CIPO did not have this power. Nevertheless, CIPO has the expertise and knowledge to engage in the balancing of polycentric interests involved with innovation and is better placed than the courts to make determinations concerning the shape of patent law in the future. Giving formal authority to CIPO to make determinations, protected by a privative clause, on matters of patentable subject matter and rule-making authority over substantive patent criteria will provide a more flexible, predictable and transparent patent system.

On the other hand, Canadian courts, in particular the Supreme Court of Canada, have issued inconsistent and confusing rulings on several questions of patent law including patentable subject matter, novelty and nonobviousness. Courts in other jurisdictions, such as the United States and the United Kingdom, have done better by providing a flexible mechanism through which to revise patent law as technology and actors evolve. Both jurisdictions have reformed the court structures to enable more consistent and simpler adjudication. The United States created a single court, the United States Court of Appeals for the Federal Circuit (CAFC), to hear all patent appeals. More than half of the judges on the CAFC have a background in patent law or patent policy. Likewise, the UK has created a County Patent Court to streamline patent trials.

Currently, in Canada, most patent cases commence at the Federal Court of Canada even though provincial superior courts also have jurisdiction. There is only one judge with significant patent experience sitting in all of Canada and he will reach retirement age within the next few years. Other judges have developed some level of expertise in patent matters through on the job experience but few have training that enables them to see the larger, complex, context in which patents contribute to innovation.

While one could be tempted to follow the US or UK route of establishing a separate patent court, whether at the trial or appeal level, this is unlikely to work in Canada. The number of patent cases is simply too low to justify the creation of a separate court to hear patent or even intellectual property matters. A better solution would be to appoint more judges with a patent background to the bench and to increase judicial training on patent matters. In my own experience, I have found openness among Canadian judges to training on patent law that ought to be encouraged.

With the absence of any governmental body with both the jurisdiction and expertise to gradually update patent law, Canada risks falling behind comparator countries. This is particularly dangerous at a time when we are negotiating free trade agreements with little analytical capacity to evaluate the effects of those treaties on Canada.

Refocus Investments on Partnerships with Canadian Control of Patents

As discussed above, there is growing evidence that partnerships and collaborations are best positioned to unlock the next generation of innovation. A number of reports and policy recommendations, including the OECD's 2010 Innovation Strategy, have converged on this conclusion. These reports uniformly conclude that there is no one-size-fits-all approach to collaborations and that experimentation will be needed in order to determine which structures work best where.

Far from business strategies that concentrate on building ever-higher patent walls around a firm's invention, current thought places emphasis on finding mechanisms to facilitate the transfer of knowledge. Despite common perceptions, knowledge is often very difficult to move around. The problem therefore becomes not how to obtain more protection for knowledge, but how to facilitate the flow of information to those within the country who have complementary technologies, distribution networks and technical skill to turn a bare idea into an innovation that will benefit the country.

Partnerships and collaborations provide natural mechanisms through which to combine a naked idea with the technological and social infrastructure necessary to bring about innovation. While taking many forms, the ingredients behind these structures are known. They include the judicious application of patent rights – not too much and not too little – the expansion of patent-free pre-competitive spaces, standard-form broad licensing platforms and a limited amount of exclusive licensing. As both CRIAQ and the SGC illustrate, these tools can be combined in different ways to achieve the particular goals of the participants.

Canada – both federally and provincially – spends significant amounts on subsidies and tax credits to technology companies, particularly in the bio-pharmaceutical industry, with little return. If these subsidies were

redirected – as the Jenkins report suggested – they could better support Canadian innovation. In particular, these funds can be used not only to support partnerships and collaborations, but to finance the purchase of key Canadian and international patent rights in priority technology areas that can be licensed out to partners who agree to invest in Canada. Michigan has experimented with this technique in the plastics industry with some success. Such an approach not only ensures that government investments will benefit Canadian industry, but introduces no artificial incentives into the innovation system.

Conclusion

Canada can best foster innovation for the benefit of Canadians in general and Canadian industry in particular by strengthening the institutions – CIPO and the courts – that are best placed to update patent law and by strategically reorienting investments from subsidies to the support of Canadian partnerships and the acquisition of key Canadian and international patents in priority areas so as to attract investment in Canada.

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Policy Brief 1

Intellectual Property Management and Technology Policy

Event

Scientific and technological discoveries leave the laboratory as intellectual property (including patents, copyright and trade secrets), but the changing roles of institutions, firms and individuals with respect to intellectual property management and technology transfer (both nationally and internationally) are often unclear.

Significance

Statistics Canada (2005) surveyed 87 universities and 34 hospitals (80% response rate) conducting research in Canada. The total amount of sponsored research funds invested in research at the 121 institutions was C$4.3B. The report identified that there were then about 3,000 items of IP held that precipitated 876 spin-off companies. The survey found that the 2003 revenue received by the 121 organizations from commercialized IP was C$55.5M, and the operational expense of those organizations was C$36.4M. The net return on the C$4.3B investment was only about 0.4%.

Analysis

The Council of Canadian Academies (2006) report on science and technology in Canada asserted that while Canada is a world leader in many research areas and is increasing research strength in emerging fields, it does not do an effective job in converting strength in basic R&D to commercial activity. The report states that the lack of commercialization success from public sector innovative research is "… a long-standing deficiency in Canada's innovation system….(p. 25)" The findings of this report were reiterated one year later when Industry Canada (2007) released *Mobilizing Science and Technology to Canada's Advantage*, Canada's science and technology strategy, which acknowledges that Canada is internationally recognized as having a strong research base, but has considerable opportunity to improve commercialization of innovative research.

Researchers face the daunting challenge of first understanding and then identifying the means of maximizing the economic contribution of public sector innovation. This task is especially complex in the areas of agriculture, food and bioproducts, where innovations may have both commercial and social value. At issue are the roles of public and private sector actors in both innovation and translating that innovation into important agricultural processes and products.

While there is a plethora of theory on the interactions between innovators and private sector commercialization of innovation, there is little theory addressing the intersection of public institutions and commercial interests. Three frameworks have been proposed that attempt to conceptualize the innovation systems that are used, or have been used, to enable the transfer of public sector innovations. These models focus, in turn, on the actors (academia, government and industry and possibly the public), 1 the agendas of the various actors involved in technology transfer2 and on the motivators and incentives within university technology transfer offices.3

Beyond theory, practice is mounting. Many universities in North America established technology transfer offices within a decade of the US Bayh-Dole Act of 1980. The vast majority of these offices were established with a 'diamonds in the sky' attitude, thinking substantial revenue streams for universities would result. With the exception of a handful of universities in North America, revenue streams are but a mere trickle of what was hoped (Siegel and Wright, 2007).

Conclusion

There are numerous indicators that existing IP strategies utilized by public institutions have fallen short of early expectations. It is an open question whether universities obtaining patents increases or limits knowledge mobilization and product development.

Policy Brief 2

Intellectual Property Landscapes for Bioproducts and Crops

Event

An intellectual property landscape helps determine who controls knowledge and the rights to make and distribute products. Companies, researchers, governments and international bodies have different motivations for creating landscapes, seldom share them, and rarely employ the same methods. Without common methods, sharing knowledge and comparing landscaping techniques is difficult, and options for leveraging value from multiple landscapes is undermined.

Significance

The development of common landscaping methods will permit the sharing of data among actors and create the opportunity for leveraged meta-analyses to support social and economic decision-making. Common methods, even if they balance design advantages and blind spots, will make explicit limitations inherent in the methods chosen and will permit users to make transparent comparisons across studies. This is particularly critical in the agricultural sector in which products often incorporate previously patented characteristics.

Analysis

Intellectual property landscapes go under many names, including freedom-to-operate analysis, patent landscapes, public policy patent landscaping, and patent mapping. These landscape methods have in common an attempt to determine what type of intellectual property exists in a technology domain, which holds intellectual property rights, how broad are the rights, and when the rights will expire.

Individual companies may conduct landscape studies to determine whether they will need to obtain licences before manufacturing and selling a product, to identify potential partners for the manufacture or distribution of products, to identify potential purchasers of their intellectual property or to identify opportunities for technological development. For example, a company wishing to introduce a new crop will need to determine who holds patents over key characteristics and methods incorporated into that crop. Governments undertake landscape analyses to determine active areas of commercial activity, to identify key actors in the economy, and to make decisions concerning funding for research and infrastructure. Social science researchers rely on landscapes to identify trends and practices in a technology domain, to explore social and economic consequences arising from intellectual property, and to determine how knowledge is mobilized in a given sector. International organizations develop landscapes in order to identify in which countries patents are obtained in order to support the development of economic policy and access to technology.

Standard methods to undertake intellectual property landscapes do not exist. Some methods rely on highly skilled patent agents, others on experts such as professors and graduate students, and others on computer-based search algorithms. Each method produces a result that is difficult to compare with results from other methods and, often, even results produced using a similar method or same method by a different practitioner. Further, because each method makes selective use of information, landscapes contain biases that are difficult to compare and measure. Last, each method has a different cost associated with it. Such diversity in methods and outputs raises much uncertainty about the quality, robustness and cost of landscapes.

Consistent quality of landscapes is desirable, as are criteria for selecting landscaping methods tailored to the purposes for which the landscape was undertaken. An analysis and comparison of landscaping methods will classify methods by type and by the purposes sought for the landscape, and will identify biases that may be inherent in the various methods.

Conclusion

Describing, categorizing and evaluating methods of intellectual property landscaping will result in more robust landscapes, encourage the development of better methods, help researchers select the most appropriate method for the purposes being sought, and permit the comparison of results from different landscape analyses.

Policy Brief 3

Intellectual Property Structures for Emerging Technologies: Historical Approaches and Contemporary Consequences

Event

There is a division between the official stance of the Canadian Patent Office regarding the patentability of genetically modified (GM) plants and judicial interpretation of the scope of biotechnology patents. According to section 17.02.01 of the Manual of Patent Office Practice (MOPOP), "[h]igher life forms include: animals, plants, seeds, mushrooms, fertilized eggs and totipotent stem cells." meaning that GM plants are unpatentable. However, the decision of the Supreme Court of Canada (SCC) in the matter of Monsanto v. Schmeiser (2004) is inconsistent with the official stance of the patent office. The decision of the SCC in Schmeiser was tantamount to allowing "Monsanto to do indirectly what Canadian patent law has not allowed them to do directly: namely, to acquire patent protection over the whole plant" (Gold and Adams 2001, 587).

Significance

This division continues to present a problem. Multiple patent applications include claims over a whole plant.

Analysis

Contextualizing the gap that exists between judicial interpretations of biotech patents and the official stance of the patent office regarding the statutory subject matter covered by the Patent Act can help shed light on the current ambiguity that surrounds the patenting of whole plants. In the early 1980s, agencies within the Government of Canada, particularly the Ministry of State for Science and Technology (MOSST -- now part of Industry Canada) identified the newly energized field of biotechnology as an integral component of the nation's future economic prosperity.

Financial, institutional, and structural support characterized the National Biotechnology Strategy, approved in 1983 and overseen by the MOSST. However, the development of a national infrastructure to encourage the development of national biotechnology capacity was not accompanied by an intellectual property (IP) plan that could ensure appropriate control of the future biological inventions.

MOSST identified the IP challenge presented by biotechnological inventions, noting that "[b]eing concerned with life forms and processes, biotechnological inventions have raised unique problems and issues of accommodation under the laws governing the granting of patents." (Patentability of New Processes and Products of Biotechnology MOSST University Branch, May 1982). The National Biotechnology Advisory Committee: Annual Report (1984) also signaled the importance of a clear stance toward biotechnology , stating "There is an urgent need to signal potential investors and the R&D community that Canada has an environment conducive to commercial investments and activities in biotechnology. The Committee has urged that the government give priority attention to intellectual property matters" (p. 18). They emphasized legislation regarding plant breeder's rights was necessary to encourage commercial investment in Canadian biotechnology.

Although there was discussion about IP challenges related to the products of this emerging technology, no significant IP changes were made until the passage of the Plant Breeders' Rights Act in 1991; however, by that time many important biotechnology patents had been decided by the patent office and the judicial branch, not the least of which was the patent approval of Monsanto's 'Glyphosate Resistant Plants'.

Conclusion

The lack of plant breeder's legislation, or a clear stance regarding the patenting of whole organisms, combined with the perceived economic potential of biotechnology, meant that many of the early biotechnology inventions had nowhere to go but the patent system, creating a precedent for IP management. However, the continuing division between the judicial interpretation of biotechnology patents and the scope purported by the MOPOP is a historical relic that needs be addressed.

Policy Brief 4

Patent Infringement Remedies Have Limited Effects

Event

A recent court decision has impact on remedies available for agricultural biotechnology patent infringement. Patent owners may have problems getting meaningful remedies, even from admittedly infringing defendants.

Significance

The decision could mean revaluing Canadian patent portfolios based on enforceability issues, and re-evaluating business strategies and intellectual property practices accordingly.

Analysis

Add the names Charles Rivett and Lawrence Janssens alongside Percy Schmeiser to the growing list of farmers to challenge the fundamentals of Canadian patent law. Unlike in Schmeiser's case, however, the Federal Court of Appeal ruled mostly in favour of two Ontario soybean growers, and against Monsanto, in cases decided together in August 2010.

Since the Supreme Court's *Schmeiser* ruling in 2004, the legal debate is no longer about whether genetically modified plant cells are patentable or whether farmers who replant saved seeds are liable for infringement. Now farmers admit that and defend lawsuits on the ground that there is relatively little gain to a farmer, or loss to a patent owner, from any particular patent infringement. Judges seem to agree.

In Canada, damages for patent infringement normally equal the royalties that would have been earned had a licence been taken, *i.e.* the value of a plaintiff's specific loss. Because that does nothing to deter infringement, plaintiffs often elect a different remedy: "accounting of profits," *i.e.* a defendant's gain. However, calculating those profits is not always easy.

For an accounting of profits, the Supreme Court said in *Schmeiser*, "a comparison is to be made between the defendant's profit attributable to the invention and his profit had he used the best non-infringing option." In Mr. Schmeiser's case, that was zero. Without evidence he had sprayed his crop with herbicide, or sold seeds for their patented herbicide resistance, Monsanto could not prove that any of his profits were attributable to its patent.

Judges in *Rivett* and *Janssens* held that the same legal rules apply to defendants who do take advantage of patented traits. The key question is how much that benefits their bottom line. Monsanto's own estimates put the profit boost attributable to its patented technology at up to 18%; other estimates are lower. The result was an award slightly higher than the licence payment would have been, but nowhere near the amounts patent owners have publicized in the past. This means the downside risk to farmers who infringe biotechnology patents may be lower than previously believed. Patent owners, however, might have a tougher time winning meaningful judgments against infringers.

Conclusion

Technological advances such as stacked genetic traits are likely to compound the legal and financial complexities around infringement remedies. Anyone with a stake in agricultural biotechnology innovation, including policymakers, farmers, scientists, firms, investors and the general public should take note of these changes for patent enforcement efforts.3

See further Jeremy de Beer and Kurtis Andrews, "Accounting of Profits to Remedy Biotechnology Patent Infringement," [2009] 47 Osgoode Hall Law Journal 619, http://ohlj.ca/english/documents/47-4_DeBeer-FINAL.pdf.

Policy Brief 5

Performance of Canadian Technology Transfer Offices

Event

Using data from a 2008 survey of intellectual property (IP) commercialization at public institutions, Statistics Canada (2010) reports that income from intellectual property (IP) commercialization was $53M, down 9% from 2007, while expenses for IP management were $51M, up 9% from 2007.

Significance

Within a decade of the American Bayh-Dole Act of 1980 that allowed public institutions to patent their research, most universities in North America had established a technology transfer office (TTO). Most TTOs were established in hope of lucrative returns in the form of royalties. Except for a handful of universities, most have been disappointed.

Analysis

In 1998, 1,250 public institution patents existed in Canada, increasing to 3,000 in 2003 and 5,900 by 2008. Corresponding to this rise in patenting activity, revenues from patent licensing has risen from $16M in 1998 to $41M in 2003 and to $53M in 2008. Expenses for IP management were $8M in 1998, $36M in 2003 and $51M in 2008. In other words, profitability is falling while the rate of patenting remains relatively constant. Little is spent to defend patents, with litigation expenditures at zero in 1998, $1.4M in 2003, and between 2005 and 2008 from $360,000 to $575,000. Clearly, the cost of IP management at public sector TTOs is rising at a faster rate than either patents or revenues. With a gross operating margin of just $2M, if one were to remove just the ten most profitable patent licences from this picture, every TTO in Canada would be losing money.

Nevertheless, technology is being transferred. In 2008, 39% of university-owned patents had been licensed. The number of spin---off companies that have been created rose rapidly, peaking with 359 spin-off firms established between 1995 and 1999. The number of spin---off firms has declined substantially in the past few years, with only 142 new spin-offs between 2005 and 2008. Although only a four-year comparison, the trend is sharply downward as only 19 spin-offs were identified in 2008. At the peak, over 70 firms were created annually, but the average is now 35 a year. The change in this trend could be partially due to the declining availability of venture capital after the late 1990s.

The final notable trend is the increase in university research from the mid-1990s until the end of the period covered by the Statistics Canada report. In 1998, the total value of university research was $290M. The total value of the research rose to $940M in 2003 and was just shy of $2B in 2008. The demands that will be placed on TTOs will continue to increase given that the level of research funding has more than doubled in the past five years. Successive Canada federal governments have pledged that Canada will continue to be strong investor in research, even though funding has now plateaued (Castle and Phillips, forthcoming).

Conclusion

While innovative research is being licensed and spun---out of universities, the costs of IP management are growing disproportionately faster than the revenues that are being generated. With the vast majority of Canadian TTOs requiring subsidization by their institution, new models for the commercialization of innovative research need to be considered. Collaboration between major anchors of research clusters could be a starting point. Instead of several distinct institutional TTOs, there could be one central TTO for the entire cluster. If Canada wishes to maintain its strong standing in terms of innovative research, innovative ideas need to be applied to the commercialization of the research.

Policy Brief 6

Commercializing Research and Patent Landscape Methodology

Event

The commercialization of technologies from research projects is the definition of a successful project. With the increase in scale and scope of life science patents over the past 25 years, concerns exist regarding the freedom to operate within the project and to ultimately be able to commercialize an outcome from the project without concerns about patent infringement.

Significance

The findings from an assessment of intellectual property (IP) will provide insights to the project Principal Investigators on how to continue with the development of a strategic plan regarding commercialization of project technologies.

Analysis

The Principal Investigators (PIs) on the technical side of the project were contacted and asked to provide keywords based on their own research that they felt would facilitate the identification of relevant patents with the potential to impede their research. We started by searching for Canadian patents through the Canadian Intellectual Property Office website and the search was then expanded to other industrialized patent databases as was relevant, including the United States, Australia, Japan, the European Union and World Intellectual Property Office.

Searches were completed using research relevant keywords provided by researchers from the project as well as a series of other related keywords taken from the project proposal. The patent database searches yielded a list of approximately 325 patents. The list of patents was divided into equal groups and sent out to the PIs and each PI was asked to go through the patent set and identify which patents they felt were most relevant to the project, labeling them from 1 (most relevant) to 3 (least relevant). This turned out to be an error and we did not know how to deal with patents that were listed as 2s which were ‘maybe’. Further use of this methodology has been refined to provide only a yes/no choice.

After the PI review, there were 30 patents identified that could present FTO issues for the project. Most of these patents are held by large private companies, including Monsanto, Pioneer and Cargill. A further 80 patents were identified as ‘maybe’ but were rejected from further assessment. A meeting was held with the Project Lead and the Project Manager. At this time, it was identified that the patent search process had only identified product patents and that the key words we used had not identified any process patents. A second search was then undertaken of the Canadian patent database, revealing a further 100 patents. The meeting also resulted in an IP expert being hired to conduct further searches online patent family lines, based on patent authors and other cited patents. This expert identified a further 400 patents, of which, only 75 were in common with the previous patent database created from key word searches. It was decided to concentrate on the Canadian and American patent databases, as this is where the technologies would be commercialized.

The combined searches identified a group of patents held by a large multinational corporation that would be barriers to the project’s research. In 2010, the firm was approached by the Project Lead and the Business Development Officer for the project. The firm indicated that they were not presently using this bundle of patents and were willing to allow the project to have access to the specific patents.

Conclusion

The combination of patent search methods ultimately provided the greatest value. Each process on its own, revealed patents that the other search did not identify and it is held that both search process should be part of a landscape assessment.

Policy Brief 7

Institutional and Behavioural Analysis of Technology Transfer

Event

Technology transfer and commercialization partnerships have become a key focus in knowledge based economies. They are deemed a necessary means to translate basic academic research to market-based solutions. These partnerships can be considered a special group of public-private partnerships, as they increasingly include universities as a central player (Munim 2009).

Significance

A study of a specific Saskatoon-based partnership initiative called the Bio-Economy Center for Commercialization and Research (BECCR) provides insights into the functioning of technology transfer and commercialization partnerships. The BECCR first proposed in 2007 by project leaders from the University of Saskatchewan, involved actors from the public and private sectors. This study provides an in-depth analysis of various institutional and behavioural factors that are considered to play an important role in determining the success, or lack thereof, of such partnerships. It utilizes the Institutional Analysis Development (IAD) framework and concepts from Prospect Theory and Bounded Rationality as the underlying theoretical building blocks.

Analysis

Interviews were conducted with key informants who were involved in the development of the BECCR proposal or subsequent discussions around it. These interviews focused on individuals' experiences regarding this particular initiative. The key findings from this case study were then grouped and analyzed in the context of the institutional and behavioral frameworks.

The survey findings suggest that from an institutional point of view community attributes and behavioral factors have exerted a negative influence on the partnership development efforts in the Saskatoon cluster. Participants suggested that developing a long-term relationship and trust was more crucial at the beginning of the process than agreeing on a set of rules. However, it was the absence or poor design of various rules that might have played negatively on other institutional variables in the partnership. For example, the scope included a broadly and loosely defined set of technologies, which constrained the ability of organizations to focus on one analytical level and judge the commercial viability of a smaller set of technologies. Furthermore, authority and aggregation rules were found to be absent in this particular initiative, which created leadership problems. Absence of these subsets of rules hampered the attempts to achieve synchronization by developing a common language and agreeing to a mutually beneficial outcome.

Similarly, differences in perceptive framing of the problem led the participants to assign different values to the proposition. While key project leaders viewed the cluster in a losing position (where almost any change would improve prospects), other organizations, due to their relatively better performance in the area of technology transfer and commercialization, were in a domain of gains (generally only willing to consider clear and unambiguous gains). These differences in perceptions caused a divergence in participants' goals and motivations. More importantly, these differences led the organizations to hold unfavorable perceptions about their prospective partners, eventually leading participants to fall prey to the win-loss mindset.

Conclusion

The study provides a framework for policy analysts and practitioners to use to study and analyze the development and management of technology transfer partnerships. It highlights the complexity underlining technology transfer partnerships and the resulting need to focus on key institutional factors that are deeply embedded at different organizational levels. These factors, in addition to the behavioral biases of individuals, may play a critical role in the establishment and success of technology transfer and commercialization partnerships.

Policy Brief 8

Open Scientific Innovation Models for IP Management

Event

Policy makers have three options for intellectual property (IP) and technology management: (1) encouraging as much acquisition and commercialization of intellectual property rights as possible, (2) supporting the public domain by freely revealing knowledge and technology, and (3) leveraging intellectual property rights through collaborative or "open" licensing models. The latter two options reflect approaches in Open Scientific Innovation (OSI).

Significance

OSI refers to any viable model for improving access to capabilities for innovation in science to ensure that intellectual property rights do not restrict the flow of scientific exchange. It aims to maintain and enhance the ability to innovate through distributed research by allowing access to the tools and skills necessary to participate in that distributed economy. Identifying alternative intellectual property strategies can maximize the social and economic benefits of publically funded research and promote Canadian innovation in genomics sciences.

Analysis

Research on the theory and practice of open innovation and an analysis of emerging business models that foster collaboration and commercialization led to the identification of four alternative open innovation intellectual property management strategies:

1. *Peer Production* is a participative process that recruits large numbers of collaborators to work on a problem. For example, the Genome@home recruits scientists to contribute to the design of new protein sequences. This distributed and decentralized approach could provide economic advantages if large groups of contributors outperform, or match the performance of, small groups of experts.
2. A *Commons* provides a social regime for managing shared resources and forging a community of shared values and purposes. A governance and protective mechanism is essential, there is a danger that participants can defect from the community, or that third parties can take the community's work and capture it in a closed, proprietary format. A good illustration is PLoS, the Public Library of Science. While everything published in its repository is publicly available for free, content remains copyright-protected and is licensed on the standard terms of the Creative Commons system which permits use and reuse on the condition of attribution of source and authorship.
3. *Patent Pools* are an agreement between two or more patent owners to license one or more of their patents to other parties. They have potential anti-competitive impacts. Such concerns can be alleviated if patent pools are used to develop common technological standards for an industry, a context that has so far been more applicable to information and communications technologies than biotechnologies.
4. *Open source* relies on a set of licensing agreements that create a protected common. A legal mechanism ensures that the parties have the capability to use technologies created within the community. The novelty of open source systems is that intellectual property is licensed to require, rather than restrict access to, the protected content or technology. Within the open source models, there is considerable variation and currently there is a lack of consensus around a precise definition.

Conclusion

There is no need for policymakers to choose only one OSI option because they are not mutually exclusive. Degrees of openness can be characterized on a continuum reflecting the porosity of boundaries separating public and private rights, and the emphasis on osmosis between them. OSI innovation will be further developed through an understanding of which actors are best positioned to address each of the highlighted issues, selecting tools for implementation and developing metrics and evaluation mechanisms.

Policy Brief 9

Institutional Roles in Patent Policy Reform

Event

The Federal Court of Appeal's (FCA) 2011 decision in The Commissioner of Patents v. Amazon.com Inc. removed policy-making authority from Canadian Intellectual Property Office (CIPO). The Commissioner of Patents had consulted on the wisdom of allowing patents on business methods under Canadian law and had declined to grant such a patent to Amazon.com. The FCA held that CIPO did not have this power.

Significance

Canada risks falling behind comparator countries due to the absence of any governmental body with both the jurisdiction and expertise to gradually update patent laws. This lack of analytical capacity is particularly dangerous at a time when Canada is negotiating free trade agreements such as the Canadian European Trade Agreement (CETA), which include clauses on intellectual property.

Analysis

Government departments often play a role in patent policy, but public engagement with user communities on this topic has been lacking. Despite several government reports calling for reform of the patent system by governmental bodies dating back to 2002, Industry Canada (IC) has yet to respond. Many proposed reforms relate specifically to the agricultural sector including calls for a research exception and clarity about the scope of patent rights over agricultural inventions that self-replicate. Rather than openly address criticism of existing policies, such as those in the pharma sector, Canada's Access to Medicines Regime and Patented Medicines (Notice of Compliance) Regulations, IC has been largely silent. Innovation takes place in a dynamic environment and therefore communication of policy around patent reform is as important as the policy itself.

Courts are now the main locus of reform, which poses challenges. Canadian courts, the Supreme Court of Canada, have issued inconsistent and confusing rulings on several questions of patent law including patentable subject matter, novelty and non-obviousness. Other jurisdictions, such as the United States (US) and the United Kingdom (UK), have done better by being flexible in their elucidation of patent law as technology and actors evolve. Those jurisdictions have reformed the court structures to enable more consistent and simpler adjudication. The US created a single court, the US Court of Appeals for the Federal Circuit (CAFC), to hear all patent appeals. More than half of the judges on the CAFC have a background in patent law or patent policy. Likewise, the UK has created a County Patent Court to streamline patent trials.

While one could be tempted to follow the US or UK route of establishing a patent court, this is unlikely to work in Canada as the number of patent cases is too low to justify the creation of a separate court. A better solution would be to appoint more judges with a patent background and to increase judicial training on patent matters. There is currently only one judge with significant, pre-appointment, patent experience sitting in Canada. Other judges have developed a level of expertise in patent matters, but require a deeper understanding of the complex context in which patents contribute to innovation.

A better solution is to extend CIPO's policy-making authority. CIPO has the expertise and knowledge to engage in balancing the polycentric interests involved with innovation and to make determinations concerning the shape of patent law in the future. CIPO could, for example, be given a greater role in defining patentable subject matter leading to more consistency and clarity than current judge-made rules. Further, if given rule-making powers, CIPO could adapt Canadian rules around non-obviousness and utility to international standards.

Conclusion

Giving formal authority to CIPO to make determinations on matters of patentable subject matter and rule-making authority over substantive patent criteria will provide a more flexible, predictable and transparent patent system. Increasing the depth of expertise at the Federal Court would assist in developing more coherent doctrine in patent law.

Policy Brief 10

Whole Organism Patents in Canada

Event

There are numerous patent applications currently under review by the Canadian Intellectual Property Office that include a claim for a whole organism. These cases bring to light Canada's inconsistent approach to the patent protection available for genetically modified (GM) crops.

Significance

There is a division between the official stance of the Canadian Intellectual Property Office regarding the patentability of GM plants and judicial interpretation of the scope of biotechnology patents. According to section 17.02.01*a* of their Manual of Patent Office Practice (MOPOP) (2010), higher life forms, including plants, are not patentable. The decision of the Supreme Court of Canada (SCC) in the matter of Monsanto Canada Inc. v. Schmeiser (2004 SCC 34) was tantamount to allowing Monsanto to indirectly gain patent protection over a whole plant (Gold and Adams 2001) and is consequently inconsistent with the official stance of patent office, which is partially based on the SCC decision in the matter of Harvard College v. Canada (2002 SCC 76).

Without a consistent approach, it is likely that patent claims for a whole organism will be rejected by the Patent Office, but essentially allowed in any judicial ruling regarding infringement. This gap between policy and practice is a consequence of the historical approach the federal government has taken to biotechnology: simultaneously encouraging the biotechnology industry in Canada to economic stimulus while providing no intellectual property adjustments to accommodate the novel products of this modern technology. This approach will only lead to costly judicial rulings and an unclear intellectual property climate in Canada, which can in turn lead to investor uncertainty.

Analysis

Contextualizing the gap historically sheds light on the current ambiguity that surrounds the patenting of whole plants. In the early 1980s, agencies within the Government of Canada, particularly the Ministry of State for Science and Technology (MOSST – now part of Industry Canada) identified biotechnology as an integral component of the nation's future economic prosperity. Financial, institutional, and structural support characterized the National Biotechnology Strategy, which was approved in 1983 and overseen by the MOSST. But, while the development of a national infrastructure to encourage the development of national biotechnology capacity, no complementary intellectual property strategy arose to ensure appropriate control of the future biological 'inventions'. Instead, the Patent Act remained largely unchanged and patent decisions mainly left to the judiciary. The lack of a clear IP stance was decried by the National Biotechnology Advisory Board as an obstacle to investment in the Canadian biotechnology economy as early as 1984 (NBAC Annual Report 1984).

Although it was recommended that the *Patent Act* be adjusted to accommodate the unique challenges posed by biotechnology, no significant intellectual property changes were made until the passage of the Plant Breeders' Rights Act in 1990; however, by that time many important biotechnology patents had been decided by the patent office and the judicial branch, not the least of which was the patent approval of Monsanto's 'Glyphosate Resistant Plants'.

Conclusion

The lack of plant breeder's legislation, or a clear stance regarding the patenting of whole organisms, combined with the perceived economic potential of biotechnology, has meant that many of the early biotechnology inventions had nowhere to go but the patent system, creating a precedent for IP management that was contrary to the standard practices of the Patent Office. The continuing inconsistency between the judicial interpretation of biotechnology patents and the scope purported by the MOPOP is a historical relic that needs to be addressed.

Policy Brief 11

Benefits of GM Crop Adoption in India

Event

Genetically modified (GM) crop adoption began in India with the 2002 commercialization of Bt cotton. To date, over 7 million farmers have adopted Bt cotton resulting in higher yields and increased farmer profits. Yet, India is continually plagued with controversies put forward by critics of the technology, suggesting that Indian farmers are exploited by multinational corporations and that a causal link exists between the Bt cotton adoption and increased farmer suicides. Qaim provides an insightful perspective on the impacts and challenges of biotechnology in India in Smyth *et* al., 2014.

Significance

Three varieties of Bt cotton were commercialized in India in 2002. By 2012, there were over 1,000 varieties of Bt cotton grown on 93% of the total cotton farmland in India. Cotton farmers in India are typically small farmers, with less than 15 acres of total farmland of which 3-4 acres would be used to produce cotton. Bt eggplant was recommended as safe for consumption by the risk assessment process. Nonetheless, the Indian Environment Minister suspended Bt eggplant due to concerns about farmer welfare advanced by anti-biotech advocates through mass media that influenced the attitudes and perceptions of policy makers and the public.

Analysis

The quantifiable benefits from the adoption of Bt cotton have been substantial. Qaim's research shows that the application of cotton pesticides had fallen between 0.95-1.3 kg/acre of active ingredient. This results in a cost savings of 879-1284 rupees. In India, farmers apply pesticides to cotton using a backpack sprayer, in most cases with little to no protective clothing. Millions of cases of acute pesticide poisonings were reported every year. The adoption of Bt cotton has reduced the number of cases of pesticide poisoning, saving the Indian Ministry of Health extensive resources.

Not only has the environment and farmer health benefited, so too has the yield and profitability of Bt cotton adopters. While Bt cotton adopters to pay a higher price for the seed, this is more than offset by the 24% increase in yield when compared to non-Bt cotton. In 2012, it was estimated that 27 million acres of Bt cotton was planted, generating a net gain for Indian farmers of US$1 billion.

Despite the impressive benefits of Bt cotton, stories about farmer suicides continue to be perpetuated by critics of GM crops. Farmer suicide is a critical issue of concern and one that required a detailed assessment to determine if a link existed with Bt cotton. Research examining the number of farmer suicides and the adoption rate of Bt cotton documented that the suicide rate leveled off and began to decline following the commercialization of Bt cotton. If the pre-Bt cotton suicide rate is extrapolated, farmer suicides are now one-third lower than what might have been the case had Bt cotton not been approved.

Conclusion

The successful commercialization of GM crops in India and the distribution of benefits to millions of small landholder farmers are threatened by opponents of biotechnology, who are openly calling for a ban on further GM crops in India. The consequences of such a ban would affect millions of some of the world's poorest farmers. Indian farmers who adopt Bt cotton are not only benefiting from higher yields and increased profits, they also benefit from a reduction in pesticide poisonings, which saves the state substantial outlays on healthcare costs. Clearly, the evidence suggests that the adoption of Bt cotton by small landholder farmers in India offers multiple benefits.

Theme 3

Governance and Regulation

Every product of the bioscience research effort is assessed, evaluated, and tested for safety, efficacy and fit by one or more actors in the global research, regulatory or commercial systems. The traditional model of research is to look at the legislation and regulation and to focus on the political debates and events. While some work at the level is still valuable, and some novel approaches such as using qualitative methods to unpack the dynamics in political discourse offer interesting insights, most of the interesting and important actions are happening inside the systems that are designed and governed by the political process. The GE³LS effort has worked to unpack what happens in the black box of operational policy making and regulatory review.

In the scholarly world, analysts suggest that the actual practice of policy and administration system sits somewhere between two endpoints. At one extreme, we have evidence-based decision making, where scientific data (health, environment etc.), quantitative analysis, and strict application of social science methods (e.g. cost-benefit analysis as a decision tool) largely frame the options and strictly order the choices. While politicians can choose other than the optimal recommendation, the public service is bound to follow where the evidence leads. In this world, puzzles are solved, inputs and options are strictly ordered and there is little room for discretion to influence the outputs. In contrast, the evidence-informed policy movement asserts that most problems do not reduce to simple cause and effect, ends-means frames. Instead, given the wide writ of public policy and administration, most policy and administrative matters are deeply contextually based, with the result that no single numeraire or objective function can capture the scope of the decision. In this context, evidence is drawn from a range of social, political, cultural, or economic contexts that explicitly or implicitly involve a range of normative assumptions. Thus, highly contextualized policy problems need a range and array of different quantitative and qualitative data. Defining the problem then is fundamentally a political act, and discretion and conscience are inextricably linked to the framing, analysis, deciding, implementation and evaluation.

The GE³LS effort has developed a range of models and methods to unpack the multi-level and multi-actor decision systems that affect new technologies, using a mix of data analytics, social network analysis, agent-based modeling and behavioural experimentation.

Critical Essay 1

Governance and Regulation

By: G. Bruce Doern and Peter W.B. Phillips

The Context

The current and future development of genomics as a science and as a set of products and processes in Canada and globally is being shaped by the "genomics regulatory-science" regime. A regime is a set of interacting ideas, agencies, laws, rules, processes, and interests in a given defined policy field. While Canadian regulators focus on the 'coordinated framework' of empowered actors and institutions that delivers services to the public and industry, there is significant value in framing any analysis at the broader and all-encompassing regime level. The genomics regulatory-science regime includes an amalgam of multi-level regulatory and governance structures and national and globalized systems of science, evidence and knowledge in support of decision making around genomics and its applications (Doern and Prince 2012). The regulatory role of the state is further complicated because genomics is an activity both promoted and regulated by the state (Phillips 2007; Bunton and Peterson 2005; Carolan 2010). This Policy Brief draws on a wide range of published empirical and conceptual studies, including the authors' own research, both to develop and substantiate where positive developments have emerged and where obstacles still undoubtedly exist.

Regulations, at the core of the regime, are "rules of behaviour backed up by the sanctions of the state" (Doern, Hill, Prince and Schultz 1999, 1) and anchored in compliance approaches and practices, including crucial product assessments and approvals and, more recently, initial steps regarding post-market monitoring. Regulation is usually delegated law (the "regs") but some operational provisions occur in parent statutes. To make things more complex, regulation extends to, and is expressed through, guidelines, formal and informal codes and standards, sometimes cast as soft law or 'rule-making in the shadow of the law' (OECD 2012; Prince 2010; 1999; May 2007).

In the Canadian federation, rules must conform to the division of powers between the federal and provincial jurisdictions and to the overarching Charter of Rights and Freedoms. Regulation inevitably encompasses a world of administrative law and principles (Jones and de Villars 1999). The early stages of regime development in different regulatory fields often set precedents for later add-on rules, products and processes.

The common characterization of the genomics regulatory system is that it is "science-based" and fundamentally built upon "sound science." This typically empowers two types of scientific expertise in the system: the theoretical and basic science that underpins regulators' efforts in regulation-making and the scientific knowledge and related expertise possessed by front-line regulatory staff engaged in assessing products, what is sometimes labelled 'related science activities' (RSA) (Kinder 2010; Doern and Kinder 2007; Jarvis 2000). More recently, regulatory regimes have been described as 'evidence-based or evidence-informed', which variably includes and empowers socio-economic expertise and networks of citizens, patients, families and workers with local, front-line knowledge of diverse spatial and product uses and their potential impacts (Maheu and Macdonald 2010; Knoppers and Isasi 2004). In the context of genomics, a diverse set of scholars and practitioners interested in the ethical, legal and social aspects of technology (called GE³LS in Canada, ELSI in the US and ELSA in the EU) are increasingly involved in defining and monitoring the ethical dimension of the science and its uses.

The underlying structure and principles of the regulatory system predates the technology. Genomics-based applications in the agricultural, forestry, fishery and health and environment fields are generally handled in comparable but separate streams (Doern and Prince 2012). While the system adapted efficiently to the introduction of first-generation, single-trait GM crops (yielding a handful of herbicide-tolerant and insect-resistant canola, corn and soybean varieties that now dominate their market segments), it has largely stalled since then. Some stacked trait crops have been adopted but second and third generation GM varieties are largely caught in the regulatory regime. GM trees and GM animals, including fish, await adjudication and, apart from a few drugs designed with the aid of genomics, human applications such as gene therapy and personalized medicine are only slowly emerging.

While some of the delayed assessments are undoubtedly due to proponents not aggressively prosecuting their cases, many of the delays are attributed by proponents and observers to hesitant responses from regulators when new applications are beings assessed. Canada is often viewed as in the middle of the field internationally—the domestic regulatory regime tends to be a bit slower than in the US, but much faster and more predictable than in the EU. A recent study for CropLife International reports that regulatory costs globally account for about 26% of the cost and 37% of the time to develop and commercialize a new GM crop product and that the regulatory process has increased from an average of 45 months for events introduced before 2002 to more than 65 months for current events (Phillips McDougall 2011). CropLife Canada undertook an internal study on Canada's regulatory performance and found "that the total time from submission to approval is generally increasing, timelines for new submissions are less predictable (some are fairly quick while others are longer, but the length of review does not appear to be correlated to complexity of the submission) and the time from the last information request to the letter of approval has increased (which the regulators assert is strictly administration time that could easily be improved)" (Tranberg 2012).

In the health field, DNA testing, in both the justice system and human therapy, and the range of techniques related to human reproductive technologies all have had long gestation periods and have been challenged by controversial and partial development of law and regulation (Supreme Court of Canada 2011; Deckha 2009; Miller-Chenier 2002; 1994; Royal Commission on New Reproductive Technologies 1993). Indeed, Assisted Human Reproduction Canada (AHRC), which was only established in 2007 after a decade of delay, was abruptly cancelled in Budget 2012 due in part to a Supreme Court of Canada ruling that had significantly reduced the federal regulatory role in assisted human reproduction.

The genomics regulatory-science regime involves intricate governance boundary problems regarding bio-food, bio-health and bio- life. Engineered foods and the prospects of more invasive genetic human health interventions have triggered concerns about what is "natural" and what should be viewed as private property and commoditized as opposed to treated as a public good (Castle 2009; Brunk and Coward 2009; Wiles 2007; Phillips *et* al. 2010; Andree 2009).

The Issues

Three genomics regulatory-science issues stand out as major concerns, each related to different aspects of the overall regime. There are of course other particular issues that arise in contexts that are more specific and in the diverse nature of changing genomic-centred product and process developments in food, health and life. Some of these issues are mentioned below but they are not among the three main overriding issues we focus on in this very brief paper.

The first issue relates to how regulations can and should be made. The federal government made a strategic decision in the 1990s to review biotechnology and genomics research through existing institutions and in the context of their application and intended uses, rather than through purpose-built or technology specific structures. In that context, the 2007 federal Cabinet Directive on Streamlining Regulation (CDSR), the main regulatory policy of the current Conservative Government, asserts that, when regulating, the federal government will: protect and advance the public interest in health, safety and security, the quality of the environment, and social and economic well-being of Canadians as expressed by Parliament in legislation; and promote a fair and competitive market economy that encourages entrepreneurship, investment, and innovation (Canada 2007, 1).

The CDSR seeks to move the federal regulation-making process away from its historic 'one regulation at a time' approach to one where regulatory priorities are more explicit (Doern 2007 and 2011). In this way, the CDSR seeks to garner better evaluation of regulatory regimes and not simply line-by-line reviews. While well intentioned, this may not come to pass. This may be complicated by the 2012 federal commitment to a 'one-for-one' rule and burden test (where any new regulations require offsetting deletions of regulations and must not add to the net cost of regulatory compliance for business) which may narrow the focus of regulatory development. A complicating factor for comprehensive review is that regulatory oversight is triggered by the novelty of the product and not the methodology used in the production, which means that specific opportunities or challenges triggered by genomics may only be fully engaged at one of the pre-planned reviews of the system related to food, drugs, forestry, energy and the environment. The federal government is not alone in trying to work through and implement a new approach to regulation. A recent OECD review of regulatory policy highlighted

the growing complexity and numerous inherent partial contradictions in delivering on the core principles of efficiency, effectiveness, transparency and engagement (OECD 2012; Pal 2012).

The second issue relates to whether and how a life-cycle approach might be adapted and embodied in product assessments for food, drugs and environmental effects of new products (National Roundtable on Environment and the Economy 2012; Health Canada 2006 and 2007). The Health Canada life-cycle concept has been proposed to move the focus away from a single "point-in-time" pre-market assessment system for new products to one that follows products and processes in post-market phases, including their ultimate use in households and the environment. The 2006 federal Blueprint for renewal in health and drug regulation has gone the furthest in recommending moving to a product life-cycle approach, which would involve post-release monitoring and reporting (Health Canada 2006, 6-25). However, the Blueprint plans are not a statutory policy provision and in times of restraint may not be implemented as proposed. The extension to post-market monitoring of products and product use would necessarily include networks of varied and dispersed expertise and knowledge in both the federal-provincial knowledge system and beyond the national borders to other scientific communities and markets, which would be a major challenge even in the best of circumstances. The 2012 report by the National Roundtable on Environment and the Economy (NRTEE) also stresses the value of life-cycle approaches to foster sustainable economic development in Canada. however, it also points to many practical obstacles along the way, including limited conceptual understanding, complexity, and serious gaps both in the science and in the front- line capacity to deliver science-based regulations and policy.

The third issue is whether any national regulatory system can be fully capable of assessing the diversity of genomics applications. Of all the sciences, genomics is probably the most global. No country is self-sufficient in the science used to develop new products and processes or that is needed to undertake assessments. This is a particular challenge as much of the knowledge embedded in these new products is protected and exploited under proprietary regimes (protected by patents, trademarks, trade secrets and various commercial and contractual mechanisms). This system privileges some actors and forms of evidence at the expense of others—at least partly because most regulators prefer to work with owners of new products so that they can more easily assign fiduciary and residual obligations related to unintended and unanticipated consequences.
This becomes more of a challenge once a product enters the market—consumers in Canada and globally have high expectations that they will be able to make their own choices about accessing and using foods, drugs and other products (Phillips and McNeil 2001).

While food labelling has been a hot topic, the health area is even more challenging as Internet-savvy Canadians and their families often have knowledge about, and access to, products well before they are approved in Canada, especially from the US. This has triggered what one author has called the "wow" to "whoa" phenomenon, as new discoveries and products with human health impacts are announced with excitement—almost immediately followed in the same rhetorical breath with human and social fears about such products and processes (Harris 2010; Wade 2010).

One particularly troubling trend is that some Canadians are beginning to buy direct-to-consumer genetic testing for health, disease and ancestry from such providers as 23andMe—these relatively inexpensive services can cause significant angst and demands on the public health system in Canada as people seek help interpreting and responding to their results (Caulfield *et* al. 2010). This issue is in some ways the flip side of the continuing concern that such tests could lead to genetic discrimination. With the support of the Canadian Coalition for Genetic Fairness (2010), a Member of Parliament from the New Democratic Party has proposed a bill to amend the Canadian Human Rights Act to prevent discrimination of people based on genetic characteristics (New Democratic Party 2010). While numerous US state governments have introduced such laws, Canada has no such restrictions in place.

Policy Background

Who then are the regulators and what are their science, evidence and knowledge capacities? A minimal mapping of the system would be centred on government regulators, but there are many others who contribute to making choices about new technologies.

The story and the foundation for the genomics "regulatory-science" regime begin with the genomics research itself (Doern and Prince 2012). There are two main streams of government investment: Genome

Canada and tri-Council investments in basic genomics research discovery and development; and government intra-mural investment in the science needed to underpin public policy and regulation. Provinces, foundations and especially private capital come on-line only as the research advances and commercial opportunities become clear. At the federal level, the Genomics R&D Initiative (GRDI) (Canada 2012; National Research Council Canada 2010) funds and coordinates seven federal departments in the fields of genomics research. Over one billion dollars have been invested since 1999 in five three-year funding cycles. This has generated quite a number of projects and discoveries, which have importance to researchers and client genomic networks, but the links to regulatory issues are complex and often hard to track in any detail. The general GRDI website says that "independent evaluations have found that GRDI is successfully supporting the core public policy, regulatory, and operational mandates of government" (Canada 2012, 1). While regulatory science is part of the GRDI mandate, the most recent evaluation of the program does not offer any specific insight into how this work has supported Canadian regulatory capacity (National Research Council Canada 2010).

Each of the federal and related research organizations undertakes de facto pre-market regulatory assessments, in that each has its own norms, rules and processes for making choices which effectively pre-screens genomics applications before they reach the main product and process regulators. Almost all organizations now adhere to some articulated set of ethical norms (such as the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans) embodied in corporate pledges, corporate social responsibility (CSR) processes or in mission and mandate statements. Most institutions also set practices for codifying, disseminating and asserting ownership for any inventions or discoveries or for biosafety (e.g. embedded in Good Laboratory Practices or other professional or industrial standards). The early phase regulatory process thus includes federal research granting bodies such as the CIHR, NSERC, SSHRC, the Networks of Centres of Excellence, Genome Canada and the Canadian Foundation for Innovation, as they impose and enforce processes and norms through their grants, including the requirement for "leveraged money" and the structure and role of peer review (Lopreite and Murphy 2009; Doern and Stoney 2009; Atkinson-Grosjean 2006).

As long as the efforts and the outcomes of research remain contained in laboratories or greenhouses, formal regulatory oversight does not really begin. If and when a genomics application is proposed for use beyond containment, then governments in Canada and around the world begin to respond. Canada uniquely uses the novelty of the product to trigger assessments—in conformity with World Trade Organization (WTO) norms. Thus, the regulator examines product attributes rather than the production and processing methods (PPM) used to produce the product. Novelty can arise either by simply transferring organisms to the eco-system from other areas or by mutagenic or transgenic techniques. Other national systems tend to trigger assessments based on the use of transgenic methods, but still focus their efforts on assessing the risk of using or consuming the resulting products. The practical effect is that the Canadian system catches and assesses more products (e.g. mutagenic crop varieties) than other competing systems. The actual assessment in Canada (and most other countries) is then based on the internationally accepted risk analysis framework (RAF), which encompasses three distinct phases—risk assessment, risk management and risk communications—with different actors assigned different tasks (National Research Council 1983, 1994 and 1996).

At the federal level, the regulators with partial direct or indirect genomic-related mandates, laws, regulations and guidance roles include: Health Canada (and several of its directorates such as the Health Products and Food Branch Inspectorate and Therapeutic Products Directorate); the Canadian Food Inspection Agency; Environment Canada (for those products that do not have Acts listed under the Canadian Environmental Protection Act); Fisheries and Oceans Canada; the Public Health Agency of Canada; the Canadian Intellectual Property Office; the Patented Medicine Prices Review Board; the Canadian Agency for Drugs and Technologies in Health; and the Privacy Commissioner of Canada. All of these agencies operate in analogous and complementary ways, with delegated groups undertaking risk analysis that is then adjudicated by a risk management group and communicated more broadly to the public and interested parties. Each system attempts to reflect the 'common regulatory principles' articulated in the 2007 Regulatory Cooperation Framework between Canada, the US and Mexico.

Genomics-based products are generally evaluated only once in Canada, at the federal level. Nevertheless, provinces at times can be key actors. Given shared constitutional jurisdiction in agriculture, provinces are often

important actors in priority setting, funding and management of agri-food research, while many provinces have carved out niches in the genomics research area targeted on their specific economic priorities (often related to health, forestry or the fisheries). BC and Quebec, through Genome BC and Genome Quebec, in particular, have invested in provincially targeted research competitions. At least as important are the universities that undertake much of the foundational research on genomics. As provincial entities governed on an arms-length basis, universities have their own internal regulatory and policy provisions and processes regarding research ethics, patenting, commercialization, and public-good science (Doern and Stoney 2009).

At the other end of the research chain, provincial agencies are often the most important market for technologies and services. Health departments and drug formularies make decisions about whether to purchase or fund within provincial Medicare programs new genomics-based products or services, including drugs, devices and tests. While products may have been granted patent rights and Health Canada approval, this does not mean that they all will be funded or used in the provincial systems (Canadian Agency for Drugs and Technologies in Health 2008). Numerous provincially- based groups of medical professionals, patients, carers and disease advocates aggressively engage with provincial authorities, seeking to bring forth new and improved prospects. The combination of variable uptake of technology and uneven lobbying by interest groups opens up potential for conflict and differential access to drugs under healthcare.

The story does not stop at the national boundary. International regulatory and policy bodies exert considerable direct and indirect influence on Canada, both through harmonizing the evidence and processes for regulating genomics research and applications and through various kinds of exhortative demonstration effects. In addition to the important scientific, commercial and regulatory links we have built with our major trading partners—especially the US, the European Union and other OECD member states—Canada belongs to a range of international organizations that work to normalize the models, methods and metrics of regulatory practice. Regulators communicate almost daily with colleagues in competent regulatory agencies in other states to identify the appropriate ways to undertake the vital tasks of hazard identification, hazard characterization, exposure assessment and risk characterization. Recent reforms to the US Food and Drug Administration (FDA) have also been important to Canada's potential regulatory reform agenda (Carpenter 2010). The Obama Administration's more aggressive stance in monitoring genomics-related research ethics is also noteworthy (Meslin 2010). Moreover, in the larger political-regulatory context, the role of religion in embryonic stem-cell research in the US has served as a cautionary tale in Canada's somewhat more secular political culture (Knowles 2010).

Policy and Governance Options

The overriding challenge is that Canadian regulators have got themselves boxed in, on the one hand, with rising expectations from industry and consumers that recent large public investments in genomics will deliver real benefits soon and, on the other hand, with slowing regulatory processes. As the Phillips McDougal and CropLife Canada studies noted, while a number of genomics-aided technologies and products have run the regulatory gauntlet, many more remain locked in the system. A number of broad policy approaches appear possible, including (1) renewing federal leadership to complete the system, (2) optimizing international regulatory co-operation and harmonization in a global effort to efficiently and effectively regulate genomics-based innovations, (3) opening up space for industry and others to self-regulate and (4) setting a tabula rasa to better engage socio-economic considerations. As with any broadly defined approach, there are inevitably more specific sub-options within or across each of these (we refer to a few of them in our set of further research questions).

Option 1: Renewing Federal Leadership to Complete the System

If one interprets the apparent lags in commercialization as simply a lack of federal effort, the most straightforward and direct approach would be for the federal government to complete the regulatory system in this domain and then to appropriately resource it. There are actionable proposals in the federal system regarding some genomic products that would enable regulators to quickly and cleanly create or amend existing rules that could then be used to guide and adjudicate any products now languishing in the system. This would entail completing the regulatory system for second and third generation crop traits, implementing rules for assessing

GM animals and fish, clarifying the rules for genetic tests and revamping the processes and procedures for drugs, medical devices and gene therapies. Complementing this, one would expect there might need to be some review of the intellectual property rules for genomics- based inventions (de Beer, Gold, and Guaranga 2011; Doern and Prince 2012).

While this seems simple and straightforward, it is not clear that it would necessarily on its own lead to more economically and socially appropriate outcomes. While federal regulators offer an opportunity for a Pre-Notification Consultation, which can provide product proponents with an opportunity to identify the steps required to achieve regulatory approval, many proponents have been hesitant to interact in advance. Part of the challenge is to get more effective engagement between regulators and the regulated. Moreover, in some cases, delays may not be due to a lack of resolve but reflect underlying concerns about the technologies and the scientific and regulatory knowledge available to assess and use these innovations.

There is also evidence that there are real limits to the power of the state, so that even definitive government action may not translate into effective outcomes. Consumers and citizens are able and willing to defy government decisions, acquiring and using technologies and products in unapproved and untested ways. A subtler yet perhaps more fundamental challenge is that the contingent nature of defining risks, hazards and errors makes it impossible for any jurisdiction to have a clean, straightforward system. This is compounded by the diffusion of responsibility and authority—regulatory authority vested in national agencies is shared with other agencies (e.g. via mutual recognition agreements) and various international intergovernmental organizations while the proponents themselves are heavily involved in any assessment.

One particularly complex issue is personalized medicine, which is fundamentally built upon the genomics revolution (Boyer 2010; Crawley 2008; Economist 2010; Personalized Medicine Coalition 2009). If this application of genomics proves to add value to the medical system, it promises to cause significant changes in the regulatory system, as the current 3-stage clinical trials process and related drug approval system may be fundamentally incompatible with the personalization of drugs and dosage in the context of a person's genome and lifestyle.

The result is that most product assessments now involve significant reference to other authorities, with many nested decision-making sub-systems contributing to the overall decision.

Option 2: Optimizing International Regulatory Cooperation and Harmonization

The processes of coordination and harmonization have varied widely in pace and scope in the recent past. The internationalization of both science and trade has led both to more coordination (i.e., gradual narrowing of differences between systems based on voluntary international codes of practice) and to harmonization (i.e., standardization of regulation in identical form) (Davies 2002). The earliest and still the most extensive international collaboration has focused on human health related to food, drugs and chemical pollutants in the environment. An array of international organizations has been created to coordinate and harmonize risk. Over the years, membership in these organizations has grown to involve most countries in the world and hundreds of technical committees of regulators, scientists and industrial managers who meet regularly to consider new risks and to develop procedures for managing the processes of evaluating and managing those risks.

These groups are for the most part closed, with admission controlled by the expert group in charge (be it national regulators, policy advisors or research scientists). At times, organizations such as the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) have sought to extend beyond this closed system by commissioning expert panels of independent scientists to consider areas of uncertainty in the international food or health systems, seeking to contribute to greater understanding of how a risk or an event might assert itself.

Other regional and functional configurations of countries and experts are also engaged in the debate about regulating risks. The Organization for Economic Cooperation and Development (OECD), involving 34 high-income democracies, engages in an array of efforts to harmonize international regulatory requirements, standards and policies in the chemical and biotechnology areas. Apart from codifying practices and providing a forum for coordinating policy development, the OECD has created a new quasi-regulatory instrument in the biotechnology area called a Consensus Document. These mutually accepted scientific reports (52 as of January 2012) codify the biology of a host crop plant or characterization of an introduced trait or transgenic method,

thereby providing a common base to be used in a regulatory assessment of an agricultural or food product derived through modern biotechnology.

The above institutions and others centred on the WTO produce practical interdependence that narrows the range of options but also offers an array of fora and processes for examining difficult aspects of emerging risks and, as required, for testing options and resolving disputes about different interpretations of any attendant risk.

Option 3: Opening up Space for Industry and Others to Self-Regulate

One response to the slow development of national and international rules has been for individual companies or parts of the industry to implement self-regulation to develop and sustain market access. Generally, these systems are effective where it is possible to safely and economically produce a product or service but there are gaps in the regulatory architecture. Provided tort laws exist and are judiciable, governments and the courts, sometimes prodded by disgruntled consumers through class-action lawsuits, can effectively focus the market in ways that governments alone sometimes find difficult. It is perhaps worth noting in passing that most individuals involved in genomics research and regulation are part of peer, epistemic groups that impose rules and norms that govern individual actions, which undoubtedly have a moderating influence on the actions of the institutions employing them.

There are a number of cases where parts of the agri-food industry, in particular, have developed systems to deliver products with higher standards than domestic or even international minimum standards. The red meats industry in Australia (Spriggs and Isaac 2001), the canola industry in Canada (Gray, Malla and Phillips 2006; Phillips and Smyth 2004), retailers and processors in the EU, North America and Asia (Phillips and McNeill 2001) and the corn industry in the US, have all adopted private standards to differentiate and control quality in the supply chain. For example, the Canola Council of Canada has an industry constructed Export Ready Program that binds seed developers to acquire foreign regulatory approval before they commercialize new varieties while the Canadian soybean industry has an industry-operated identity preservation system to differentiate conventional soy from GM soy, facilitating high-value export markets in Japan.

This approach is increasingly subsumed in the broader debate and effort to sustain co-existence of GM and non-GM production in core agri-food markets (GMCC 2011). Over time, private standards, supplemented by Hazard Analysis and Critical Control Processes (HACCP) protocols or International Standards Organization ratings (particularly ISO 9000 and 14000 series) could realistically supplement public regulation—especially regulation that goes beyond considering the narrow public health and safety agenda. In order to address market demands for traceability and separability, new physical and organizational infrastructure are emerging. Already the ISO has developed new eco-labeling standards (ISO 14020 and ISO 14024) which offer industry the opportunity to use the standards to support environmental goals but also as a way to avoid some environmental challenges to their products in domestic or foreign markets.

While currently underdeveloped, this approach represents an interesting possibility for industry to manage its own regulatory space through creating and promoting higher industry standards that ensure both regulatory and market acceptance of their products. A major advantage is that such an approach would not require industry to carve off large chunks of the regulatory pie. Instead, problems can be resolved in bite-sized pieces as problems and opportunities are identified—as in the past, private standards setting can then be institutionalized through reference and recognition in the formal regulatory system.

Option 4: Setting a Tabula Rasa to Better Engage Socio-Economic Considerations

Genomics applications at times challenge the current architecture for science, regulation and intellectual property rights, opening the door to new actors with new questions and new values, interests and beliefs. To many, 'science' is simply not adequate. In the absence of agreement on what makes a 'scientific consensus' (Kuhn 1970 called consensus a 'paradigm' that incorporates known theories and known evidence, or his known-knowns), it is not clear when there is enough science. Simply filling in Kuhn's unknowns (i.e., where we either have a lack of theory or evidence) will not satisfy many, as they assert paradigms are simply reflections of the prevailing power systems and not ultimate truths.

Those unwilling to simply continue the slow, patient work of filling in the unknowns generally fall into two camps. Some want a completely new set of rules that reflect new norms while others simply want a way to

pause the process for a while. Both camps have looked to use the emerging norm of 'precaution' as a way to achieve a different outcome (Vogel 2012). All countries have some form of precaution in their systems, either formally articulated or informally used, that enables them to delay or suspend judgment on a product that is suspected to pose unacceptable and irreversible risks. The first articulation of precaution was in the World Charter for Nature in 1982. Since that time, the policy has been expressed in numerous national and international regulatory systems. Principle 15 of the 1992 Rio Declaration on the Environment and Development states, “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” The Commission of European Communities offered guidelines for using its version in a politically transparent manner: "measures ... must not be disproportionate to the desired level of protection and must not aim at zero risk ... comparable situations should not be treated differently and ... different situations should not be treated in the same way, unless there are objective grounds for doing so ... measures ... should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available ... measures must be of a provisional nature pending the availability of more reliable scientific data ... scientific research shall be continued with a view to obtaining more complete data" (Commission of the European Communities 2000, 19-21). International law is conflicted about how to deal with precaution—the World Trade Organization (WTO) offers a narrow and science-based process for managing precaution while the Cartegena Protocol on Biosafety (CPB) embodies a definition of precaution that is more expansive and which could lead to extended delays. While Canada and the US reject the EU and CPB conception of the precautionary principle (which they argue has been used to delay decisions excessively), they both have precaution as a guiding principle in their assessment systems. The difference would appear to be more in intent and effect rather than in general principles.

Those who want a more permanent change in the power system are seeking to place socio-economic considerations (SEC) at the centre of decision-making. Some assert that the scope for SEC in the WTO is not fully tested—the preamble of the Marrakesh Agreement (1994) affirms “...the objective of sustainable development, seeking both to protect and preserve the environment...” It is not clear what flexibility and policy space is available in the sub-agreements, in particular. Risk assessment under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), for example, already involves a mix of scientific and economic considerations: “Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks” (Article 5.3). In the meantime, other venues have emerged where socio-economic considerations are accepted and at times are more influential than science in determining decisions.

Those opposed to opening the regulatory system to more non-scientific considerations express concern that it would generate more red tape, undermine regulatory predictability and delay innovation. Such measures could also undermine Canada's trade advocacy work, which often relies on scientific arguments to open and maintain foreign markets for Canadian goods. Changing Canada's policy for genomics applications might create a precedent that would have unintended consequences for other aspects of Canada's economy.

Practical Application and Considerations

A number of practical issues that emerge from the above analysis were discussed by three commentators at the Canadian Science Policy Conference in November 2011, by other reviewers and by participants in the workshop session that followed. Three specific considerations flow from the ongoing evolution of the genomics regulatory-science regime.

First, while all four of the policy and governance options provide different separate focal points for change, they also overlap and interact with each other. Thus, the federal, international, self-regulatory, and socio-economic arenas are likely to change both in response to internal pressures and due to their deepening links and complexities. Each represents simultaneously multi-level and spatial arenas of politics, power, government versus governance, values, science and knowledge related to and involved with genomics. Indeed, one of the

specific suggestions to emerge from the discussion was that the federal government, in concert with other players, needed to take explicit steps to foster better basic public understanding of the current system.

A second practical matter is whether the current system is up to the challenges to be faced and whether overall these challenges require new laws and regulations or whether, on balance, it is best to work towards gradual and incremental change. There are already laws and regulations in place—many regulatory practitioners, in the face of considerable technical and political uncertainty, assert that laws and regulations are complex and time consuming to change and implement through the full Parliamentary or Cabinet processes, especially if they require federal-provincial or international coordination and agreement. This logic then leads one to consider softer guidance and guideline approaches and for governance rather than just government approaches. The dilemmas were illustrated by discussion in the workshop. While the federal Cabinet Directive on Streamlining Regulation (CDSR) and Health Canada Blueprint announcements related to life-cycle approaches suggests major changes are in the offing, both so far are more aspirational than operational. Similarly, while there is extensive effort to develop greater coordination and harmonization at the international level, the extent of change that is possible depends on differences in the core political economy of North American and Europe. Currently there appears to be more opportunity for convergence in processes guiding the regulation of health products, but less in the areas of agriculture, food, fisheries and the environment.

A third concern is whether greater practical clarity can be provided to differentiate the regulatory functions from promotional considerations. The Canadian government is quite legitimately concerned about and engaged in regulation making and assessment of genomics applications and in the development and promotion of genomics-based innovation. The challenge is that both roles create new linkages domestically and internationally that would be difficult if not impossible to codify in statute or regulation. It is far from clear whether further guidance is possible or whether this is inevitably an area of regulatory judgement and discretion left to front-line regulators.

Future Research Questions

Five areas for further research emerged in the context of the development of this policy brief.

1. Precisely how, and to what extent, can different forms of self- regulation complement or reinforce the current science-based formal regulatory system?

2. What forms should the federal CDSR and Health Canada post-market monitoring life-cycle approach take? Should it remain a policy and governance aspiration or can it actually be implemented? How can or should we balance effectiveness, efficiency and democratic ideals in the full life cycle?

3. Are periodic large-scale technology assessment processes desirable as a complement to the current novel-product-centred assessment system? The current genomics regulatory-science regime does not purport to regulate genomics as a transformative technology per se but rather focusses on particular novel products and applications. If a more comprehensive review is needed, how could it be structured (e.g., as periodic reviews every five to seven years)? How should it engage experts and the public?

4. Rather than try to tinker with the current nationally based set of regulatory assessments to accommodate new perspectives, is there any potential for an entirely new approach that might instead offer an authoritative, globally based, open-source regulatory science and assessment process? Given that no single country is fully competent to undertake the current tasks, is there some way to pool our resources and competencies to strengthen the system that will enhance both safety and innovation?

5. In the context of federal austerity measures and budget and staff cuts, are the core science and evidence-based regulatory capacities of the current system being maintained? Moreover, will there be adequate resourcing to develop the new capacities that may be needed as genomic research and products increase in volume and complexity?

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Policy Brief 1

Scenario Methods for the Governance of ABC Technologies

Event

Uncertainties associated with the research, development and regulation of new crop genomics, bioproducts and related services creates significant governance challenges. Foresight methods, especially scenarios, are being developed by the public sector to validate normative underpinnings of governance options in strategic planning exercises.

Significance

Scenario methods have been used for nearly three decades in private sector energy strategies, but their adoption by the public sector and in large-scale research projects like VALGEN is new.

Analysis

Foresight methodology is in general based on the idea that the future is not yet determined and that a myriad of factors will interact to shape it. With this accommodating starting point, foresight applies to nearly any problem or context important enough to seek ways to bring about desirable outcomes and lessen undesirable futures. Shaping the future is an activity based partly on facts as they are known now or reasonably predicted, but it is also a creative act of envisioning alternative pathways. Used strategically, foresight prepares one for different possible futures, enabling one to anticipate and react in the present. The foresight method best suited to this undertaking is the development of scenarios.

Developed as a formal system in response to Shell's market position jeopardized by the environmental movement and the emergence of OPEC in the 1970s, scenario-building methodology has since been used extensively as an aid to decision-making in the private and public sectors. In recent years, governments have also begun to use scenarios and there has been a surge in the literature of practice guidelines to conduct scenario exercises. In the past two years, Health Canada, Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency have used foresight and scenario methods

Many different scenarios methods exist, but the most common one that has emerged is the use of the matrix model in scenarios workshops. In workshops, carefully selected participants are led through a brainstorming situation to identify all possible drivers of change. These are factors, trends or situations that would drive future possible states. Once a list of potential drivers has been brainstormed, they are discussed and analyzed to determine which two carry the highest degree of impact and uncertainty. These are then used as two axes to form a four-quadrant matrix from which potential scenarios are derived. The candidate scenarios can then be tested analysed and compared via thought-experiments. When scenarios are developed, they represent future states and the potential for action. The 'time signature' can be reversed through a back-casting exercise in which the steps necessary to reach the targets in the scenario are reverse-engineered. By creating scenarios based on drivers and trends that are uncertain, the process does not need to make an explicit value judgment about which scenarios are preferable to others.

Conclusion

The scenarios method is particularly useful for addressing challenges in the governance of agro-industrial biotechnology because it shapes possible futures from present uncertainties and captures these in an action-oriented matrix which enable one to 'back cast' to initial steps. The public sector, facing governance challenges associated with research, development and regulation, is finding scenarios effective in strategic planning. VALGEN researchers have participated in recent public sector planning exercises and will be conducting a series of scenarios workshops along the lines of the three research themes in VALGEN.

Policy Brief 2

Ethics as a Part of Regulatory Decision-making Processes

Event

Article 26 of the Cartagena Protocol on Biosafety (CPB) provides for the inclusion of socio-economic considerations (SECs) for decision-making in domestic regulatory frameworks. The primary concern to which the Article responds is transboundary movements of genetically modified (GM) products for deliberate release. Countries now have the option of including SECs in their assessment of the impact of new crops on conservation and sustainable biodiversity (subject to any other international obligations). Ethical considerations are among several proposed by advocates of SEC inclusion.

Significance

In-depth analysis of the process by which these factors would be included in decision-making processes reveals a gap in the ability to effectively incorporate SECs. Not only is there no standard methodology for outlining a process by which they would be included, there is often no existing benchmark data to determine if the potential SEC being assessed improves, harms or has no effect on biodiversity (Ludlow, Smyth and Falck-Zepeda 2014).

Analysis

Current Western concepts of ethics are grounded in a number of long-standing philosophical theories, one of which focuses on the utility (Bentham) or consequences (Mill) of one course of action compared with another. A focus on the consequences arising from a course of action is embedded in decision-making processes that consider costs, benefits and risks. An action like the approval of a new GM crop must produce net social utility, often defined as the greatest good for the largest number of people. For policy makers, this entails measuring all of the effects or impacts and assessing the total utility that the action, including alternatives, has on individuals within society.

A challenge for the inclusion of ethics in a decision-making process is that someone has to make a value judgment, which may not be objectively quantifiable, about the expected or perceived level of utility. Two individuals could view a situation with contradicting perspectives. For example, agricultural innovations, such as the mechanization of equipment, have historically resulted in labour reallocations. This new surplus labour is no longer tied to the land and is free to migrate to urban centers, receive training and enter the skilled labour market.

One view might hold that utility is enhanced by engagement in agrarian activities and that social utility decreases when engagement is reduced. The other view may hold that there is increased economic value from the higher skilled labourer than from the non-skilled agrarian labourer. For the latter view, it may be possible to determine the economic potential of a higher level of utility. However, quantifying the level of utility achieved for the former is quite problematic.

The ethical dilemma facing the decision-maker is based on the value judgment of whether it is better to adopt a technology that reduces or retains non-skilled agrarian labour. Measuring quantifiable utility from an innovation improves the probability of making the most appropriate decision. Basing decision-making on ethical norms that are difficult to quantify objectively can create a scenario whereby public policy is based on the values held by the few.

Conclusion

Ethics are more about balancing demands among individuals than about securing entitlements. Innovations are by their very nature economically and socially disruptive. While those propounding the use of SECs in decision-making assert they are concerned about the disenfranchised (the uneducated, low skilled and poor), in many cases they are simply acting as rent-seekers. Their proclivity to over-estimate potential harms and under-estimate benefits biases the outcome of the socio-economic assessment.

Policy Brief 3

Improving Regulatory Oversight and Governance Management

Event

Many breakthrough agricultural technologies and bioproducts flowing from publicly supported research stall because of regulatory bottlenecks. Complicated, complex, networked regulatory systems create gaps, overlaps and inconsistencies. For Canadians to get their money's worth from investment in science R&D, new products need to be evaluated and accepted or rejected as quickly and efficiently as possible.

Significance

Given the array of crops-based innovations that have been and are planned to flow from research, there are going to be challenges in regulating these new technologies and applications (Graff, Zilberman, and Bennet 2009).

Analysis

The advent of knowledge-based economies has raised new concerns about who is in charge of governing the economy. In the knowledge economy, the key asset is the ability to innovate – the facility to develop, adopt and adapt new ideas, products, and organizational structures by combining existing ideas, products and structures in new ways. Ultimately, this process involves the identification, assembly and use of disparate types of information and knowledge through a wide range of social governing systems. Finding the right tools to effectively govern in this environment is difficult because these knowledge networks are plurifom (diverse), self-referential, asymmetrically interdependent and dynamic, and consequently do not share the same goals, operating styles, skills, worldviews, incentives and priorities (Salamon and Elliot 2002).

The complex nature of transformative change leads to much more extensive innovation processes, which involve a much wider array of actors. Translating an invention into a socially embedded innovation involves a complex web of principals, agents, promoters and regulators on the supply side and intermediaries, marketers and consumers on the demand side. Constructing new markets for new products or services is seldom straightforward or simple. Transformative changes thus mobilize a much wider range of actors, many who have never before expressed concerns or interest in change (Phillips 2007).

Traditionally, theories have focused on explaining the causes and consequences of choosing particular policy tools to tackle relatively simple policy problems. In response to the increasing complexity of a number of policy fields, recent theoretical developments have tried to characterize entire policy regimes comprising multiple policy goals and a mix of policy tools designed to achieve these goals (Howlett and Raynor 2006). Within a policy sector, policy regimes may have different goals with respect to different issues: policy regimes can be classified as promotional, permissive, precautionary or preventive (Paarlberg 2000) or distinguished between restrictive and permissive policy designs (Montpetit, Rothmayr and Varone 2005). Moreover, while transformative change will mobilize a wider range of actors in a more complex set of relationships, the fundamental distinction between the policy network engaged in policy design and the larger policy community impacted by the choice of goals and tools is likely to remain valid in spite of the different terms used to capture the distinction. If so, the theoretical distinction between the appropriate tools needed to *coordinate* the activities of the policy network and those needed to *communicate* between the network and the larger policy community and attentive publics will continue to apply.

Conclusion

New models, methods and metrics of regulatory assessment and development are needed to address the rising complexity of regulatory processes designed to handle the risks of transformative agri-food and bioproduct innovation.

Policy Brief 4

Type I and Type II Errors in Decision Systems

Event

While decision systems are inevitably prone to error, the nature of the errors in a system varies as the structure of the system changes. Systems can be simple, complicated or complex, which respectively face greater challenges in making optimal decisions.

Significance

The terminology of Type I and Type II errors is borrowed from statistical decision theory and applied to decision-making systems, including risk regulatory processes. A Type I error is made when regulators approve an unsafe product. A Type II error occurs when regulators reject a safe product. Both types of errors have far reaching consequences, as Type I errors may harm citizens or consumers and Type II errors often act to stifle further innovation.

In *simple systems*, managing errors is a relatively straightforward process, as the cause, effect and remedy are often readily identifiable. In *complicated systems*, dense, often simultaneous and sometimes redundant sets of simple decision-stages make managing errors more difficult. Generally, complicated systems minimize Type I errors, at the expense of more Type II errors. *Complex systems*, with multiple positive and negative feedback loops between different stages in a decision-system that can amplify or mute messages, are difficult to manage and navigate, frequently resulting in magnification of *both* Type I and Type II errors.

Organizations seeking to minimize errors face two distinct challenges. First, it is impossible to minimize both kinds of errors simultaneously. Regulators can decide to err on the side of caution and subject new products or technologies to comprehensive and aggressive testing or can undertake narrow, 'efficient' reviews. Each option minimizes only one type of error. The impossibility of reaching a single equilibrium is a policy problem – regulators must implicitly or explicitly choose which type of error to minimize and which one to tolerate. The result is either harm to public safety or impeded innovation. Second, most modern decision systems are inherently complicated, where the processes, issues and responses are generated within a largely closed system that adapts in real time as actors learn and respond based on experiences. Thus, decision systems cannot be viewed as a box of gears or hardwired algorithms – thinking, responsive individuals who have different frames, motivations, values and beliefs are at the heart of these systems.

Analysis

Analysing and measuring the scope of Type II errors in modern decision systems is difficult because they are largely counterfactual – the realm of 'what might have been.' Excessive delays or the withdrawal from the development process of what could have been a successful product or technology are often ignored or not counted because they do not affect current producers and consumers. Most quantitative work on the incidence of errors thus focuses on Type I errors.

Moreover, the analysis of Type I errors is not necessarily as clear as many might think. Decision systems often have great difficulty in determining the appropriate methods for assessing risks and in setting the acceptable tolerances for Type I errors – this is especially difficult for new technologies and products without obvious comparators and for new products that are near the margins of acceptability.

Conclusion

Regulatory decision systems require new models of risk analysis that take regulatory complexity, human behaviours and error management into account in order to minimize different types of errors in decision-making.

Policy Brief 5

Novelty as a Regulatory Trigger for New Bioproducts and Crops

Event

The regulation of plant varieties in Canada as plants with novel traits (PNTs) is unique. This divergence from the regulatory systems of Canada's trading partners creates challenges both for researchers seeking to introduce new crop varieties and for regulators attempting to harmonize regulations at the international level.

Significance

The application of biotechnology and the 'omic' sciences underlies Canadian research into new crop varieties. On average, between 1 and 30 new varieties in each key commercial species may be introduced every year to sustain competitive competitiveness. The PNT rules often makes the Canadian regulatory approval process more costly and time consuming than elsewhere, and impedes needed technological change.

Analysis

In Canada, new plant varieties are regulated as PNTs, based upon the presence of a newly expressed trait that is either entirely foreign to Canada or exists at significantly different levels in the Canadian environment and food system than elsewhere. Determination of novelty is entirely based upon the trait in question and does not consider the method of introduction. That is, it is based on 'products' not 'processes.' The regulatory system thus captures all forms of plant modification, including living modified organisms (LMOs) produced through direct genetic modification and non---LMOs developed via mutagenesis, mutation breeding and conventional breeding.

In the 1970s and 1980s the concept of novelty and risk assessment were introduced to set laboratory safety standards for rDNA technologies. The concept of novelty was found to be useful in multilateral policy development surrounding the approval of bio---products for environmental release. The FAO and the OECD subsequently reached consensus that risk assessment, as applied to biotechnology, should not be exclusively product---based, but should also include safety reviews triggered by the use of rDNA technology, integrated into existing food and agricultural safety protocols. Most national regulatory systems followed that lead and use the presence of rDNA as the trigger for regulatory review of new products. In Canada, the regulatory system institutionalized a 'novelty trigger' in its risk assessment procedures for PNTs, reflecting a strict product---based approach. All PNTs are subject to the same regulatory standards regardless of method of modification.

There is a debate about its merits. One perceived drawback to the novelty trigger is that the Canadian Food Inspection Agency's conditions for PNTs status are broad, requiring intensive regulatory evaluations of more and different products than in other agri-food producing and exporting countries. The PNT assessment process can take up to a decade to complete and requires substantial financial resources, which is perceived as a barrier to innovation by some firms and researchers and an obstacle to international regulatory harmonization. Regulatory scientists, in response, argue the novelty approach has long---term value. The PNT rule captures all new products regardless of the method of modification. Given what has been and promises to be substantial innovation in methods for developing new crops, rDNA---based systems may miss new risks.

Conclusion

While the novelty trigger for PNTs is viewed by many regulatory scientists as the safest regulatory method, its unique character presents challenges to investment and trade in bio--- products for Canada. One option some have suggested is to revise the PNT system to introduce a tiered regulatory approach that takes into account variable levels of risk arising from breeding methods and the regulatory schemes of major trading partners.

Policy Brief 6

The Integration of Ethics into Regulation of Biotechnology

Event

Policymakers are being asked to take "ethics" into account as an integral part of the regulatory regimes that apply to biotechnology innovations in agriculture. While some countries have formalized this recommendation (e.g. Norway), there is no consensus over what should be the role for ethics in the regulatory system (Lord and Letourneau 2010).

Significance

Many countries including Canada and the United States have regulatory regimes that include a science-based process to approve novel products. If "ethics" were to influence, or become an integral part of this process, it would change the conditions under which novel products are developed.

Analysis

Commentators have put forward various proposals for the integration of ethics. The proposals critique the existing regulatory model, which is embodied in science-based risk assessment. The proposals are presented as reforms of this dominant model. Some aim to recognize the role of ethics as an integral part of the actual approval process, while would like to see a wide-range of non-scientific issues (e.g. economic, trade etc.) included in the regulatory scope.

Science-based risk assessment has been shown to be inextricably linked with normative judgments, as opposed to purely empirical, or scientific, findings. The inseparability of ethics from risk assessment is often seen as inevitable. It only becomes problematic when the interdependence of scientific and ethical features cannot be examined for lack of transparency. Thus, one purpose of integrating ethics into regulation is to acknowledge the role that ethical norms and values already play in the approval process, by making sure that any inherent value judgment is dealt with explicitly and appropriately. According to its proponents, such formal recognition would promote transparent and open discussion on the acceptability of risk as well as critical review of all normative issues involved in science-based risk assessment.

Another objective of integrating ethics relates to the enforcement of ethical standards. Many commentators deplore the fact that science-based regulation is only concerned with a narrow set of technical or scientific issues. Therefore, they propose to alter the standard regulatory functions *i.e.* protection of human health and environment, in order to safeguard socially shared values and societal structures. Following this view, both science and ethics are deemed as necessary components of satisfactory regulatory regimes. However, since the existing science-based model is limited in its ability to anticipate and control the full range of "non-scientific" risks and issues such as socioeconomic impact, fairness and social justice, the current model should be amended to offer formal and explicit treatment of these concerns.

Conclusion

The integration of ethics aims to reform the regulation of novel products. To do so, it first seeks to raise transparency by causing to be explicit - and thus accountable - the value judgments that are inherent to science-based risk assessment. Second, it intends to broaden existing regulatory requirements by introducing ethical standards as approval criteria. Concrete means to achieve these objectives (e.g. ethics committee, risk assessment policy, prohibitions) remain to be developed before they can be presented as a credible alternative to current regulatory models. Ultimately, the integration of ethics proposes to crystallize different societal priorities or ideals and to grant more influence to "ethical experts" within the regulatory process. Despite being presented as a technical and organizational issue, the integration of ethics is therefore, first and foremost, a political issue.

Policy Brief 7

Socio-economic Considerations in Biotechnology Regulation

Event

The inclusion of socio-economic considerations (SECs) in the biosafety regulatory framework is a hotly contested topic leading up to COP/MOP 7 in Seoul, South Korea, in October 2014. In anticipation of this important international meeting of the Convention on Biological Diversity's Cartagena Protocol on Biosafety (CPB), a group of scholars in VALGEN collaborated with 15 international experts to provide a resource guide book on SEC methodologies, data requirements and international obligation commitments for those attending COP/MOP 7 and contemplating the inclusion of SECs into their domestic regulatory framework (Ludlow, Smyth and Falck-Zepeda 2014).

Significance

Article 26 of the CPB provides countries with the option of such inclusion in their decision-making regarding the conservation and sustainable use of biodiversity, subject to a country's international obligations. This moves risk assessment for regulatory decision-making away from science-based models to one that increasingly incorporates elements of the precautionary principle.

Analysis

While there is a wide-ranging debate pertaining to the inclusion of SECs in domestic biosafety regulatory frameworks, this assessment reveals that there have been minimal substantial contributions to the debate or the literature. The inclusion of SEC assessments, especially in those systems where there is very little clarity in terms of methods and decision-making rules, can introduce the potential of increasing regulatory lags due to delays, and certainly will increase the cost of conducting such assessments. In both cases, there are social costs that may even negatively affect the deployment of technologies that address crops and traits of interest to developing countries. Irrespective of how countries deal with having more guidance in terms of methods, they need to have clarity in terms of how to use SECs in their decision-making to guide efficient deployment and safe use of effective technologies. A liberal interpretation of Article 26.1 of the CPB, as has been suggested by numerous non-governmental organizations, would jeopardize the sovereign right of nations to comply with their existing international obligations.

The book is a balanced resource guide that includes expert analysis of 15 different SEC factors: benefits to society, consumer choice, environmental impacts, ethics and equity, food security and safety, health impacts, biodiversity impacts, traditional knowledge, intellectual property, labour impacts, market access and trade, national trade interests, producer choice, culture and religion and animal welfare. So far, the experience of the few nations that have included SECs into their biosafety regulatory frameworks, some formally, others informally, generally reveals a considerable lack of understanding about the process.

The crux of the issue is ultimately one of whether or not the increased cost of regulation actually results in better or safer products for society or products that are simply more expensive.

Conclusion

All other things being equal, the market should be allowed to decide if safe and efficacious products are appropriate or not. The addition of SECs has the potential to needlessly delay the commercialization of technologies without contributing to risk mitigation. The reality is that for many SECs there are no proven methodologies available, a lack of baseline data and a lack of resources to gather and assess the data in many developing nations. This jeopardizes not only private sector development projects but also products commercialized from public sector research programs explicitly targeting to improve livelihoods of domestic landholders.

Policy Brief 8

Improving Regulatory and Governance Oversight and Management

Event

Cutbacks to government funded agricultural R&D have led to the development of public-private partnerships (P3s) as a replacement source of R&D funding. These cutbacks have also created the "orphan crop", a crop that is neglected by both the public and private sectors. Pulses classify as an orphan crop. Internationally, nationally and locally a number of highly individualized P3s have developed to finance and manage the pulse crop R&D process. The development and expansion of the use of P3s have facilitated the development of R&D networks centered on these P3s.

Significance

Innovation is increasingly viewed as a key determinant of economic growth. Recent research suggests that innovation occurs at the global level and the key to economic growth is developing an institutional framework that connects local capabilities to global knowledge flows to create a value-added process. Specifically, codified knowledge consisting of intellectual property rights and specialized proprietary technologies exist in global flows that are available to any entity with the requisite institutional characteristics to connect to the innumerable global network of knowledge pipelines, while tacit knowledge is "interaction and exchange dependent" and exists locally.

Analysis

There are 248 independent actors in the global pulse R&D system. The global system is constructed from three regional R&D networks. The European Union (EU) system consists of 134 actors, and is centered on an intergovernmental P3, Grains Legume Integrative Project (GLIP). The Export System has 66 actors and consists of Australia, Canada, the US and a small number of international actors and is constructed on a small number of producer governed and financed R&D P3s, the Grains Research and Development Corporation (GRDC) and the Center for Legumes in a Mediterranean Area (CLIMA) of Australia and the Saskatchewan Pulse Growers (SPG) of Canada. The developing world system is centered on two developmental and capacity building P3s, the International Center for Agricultural Research in Dry Areas (ICARDA) and the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), of the Consultative Group on International Agricultural Research.

Each of the three component pulse networks and the global network are characterized by the critical role P3s occupy regarding network cohesion and composition. Removing just four P3s from the Global System, GLIP, ICARDA and ICRISAT and the SPG, reduces the network coherence from 25% to 98%, depending on the measure, and leaves 60 components including a new network of 159 actors, 50 isolates and leaves Canada isolated from the global system with an independent national network of 21 actors. The same pattern exists within the three component networks as removing one to three P3s dramatically reduces the size and composition of each of the R&D networks.

Of interest is the role of policy in determining national network redundancy. Specifically, Australia's pulse R&D networks owe their origins to the development of two national R&D programs that have spawned a significant number of well-connected and internationalized P3s, while in Canada local statutes have led to the development of a single highly connected and internationalized P3. At the global and component level the removal of a small number of P3s results in the isolation of the entire Canadian network of 21 actors, while the Australian system continues to be tightly interwoven with the reconfigured systems.

Conclusion

P3s present governments with a new policy option (the new institutional arrangement) and a new practical option (the new organizational structure) for facilitating R&D dependent economic growth in an environment where innovation is dependent upon connecting to global flows of knowledge. Each pulse R&D network and sub-network is characterized by the location, number of and the function of the P3s in use.

Policy Brief 9

Safety and Non-Safety Issues in the Evaluation of GM Wheat

Event

In December 2002, Monsanto submitted an application to the Canadian Food Inspection Agency (CFIA) for the unconfined release of its herbicide tolerant wheat (Roundup Ready® wheat). As the agency was conducting an environmental risk assessment, several concerns beyond safety issues were brought by different actors. In the face of growing controversy, Monsanto withdrew its application in May 2004.

Significance

The analysis of the evaluation process steered by the CFIA in the case of GM wheat sheds light on the governance of biotechnology in Canada. Beyond the environmental criteria that were used to assess this technology, the climate of controversy raised by the presence of socioeconomic considerations appears to have affected the outcome of GM wheat. Future applications may face similar circumstances.

Analysis

Finding its origin in international principles and norms, the regulation of biotechnology in Canada relies solely on safety issues that are based on scientific evidence. The *Seeds Regulations* and the *Directive 94-08(*CFIA 1994*)* apply to the unconfined release of plants with novel traits (PNTs). In conformity with these documents, the CFIA conducts an environmental risk assessment according to five science-based criteria: 1) the potential of the PNT to become a weed of agriculture or be invasive of natural habitats; 2) the potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive; 3) the potential for the PNT to become a plant pest; 4) the potential impact of the PNT or its gene products on non-target species, including humans; and 5) the potential impact on biodiversity. The evaluation process, however, is not circumscribed by any specific procedure. In cases of controversial applications or uncertain science, this flexibility leaves room for regulators to request additional scientific data without reaching a formal decision. Those who want to bring non-safety concerns into the regulatory process at times seek to use delays to influence the outcomes.

In the case of GM wheat, the absence of a mechanism to handle socioeconomic issues led Monsanto, interest groups and academics to engage in an informal debate centered on potential loss of export market share. Parliament standing committees echoed the non-safety issues that were raised by these actors. CFIA's regulators thus faced a highly-politicized environment. Amidst the controversy, in September 2003, the agency sent a letter to Monsanto asking for more data regarding the potential impacts of this seed in reduced-tillage cropping systems. While previous unconfined releases of other herbicide tolerant seeds had been authorized in Canada, one possible interpretation is that in the absence of a mechanism to handle socioeconomic issues, regulators were faced with a distorted regulatory landscape and thus refrained from making a formal decision.

Conclusion

The evaluation of the unconfined release of GM wheat formally relied on safety concerns. Nevertheless, some have interpreted that the outcome—the withdrawal of the application—was affected by non-safety issues that emerged through informal mechanisms, in parallel with the formal evaluation process.

Policy Brief 10

Public-Private Partnerships and Canada's Agricultural Sector

Event

Two recent events have illuminated the requirement for federal policies and initiatives to support the use of public-private partnerships (P3s) in agriculture. First, in early 2012, several wheat summits were held in Western Canada to discuss the need to develop and implement P3s to finance, manage, and commercialize the development of new wheat varieties and new breeding technologies to support Canada's wheat sector. Second, the federal and provincial ministries of agriculture are currently negotiating the renewal of the Growing Forward policy—what is expected to be called Growing Forward 2 and launch in March 2013. This revised policy has identified several strategic priorities that specify an expansion in use of P3s to develop deeper linkages between producers, universities, government research centers, and the private sector to enhance Canadian international competiveness and improve technology transfer and commercialization capabilities (Growing Forward 2. 2012).

Significance

Several factors are driving the need for the greater use of P3s in Canada. First, investments in wheat research and development (R&D) are lagging investments in pulse and canola R&D, leading to the marginalization of wheat as a viable crop in Western Canada because yields in wheat are not growing fast enough (Western Producer 2012/02). Second, Canada's share of the global export market is being challenged by Australia, which is outspending Canada by a 4:1 ($80 million to $20 million) ratio in wheat R&D (Western Producer 2012/01). Third, agricultural productivity, as measured by the value added per employed person, is declining compared to other sectors in the Canadian economy, indicating a need for greater coordination of agricultural R&D activities (Phillips 2011).

Analysis

Canadian producers in both the pulse and canola sectors developed the first producer-governed and -financed P3s in agriculture. Previous research has demonstrated the critical role of producer-financed and -governed P3s in the expansion of both the canola and pulse sectors in Western Canada from marginal crops in the 1960s and 1970s to the current multi-billion-dollar export commodities. Despite this experience, agricultural experts in Canada have acknowledged building P3s is an extremely arduous process. Developing and implementing P3s is a hands-on, bootstrap process, as each P3 is unique in structure and composition. Therefore, P3s represent more of an art, rather than a rational- and procedural-oriented process. Most P3s rely on key individuals responding to intractable problems for their start, without benefitting from the lessons of the formation of previous P3s.

Unlike Canada, Australia has a national P3 strategy in agriculture that has been in place for over 15 years. A national P3 strategy led, by an organization such as Agriculture and Agri-Food Canada (AAFC) would address the current institutional vacuum and enable wheat and other crop sectors to absorb the lessons of previous P3s. In the continued absence of a national P3 strategy and policy, each P3 must engage in an expensive and time-consuming process of building relationships, developing financing and levy programs, and negotiating operational procedures with partners of dissimilar institutional design in multiple jurisdictions.

Conclusion

As the Growing Forward 2 policy frameworks and the wheat summits suggest, it is time to develop policies and initiatives to expand the use of P3s to enhance Canada's agricultural economy. The implementation of a national coordinating mechanism to guide the development of P3s would greatly facilitate this process.

Policy Brief 11

Public-Private-Producer Partnerships in Canada

Event

A recent case study analysis conducted on seven Canadian agricultural public-private-producer partnerships (P4s), during the fourth quarter of 2012, financed by Agriculture and Agri-Food Canada (AAFC), illuminated numerous deficiencies in the theory, analysis and policy review of these new business models that occupy critical roles in Canada's research and development (R&D) system. The objective of this study is to provide policy-makers with the tools and knowledge to support and evaluate these emerging science and technology-transfer organizations.

Significance

As P4s are an emerging phenomenon, they defy easy explanation and direct analysis. A literature review demonstrated that over 50% of the peer-reviewed articles on P4s were published in the last five years, suggesting the analysis is also an emerging field. Therefore, the theory, analysis and policy review of P4s is under-developed and presents challenges to the researcher and policy makers. Most the previous research into P4s has been descriptive and normative; therefore, no benchmarks exist for comparative analysis among P4s or between P4s.

Analysis

P4s in the analysis exhibit highly differentiated business models. They range in size from seven employees to 70 employees and have annual expenditures of C$1.2 million to $15 million. They tend to be commodity-specific; all P4s examined involve producer associations. Producer levies contribute between zero and $11 million. Not all producer groups are capable of funding R&D. P4s have long gestational periods where they remain dependent on public funds. Generally, it takes 15 years to develop independent revenue streams. A small group of insiders responding to intractable problems formed all the P4s in this report. P4s represent a new paradigm for financing and commercializing science that is collaborative by nature and structured to operate in a networked environment, often globally. Yet, the success of these new P4s is endangered because they must co-exist with the current system and compete for the same limited resources. Successful P4s must specialize by filling a niche that cannot be supplied by other sectors using existing models.

Conclusion

There are seven key findings. First, the size of a P4 is dependent on its purpose. Federal and provincial programming will need to be as flexible as possible to enable a diverse set of institutions to emerge. Second, as the formation of P4s is dependent on a small group of insiders who motivate and sustain the P4, new models of incenting leaders to emerge may be possible. AAFC policy makers may need to revisit how they incent groups to form. Third, long-term, consistent federal financial and strategic support is vital. Real and sustained interest by senior officials seals the bond in P4s. AAFC should investigate ways to sustain the link between their senior officials who are assigned duties with P4s if possible. Fourth, P4s should not simply become government by third-party management. P4s are inherently expensive and high-risk ventures, and should therefore be directed to equally high risk-high activities, such as research, innovation and market development. In brief, if voice is not needed, then the P4 is not the best model. Fifth, federal policy should be to encourage Canadian P4s to globalize. None of Canada's P4s had any significant private commercial involvement or formal international partnering. Given the high export-dependence of Canada's agricultural sector, it would only make sense to extend these relationships into global systems. Sixth, P4s provide a structure and process for producer associations to fund and direct R&D and technology commercialization. P4s represent the new science–business model, where technology transfer is built into projects and programs, rather than a top-down system. The new model of technology transfer depends vitally on professional project management skills. Seventh, P4s are not simply a tool for governments to privatize or download responsibilities to producers. P4s represent a new paradigm in agricultural R&D and innovation based upon collaboration and interconnectedness.

Policy Brief 12

Biofuels: Economic and Regulatory Barriers

Event

Through its diverse range of economic, environmental and policy impacts, the use of biofuels has been routinely polarized by the mass media and in the academic literature. Although the body of literature investigating macro- and micro-economic biofuel effects is rapidly growing, a clear depiction of the Canadian biofuel industry was needed.

Significance

Our research identifies leading economic and regulatory barriers presently existing for the Canadian biofuel industry. A modified expert Delphi survey was used to collect qualitative information from Canadian public sector biofuel researchers and private sector industry managers.

Analysis

The expert Delphi methodology comprised two survey rounds, administered between June and December 2010. The targeted expert group of respondents to the survey consisted of a roughly equal number of participants from research scientists within Canadian academia and biofuel industry managers. The rationale for choosing the two groups of respondents was to identify any information gaps and to be able to contrast opinions between public and private sectors of the biofuel industry.

The first round of the survey was sent to 88 researchers and 91 managers. The response rate to the first round of the survey was 22 researchers (24.7%) and 15 managers (16.5%), for a total response rate of 37 persons (20.4%). This round of the survey comprised mainly open-ended questions that sought respondents' opinions on Canadian biofuel industry policy, economic and ethical issues.

The first-round objective was to collect views on current Canadian biofuel industry issues, with the second-round objective of ranking the first-round responses. Prior to the launch of the second round, participants' answers were carefully analyzed and in some instances, grouped into a single response according to similarities. The rationale for this grouping was to first, identify the level of consensus among experts and second, to send participants a reasonable number of answers to rank. The second round of the survey was only sent out to the 37 participants that submitted a response to the first survey. This response rate was 65% (24 completed surveys).

As the survey was carried out prior to new federal mandates coming into effect, one of the identified policy barriers was the lack of blend mandate harmonization between federal and provincial jurisdictions. The fragmented policy jurisdictions regarding blend mandates was creating uncertainties and frustration, more so for the biofuel firms than public researchers.

Other barriers were identified as the continued subsidization of ethanol production and the lack of research and development (R&D) funding for second-generation biofuel production. Numerous respondents expressed concerns about whether the Canadian ethanol industry can be profitable without government subsidies. The importance of realigning Canadian biofuel policy towards increased funding of second-generation biofuels was identified as the third most relevant policy barrier.

A final important policy issue requiring consideration is the sustainability of producing biofuels. All the preferred feedstock options identified by respondents are second-generation technologies, all of which require further R&D funding and all having an identified lag in technological capacity. If second generation biofuel technologies can be more sustainable, there is a strong interest in developing these technologies.

Conclusion

The top three barriers to the development of biofuels in Canada are: first, the absence of a co-ordinated and integrated federal-provincial policy framework; second, the technical capacity for scale-up of second generation biofuels is currently lagging; and third, the lack of integration between the increased use of biofuels and sustainability.

Policy Brief 13

Legal Incentives Applicable to Cellulosic Biofuels

Event

In April 2012, Royal Dutch Shell PLC and Iogen Corp. cancelled a project to build a commercial-scale plant of cellulosic ethanol in Manitoba, raising doubts on the future of producing biofuels from cellulosic or lignocellulosic conversion.

Significance

The commercial production of cellulosic biofuels is at a crossroads. The use of wastes and residues as feedstocks to produce these second-generation biofuels present several benefits. In addition to avoid competing demand for food, they appear to generate greater greenhouse gas (GHG) emissions saving than first generation biofuels. Yet, the conversion of cellulose to ethanol relies on high costs that can jeopardize the commercial viability of this technology. Legal incentives related to the production of cellulosic biofuels are therefore one of many avenues to support their integration in the economy.

Analysis

Comparing the legislation applicable to renewable fuels in Canada, in the European Union (EU) and in the United States (US) allows identifying three different types of legal incentives related to the production of cellulosic biofuels. First, states can choose to differentiate the contribution of products derived from cellulosic materials when establishing mandatory targets pertaining to the production of renewable fuels. Second, the legislation may provide limits to the contribution of biofuels made from food crops when calculating compliance to these targets. Third, in order to optimize environmental benefits, states can include GHG emissions saving thresholds and land-related criteria that must be met so that the biofuels be taken into account in the calculation of regulatory targets.

While Canada adopted required mandates for renewable fuels of 5% in gasoline and 2% in diesel fuel and heating oil, the regulations do not distinguish the contribution of fuels made from cellulosic materials to achieve these targets[1]. By contrast, the EU established a 2-to-1 ratio for cellulosic biofuels when calculating compliance with a mandatory target of 10% of renewable fuels in transport[2] and even proposed to limit the contribution of biofuels derived from cereals and various crops to 5%[3]. In the same vein, the US adopted volumes that specifically apply to cellulosic biofuels and indirectly established a cap of 15 billion gallons for biofuels produced from cornstarch after 2015[4]. Moreover, both the EU and the US added specific GHG emissions saving thresholds and requirements concerning the land from which the feedstocks are produced in order to have the products considered in the calculation of the mandates[5].

Conclusion

Although it is not the sole factor influencing the commercial viability of cellulosic biofuels, existing legislation renders a considerable divide between Canada and other important producers of ethanol in terms of legal incentives related to the production of cellulosic biofuels.

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[1] *Renewable Fuels Regulations*, SOR/2010-189, s. 5(1) and s. 5(2).
[2] *Directive 2003/30/EC of the European Parliament and of the Council of 8 May 2003 on the Promotion of the Use of Biofuels or other Renewable Fuels for Transport*, 2003, OJ, L123/42, art. 21(2).
[3] European Commission, Proposal for a Directive of the European Parliament and of the Council amending Directive 98/70/EC relating to the quality of petrol and diesel fuels and mending Directive 2009/28/EC on the promotion of the use of energy from renewable sources. *European Commission*, 2012, http://ec.europa.eu/clima/policies/transport/fuel/docs/com_2012_595_en.pdf (retrieved 8 May 2013), art. 2(2)(b) and art. 2(2)(c)(ii).
[4] *Cle an Air Act***,** 42 USC §7545, s. 211(o)(2).
[5] Directive 2003/30/EC, *supra* note 2, art. 17; *Clean Air Act***,** *supra* note 4, s. 211(o)(1).

Policy Brief 14

Mobilizing Scientific Expertise for Evidence-Informed Policy

Event

Both internationally and domestically, policy advocates are debating the role of 'sound science' in decision-making. The United Nations Environment Programme (UNEP) 2010-2013 medium-term strategy to enhance environmental governance targets to provide decision makers with access to ‘sound science’. Meanwhile, science-funding decisions in the 2012 and 2013 federal budgets in Canada generated significant debate about whether the revised system can deliver appropriate evidence for policymaking.

Significance

Accurate, objective and independent information is required to inform debate leading to the formation of government policy and action. It is not clear how governments access and assess scientific information in the policy development process, or if it is being accessed at the appropriate stage. Few governments have in-house scientific capacity to assemble and assess the information needed to inform policymaking. How (and if) policymakers acquire and use scientific information to inform decision-making is fundamental to governance in the 21st century.

Analysis

If an overriding goal of public policy is effective, efficient and democratic decision-making, then it follows that we need to access and appropriately use sound scientific and technological information. The tri-partite test of accountability, responsibility and transparency offers insights into the gaps we have in our current systems.

Nested decision-making systems involving complex subroutines blur accountability. In many instances, we have delegated authority to groups; this is always viewed with some suspicion by the average citizen, particularly with poorly defined procedures and decisions that are difficult to put into context. Clarity of process and method are vital to making these systems effective and democratic—codified, public, standard operating procedures are needed.

Responsibility in many systems is diffused to the point that there is no single place where "the buck stops". Political oversight has increased (with visible downgrading and sidelining of scientific expertise in decisions) while ministerial accountability has decreased. Some governments have experimented with chief scientific advisors or third-party advisory groups to fill the gap—but responsibility remains ill-defined and diffuse.

In absence of easy fixes to instill greater accountability and responsibility, transparency offers one possible remedy. Given that much of the information needed to assess the impact of new technologies and products is inextricably nested in private and collective domains, objective, arms-length measurement and analysis is challenging but vitally important. Hidden actors and secret value-systems can skew the uptake and use of information, which can distort decisions. It is unrealistic to hope for public-spirited engagement—opportunistic 'rent seeking' must be assumed. Nevertheless, full disclosure of the identity of all actors and provenance of all information can enhance transparency in decision-making—anything that cannot be tracked and independently audited fails the transparency test and should be excluded.

Conclusion

Governments *do* need access to the most up-to-date, objective, accurate scientific and technical information available when formulating policy. Scientific and technical information (and sources) must be transparent, complete (addressing both pros and cons), accurate and relevant. Science experts must be engaged and their expertise leveraged in a timely but transparent manner. Universities are a great source of scientific expertise as they are perceived to be independent, non-partisan and authoritative, but other private and collective sources are also important. Ultimately, governance systems must to be established to support optimal knowledge mobilization—, which will require a wider range of processes and structures that are open to audit to ensure accountability, transparency and integrity.

Policy Brief 15

Impacts on Biodiversity and Biosafety Regulatory Frameworks

Event

Article 26 of the Cartagena Protocol on Biosafety (CPB) allows member states to use socio-economic considerations related to conservation and sustainability to guide decisions on transboundary movements of living modified organisms.

Significance

There is considerable debate as to how to interpret Article 26. Some advocate for a very narrow interpretation while others argue that it should be widely interpreted (Ludlow *et* al. 2014). The scale of analysis is vital—the results of a broad ecosystem assessment and a narrow agricultural system assessment will vary considerably.

Analysis

Biodiversity at the global and ecosystem level is complicated. Many benefits of agri-food innovation are tangible and while valuations may vary, there are established methods and external yardsticks for judging any estimates. The bigger challenge is to try to assign value to subtler yet important aspects of biodiversity for which there are no markets or arms-length transactions that can provide transparent valuations.

Commercialization of any new crop variety will affect biodiversity in a range of ways, both negative and positive. There is growing concern in policy circles that genetically modified (GM) crops might adversely affect sensitive biodiverse regions or generate new system-wide effects due to overloading in agro-industrial landscapes. Conversely, others note that GM crops frequently act to curtail farmland expansion, thereby protecting sensitive biodiverse regions from agricultural encroachment. Three leading methods can be employed to assess impacts on biodiversity.

First, quantitative indicators can be developed to measure the outputs and outcomes of technical biodiversity over time and space—the focus is ecosystem services derived from biosystem function. Results from global, continental, national, regional or local level measurements can be used to aid in policy formation and decision-making. Numerous international organizations have combined efforts to create the Biodiversity Indicators Partnership, which strives to improve existing biodiversity information and to assist in the monitoring of trends.

Second, taxonomic diversity of ecosystems can be measured and used to judge the sustainability of ecological structures and functions. These metrics are designed to create quantitative indexes and related values to concepts like species richness or abundance. These indexes can be calculated at the global, national, regional or ecosystem level and even scaled to and made visible at the farm level to assist producers to manage biodiversity directly.

Third, economists and policy makers assign economic and non-pecuniary valuations to ecosystems services and the richness and abundance of biodiversity. Values can be either direct (products arising from an ecosystem such as timber, food or biomass) or indirect (e.g. nutrient retention or climate regulation). Options values—the premium between the immediate vs. delayed use of a resource—are often constructed, using a mix of revealed preferences (based on observation of similar choices), stated preferences (derived from surveys or experiments) and cost-based models (constructed using expert judgment). A key problem of each valuation method is that no one actually undertakes the measured behaviours—the use of proxies generates potential for operator error and bias.

Conclusion

Valuing ecosystem services and biodiversity can be critical to advancing policy formulation and decision-making. The lack of comprehensive data and variable methods leads to incomplete data and both over and underestimates of the value of the ecosystem effects of new agri-food technologies, leading to biased and inconsistent decisions that undercut effective policy and management of biodiversity.

Policy Brief 16

Measuring Complexity in Regulatory Frameworks

Event

The seemingly disconnected exchanges between actors within sub-components of hierarchical decision-making systems can contribute to unanticipated broader-system effects. Though decision-making systems are designed to produce outcomes in the most efficient and effective manner, there are many 'invisible' internal interactions that may influence outcomes. 'Complexity' helps to explain the interaction between structured rules and actors' informal behaviors in decision-making systems (Simon 1962) Kurtosis analysis is a useful analytic method to evaluate the effectiveness of regulatory frameworks, by measuring whether inputs filter through regulatory systems and emerge as outputs at a predicted, 'normal' rate.

Significance

Complexity draws attention to how interactions between actors may influence the behavior of a system over time and may alter outcomes. Kurtosis analysis determines the 'peakedness' of the probable distribution of cases in a population. It indicates whether a distribution of cases is more spread out from the mean or if the distribution has more than an expected number of cases crowding the mean. The test for kurtosis measures the distribution of outcomes emerging from the system to diagnose how inputs are filtered through decision-making. This metric can reveal instances where a variable such as a system output deviates from expected distributional patterns based on the distribution of inputs into the system; it can help to indicate that complexity may be influencing the performance of a decision-making system.

Analysis

By decomposing the system into its compositional parts (inputs, outputs), interactions within the system can be identified and analyzed. The kurtosis test indicates whether a distribution curve is normal, leptokurtic, or platykurtic. Leptokurtosis ('peaked' distributions) and platykurtosis ('flattened distributions') indicate the shape of the distribution and the extent of the deviation from the normal distribution curve. Kurtosis analysis can help to identify locations within the decision-making system that may be contributing to the generation of complexity. The mismatch between expected input and output patterns (or lack of a pattern in either inputs and outputs) may be an indication of complexity.

Kurtosis analysis can evaluate whether a decision-making system solves—or fails to solve—problems as opposed to focusing on how individual preferences or attributes are realized through policy action (Jones, and Baumgartner, 2005). It can also indicate where to look within a decision-making system to locate obstacles to effective management of decision-making processes. Operationalizing complexity with kurtosis analysis is particularly useful for understanding where communication within decision-making systems for bioproducts and crops may need adjustment and where perceptions of risk and uncertainty regarding future, unknown hazards may be influencing how policy is designed and the nature of engagement between sub-system components like government agencies or departments (Clark and Phillips). Documenting complexity can help to identify types of interactions that contribute to inefficient outcomes to improve the distribution of information among sub-system components, which may contribute to improved performance of the system.

Conclusion

Kurtosis analysis and complexity have been applied to various decision-making settings where multiple elements such as sub-system components and rules interact in ways that are not always clearly understood. They are useful methods to understand better seemingly invisible exchanges that may contribute to inefficient outcomes exiting decision-making systems.

Theme 4
Democratic Engagement

Concerns about governance in the knowledge economy – especially concerns about who is responsible for assessing and managing the impacts of transformative technologies – are rapidly reflected in public mistrust and allegations that innovation in applied genomics has escaped the conventional mechanisms of accountability in a democratic society. For all their other advantages in terms of improving the efficiency of outputs, networks based on the exchange of information, the value of which is determined by network members themselves, raise serious problems of input legitimacy. In particular, the hard currency of scientific knowledge in innovation networks tends to exclude participation by non-scientific actors.

Network actors have responded in a variety of ways, many of which focus on efforts to improve the flow of accessible information from the network to potential audiences such as policy-makers, regulatory decision-makers, citizens and consumers. These efforts suffer from the drawback that the audience is constructed as passive recipients of messages designed to address "misunderstandings" about genomics research. The traditional methods of survey research and intensive small group studies are well developed and used to understand the characteristics of the audiences in order to craft the message. The primary research problem, which remains important, is to understand how an information source becomes known and trusted and its audience is transformed from a passive recipient to active seekers and users of the information on offer.

This conceptualization of the problem, however, contains two seriously under-theorized elements. First, 'the public' is presented as an undifferentiated and passive mass, eager to 're-engage' with scientists and regulatory institutions. Second, the policy problem is often framed as one of reversing a decline in public confidence through better communication. Neither is an appropriate way of framing the problem. The public is highly differentiated, and rather than re-engaging, many publics wish to move the whole debate to new venues with entirely different framings. Understanding and exploring those realities takes new models and methods.

Addressing the issue means taking seriously the possibility of alternative ways of framing policy-relevant questions other than how to provide reassurance. Our GE³LS team tackled this through a program of theoretical development and empirical case studies of democratic re-engagement in the era of network governance.

Critical Essay 1

Maintaining scientific integrity in Canadian regulatory protocols: Using strategic thinking to facilitate innovation and enhance engagement and transparency

By Lisa F. Clark, Michele Mastroeni and Cami Ryan

The Context

One of the most important components for fostering the growth of technological innovation is an effective and efficient regulatory system with the capacity to evaluate technologies based on safety, usefulness and commercial potential. In Kline and Rosenberg's (1986) seminal mapping of the innovation process, they note that innovation is messy, uncertain and complex. The "process of innovation must be viewed as a series of changes in a complete system not only of hardware, but also of market environment, production facilities and knowledge, and the social contexts of the innovation organization" (Kline and Rosenberg 1986: 1). Uncertainty is an inherent component of complex systems, and it comes from the technological side as well as the socio-economic dimensions (Cooke 2011; Metcalfe 1995). If one takes the view that innovation occurs in a system as Kline and Rosenberg describe, then the regulatory structure adds to its complexity by adding a component to the innovation process where the technology is tested and where stakeholders can alter its composition or reject it altogether. An objective lens on the regulatory process requires "a recognition of its complexities and dynamic fluctuations" and that "a clear, resolute path in any phase of regulation" is not realizable or achievable (Massel 1961: 202). A focus strictly on what is procedural only serves to distract from complicated policy issues associated with technology. It also negates the importance of the politics of incorporating innovative technologies into existing systems and the role values play in policy controversies surrounding innovation. While accepting that a functioning regulatory structure is complex means that it may be more difficult to implement, accepting its complexity and considering the politics of innovation, control of information (intellectual property) and other resources in the policy process also means that it could be more transparent, fair and legitimate.

The current regulatory system for approving and commercializing technologies adheres to the principle that decisions must be based on scientific evidence generated through reproducible and repeatable sets of rules and standard operating procedures (Doern and Phillips 2012). Using rigorous scientific methods to calculate the probability of harm upon which to base risk assessment and management arguably produces optimal outcomes free of value-laden conceptions of risk. Increasingly within deliberative democracies, however, this assumption is being challenged as varying perspectives drawing on different evidence-bases are considered in decision-making. The uncertainty regarding unknown, future environmental risks and potential socio-economic impacts associated with the commercialization of innovative technologies is often cited by certain stakeholder groups as grounds to contest and challenge the evaluative 'science-based model' that establishes safe use of the technology. An exclusively evidence-based approach is also argued to erode the normative basis of policy-making and effectively undermines the capacity to developing appropriate policy aligned with broader social values (Sanderson 2009). Consideration of the way in which perceptions of uncertainty function within policy spaces designated to govern technology and risk is vital to understanding the role of politics in the design of the regulatory system, and how innovations are regulated and managed within the system.

In this brief, we take a systems approach to exploring how Canadian regulation protocols for Genetically Modified (GM) crops and foods can maintain scientific integrity while encouraging effective engagement by stakeholder groups. We discuss the challenges faced by the regulatory system for GM crops and foods in the context of broader science and technology policy initiatives in Canada. The suggestions in this brief are not a one-size-fits-all solution to the challenges of engagement and transparency in the governance of GM crops and foods. Instead, the policy options presented will hopefully lead to a set of explicit first principles upon which the majority of stakeholders can agree to use as a foundation for a regulatory system that provides high levels of safety, encourages beneficial innovation and approves products and/or processes that are socially acceptable. Policy options include the incorporation of science and technology councils into current decision-making platforms, integrating mechanisms for deliberation into regulatory protocols, and strategies to mobilize scientific

knowledge. All options encourage stakeholders to rethink how uncertainty is perceived within regulatory environments in order to foster transparency in decision-making, strengthen constructive engagement and dialogue amongst stakeholders, while applying consistent and reliable standards of evidence. The goal is to facilitate the delivery of beneficial innovations while maintaining high levels of food safety.

The Issue

Within deliberative democracies like Canada, patterns of political engagement are largely dependent upon the policy issue at hand. They often but not always draw from established 'best practices' and standards developed in other jurisdictions (e.g. the US) that function based on similar decision-making structures for the regulation and domestic use of innovative technologies. In policy issues concerning the approval and commercialization of a technology that has no prior use beyond the lab, scientific expertise plays a heightened role in identifying hazards of interaction between the technology's usage and its detectable effects on human, animal and environmental health and safety. Stakeholders, including members of the scientific community, are consulted to determine what constitutes a tolerable level of risk to the safety of humans and the environment, what is defined as a 'hazard' to maintaining health and safety, and what types of evidence should be included in regulatory decision-making to determine what is 'safe'. Decisions regarding whether an innovative technology is safe enough, and the role it will play within broader society, are often dominated by discussions regarding the appropriateness of evidence. This is especially the case when dealing with 'contentious' technologies commonly associated with future, unknown risks like GM crops (Goncalves 2004; Beck 1992).

In situations of complexity, knowledge is always evolving and it is not possible to foresight or predict how it will evolve, shape, or be shaped by socio-technical factors. As a result, whenever a policy mix is introduced into an economy, the likelihood of it meeting all of the immediate needs of a situation tends to be low, particularly if the economic system is undergoing change (Uyarra 2010). This concern is especially true for regulatory systems; they may not adequately meet all needs, especially considering the shifting scientific benchmarks of the products regulated and the tools used to assess such products. Uncertainty of future risk cannot be eliminated but it may be reduced through appropriate information gathering and analysis that is translated into careful policy design. Uncertainty can also be reduced by periodically revisiting risk assessments to determine if any new risks have emerged over time as knowledge of how a technology behaves in relation to other technologies, human health or the environment is accumulated.

What is fundamental to understanding why and how 'science-based' systems of regulatory approval for GM crops and foods do not always perform as expected has a lot to do with how perceptions of uncertainty surrounding risk intersect with the way 'issues' (such as the safety of a technology and its potential hazards to human health and the environment), values and knowledge are packaged in political debates over regulation (Clark 2013). Gold (2009) distinguishes multiple pathways through which information may be utilized in policymaking. These pathways emphasize different strategies, stakeholders and motivations, which may help or hinder movement along the pathway (Ryan *et* al. 2013). Scientific approaches can still differ depending on what stakeholders are involved in shaping the regulatory system. Understanding how stakeholders perceive technology-related uncertainties from their particular vantage point is crucial to facilitating productive stakeholder engagement.

Canada is not immune from controversies over the approval and use of Genetically Modified Organisms (GMOs) in its food system. In response to growing public concerns over uncertainties related to GMOs' role in the food system and their potential impacts on human and environmental health, the Canadian government launched the Canadian Biotechnology Strategy (CBS) taskforce in 1998. The findings of the taskforce were published in a document entitled *Biotechnology Transforming Society – Report on Biotechnology 1998-2003*. With a focus on engagement and public consultation, the taskforce reported that Canadians wanted "an independent advisory body that would operate at arm's length from government, to provide independent and comprehensive advice on crucial policy surrounding biotechnology" (Industry Canada 2014a). The formal response to the concerns noted in the report was the creation of the Canadian Biotechnology Advisory Committee (CBAC). The intent of CBAC was to provide independent advice to the Biotechnology Ministerial Coordinating Committee (BMCC) on biotechnology topics that cut across the mandates of various federal

departments and agencies, and act as an ongoing forum for Canadians to voice their views and participate on relevant social and ethical issues related to biotechnology in the Canadian food system. Yet, as CBAC proceeded with its activities, several key problems were identified as barriers to its effectiveness: 1) lack of engagement on the part of federal officials; 2) budget constraints limited public consultation events and potential impacts; 3) communication of information to and from Canadians were primarily limited to its website and public documents / reports, and limited public opinion polling; and 4) there were questions regarding the committee's composition that indicated that the ethical and societal aspects of biotechnology may not have been fully represented (Industry Canada 2005: v-vi).

In another effort to respond to growing public concern over the use and commercialization of GM crops and foods, the Royal Society of Canada's Expert Panel Report issued in 2001 requested that transparency between government decision-making and the public be improved. In response to the Royal Society's requests, several new pieces of legislation were added to existing regulatory frameworks for GM crops and foods. These efforts include the public release of Decision Documents, which provide interested parties with information about the biological traits of the GM crop or food, how the plant is used and its potential to comingle with other species. Decision Documents are written and issued by the original applicants that are primarily private biotech firms, but also public research and development institutions seeking approval for their product to be sold as food or feed in Canada (Hibbert and Clark 2014). The Notices of Submission feature of the approval system in Canada allows the government to respond to environmental petitions presented to the Auditor General by a member of the public (CFIA 2014). These strides towards addressing transparency have provided the public with access to information about GM crops and foods in the Canadian food system, but the formal decision-making structures regarding the approvals of GM crops and foods have not been fundamentally altered. It continues to be defined as a 'science-based' system of management and approval with decision-making responsibilities horizontally distributed across governmental departments and agencies (Canadian Food Inspection Agency and Health Canada).

Policy Background

Traditionally, the safety of innovative technologies like GM crops have been evaluated based on the well-established Risk Analysis Framework (RAF). The RAF is based on manuals published by the US National Research Council on how to best assess and manage products or processes that carry a degree of risk, and how to best communicate those risks to the public (NRC 1983; 1996). Yet, innovative technologies present some challenges to this method of safety assessment. As noted by Phillips (2009), the RAF frames all technologies as equally hazardous in the same way, which can contribute to negative perceptions of some technologies as similarly 'risky' to others that have gone through the RAF despite scientific evidence proving otherwise. The framework also faces some difficulty because of its lack of flexibility to accommodate the possibility that as new information emerges the definition of the problem in need of solving may change. Though the most recent RAF manual stresses the importance of deliberation amongst stakeholders to determine how uncertainties can be collectively addressed within the risk assessment processes, this has not fully dealt with some concerns stakeholders have over the transparency of how information is used in the approvals process (Wolt and Peterson, 2000). With varying degrees of success, the RAF continues to be the primary approach guiding the design and function of science-based regulatory systems for innovative technologies in Canada and the US.

One of the core principles of the approval system for GM crops and foods is that a 'novel' plant[6] must be put through a rigorous set of risk-assessment and biosafety procedures before it is declared 'safe' for unconfined environmental release and commercialization (see Doern and Phillips 2012; VALGEN 2010). Although Canada's Plants with Novel Traits (PNT) regulatory system for innovative crop-based technologies is generally deemed efficient in minimizing risks (Smyth and McHughen 2013), challenges remain to this approach.

Challenges to effective and efficient policy to manage the use of GM crops and foods in the food system are closely linked to broader issues facing science and innovation policy in Canada, as described above regarding

[6] Plants with Novel Traits (PNTs) refers to all plants that undergo some form of modification (e.g., mutagenesis, cell fusion, and traditional breeding) that have no previous use in the Canadian environment.

knowledge flows and transparency of decision-making. Some steps were taken to try to address these issues, such as the government science and technology strategy in 1996. One of the goals of the strategy, released by the Government of Canada in March 1996, was to ensure that the government was well positioned to respond to challenges through availability of scientific advice (Government of Canada 1996). Within the document, a new Council of Science and Technology Advisors (CSTA) was created, which issued several reports between the late 1990s and the mid-2000s. The reports and activities of the CSTA were intended to provide external expert advice on internal federal government science and technology issues that require strategic attention with the hope that, "more effective use of science advice will reduce science-related crises of public confidence… issues facing governments are increasingly complex and require decisions that have profound impacts on societies and economies" (CSTA 1999: 1-3).

The CSTA devised a list of recommended actions to be taken by the Government of Canada, including consulting a wide-range of sources with diversity in schools of thought on science policy matters and to strive for openness and transparency in government decisions concerning policy change. However, a change in the Canadian government in 2006 led to the absorption of the CSTA into the newly formed Science, Technology and Innovation Council (STIC) in 2007. STIC is an independent advisory body mandated by the Government of Canada to provide advice on science, technology and innovation policy issues. The content of the correspondence between the two bodies remains confidential. It is unclear at this point, whether the STIC has operationalized the objectives outlined by the CSTA but the CSTA did establish guidelines regarding the direction science and innovation policy must take in order to maximize its commercial potential and be responsive to broader questions regarding the appropriate use and acceptability of particular innovations in society.

In view of the stated government goals issued in the 1996 strategy and CSTA recommendations, the STIC shift towards confidential correspondence is a step back from transparency. The current federal government has been criticized for allegedly "muzzling scientists" for political reasons (Gibbs *et* al. 2012; Fitzpatrick 2012). An investigation by the Information Commissioner suggests that the level of trust between the government and Canada's research community has been damaged. A public consultation process, affiliated with the federal initiative *Seizing Canada's Moment*, ended in early February of 2014 (Industry Canada 2014b). The process, however, has been criticized for its lack of transparency and accountability (Stewart 2014).

Policy Options

Besides transparency, accountability means that governance structures for GM crops and foods need to be inclusive and to consider socio-economic concerns, as well as questions regarding the management of, and contingency plans for, addressing uncertainty in future outcomes in the decision-making process. These are essential components to a platform of responsible governance focused on developing policy outcomes that are 'acceptable' to stakeholders as opposed to a universally 'agreed' upon option, which is typically difficult to attain in complex system with multiple stakeholders. Emphasizing strategies to enhance transparency and engagement to help move towards developing acceptable outcomes that all stakeholders can support is the central tenet of this approach. Faults in the governance structure and changing levels of transparency mean that stakeholders lose a source of information that can help them cope with uncertainty. As a result, the legitimacy of the system may be negatively impacted.

The Strategic Thinking Model (STM) helps to frame policy options. The value of the STM for the governance of science and technology policy frameworks is its prioritization of future uncertainties as valid considerations in decision-making, as well as considering both benefits and risks in policy design (Partidario 2012; Noble 2009; Gunn and Noble, 2009). The STM includes the consideration of how normative factors such as values and social acceptability of risk and uncertainty factor into policy development and application. It is also premised on evaluating the information between systems of regulatory decision-making, economic organization and public engagement. By using the STM lens to focus on these aspects of innovation and technology, we are able to discuss ways of enhancing transparency and facilitate knowledge flows among stakeholders in the agricultural biotechnology policy arena. We draw from current efforts to effectively govern broader science and technology sectors, policy options that can be applied to GM crops and foods, and policies

specific to the agricultural biotechnology sector. Both levels of policy have several overlapping goals and challenges, and lessons can be drawn from both levels of policymaking.

Option 1: Science and Technology Advisory Councils

Several countries (USA, UK, and Australia) have formalized informational exchanges between regulators and scientists through the creation of science and technology advisory councils. Structured, scientific advisory councils demonstrate the value of a systems-thinking approach to evidence-based policy making. The formal linkages between regulators and scientists help to build networks and encourage information flows with the goal of establishing a robust tradition of informed decision-making. On October 8, 2003, the Jefferson Science Fellows (JSF) program at the US Department of State was launched. The purpose behind its creation was the need for government to have "accurate, timely understanding of rapidly advancing science, technology and engineering issues" (JSF 2014). The JSF program is administered by the National Academies and supported through a partnership between the US academic community, professional scientific societies, the US Department of State and the US Agency for International Development (USAID). The program is open to tenured, or similarly ranked, faculty from US institutions of higher learning who are US citizens. Fellows spend one year on assignment at the US Department of State or USAID as science advisors on domestic and foreign policy issues and these assignments are tailored to the needs of the hosting office, while taking into account the Fellows' interests and areas of expertise. At the conclusion of the fellowship tenure year, Fellows continue to serve as a resource to the State Department and USAID for an additional five years (JSF 2014).

While the JSF brings in only tenured professors for fellowships, the American Academy for the Advancement of Science (AAAS) hosts a Science and Technology Policy Fellowship that provides opportunities for outstanding scientists and engineers from a broad range of levels, disciplines and backgrounds to learn first-hand about policy-making and implementation while acting as a knowledge and expert resource for government. The AAAS Science Policy Fellows program is larger and brings in people at all levels to serve in various branches of the US government. The fellowships are highly competitive and employ a peer-review selection process in selection (AAAS 2014).

In the United Kingdom (UK), 'pairing schemes' are designed to bridge gaps between parliamentarians, civil servants and some of the top research scientists in the British Isles. Participating scientists are paired with either a parliamentarian or civil servant and the Royal Society supports them by arranging a 'Week in Westminster' and for reciprocal visits (Royal Society 2014). This program aims to help parliamentarians and civil servants establish longstanding links with practicing research scientists to help them understand political decision-making and its associated pressures. Since 2001, over 250 scientists have been paired with parliamentarians and civil servants to strengthen knowledge flows between researchers and regulators. In addition to pairing schemes, the UK Office of Science and Technology produces a bimonthly briefing for members of parliament to contribute to their scientific literacy around current issues. Bolstering the exchange of information has proven a useful mechanism for achieving greater scientific literacy within governments (Collins 2012).

The UK also has a non-governmental council, funded by charities and the UK Medical Research Council, which specifically addresses transparency and engagement issues relevant to bio-based technologies. The Nuffield Council on Bioethics engages with the multiple ethical, technical and economic issues and concerns surrounding technologies such as biofuel production. For example, the result of an extensive study of complex socio-economic issues as they relate to technology was the creation of a set of six principles they believed most stakeholders could agree upon. The principles, in the context of biofuels, cover concerns for human rights, environmental sustainability, fair trade practices, attention to climate change and ethical agricultural practices (Nuffield 2011). While these principles are focused on the question of biofuel development, it is possible to see how they can be applied more generally to other emerging technologies used in the agricultural, environmental and energy fields. The Nuffield Council's approach is of note because of how technology is discussed in light of each principle and how standards and a regulatory system can be used to facilitate rather than block solutions to the overall challenge. What is particularly important is how uncertainty surrounding innovative technology is accepted, and how principles are designed to allow for flexibility in regulation and governance strategies, adapting and changing to new knowledge and policy solutions.

On a less-formal level, Australia established the 'Parliamentary Friends of Science' group in 2012. The non-partisan group supports science and scientific endeavours to foster dialogue and engagement between scientific leaders and parliamentarians seeking scientific expertise. It started with 50 inaugural members and now has over 76 members (PFS 2012). As the Academy Secretary for Science policy states, the interest of members demonstrates the "broad recognition among members of all parties that science is relevant and underpins policy in many spheres" and that "constructive debate needs to be founded on a common understanding of the best available science" (AAS 2012). The group has developed three goals, which cover issues like increasing the frequency of dialogue and engagement between scientific leaders and parliamentarians and building infrastructure to support efforts made by parliamentarians seeking scientific advice on relevant policy issues (AAS 2012).

While these examples show beneficial exchanges between scientists and policy makers, the scientific council model does not go far enough to expand the mandates to include stakeholders that may not have science backgrounds, but would be useful to consult in order to gain a better understanding of the social acceptability of commercializing innovative technologies like GM crops and foods. However, these examples demonstrate ways of fostering engagement and transparency among a select group of stakeholders that can act as foundational institutions to further bridge knowledge gaps among the broader set of stakeholders.

Option 2: Enhancing Deliberation in Policy Frameworks

Including or enhancing deliberative elements into decision-making structures for regulating innovative technologies within a 'science-based' system of assessment is challenging, but addressing transparency and engagement issues by including multi-stakeholder deliberation is still possible within current regulatory frameworks. The examples discussed here are drawn from policies in place at the European Union (EU) level of decision-making, the Norwegian approach, and a third not yet realized option for enhancing deliberation is drawn from the Canadian context.

In contrast to the framework used by Canada and the US to evaluate the biosafety of GM crops and foods seeking regulatory approval, the EU bases its regulatory system on the Precautionary Principle. This principle expresses the need to address future unknown risks, or at the very least have contingency plans in place to deal with any instances of unanticipated harms that may occur as a result of unconfined environmental release of GMOs (UNEP 1992; Clark 2013). The European case shows the difficulties of including deliberative elements into decision-making. For example, the European Commission can vote to withhold the approval of a bioproduct even if no evidence of potential harm to humans, animals or the environment is presented to the European Food Safety Administration (EFSA) (EFSA 2010; Costa and Novillo 2012). The result is a system that demands regulatory consensus among EU members that may not share similar levels of risk aversion to potential future, unknown risks associated with GM crops or foods. For example, Germany's anti-GM stance diverges significantly from Spain's more permissive view towards cultivating GM crops within its borders. Some have argued that the EU model of biosafety approval has prioritized deliberative elements over the role of scientific evidence in approvals of GMOs in the food system, which has led to severe restrictions on the cultivation of GM crops (Morris and Spillane 2008). Others have pointed out that the political decision to restrict GM crop cultivation in Europe is not necessarily democratic. For example, farm and consumer groups have expressed the desire to have the option of purchasing or cultivating GM crops such as maize (Europabio 2010). The debate, conditioned by the demand for more stringent regulatory protocols in the wake of food safety scares across Europe in the 1990s (e.g., BSE and Hoof-and-Mouth disease), has been shaped by non-governmental organizations and other groups that do not necessarily represent the perspectives of broader society and sometimes over-emphasize the possible future uncertainties regarding biotechnology in order to further political goals. The EU regulatory system based on the precautionary principle was intended to evolve as new information was obtained but has instead ossified (Tait 2001). This has prompted some within the system to demand a re-thinking of the current consensus-based model. In 2010, the European Commission reviewed existing EU-level legislation pertaining to GMOs and the key findings stated that the regulatory framework is in need of more flexibility on GMO cultivation, the authorization system is in need of streamlining and the risk assessment procedures need further harmonization (EC 2010).

Norway, which is not subject to the regulatory framework of the EFSA, has devised its own biosafety framework that weaves deliberative elements into its decision-making activities. The Norwegian Gene Technology Act (the Act) introduced in 1993 is an attempt at integrating multiple types of evidence into the assessment of GM crops, as well as cloned animals. Socio-economic considerations and environmental sustainability goals are explicitly included in the approval process of the Act as was the creation of the Norwegian Biotechnology Advisory Board (NBAB). Revised in 2005, the Act is now more precise in terms of what constitutes socio-economic considerations, 'ethics', 'sustainable development' and 'social impact' within regulatory evaluative frameworks. Three features of this Act are worth noting in the context of enhancing transparency and engagement as it relates to GM crops and foods: the elevated role of public consultation, the prioritization of freedom of information and mandatory 'impact assessments'.

Norway has approved very few GM crops for cultivation within its borders, and some point towards the inclusion of socio-economic concerns in the regulatory process as a partial explanation. For example, all applications for unconfined environmental release of GMOs, in addition to providing evidence of safety, must demonstrate that the GMO has a valid use, and contribute to sustainable agricultural practices. The NBAB holds public meetings regarding biosafety and GMOs as part of the deliberative element of the approval process. This has been an important tool in engaging the public in discussions regarding how GM products are used (Husby, 2007). There is special emphasis placed on transparency and public participation in decision-making over GM products used in Norway. Information about the GM product seeking approval is made public before the decision over approval is made. Chapter 2, sec. 12 states, "Notwithstanding the duty of secrecy, the following information shall, however, always be public, unless it comes within the scope of section 6, subsection 1, of the Freedom of Information Act" (Chapter. 2, sec. 12, NME, 1993; NDNM, 2011).

While the regulatory burden may increase with the inclusion of deliberative elements, there are lessons to be drawn from the Norwegian experience. Though replicating all aspects of Norway's approach to regulating GMOs may not be appropriate in the Canadian context, it offers some insight into how to include socio-economic and democratic elements in decision-making within policy areas covering technological innovations. It represents an example of how to deepen democratic legitimacy in GM food governance by including deliberation as part of the regulatory process, not only as part of a contingency plan if commercialization of a product generates critiques regarding its social acceptability. It also opens up regulatory spaces to seriously consider how the deep value differences among stakeholders can have significant implications for policy outcomes.

Shifting the public's role in decision-making concerning the approval and commercialization of GM crops and foods has also been suggested for the Canadian regulatory system. The Public Interest Accountability Framework (PIAF) developed by Pal and Maxwell (2004), is an attempt to develop a strategy to address efficiency, accountability and effectiveness in regulatory decision-making for GM foods. It proposes a set of policy processes invoking accessibility, transparency and public participation as central tenets of a responsive regulatory system (responsible government) (Pal and Maxwell 2004. By recommending a softening of the 'top down' approach to the regulation of GM foods, Pal and Maxwell argue for a move towards higher standards and penalties for those who fail to meet strict regulations and a more cost-effective system of regulation that can serve to strengthen engagement among stakeholders, primarily the concerned public (Pal and Maxwell 2004). A more time and cost effective system can also address the concerns of Small and Medium Enterprises (SMEs) within the Canadian system. SMEs often have fewer financial resources to draw upon to fund approval applications compared to multi-national biotech firms. High transaction costs put SMEs at a competitive disadvantage within regulatory systems, may prohibit their involvement in the sector, and thus may stifle innovation. Transparency of the decision-making process can help SMEs make informed decisions regarding research and development and how to better navigate the regulatory system.

In practice, the PIAF essentially amounts to prioritizing uncertainty as a factor in decision-making within regulatory frameworks, much like the strategic thinking model suggests. As argued by others, governance structures must move towards being more reflexive and inclusive of multiple perceptions of risk to bolster regulatory legitimacy by seriously considering social acceptability of the risks associated with an innovative technology as part of decision-making (Street 2006; Weale 2002). If decisions about commercialization of innovative technologies are made with minimal or no public participation, institutions run the risk of having

their legitimacy called into question and risk damaging the public trust (Street 2006). At the same time, greater inclusion and engagement with the public and/or organizations claiming to represent public interest needs to be moderated so that the regulatory system does not become political and burdensome, as in the European case. Evidence-based decision-making should mean that high standards of evidence should be held for both those trying to demonstrate benefit *and* harm of a product.

Option 3: Knowledge Mobilization Strategies

Knowledge mobilization (KM) is a less direct policy option to help address the uncertainties pertaining to GM crops and foods, but it is important to any engagement strategy and paramount to addressing concerns over the uncertainty of future risks associated with GM crops and foods. KM is used to describe a range of strategies and relationships that link upstream scientific research with policy and practice. Ensuring knowledge reaches end-users (e.g., government, the public) requires strategies for knowledge synthesis and exchange. KM pathways are multifaceted, nuanced, dynamic and iterative, indicating the complexity of KM model development (Gold 2009; Ryan *et* al. 2013).

Despite their complexity, KM models are crucial in ensuring that views balanced by evidence rather than emotional reaction to uncertainty can be developed by all stakeholders involved. Greater understanding of science, research and the most recent knowledge on a particular issue area can help stakeholders sift through contrasting evidence and judge the merit of often times, over-simplified messages coming from competing interest groups. The implication is wider than simply GM crops. The negative perception of GM technologies amongst large portions of the public despite scientific evidence to the contrary is also worrisome for scientists, industry and government in regard to other emerging technologies. Nanotechnology, for example, is still being defined in terms of its applications, benefits and risks. Potential benefits include new 'smart' materials, nano-robotics and medicinal applications such as cancer treatment or advanced diagnostics. The risks speculated include environmental damage, terrorist use of nanotechnology, and health and safety concerns for consumers and those who work with nanotechnology (Marchant and Sylvester 2006; Sylvester *et* al. 2009). Synthetic biology, the ability to build and manipulate biological (e.g. genetic materials) from scratch, is another emerging technology facing similar concerns (Calvert and Martin 2009). The evidence around these different scenarios is tenuous at best, but the possibility of harm has already prompted calls for early regulation. These calls are motivated by the desire to minimize any potentially harmful effects before they emerge, and to engage the public early on so that the negative perception and caustic opposition that arose around GM crops would not be repeated. The fact that different groups, both in support of and against these technologies, all want to see regulation developed is understandable given its potential scope: regulation can be permissive, prophylactic or preventive, and it can be used to signal to funders what research to support (Marchant and Sylvester, 2006).

Access to relevant, independent and reliable information on agriculture and science is an ongoing challenge for stakeholders in the agricultural biotechnology policy sphere. For regulators who are responsible for making crucial decisions that impact social and economic welfare of the public, access to knowledge networks populated by a range of expertise is fundamental. Governments require access to the most up-to-date and accurate information related to policy decisions concerning science and technology if they are expected to formulate balanced, informed policy. A process of participation balancing both top-down and bottom-up effects in informing the process and whether objectives are being met and/or changed is required. Because of the complexity present in governance structures, even small interventions might have serious consequences. Therefore, adaptive and reflexive governance principles are needed to monitor the system and delivering non-biased (or at least balanced) evidence about potential risks *and* benefits associated with innovative technologies is central to any KM strategy for GM foods and crops.

A KM strategy is endorsed by Canada's Social Science and Humanities Research Council (SSHRC) and the United Kingdom's National Institute for Health Research (NIHR). KM strategies can extend beyond efforts to inform policy-makers and the public by promoting science literacy in schools to educate students about the roles of science and technology in society. This is an important part of nurturing critical, analytical thinking in the populace. As part of the information revolution, the digital commons serves as an invaluable resource for information about science and technology and their uses and roles in society, but some types of information presented as evidence may lack rigorous assessment and evaluation. Stakeholders, including citizens, need

access to tools to help them distinguish between opinion and evidence to inform their own decision-making, and ultimately their risk perceptions regarding innovative technologies and uncertainty. There are, however, some challenges to implementing KM strategy in the current system of information exchange networks existing among stakeholders. Knowledge pathways are often complicated when the facilities and incentive structures to connect experts with other stakeholders through non-traditional outreach activities are under-developed (Ryan and Doerksen 2013). Communication skills are necessary on both sides in order to share and to receive information. Mobilization models need to be more fully investigated and actualized in order to facilitate goals for transparent and optimized knowledge management strategies.

Future Research Questions

Given the different policy options described above, from advisory councils to knowledge mobilization techniques and mechanisms, several future research questions are in need of further investigation:

1. What governance mechanisms need to be developed to facilitate the transfer of science for use by decisions makers?
2. What should a deliberative model look like within the Canadian system? What are the lessons learned and models can we draw from?
3. How can Canada best implement a *strategic thinking model* approach in its pursuit for best practices?
4.

It is evident that gaps exist within the current Canadian regulatory system that influences its efficacy. We need to step beyond this preliminary analysis of the regulatory 'landscape' of opportunities and challenges and attempt to identify best practices and study how models can be adapted and adopted within a Canadian context. Evidence-based models that integrate the best and most up-to-date scientific knowledge while incorporating more inclusive, deliberative models for stakeholder engagements would go a long way in building trust in the regulatory system. How to accomplish this is an ongoing challenge. Next steps might include a Delphi survey of experts in this issue area in addition to policy and decision-makers, as well as public sector scientists. The ultimate goal is to optimize the innovation process while ensuring health and safety of humans and the environment while considering the social acceptability of useful innovative technologies.

Conclusion

The challenge facing any regulatory system is that it is not being asked to address simply safety. It is being asked to address the public's perception of risk and concerns regarding unknown (but possible) negative effects of emerging technologies. It is being asked to address the concerns of industry in terms of facilitating their development of new markets, while providing a mechanism that can help prevent public backlash against their products. It is seen as a mechanism by interest groups to protect their own interests in regard to a technology or industry.

What should the regulation of science and technology actually achieve? Regulation should be seen as a mechanism that provides a balance between safety and facilitating the delivery of a technology's benefits to society. For example, the Nuffield Council on Bioethics not only has several principles protecting human rights and the environment, but they also have a principle that if the benefits of a technology outweigh the potential risks, then there is an obligation to develop it. This requires transparency of information regarding the possible impacts of a technology; and in order to achieve this it is necessary to have a broadly accepted level of scientific grounding and rigour in the research that provides it. Transparency of information also means the provision of information to the public in a non-technical manner (Lewandowsky *et* al. 2011).

The provision of information must also be seen as extending from a neutral party; part of the problem (Cobb and Macoubrie 2004) is that industry and government have been portrayed as biased (and implicitly or explicitly as dishonest) regarding technologies such as GM foods and crops. For this reason, all parties engaging in the regulatory debate should be welcome to provide their evidence, but also expected to adhere to the standards of rigour and transparency, namely explaining the sources of their provided evidence, how their research is funded

and whom they represent. For example, some anti-GM groups are funded by organic farming organizations, which stand to benefit from market share and improved public perception of their products if GM foods are portrayed as unhealthy or dangerous (Schroeder 2014; Byrne 2003; Forrer *et* al. 2000).

The continued support for basic and applied research in universities from public funds would go a long way in helping build trust in the science and information provided around these technologies; third party funding can be seen as separate from industry other private agendas (e.g. from NGOs, lobby groups). Finally, the structures of a regulatory system should reflect the values broadly representing society, but these should only be the starting point of a regulatory process.

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Policy Brief 1

Impact and Uptake of Democratic Engagement in Science Policy

Event

Science policy and regulatory assessment are being challenged to engage the public in more reflexive, open deliberation about the choices we are making related to technologies including bioproducts and crops.

Significance

Concerns about governance in the knowledge economy – especially about who is responsible for assessing and managing the impacts of transformative technologies – are reflected in public mistrust and allegations that innovation in applied genomics has escaped conventional mechanisms of democratic accountability. For all their advantages in terms of improving efficiency, expert-based networks raise serious problems of legitimacy when they exclude participation by non-scientific actors, especially members of the public.

Analysis

More openness and transparency about research on applied genomics is being encouraged, yet the public is often treated as the passive recipient of messages designed to fix "misunderstandings" about genomics research. The traditional methods of survey research and intensive small group studies are well developed and used to understand the characteristics of audiences in order to craft messages for those processes.

How can information sources become known and trusted and how can audiences be transformed from passive recipients to active seekers and users of the information? Two seriously under-theorized elements currently constrain efforts to achieve an open, transparent and engaged debate.

First, "the public" is often presented as undifferentiated and passive, eager to "re-engage" with scientists and public institutions. Experience shows that the public consists of a variety of publics, each with their own motivations for engagement, often with very little to do with the project of restoring public confidence in applied genomics.

Second, while misunderstandings about applied genomics could be resolved by better communication, dismissal of public concerns by scientific and policy institutions – the so-called "deficit model" – perpetuate mistrust and underlying resentments.

In response to these constraints, it is increasingly necessary to investigate the social construction of target populations, focusing on the central or prominent positions in social networks. Who, for example, is the first resource to which active seekers of information will turn? Equally, new approaches to engagement are sought to open network governance to democratic decision-making. These include deliberative democracy, e-democracy, public conversations, participatory budgeting, citizen juries, study circles, collaborative policymaking, and other forms of deliberation and dialogue among groups of stakeholders or citizens.

Conclusion

Much empirical research exists on the advantages and disadvantages of particular methods of engagement. There remains a need to compare the specific vehicles for engagement that deliver improved legitimacy for network governance with a better understanding of the resonance that engagement vehicles have with particular issue areas, regulatory styles, institutional structures and cultural contexts. The kinds of engagement that work in a context of adversarial legalism – participatory rule making, for example – are unlikely to be the same as those that have proved effective in more collaborative environments, such as consensus conferences (Einsiedel, Jelsøe, and Breck 2001).

Policy Brief 2

Policy Network: An Essential Component of Policy Design

Event

Policy networks involving a mixture of government and non-governmental participants are increasingly acknowledged as an effective tool for designing and implementing public policy in complex policy areas involving science, risk and uncertainty.

Significance

Public decision-makers and their advisors lack the capacity to design and implement policy in areas involving scientific uncertainty, contested risk assessment, and value conflict. Informal consultation and *ad hoc* engagement to supplement in-house capacity is no substitute for the development of a continuing relationship with key stakeholders. For more than twenty years, political scientists have studied the growth of the policy networks that have developed to fill this need, where information is exchanged amongst participants based on mutual trust. Nonetheless, key questions such as the impact of network structure on the quality of policy design, the legitimacy of different networks, or the ability of government actors to 'steer' networks towards public goals remain unanswered.

Analysis

A 'network' is an umbrella term used to describe a collection of actors (nodes) linked through some relationship (ties). In the familiar social networks, individuals are the nodes and their ties are such things as deliberate linking on social network websites or other social interaction. Policy networks are usually analyzed as a subset of social networks using many of the same principles of social network theory. The nodes are actors and institutions that interact in a continuous way to formulate, implement and evaluate public policy.
Two kinds of analysis of policy networks are common. In the first, the object of study is the network itself and the focus is to understand the structure and behavior of the network. Measures such as network density and centrality characterize the network as a whole (Policy Brief Nº2 explores social network analysis). Networks with similar structural properties are given generic names and are believed to produce similar policy outputs. The 'expert network' described in Policy Brief N°5 (Impact and Uptake of Democratic Engagement in Science Policy) is an example of this kind of descriptor, as is 'state-directed network' or 'issue network.' There is a small inventory of such terms in the literature and much is now known about the effectiveness of different kinds of networks in different policy contexts.

A different kind of analysis concerns itself with the question of whether policy networks can be steered by the government actors in the network to achieve the goals of public policy. Looser network structures featuring 'structural holes' have been shown to promote learning and innovation but are much more difficult to steer. This kind of 'reflexive governance' is often recommended when public values are divided or knowledge claims are contested but public agencies responsible for citizens' health and safety are understandably reluctant to embrace it. The object of study here is the behaviour of the network actors themselves.

In seeking to understand and influence policy development for transformative agri-food and bioproducts, it is important to realize that policy networks have developed spontaneously and are embedded in a larger context of ideas and institutions with extensive histories. Networks can neither be created nor steered at will.

Conclusion

Understanding the structure and development of policy networks in the agricultural biotechnology and biofuels sectors is critical to understanding the current problems of policy design and the opportunities for improvement. Finding ways of making the policy networks more open to learning and innovation must be balanced by the need to produce legitimate and effective public policy.

Policy Brief 3

Democracy, Governance and Public Engagement

Event

Significant amounts of time and money are being invested in public engagement processes without any evidence that the outputs are being used to improve public policy.

Significance

Governments across the OECD continue to engage publics in various forms of consultation and collective decision-making. This effort has been particularly focused on questions related to emerging, transformative technologies and in many cases is now required by law.

Analysis

Some assert the move to engage the public is a strategic response to a perceived democratic deficit – either grounded in conventional critiques of electoral democracy or derived from broader concerns with legitimate governance —while others suggest it is simply a tactical reaction to widespread controversy.

There is a broad spectrum of mechanisms and methods for public engagement, each with their own strengths and weaknesses. Within this spectrum, the number of participation mechanisms is apparently very large, with various inventories showing more than 100 different types of engagement. To complicate matters, many involve common elements and can be interchangeably named. Rowe and Frewer (2000) suggest an appropriate array of models of public engagement: referenda; public hearings; public opinion surveys; negotiated rule making; consensus conferences; citizen's juries or panels; citizen's advisory committees; and focus groups. One additional model – the expert advisory group, often augmented by one or more representatives of the *Vox populi* – is also mooted as a proxy for public input.

These nine methods encompass the normal range of options used in OECD countries. Their value depends on their use. Phillips (2009) assesses the nine public engagement models against five objectives. First, none completely maps onto democratic norms. Hence, we cannot offer unambiguous advice to policy makers on which ones would solve the 'democratic deficit.' Second, no single system unambiguously offers reflexive decisions that are accountable, responsible and transparent – policy makers inevitably need to choose among those goals or use more than one mechanism and then figure out how to reconcile any differences. Third, if the goal is to engage ordinary citizens who possess no special expertise, none can vest them with full engagement without offending other objectives. Fourth, the nature of the decision-making criteria (e.g. majoritarian, procedural or utilitarian) pairs more naturally with some types of engagement. Finally, while none of the public consultation methods are truly ethically grounded, mostly because those controlling the levers of power refuse to bind themselves to using public input in decision making, some can retrofit existing institutions by providing greater legitimacy for their decisions (Warren 2009).

Conclusion

Governments often face a challenge in using the output of these public engagement processes in the traditional hierarchy of decision-making in government. New norms of governance demand accountable, responsible and transparent outcomes. There is a need for a better understanding of how public engagement processes can enhance or undercut those goals, depending on how and when they are used.

Policy Brief 4

Discourse Analysis and the Impact of Public Engagement on Policy

Event

Discourse analysis is an established social sciences method that is finding new uses in identifying and tracking the linkages between public engagement and public policy development. Whereas it was formerly difficult to demonstrate the uptake and impact of public engagement on policy development, discourse analysis provides a valuable tool for analyzing the outcomes of public engagement.

Significance

The extent to which public engagement influences policy outcomes is difficult to assess. Often, government-sponsored public engagement events are criticized for lack of follow-through, or co-optation by consultation. The latter involves the claim to have broad support for a policy solely by the fact of having consulted the public, without making any commitment to respond to public concerns. If citizens have sufficient grounds to believe their views have been disregarded, government incurs risks to its legitimacy.

Analysis

Democratic governments increasingly rely upon public engagement as part of policy development in complex or controversial matters. Engagement is used to assess citizens' perspectives, gauge support or resistance for new initiatives, and gather information prior to setting public policy. Where a concrete recommendation is taken up, for example if a public engagement recommends a moratorium on a technology, and government institutes one, it is easy to identify impact. Other impacts on policy are rarely so evident, however, as it often depends on how a policy outcome is defined. Impacts may take the form of rhetorical acknowledgement, policy learning and incremental change over time or procedural impacts. One means of exploring impacts is by systematically tracing the occurrence of themes, patterns, and terminology from sources in the public sphere through to policy outcomes. This can be done through a form of discourse analysis. The application of discourse analysis to policy problems has been used to significant effect in studies of organizations (Alvesson and Karreman 2000), public political discourse (Chadwick 2000) and the political institutionalization of marginal environmental discourses (Eder 1996), among others. In relation to public engagement, Hampton (2004) argues that reports from, evaluations of, and responses to public engagement activities can be broken down into pieces of a meta-narrative which express public preferences, key points in a controversy, and policy options. Studying these texts and the policies and regulations developed pursuant to these exercises can provide insight into the uptake of network discourses into governance rhetoric – and in some cases, action.

Conclusion

While discourse analysis will not always allow the researcher to definitively show impact, it enables the identification of phraseology and recurring themes generated through records of public discussion that are subsequently reflected in policy outputs and outcomes. In addition, this approach may provide unique insights into moments where the path taken by an idea or concept, as it migrates from the public sphere to policy outcome, is obstructed or broken and why. This in turn suggests possibilities for determining best practices for productive forms of engagement in different contexts.

Policy Brief 5

Media Analysis through Narrative

Event

Media analysis has a long history in the communications and other social science fields. It is increasingly being deployed to understand the emergence of policy frames in the public sphere through narrative analysis. Such policy frames in turn function as narrative "hooks" for engaging publics.

Significance

Public engagement occurs in many forms, from the formal participation of "mini-publics" in organized events, to informal engagement with issues through public fora including the media. Analyses of media content can track technological trajectories, policy options and public preferences, or can highlight policy lessons.

Analysis

Media representations are nothing more than stories and storytelling. Stories can establish themselves as the dominant narrative or can be challenged with counter-stories. In either case, narrative accounts embodied frames may in turn influence a policy approach. Narratives are more than discourse; they are social acts (Tilly 1999). Events or characters are related according to some overarching structure, typically an opposition or a struggle. Narrative analysis can be utilized as one heuristic for understanding public engagement.

Social movements deploy cultural toolkits to mobilize thinking about an issue ways. Such toolkits are also useful in aligning new technological forms with issues already in the public consciousness. The use of the term "terminator technology" (in contrast to the original term "gene use restriction technology") to describe a technological form of patent protection of plant varieties by making seeds sterile after first planting has successfully evoked media attention by its play on popular culture through a well-known film character and developing a storyline that pitted big multi-national corporate interests against poor farmers in developing countries and their tradition of saving and sharing seed.

Narratives are designed to "accommodate, favorably frame, and utilize scientific evidence". Narratives provide structural coherence and can demonstrate the ways different stories frame policy problems. Biotechnology and other emerging strategic technologies lend themselves well to the development and use of policy 'metanarratives' which are important for dealing with "situations characterized by a high degree of problem uncertainty, socio-complexity, and political polarization" (Fischer 2003).

Such analytical approaches are not without problems. The "trouble with stories", is that counter evidence may not be as readily available and, despite the emergence of discrete facts, may fail to dislodge a compelling and holistic narrative account (Tilly 2002). While this limitation is recognized, the power of narratives becomes even more compelling.

Conclusion

Narrative analysis can be one of the analytical tools for understanding how technologies develop in a social context, how an issue comes to be defined as a problem, how a policy account might become dominant over another and how narrative strategies might be deployed by competing interest groups. This is in short a public engagement arena writ large.

Policy Brief 6

Public Participation in Science Policy: Cross-National Differences

Event

There is considerable variability in the forms democratic engagement might take. This is particularly apparent when comparing how engagement occurs across different sociopolitical contexts. A review of English language scholarship on democratic engagement in science policy reveals that contributions have been made by academics in several countries and across disciplines including sociology, policy studies, education, psychology, philosophy, and the sciences.

Significance

Governments faced with developing policy on complex and/or controversial technological innovations increasingly rely upon democratic engagement. Once an issue has been targeted for public input, organizers must still determine what type of instrument best suits their objectives, who to involve and invite, and how to evaluate the success of what they have done and measure the impact of its resolution.

Analysis

Comparing themes in the literature across national contexts illuminates what may be regarded from a more synoptic perspective as *taken---for---granted* themes and commonalities. Common concerns include:

1. *Effective design*: Even instruments that have been used with great success (e.g. consensus conferences) are vulnerable to poor design. For example, if the sponsor of the exercise limits possible outcomes to its own favoured choices, the consultation risks appearing 'illegitimate' with the possible consequence of compromising the sponsor's legitimacy as well.
2. *Persistent assumptions about 'lay' knowledge*: There have been many cases where perspectives gleaned from public consultation have contributed to better policy making. There are also strong arguments to be made for simply promoting more frequent dialogue between scientists, policy makers, and citizens; most deliberative engagement processes, upon evaluation, have found this to be a positive outcome for participants (Wynne 1996).
3. *Reflexivity*, with regard to design and in acknowledging the social commitments in technological development. If technologies are reflective of social commitments, it is reasonable to suggest that some form of social adjudication should be exercised in their development.
4. *Impact and uptake*: Policymaking requires making the best available choice based on a synthesis of evidence with a plurality of social viewpoints. Small---scale deliberative activities have frequently shown that achieving such a synthesis is possible, but plurality is still seen as an obstacle to effective use of consultation findings. Many governments are still not competent in following through after engagement (despite risks to accountability and legitimacy).

Conclusion

The increasing drive to find new ways to engage publics earlier in, and in more aspects of, the decision-making process may challenge the usual workings of a scientific evidence-based policy system which is accustomed to puzzling through issues prior to offering advice, but both are essential elements of new governance formations. The type of cross-national analysis described here – which includes the identification of common themes across contexts – can contribute insights to both scholarly and practical approaches to participation in science and technology policy.

Policy Brief 7

Anti-GM Activism and Social Media: The Price of Apathy

Event

According to a study done by the Pew Research Centre in 2010 six in ten (59%) Americans get news from a combination of online and offline sources on a typical day (Purcell *et* al. 2010). Online sources are the third major source behind local and national televised news, and the trend toward online news continues. Why does this trend matter in the context of agriculture innovation and to the people working in agri-food research and development? Anti-GM lobbyists have changed their 'modus operandi' and a whole new generation of activism has evolved using online channels that blur the distinction between news and activism. Where once interest groups would demonstrate or, in some extreme cases, resort to vandalizing field trials, interest groups are now rapidly adopting social media as a way to influence public opinion and to disparage modern plant biotechnology and associated practices.

Significance

Poor scientific information, pseudoscience or 'yellow' science involves the portrayal of claims as if they are credible. These claims may be inaccurate, which can be problematic, and a lack of accountability mechanisms means they may go unchallenged. Inaccuracies and falsehoods can persist, or worse, circulate rapidly through interconnected, fast-moving channels of Twitter, Facebook and other social media tools. Activists opposed to agri-food innovation use these tools to get their messages out quickly and into wide circulation. According to Paarlberg and Pray (2008), these claims "…often gain quick acceptance …and on occasion they do have direct impacts on government policy...."

Analysis

Given the Internet's capacity to hyperlink across geographic boundaries and the relative low-cost of access to the Web and affiliated tools, it is used as a primary organizing tool for many non-government organizations (activists, civil society organizations, etc.). As more advocacy activities move online, the need for off-line staffing and memberships to support these organizations dwindles. Thus, even the smallest of interest groups can greatly impact public opinion on a subject with a well-executed online campaign strategy. They can quickly build coalitions and mobilize the public around specific issues of interest at relatively low marginal costs (Ryan 2010).

A complicating factor is that scientists have been slow in terms of taking up social media as communication tools to respond in the same format. According to Lackes, *et* al. (2009), very few scientists use social media tools, significantly lagging in adoption rates for both business and personal use. VALGEN researchers conducted a poll of other researchers at the first VALGEN ABC Workshop in January 2010. Of the 28 scientists in the room, only 58.3% stated that they used social media tools and only 36.9% of those used social media for professional purposes (professional networking, recruitment, sharing/accessing knowledge). It seems that very few scientists are equipped to respond to the anti-GM movement in the context of the Internet.

Conclusion

A perfect storm of factors is emerging that, in combination, could spell immediate trouble for agriculture innovation and long-term consequences for food security. The anti-GM agenda is rapidly gaining traction via the Internet through social media tools, and fuelled by the influence of 'the celebrity'. This activity, combined with the lack of uptake of social media as a communication tool by scientists and science-advocates, promises to advance only the anti-GM agenda, when society needs balanced messages and open discussion about new science and technology.

Policy Brief 8

Understanding Ambivalence: An Output of Biofuels Engagement

Event

Discourse analysis of public consultations on policy development for first generation biofuels in Canada and the United Kingdom revealed significant ambivalence towards biofuels developments on the part of non-industrial stakeholders. Individuals appear to hold conflicting values without attempting to reconcile or order these values in a systematic way. Ambivalence, as Hajer and Laws (2006) point out, poses a challenge to policy analysis. Decision makers generally want clear, unambiguous signals on what to do.

Significance

Faced with ambiguous signals, it becomes tempting to provide advice by suppressing ambivalence or by rejecting it as a symptom of confusion. However, suppressing it can seriously misrepresent both stakeholders' views on an issue and the possibility of policy solutions that command broad assent. Further, there is evidence that second and third generation biofuels are expected to continue to generate ambivalence in non-industrial stakeholders, comprised of positive valuations of the increased efficiencies and contribution to climate change mitigation matched with concerns about the uncertainties involved in the treatments of the feedstock.

Analysis

Hajer and Laws suggest that ambivalence towards new technologies is part of a general uneasiness towards those novel situations that can reasonably be assigned to multiple, potentially conflicting categories or frames. In the case of first generation biofuels, many non-industrial stakeholders, especially in the UK, originally welcomed development policies such as mandatory blending, only to change their attitudes in the face of evidence that some feedstock production was competing with food crops and causing undesirable land use changes.

The prevailing interpretation that the new attitudes constituted an "about face" overlooks the fact that the stakeholders who began to oppose biofuels development rarely changed their original position that biofuels are, for example, useful in climate change mitigation. Suppressing stakeholders' ambivalence towards biofuels by either counting them as opponents to development or writing them off as having no consistent position overlooks the possibility that there is actually more agreement about shared values than seems to be the case. Instead of the classic "wicked problem" where disagreement over the nature of the problem prevents any progress towards a solution, stakeholders may actually agree on problem structuring to such an extent that progress towards consensus is more likely than might be supposed. However, if decision makers persist in ignoring ambivalence, they may end up with the classic mismatch of problems and solutions analyzed by Hoppe (2010), where the regulatory framework addresses a problem that is clear to the regulators but not to sections of the public. One commonly experienced result of the "wrong problem" problem is burdensome regulation on an industry that still fails to reassure citizens that their concerns are being addressed.

The key to accurate problem description, as Hajer and Laws argue, is to find a balance between the analyst's need to reduce complexity in order to give clear advice and the recognition of ambivalence and doubt as an inevitable part of a policy domain that contributes to good policy.

Conclusion

There is an urgent need to arrive at an accurate statement of the problems that these technologies pose for public policy, one that succeeds in recognizing ambivalence. Learning from the experience of first generation consultations about practices that encourage recognition of ambivalence will help remove a potential obstacle to commercialization of second and third generation biofuels.

Policy Brief 9

Policy Stories and Conflict over Biofuels

Event

Virtually every country in the world has targeted development or use of biofuels as a response to climate change or in pursuit of energy self-sufficiency. In the debate over biofuels, different actors tell different stories about the risks, benefits and consequences of expanded biofuels production. Policy stories matter because the venues for storytelling are increasing as public engagement becomes more critical to the legitimacy of policy outputs.

Significance

A complete policy story will include various components, including heroes, villains and victims, idealized pasts and disturbed presents. Policy stories are distinct from policy frames, which are typically more succinct and require the audience to put more effort into unpacking their meaning. Policy stories are functional constructions that attempt to simplify complex issues and reduce uncertainty to a manageable level, thus fixing the dimensions of an issue long enough for decision making to occur (Stone 1989). Policy stories are often transferable across disciplinary boundaries and, perhaps more importantly, across the body politic. As stories are transferred, the relationships between their components (the heroes, villains, victims) become implicit causal connections that are increasingly perceived as a legitimate basis for policymaking. However, incomplete stories with missing components (e.g. a story with a villain but no plot to follow in defeating him) cannot serve the issue-fixing and action-legitimating functions. Instead, they become policy critiques that cannot influence policy until their gaps are filled and causal connections are created. An issue that lacks clear policy stories altogether will be characterized by both indecision and weak implementation (Roe 1994).

Analysis

In Canada and the UK, biofuels stories can be systematically identified by formal analysis of policy papers, submissions to public consultations and media campaigns developed by various actors. In Canada, for example, eNGOs tell an incomplete story about biofuels—the disturbed present is a world where expanded first-generation biofuels are linked to respiratory disease and deforestation and the villains are petroleum, forestry, and agribusiness corporations seeking to profit from the climate crisis they caused in the first place (Beyond Factory Farming Coalition 2007). While Canadian eNGOs can define the problem and identify groups responsible for it, the story they offer is incomplete as it fails to identify the heroes and the means by which they might vanquish the villains. Accordingly, the Canadian eNGO story is a policy critique that does not provide policy makers with a basis for action. Meanwhile, in the UK, opponents of biofuels have developed a complete policy story which could influence decision makers, should the dominant story regarding the need for expanded biofuels be sufficiently discredited (UK Renewable Energy Public Consultations 2008).

In contrast, in Canada there is a complete policy story related to second-generation biofuels story which promotes uptake; this is lacking in the UK. However, the story has not yet been latched onto by decision makers, possibly because of the dissonance with the eNGO's policy critique of first-generation fuels. This conflict appears to contribute to uncertainty by posing questions that cannot be dismissed or resolved by the disconnected and at times incomplete stories being told in the same policy space. In essence, Canadian policy makers are operating in a space where uncertainty has not been firmly bounded by a policy story, forestalling decision-making and action.

Conclusion

While empirical methods are important inputs to decision making, policy stories are vital to simplifying complex realities, reducing uncertainty to manageable levels and generating policy legitimacy. Through a proactive role in refining these stories, analysts can help decision makers to act decisively and can facilitate strong implementation**.**

Policy Brief 10

Worldviews Clash on GM Foods: Implications for Deliberation

Event

A recent Eurobarometer survey demonstrated a divergence in public attitudes towards transgenic and cisgenic crops. With 72% of Europeans viewing transgenic apples as unnatural, compared to only 52% for cisgenic apples (Gaskell, *et* al. 2010). This distinction is also reflected in a reduced likelihood of purchasing transgenic foods, with 56% of respondents in a national survey of Danish adults indicating a willingness to consider purchasing "bread made from cereals modified with related genes," while only 19% would do the same if the cereals were modified with "genes derived from a bacterium" (Mielby, Sandoe, and Lassen 2012). This illustrates a gap in worldviews espoused by proponents and opponents of the technology.

Significance

Effective public consultation increases the legitimacy of policy outputs based on the inclusive nature of the policy development process and may also lead to better policies. A gap in worldviews can hamper productive dialog required for deliberation, posing a fundamental challenge to the democratic governance of GM foods.

Analysis

The divergence in public attitudes towards transgenic and cisgenic crops could be attributed to two scenarios, each of which has distinct implications for deliberation outcomes. In the first scenario, opposition to GM technologies emerges from a perception that it violates sacred values and is therefore impermissible under any circumstances. For example, GM foods might be perceived as an affront to "nature" which is viewed as sacred and inviolable, or may involve "playing God," which represents a challenge to divine authority. If opponents view the issue in this way, deliberation is unlikely to be productive since there is no room for compromise, and resolution of this value conflict is best left to the political arena. While this will likely result in the marginalization of opponents, if the value in question is widely shared, a blanket prohibition may be imposed through the political process.

In the second scenario, a techno-skeptic worldview leads opponents to be more skeptical about the likely benefits of genomic technologies and more sensitive to the uncertainty about their potential long-term risks. In this case, participants' worldviews are not fundamentally incompatible, since they both base policy prescriptions on risk/benefit evaluations, even though opponents' concerns may be expressed in the same vague language used to express moral opposition (concerns about "unnaturalness" or "playing God", for example). In this case, productive deliberation can be facilitated by encouraging opponents to express their concerns in more specific and "scientific" terms (Cuppen, Hisschemöller, and Midden 2009) and by encouraging proponents to consider additional risk management strategies, including a precautionary approach. The ideal outcome for this type of "competitive" deliberation is compromise (Horst 2010), resulting in improved risk management and in increased legitimacy for policy output.

Conclusion

A clash of worldviews on GM foods need not lead to impasse or political confrontation, but this depends on the nature of the gap. If the divergence lies in the perceived moral implications of the technology, deliberation is unlikely to be productive. If the different worldviews result in different risk/benefit perceptions, however, then genuine deliberation can be useful for proponents of GM technologies from both a practical and an instrumental perspective. The key challenge for policymakers and proponents is to identify which scenario dominates in any given situation.

Policy Brief 11

Designing Successful Public Engagement: What is the Problem?

Event

Public engagement in the policy process is usually intended to provide feedback on public perception of policy problems. Such feedback improves the chances that policy design will avoid the "wrong problem" problem, where a policy addresses a problem framed by policy makers in ways that differ significantly from the way the problem is experienced by stakeholders and the broader public. Public engagement aimed at avoiding the "wrong problem" problem should be distinguished from the more unusual kind of engagement designed to share decision making with selected publics.

Significance

The literature on public engagement is strongly influenced by contemporary theories of democracy and tends to run together these different kinds of engagement. This literature has sometimes proceeded assuming that shared decision-making is superior to the kind of public engagement that explores "back talk" from the targets of policy interventions (Schoen and Rein 1995) and aims at accurate and inclusive problem definition. As a result, the discussion of critical problems of democratic decision making, for example, questions of who should be included or excluded from engagement, has tended to predominate at the expense of analysis of how to design engagement as part of the general process of policy learning.

Analysis

Peter Hall provides a useful distinction of three component elements of public policy. At the highest level are the general *goals* that policies seek to achieve; at an intermediate level there are *policy instruments* or the means chosen to achieve the goals; and at the sharp end are the specific *settings* of the instruments. For example, a policy may aim to reduce the use of fossil fuels and associated greenhouse gas emissions (goals); it may do so by a regulation that mandates an ethanol blend in transportation fuels (instrument); and the mandatory blend may be 10 percent ethanol (setting). Public engagement may aim at learning about any particular element of a policy, about elements in combination, or about the whole policy mix. Engagement designed to learn about settings most often entails identifying stakeholders who understand the technical implications of particular instrument settings – in the example of biofuels, with discussions of how a particular setting will affect vehicle performance or maintenance – and the goal is policy learning in the simplest sense of more effective policies. The choice of policy instruments on the other hand, though it may seem equally technical, raises broader implications that call for different engagement designs. The choice of more rather than less intrusive policy instruments, using regulatory rather than information-based approaches, for example, is a way that policy makers send signals about their assessment of the severity of a problem and the urgency of solving it. Here, a disconnect between policy makers' framings and those of stakeholders and the affected public can only be resolved through engagement revealing not just the effectiveness but also the legitimacy of different policy instruments and allows for the systematic overhaul of existing policy designs based on experience of the policy in action. Finally, engagement directed at discussion of policy goals must incorporate deliberative elements that enable the exploration of broad policy framings. Such goal-oriented engagement exercises should take place before policy is made or in the context of decisions to embark on new directions in public policy. If not, the result can be the addition of new goals without removing older ones, creating very complex policy mixes including multiple and potentially contradictory goals.

Conclusion

Understanding public engagement as a contribution to policy learning rather than to shared decision-making helps answer some longstanding questions in the design of engagement, especially who should be involved (inclusiveness) and at what point in the policy process this should take place (timing). In all cases, policy makers need to become more aware of alternative problem framings, although engagement design will depend on the policy element(s) in question.

Policy Brief 12

Food vs. Fuel: Media Framing and the Rise of Cellulosic Biofuels

Event

On January 1, 2012, the U.S. federal subsidy for corn ethanol – originally put in place by the Energy Tax Act of 1978 – was allowed to expire. The subsidy for cellulosic biofuels established by the Food, Conservation, and Energy Act of 2008, however, remained unaffected, reshaping the policy environment in which biofuels producers must operate.

Significance

U.S. news coverage of biofuels began to focus on the potential externalities of using edible feedstocks (such as increased food prices) in the 2000s, leading to a decline in public support for corn-based ethanol by the end of the decade (Delshad and Raymond 2013). Government policy documents, moreover, began to reflect the news media's agenda (which focused on economic and political questions) rather than the scientific community's focus on technological progress (Talamini *et* al. 2012). The shift in the narrative surrounding biofuels contributed to the policy shift towards cellulosic ethanol. Public perceptions of biofuels in Canada are largely unexplored, but a similar evolution could prompt substantial changes in federal and provincial biofuels mandates, which currently do not discriminate based on feedstock. Indeed, cellulosic biofuels could themselves become controversial in both Canada and the United States, leading to further instability in the policy environment.

Analysis

U.S. consumers exhibit a clear preference for biofuels derived from cellulosic feedstocks (Delshad and Raymond 2013). While national willingness-to-pay (WTP) studies have shown a general preference for E85 over E10 fuels, regardless of feedstock, WTP was greater for cellulosic than for corn-based E85 (Jensen *et* al. 2010) Americans are largely uninformed about biofuels, however, so their attitudes are malleable (Wegener and Kelly 2008) and, indeed, become more negative as they learn more about the topic (Cacciatore *et* al. 2012). The largely positive evaluations of corn ethanol in the early 2000s became increasingly negative as consumers paid attention to the food vs. fuel debate in the news (Delshad and Raymond 2013). Currently positive attitudes towards cellulosic biofuels could therefore also change in the future due to feedstock concerns. WTP for switchgrass ethanol is greater than for wood ethanol (Jensen *et* al 2010), for example, and wood ethanol is viewed significantly less positively than ethanol produced using other feedstocks (Wegener and Kelly 2008). This may reflect concerns about deforestation and the appropriate use of forest resources, and points to a potential source of controversy as producers transition to second-generation biofuels. Such concerns could prove particularly powerful in jurisdictions like British Columbia, which harbours a significant forestry sector and a strong environmental movement, particularly if woody biomass is harvested from "low value" forests that would otherwise remain unofficial wilderness areas.

Conclusion

The recent re-focusing of U.S. federal policy on cellulosic biofuels was preceded by a negative debate over corn ethanol and a change in public attitudes. The same factors that facilitated this evolution – low levels of public awareness about biofuels and a change in media framing – could lead to a similar debate and policy shift in Canada. The framing of cellulosic biofuels as triggering deforestation or other undesirable land use changes could similarly trigger a move away from cellulosic feedstocks in the future, particularly in jurisdictions where the forest industry is a salient political issue.

Theme 5
The policy landscape

The conventional approach in policy studies is to assume that the systems are well structured and, if not linear or predictably cyclical, at least exhibit common flows where external stimuli—often called evidence—engages with the system to frame a problem, which then triggers a series of deliberations and responses. In essence, this model asserts that policy is influenced, decided and done in response to outside stimuli. This conception drives much of the policy literature and motivates many of those engaged in the policy process—especially intergovernmental policy negotiators, consultants, advisors and lobbyists. In this context, policy is often seen as deterministically derived.

The top-down rational-actor view of policy, often framed as deductive, is actually quite normative (Lindbloom 1957). This approach imposes theory on practice, with little effort to assess the nuances and inconsistencies of actual practice with that theory. Most of the current policy systems/studies literature examines one or more of the three 'Is'—ideas, institutions and individuals—either from the macro whole-of-system or the micro component-parts perspective, including the role of scientists, administrators, politicians and the media in selecting and advancing specific measures. This leaves unexplored the meso-level interactions within and between groups of participants in the system that often determine the choices and the impact of the choices.

Recent efforts to fill this gap, through adding multi-level governance, networks and systems theory, has helped to measure the scale of the gap, but has not provided strong causal explanations for how, if at all, this gap is governed. A more inductive approach, looking from the practice to theory, suggests major gaps in our understanding of policy systems. Network, systems and complexity theorists have identified this problem but not formally framed what drives these critical action arenas.

GE³LS research starts from an assumption that in many (but not all) policy spheres, this critical space is heterarchical, whereby power, authority and leadership changes hands frequently depending on the context. In effect, we have moved to a world similar to the childhood game of rock-paper-scissors, where there is no absolute power and all positions of strength are contingent on the choices and actions of others. One key implication is that many and perhaps most policies are effectively emergent and can only be forecast by a systems analysis—it cannot consistently be understood by focusing on the micro-level components of the system, the ideas, inputs, actors, structures and processes, or alternatively the ends-means relationships that drive macro-level analyses of outcomes.

These concluding essays offer some insight into the future for GE³LS studies and their contribution to the policy literature.

Critical essay 1:

Micro Policy Foundations: Receptor Capacity for Biotechnology Innovation in Canada

By David Castle, John Bell, Robert Hanner, Tania Bubela, Peter Phillips, and Keith Culver

Context

Canada's R&D and innovation performance is now back in the spotlight. Since 2008, the federal government, a number of provinces, most of the granting agencies, many firms, and a number of sectors are undergoing a period of introspection and evaluation. The federal government has signaled its impatience with a science focus that is not yielding transformative technologies that enhance Canada's economy. Backed by a wave of studies, reviews and expert panels on the state of science, technology and innovation (STI) in Canada, the federal government has begun to act.

As one of the first and arguably one of the few sustained federal instruments to advance STI in Canada, the National Research Council (NRC) has been a sentinel institution for transformations in Canada's STI policy. In recent years, the NRC has been targeted with operating cuts and a reorientation toward strategic R&D to leverage private capital and engage with industrial assistance and infrastructure programs more directly (Potter 2011). History appears to repeat itself; more than four decades ago, a Canadian federal government commission expressed concern about the gulf between Canada's science base and the interests of industry. The Glassco Commission noted the National Research Council's (NRC) tendency to serve the interests of university-based research scientists while ignoring the interests of industry. This criticism of the NRC drew upon the conviction that one of the "original purposes of government in devoting money to research was to encourage and stimulate Canadian industry" (Government of Canada (Glassco) 1962). Given that the NRC was not originally intended to have the strength of industrial linkages implied by Glassco's remark, the criticism can be viewed as a provocation to reorient public investment in scientific research in Canada. The Science Council of Canada (SCC) was formed in 1966 with this objective in mind (Wilks 2004), and, buttressed by the calls in the Lamontagne Report to improve upon and exploit the science-industry nexus (Special Committee on Science Policy (Lamontagne) 1970-3), Canadian science policy moved in the direction of state-managed publicly funded science with an industrial outlook (Atkinson-Grosjean 2006).

From the 1960s onward, Canadian science policy embraced the view that it is the 'proper business' – in the sense suggested by the Vannevar Bush report Science: The Endless Frontier two decades previously – of government to encourage and enable scientific and technological knowledge flows from universities to industry (Bush 1945). State-mediate coordination of university research and private sector interests intensified in the 1970s. In 1971, the Ministry of State for Science and Technology (MOSST) was formed to promote the "application and development of science and technology in Canada" (Privy Council Office 1971). Anachronistically speaking, the reorganization of MOSST in 1975 into three coordinated Branches, one for government, industry and university, made it an early exemplar in Canada of the Triple Helix model of innovation. By 1983, MOSST took over as the Chief Scientific Advisory body to government, completing a process through which the SCC had taken over from the NRC, and was now itself usurped.

In a 1980 background paper, MOSST observed that developments in cellular and molecular biology "thrust the world onto the threshold of a new technological revolution" (Ministry of State for Science and Technology (MOSST) 1980) because the inputs of biotechnology are renewable and the outputs are generally non-hazardous – on the face of it a potentially perfect industrial system for the resource-based Canadian economy. The National Biotechnology Strategy (NBS) (1983) and National Biotechnology Advisory Committee (NBAC) focused on growing the Canadian biotechnology industry. The 1998 renewal of the NBS as the Canadian Biotechnology Strategy (CBS) described biotechnology as a "powerful 'enabling technology'" that would transform many sectors of the Canadian economy while generating jobs and making Canada more competitive (Canadian Biotechnology Strategy Secretariat 1998). This strategy was expanded through the creation of Genome Canada in 2000 to take advantage of the genomics and proteomics revolution through the translation of research results for the "benefit of all Canadians."

While explicit links between university-based research in science and technology and the private sector have existed for more than a century, the dynamics of university-industry linkages shifted radically in the post-war period toward a state-coordinated system to take advantage of university and industry roles in R&D. Canada has been slower than the United States in coordinating its system, but Canadian science policy of the last few decades reflects an aspiration to develop research and industrial capacity in biotechnology. Yet, for more than two decades, there has been awareness that biotechnology capacity in Canada is nascent and needs cultivation. As the NBAC Task Force remarked about its deliberations leading up to its 1984 report, it was... well aware of the advantages of a "market-pull" rather than a "technology-push" approach to industrial development. However, the almost total absence of biotechnology industrial activity in Canada necessitated recommendations supporting a technology orientation, at least in the short term, for this country's development of biotechnology (National Biotechnology Advisory Committee (NBAC) 1984).

Whereas the Swedish Paradox refers to the observed discontinuity observed between increased expenditure on S&T research and returns on innovation-led growth, the 'Canadian Paradox' is the discontinuity between the rising number of well-crafted, critical reports about Canadian innovation versus weak and declining indicators of Canadian innovation performance (Science Technology and Innovation Council 2009, 2011, 2013; Council of Canadian Academies (CCA) 2009, 2013). The Canadian Paradox led Globe and Mail columnist Jeffery Simpson to remark that unlike our competitors who focus on innovation issues with an "intensity that reflects the urgency they deserve," in Canada "we write reports" (Simpson 2009).

The issue that Canada should be focused on with the intensity it deserves is that while Canadian science and technology may be competitive, our innovation performance is relatively weak and not improving. Despite recent World Economic Forum promises of "major transformations to position Canada for growth over the next generation" through key investments in science and technology (Harper 2012), the federal government's long term plans for science, technology, innovation and industrial policy renewal are uncertain. Federal government investments in scientific research (GERD) have fallen over the last decade (Castle and Phillips 2011), but despite this drop, Canada momentarily maintains a strong presence in the top 100 universities ranked by the Times Higher Education and QS survey and produces around 4% of the world's scientific publications (Science Technology and Innovation Council 2011). Canada remains a competent publicly funded producer of scientific knowledge, but is less successful at exploiting scientific and technological knowledge in the private sector. Canadian STI performance has several well-documented aspects that are targets for potential reform:

- Canada's multifactor productivity (MFP) over the last decade raises questions about the sustainability prided social services and economic resilience in light of rising labour costs (OECD 2012). Neither the OECD report of MFP productivity gains of just 0.28% from 1969 to 2011 nor the Statistics Canada data suggesting 1.03% growth (Diewertand and Yu 2012) are grounds for optimism relative to OECD competitors.
- Canadian business' aversion to risk, reflected in low Business Enterprise Research and Development spending (BERD) and a tendency to reinvest in personnel but not process innovation (Council of Canadian Academies 2013), undermines business' ability to keep a virtuous cycle of interaction with venture capital firms (Science Technology and Innovation Council 2011).
- The 2013 CCA report on industrial R&D (IRD) comments on a structural mismatch between areas of research excellence (clinical medicine, historical studies, information & communication technologies, physics & astronomy, psychology & cognitive science and visual & performing arts) and sectors with respectable levels of IRD (aerospace products & parts manufacturing, information & communication technologies, oil & gas extraction, pharmaceutical & medicine manufacturing).
- Federal tax credits for industry exceed $4 billion per year with the provinces absorbing an additional $1B, but the OECD argues for a more targeted approach to improve the 'connective tissue' to translate research into commercial opportunities: "innovation might be encouraged more effectively, and risks better balanced, by reducing the importance of tax expenditures and relying more on grants" (OECD 2012).
- 80% of direct support to Canadian industry is through SR&ED (Nicholson 2009). Canada and the US spend roughly 0.25% of gross domestic product (GDP) on direct IRD supports, but in the U.S. the mix of tax credits to other forms of direct government support is inversely proportional to Canada. Direct supports

in the U.S. helped American firms like Google and Apple to succeed (Mazzucato 2013) whereas Canada takes a passive but more laissez faire approach with SR&ED credits.

Returning to the post-war focus of improving university-industry coordination, and the multi-decade agenda of developing a Canadian biotechnology industry, the foregoing makes clear the systemic challenges to developing the commercial potential of publicly funded research. Furthermore, the Canadian biotechnology industry, while long in the making, is certainly far from mature. Notably, among Canada's research and industrial strengths, biotechnology continues to receive very little attention in the reports already cited – for example, life science innovation is not prominent in the most recent Council of Canadian Academies report on industrial R&D capacity.

The basic but largely undefined problem is whether/how Canada can generate appropriate absorptive and receptor capacity to translate our competitive performance in bio-based science and technology into industrial innovation.

Background and Theoretical Underpinnings

The linkage between risk aversion, BERD, the role of SR&ED credits, and innovation performance can be linked to business' ability to become a better receptor for knowledge flows arising in particular from universities. Commenting in The Globe and Mail, two now-former university presidents said, *Universities, colleges and hospitals could all do better at turning discoveries into marketable services and products. However, Canada's total R&D spending as a percentage of GDP is middle of the pack in the OECD, primarily due to Canada's low and falling level of spending in business R&D. Thus, while researchers in public institutions will continue to push out ideas and inventions, it is the receptor capacity in the private sector that needs urgent attention* (Naylor and Toope 2010).

Direct discussion of 'receptor capacity' in Canada is relatively uncommon, which is puzzling given that it is a widely recognized critical attribute of the private sector in innovation scholarship and policymaking. In three STIC reports for example, there are two mentions of 'receptor capacity.' These refer to potential improvements to internships and cooperative programs that would make firms better receptors of new knowledge (STIC 2009; 2011), development of firm research programs to assimilate new knowledge more easily (STIC 2011), and a comment about the "weak receptor capacity to take advantage of and exploit science, technology and innovation opportunities" (STIC 2013). Yet 'receptor capacity' is the concept that underpins the idea that firms will have the resources and ability to help co-develop and benefit directly from scientific research and Technology development is in a 'pull' rather than a 'push' model. Genome Canada's five-year plan, for example, describes the desired transition: *There appears to be strong interest in moving from a "push" based approach wherein scientific discoveries are used to fuel downstream activities to a "pull" based model wherein science is conducted in the context of a defined challenge. This is not the same as emphasizing one or the other in the term "R&D". Rather it is growing recognition that there is no point in solving a problem without a need to solve it. Increasingly, downstream expertise is required to apply the knowledge gained through science to create something of significant impact. It is about innovation* (Genome Canada 2012).

'Downstream expertise' can be articulated in terms of the 'receptor capacity' that enables firms to take advantage of new knowledge.

In ordinary speech, 'receptor capacity' refers to the presence of a firm that is potentially able to use new knowledge. In the technical sense, 'receptor capacity' refers to the specific characteristics and abilities of firms that make them not only able, but also willing, to seek, adapt, adopt and use knowledge. In contrast with large firms that are capable of buying-in and retaining knowledge and expertise through mergers and acquisitions, many smaller firms exploit external knowledge without necessarily increasing their size or scope or diversifying their operations. The ability to "recognize the value of new information, assimilate it, and apply it to commercial ends" is a firm's 'absorptive capacity,' and the central idea is that firms that undertake their own R&D, or have experience exploiting external R&D, will have the "prior knowledge to assimilate and use new knowledge" (Cohen and Levinthal 1990). Absorptive capacity is therefore at once a function of the experiences of the people and the collective memory of a firm, especially if it is engaged in IRD and complements its own activity with

exogenous knowledge exploitation. Absorptive capacity also creates path dependencies in which accrual of new knowledge is conditioned by the type of knowledge and sources previously encountered.

Teece and Pisano (1994) contrast 'resource-based strategy,' in which firms accumulate technology assets and seek aggressive intellectual property stances to protect them, with firms that deploy 'dynamic capabilities.' Dynamic capabilities are defined as:

> *...the firm's ability to integrate, build and reconfigure internal and external competencies to address rapidly changing environments. Dynamic capabilities thus reflect an organization's ability to achieve new and innovative forms of competitive advantage given path dependencies and market positions* (Teece, Pisano and Shuen 1997).

A firm's dynamic capabilities are analyzable in terms of processes (organizational and managerial, learning, reconfiguration and transformation), positions (complementary, financial and locational assets) and paths (dependencies, opportunities). The assessment of dynamic capabilities is difficult, however, and does not admit of easy metrology because behaviour and performance are firm specific and are difficult to replicate or imitate. Like all intangible assets, dynamic capabilities such as firm experience and organization are not captured on balance sheets or company reports, and therefore "generally cannot be bought; they must be built" (Teece and Pisano 1994). The process of building capabilities can take decades to achieve (Teece, Pisano, and Shuen 1997), which explains why attempts to emulate, imitate or replicate success observed elsewhere are doomed – particularly in the case of cookie-cutter approaches to cluster formation promulgated in the 1990s.

Absorptive capacity has been conceived as a dynamic capability with two modalities – realised and potential absorptive capacity – and four routines or processes: acquiring, assimilating, transforming and exploiting knowledge (Zahra and George 2002). This approach focuses primarily on the potential for absorptive capacity, since this relates most directly to firm strategy in dynamic environments. Importantly, the ratio of realised to potential absorptive capacity, which is called an 'efficiency factor,' indicates the extent to which a firm can draw on the kind of learning and experiences described by Cohen and Levinthal as it identifies, absorbs and uses exogenous knowledge. Some of this learning can be developed through partnerships with universities. Recent scholarship on university-industry partnerships emphasises the over-arching importance of relationships that foster innovation, rather than focusing on metrics of technology transfer (Perkmann and Walsh 2007). This is particularly important from the firm standpoint in which learning or absorptive capacity and the development of dynamic capabilities influence organizational culture and behaviour.

Case Studies

The following five condensed case studies demonstrate the range of biotechnology receptor capacity in Canada, and give real examples of positive and negative experiences that can serve as guides for the future. The case studies confront directly the view that the private sector in Canada is unable or unwilling to adopt new technology so as to explore presumptions about the lack of 'receptor capacity,' including: a) the lack of 'absorptive' capacity in Canadian firms leading to low levels of firm learning and innovativeness; b) lack of enabling developer-user interfaces; c) culture of risk-aversion in Canadian firms; d) absence of innovative funding models; e) relative lack of direct supports to technology intensive firms by government. Each case study illustrates commercialization performance with which a Genome Canada related technology has been commercialised, and each emphasises the development and exploitation of private sector receptor capacity or the exploitation of existing receptor capacity.

1. Investments in Canadian Aquaculture

Canadian aquaculture of marine and freshwater finfish, shellfish and plants had a production value of $926.5 million in 2010 (Department of Fisheries and Oceans 2012), making it relatively small in global terms. Canadian aquaculture has nonetheless benefited from nationally subsidized R&D programs including the AquaNet Network of Centres of Excellence (1999–2006), a 2008 NSERC Strategic Grant (NSERC 2008) and the current Department of Fisheries and Oceans Aquaculture Collaborative Research and Development Program (Fisheries and Oceans Canada 2013). Completed genomics R&D projects include the 2001–2005 $6.2 million Genomic Research on All Salmon Project (GRASP) and 2006–2010 $15 million cGRASP (consortium GRASP) projects investigating salmon; the 2004–2007 $4.1 million Pleurogene project investigating halibut; and the 2006–2010

$18.4 million Atlantic Cod Genomics and Broodstock Development Project (Fisheries and Oceans Canada 2013). Through GRASP and cGRASP widely used microarrays were developed (Genome British Columbia 2013), the technology and underlying knowledge formed the basis of international partnerships, (Davidson *et* al. 2010), and commercial collaborator Mainstream Canada use the knowledge (Gutierrez *et* al. 2012). The Pleurogene project's commercialization partner Scotian Halibut diversified its activities as a result of the project (Scarratt 2012). By contrast, the Atlantic cod genomics project did not lead to Cooke Aquaculture to farm Atlantic cod (CBC News 2010) and the remaining elite Atlantic cod brood stock are now maintained for Genome Atlantic at the International Aquaculture Innovation Centre (www.huntsmanmarine.ca).

2. A Decade of DNA Barcoding: The Technology and its Uptake

DNA barcoding is the sequencing of sequencing a short, standardized mitochondrial gene region for all animals to build a comparative sequence database (Ratnasingham and Hebert 2007) that could support the rapid, accurate and cost-effective identification of species (Hebert, Cywinska, and Ball 2003). Investments of more than $80M into barcoding infrastructure and direct costs of research include Genome Canada sponsors the International Barcode of Life (iBOL.org) project, the largest biodiversity genomics initiative ever undertaken. Barcoding's applications have been recognized (Stoeckle 2003): for parasites and vectors of zoonotic diseases (Besansky, Severson, and Ferdig 2003); agricultural and forestry pests (Armstrong and Ball 2005) (Floyd *et* al. 2010); other species of socio-economic importance (Schander and Willassen 2005); authentication of cell lines used in research (Lee *et* al. 2011); detection of seafood fraud (Wong and Hanner 2008); illegally traded wildlife products (Eaton *et* al. 2010); forensics (Dawnay *et* al. 2007); and environmental metabarcoding (Shokralla *et* al. 2012). While Canada leads the world in DNA barcoding research, and despite the fact that public sector 'receptor capacity' has been cultivated in federal government departments and agencies, low levels of policy uptake means that the Canadian public benefits less from its research investment than other nations like the U.S. and New Zealand where barcoding uptake is stronger. Moreover, this lack of policy uptake also means that private sector jobs created in this sector are emerging in other markets and that Canadian-trained experts are leaving the nation in order to capitalize on them.

3. Genetics and Genomics in Canadian Crop Biotechnology

Canada's agricultural sector had the highest growth in labour productivity in 2000–2010, is one of only three sectors posting rising competitiveness versus the US and, as a precursor to future change, has the highest ICT use per hour worked in Canada relative to the US (Science Technology and Innovation Council 2013). In short, agriculture in Canada seems to have a winning formula. An example of Canadian agri-food innovation capacity was development in the 1990s of herbicide tolerant canola, which by 2007 became the world's third most important source of edible oils.

Developed in the Saskatoon 'entrepot' (Bathelt, Malmberg, and Maskell 2004) (Phillips 2002), canola development started in the 1980s (Phillips and Webb 2013; Phillips and Khachatourians 2001). With interest in exploiting new techniques in plant biotechnology
and a desire to adopt plant variety protection (Malla, Gray, and Phillips 2004), the NRC recruited top biotechnologists to its newly repurposed Plant Biotechnology Institute while Agriculture Canada developed a Saskatoon oilseeds research centre. Local expertise was further concentrated as Monsanto, AgrEvo and Dow relocated research staff to access the capacity in the local public institutions. Between 1985 and 2000, joint investment by industry and government of more than C$200M globally (much of it in or linked to Saskatoon) produced five new traits expressed in more than 60 varieties that generated more than C$240M benefits annually in 2000 (Phillips 2003). Canadian share of the global market has risen correspondingly. After 2000, the innovation focus turned to differentiation with quality-enhanced traits and plant-made products, but changes in federally funded research have changed how attractive plant biotechnology is to foreign investors. Meanwhile market access for new traits and overall canola profitability are dampening enthusiasm for continued investment in canola innovation.

4. Innovative Cancer Therapies

Dr. John Bell, Director of the Ontario Institute for Cancer Research in Biotherapeutics, and San Francisco-based biotech entrepreneur, Dr. David Kirn (currently of Johnson & Johnson, 4D Molecular Therapeutics) formed a clinical trials company, Jennerex Biotherapeutics (www.jennerex.com) in 2006, to test oncolytic virus based therapeutics in cancer patients. Dr. Bell contributed his Rhabdovirus platform and associated intellectual property to the company and Dr. Kirn brought a licence for a Vaccinia virus platform, developed by scientists supported by the National Institutes of Health (NIH). An initial round of Canadian seed funding enable Jennerex to commence clinical trials in the United States, Korea and Canada. Dr. Bell established a manufacturing facility at Ottawa Health Research Institute (OHRI) using funds provided by the Canadian Foundation for Innovation, the Ontario Institute for Cancer Research, and private donations from local benefactors. Jennerex established regional partnerships in Korea, China and Europe to help provide further funding for the company. Initially, Jennerex was majority owned by Canadian investors, but to mature the company from phase I through phase III clinical trials and commercial launch required the company to move to the U.S. An appeal to the Government of Ontario to establish domestic manufacturing capability did not succeed. Bell and one of the Jennerex Board members approached the Ontario government with the idea of establishing a commercial manufacturing facility in Ontario. At present Jennerex is sponsoring 11 clinical trials, with one recruiting and three completed. Despite returning Jennerex intellectual property to the Ontario research institutes where it was discovered and developing a collaborative agreement between McMaster University, OHRI and the Children's Hospital of Eastern Ontario, Jennerex products are manufactured outside Canada, and GLP certified laboratories suitable for animal model testing of virus products are located in the U.S. Dr. Bell and colleagues remain committed to developing an Ontario based company, and international pharmaceutical companies have expressed interest in their technology, but it remains to be seen whether a successful, innovative biotechnology company for cancer therapeutics can be created and sustained in Canada.

5. Regenerative Medicine

Stem cell research is considered by some to be a Canadian export following the Till and McCulloch demonstration of the existence of multipotent stem cells published in Nature in 1963. The Canadian Stem Cell Network (SCN) has supported stem cell researchers in Canada since 2001. The caliber of Canadian stem cell science is high, with 14 SCN investigators among the one hundred most highly cited researchers in the entire field (Bubela *et* al. 2010). Now in its final round of funding, further commercialization initiatives will be developed by the Centre for Commercialization of Regenerative Medicine, supported under the Centres of Excellence for Commercialization and Research (CECR) Program. This replaces the original commercialization model of Aggregate Therapeutics Inc. (ATI: 2006–2009), a company charged with licensing stem cell technologies developed by SCN investigators and supporting commercialization through specialized business, legal and financing services. In Canada, the most successful regenerative medicine company is STEMCELL Technologies Inc., (http://www.stemcell.com/en/About-Us.aspx) a privately-owned Vancouver-based biotechnology company. In 2011, it reported operating revenue of $20,387,440 (USD), down from a peak of $29,117,880 in 2007, and employed 400 individuals. Its United States subsidiary reported $15,867,000 (USD) operating revenue in 2012 with 80 employees. A second company is Verio Therapeutics Inc., an Ottawa based privately held company founded in 2008. In April 2010, San Diego-based Fate Therapeutics acquired Verio Therapeutics for undisclosed financial terms, and formed a Canadian subsidiary. In 2011, Orbis reports Fate Therapeutics operating revenue as $2.2 M (USD) with 20 employees. Much cutting-edge stem cell research is conducted in Canada, but significant barriers exist to its commercialization and clinical translation. Risk averse global investors expect a secure patent estate combined with positive data from phase 2 clinical trials, yet Canada lacks the capacity to manufacture clinical grade material (cGMP) and funding for the conduct of early-stage clinical trials. Success in Canadian clinical research capacity points to commercialization success in streams of research that either do not require clinical trials, or involve the export of innovative Canadian research and IP to biotechnology companies in larger, less risk-averse markets.

Policy Options

Option 1: Promote Smart Specialization for Regional Innovation and Growth

As the aquaculture and crop biotechnology case studies demonstrate, the combination of science, technology, people and regional context can be a winning formula for innovation. Smart specialization refers to the ability of regions to use their specialised abilities to absorb, disseminate and exploit general purpose technology (McCann and Ortega-Argilés 2013), and to promote innovation and enhance productivity according to the region's unique needs and economic strengths (Aghion *et* al. 2009), increase receptor capacity, and remove impediments to knowledge flows. Given Canada's size, geography, and regional concentrations of populations, research organizations, and business, smart specialization is an approach to the prioritization and concentration of effort. Although increasingly adopted in Europe and recommended by the OECD, smart specialization has yet to make policy inroads in Canada.

Option 2: Develop Programs to Support Domestic Early Stage Innovation

The cases of regenerative medicine, novel cancer therapeutics, and DNA barcoding are situations where Canada is either the leader, or among the leaders, in an emerging field of science and technology, yet where technology development and commercialization occurs beyond Canada's borders. In these cases, the intellectual capital that is created is either moved by legal means as patent portfolios are bought up and exploited across borders, or where trained personnel have to move to follow the potential for job creation in other jurisdictions. As the Council of Canadian Academies has pointed out, the direct investment in early stage innovation characteristic of the U.S. innovation system is responsible for the retention of intellectual capital as well as the retention of business and their employees. The United Kingdom might provide a useful model for Canada to consider, since the Department for Business, Innovation and Skills and the Technology Strategy Board make strategic investment decisions based on an appraisal of the Technology Readiness Level of emerging technologies (NASA 2013).

Future Research or Future Action?

Instead of further prospective research, the solution is staring us in the face. As a continental economy with highly segmented regional economies and differentiated sectoral strengths, Canada is a natural living laboratory for implementing regional specialization through targeted and purpose-built programs for early stage innovation. In the past Canada has pursued national programs, albeit tailored to regional necessities through industrial and regional benefits. As those initiatives have wound down, provinces, communities and key sectors have emerged as innovators of programming for early stage innovation. Providing incentives for more innovations and comparing, contrasting and evaluating their respective success in advancing STI outputs and outcomes offers a valid and appropriate response to the needs of the Canadian bioeconomy (and undoubtedly other sectors). Piloting, prototyping and learning-by-doing (Sanderson 2002) offer one credible response to the Canadian paradox, by replacing action for perpetual study.

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Critical Essay 2:

Macro Policy Foundations: Bioscience Policy, Strategy and Tactics

By Peter W.B. Phillips and David Castle

Introduction

Science and technology led innovation is often posited as the driving force behind 21st century economies. Canada differs from many other OECD countries in that government (especially the federal government) is a relatively large investor and funder in science and technology, investing heavily in basic and early applied research (either through grants and funding for post-secondary education and research, for infrastructure projects, through special operating agencies such as Genome Canada, through intramural research and to firms through tax expenditures). In 2012, Canada invested nearly $25 billion in research and development (R&D), 34.5% of this financed by governments (OECD, 2014).

In spite of the investments, Canada has, compared to other OECD countries, poor productivity growth. Answers to this mysterious gap between inputs and outputs may be found in the theoretical foundations, the practical implementation and the conceptual framing of the government's science and innovation policy.

Theoretical foundations

Underlying the current federal policy is the assumption that government incentives reduce market entry and operating barriers otherwise faced by the private sector. Crucial to this point of view, and perhaps its central weakness, is that the private sector will respond to these incentives by investing in research, development and commercialization, essentially turning inventions and discoveries into innovations (i.e. products, services and organizational structures that bring benefit to Canadians). The economic theory of technological change has for many years focused on the firm as the primary research unit (e.g. Nobel Prize winning economists Kenneth Arrow and Robert Solow) and, in the footsteps of Joseph Schumpeter, has examined the microeconomic incentives and impacts of private research and commercialization. More recently, economists have examined the role of firms in "endogenously" generating innovation through planned, systematic effort to add value through R&D. This is generally modeled as a rational linear process where basic research leads successively to applied research, development, commercialization, use and benefit. The policy challenge, however, is that the outputs from the R&D phases are usually non-rival and non-excludable ideas, recipes or business models. Without some intervention by government (as either incentives or other practical support), investors are unlikely to invest optimally in these stages as they cannot be certain of recouping the costs of their investments through commercialization and use of the resulting invention.

Much of the federal government's science and technology (S&T) policy and programming fit with this firm-centric view of innovation. Federal support for strong intellectual property (IP) protection through patents, industrial trade secrets and other IP mechanisms is a major instrument in the nation's innovation policy. In addition, government funding and performance for primary and applied research in public labs, combined with generous tax incentives for private sector R&D and extensive grants and contributions for scientific and research activities in universities, are attempts to provide incentives for individuals and entrepreneurs to undertake research activities and adapt and adopt technology that will lead to economic and social innovation.

As an alternative to firm-centric approaches, political economists and sociologists have developed a range of theoretical "systems" approaches to innovation. They argue that innovation is a diffuse process, where no single firm or region can truly be viewed as self-sufficient or self-sustaining. Economists Stephen Kline and Nathan Rosenberg explicitly identify the potential for open research systems in their 'chain-link model of innovation', which begins with a basically linear process moving from potential market to invention, design, adaptation and adoption but adds feedback loops from each stage to previous stages and the potential for the innovator to seek out existing knowledge or to undertake or commission research to solve problems in the innovation process (Phillips 2007 offers a complementary vision of innovation as a knowledge-management cycle).

This dynamic process has been variously modeled as a regional innovation system, an industrial cluster or a triple helix of governments, universities and firms. Michael Gibbons and a number of colleagues posit that two modes of knowledge generation flow from such systems. Mode 1 knowledge, which they call traditional

knowledge, is generated within disciplinary, primarily cognitive, contexts and generally commercialized through the linear, firm centric innovation system. Mode 2 knowledge, which is created in broader 'transdisciplinary' social and economic dynamic systems, creates a profound challenge to the traditional governing system because communications tends increasingly to take place across institutional boundaries and not simply within established hierarchies. This conception of innovation suggests that policy needs to both remove barriers to and create incentives for these dynamic systems to develop and operate.

Worrying trends

Aggregated indicators for science, research and development mask some important features of Canada's relative performance in S&T-related R&D. Canada has about 20% more researchers per capita than the OECD average (but about 20% fewer than the US) and publishes approximately 4.5% of all basic research in academic journals, yet at the same time the cost of each scientific publication is above OECD average (OECD 2010). Conventional wisdom says if there is a strong science and technology R&D base acting as an "ideas pump" into the economy, wealth and prosperity should flow. The Canadian dilemma is that this is not occurring. Productivity is lagging both expectations and key comparator countries (Castle and Phillips 2011).

The fundamental challenge is that the lack of higher productivity erodes Canada's foundation for a rising standard of living. The OECD data for 2009 shows that the average Canadian works about 8% longer than an American, harder than the OECD average (almost 13% more than the average for the OECD), and more than all of our key comparator countries. Despite this extra effort, we generate a GDP per capita that is about 19% below the US average and barely equal to the average of the OECD countries.

Meanwhile, the federal government continues to ring-fence its spending by narrowing its interpretation of federal responsibility. The government has signalled, in the health and higher education sectors, that where provincial jurisdiction applies the federal government can be expected to observe constitutional arrangements—that is, federal agencies will retreat from spending in those areas. Provinces wishing to increase S&T and R&D therefore face this challenge alone and do so with varying results. Provincial attempts to fill the gap are uneven because of the significant inequalities in their fiscal and R&D capacity. National gross domestic expenditures on research and development (GERD) peaked in 2001 at 2.09%, held steady until 2006, but thereafter dropped to an average of 1.92 from 2007-09 (and as low as 1.87% in 2008) (Statistics Canada 2010a). By province in 2008, the last year for which there is reported expenditure data, the range was 0.81 for Saskatchewan to 2.61 for Quebec, and only Ontario and Quebec were above the national average of 1.87, which translates to per capita expenditure of $1080 and $1023 respectively (Statistics Canada 2010b). By performing sector, Ontario tends to do better than other provinces (64%) because the province includes the majority of the federal labs and because of the concentration of Canada's industrial GERD. Alberta and Saskatchewan maintain relatively high levels of provincial funding compared to their total GERD. In Quebec, Ontario and Alberta, the private sector contribution hovers around 50%, much higher than in Atlantic Canada.

When these events are considered in light of the innovation gap and potential productivity trap, the trajectory does not look good for Canadian prosperity.

A different set of questions

Most individuals and groups involved in science, technology and innovation policy agree that Canada can and should do better in terms of innovation. Many studies critical of Canadian science and technology innovation have focused on different problems within the innovation system and its implications for productivity (Conference Board of Canada 2008), global competiveness (Industry Canada 2008), drivers of commercialization (Industry Canada 2006), and the productivity gap (STIC 2009 and Council of Canadian Academies 2009). These and other studies conclude that Canada invests heavily in science and technology, but does not have a well-coordinated governance system to efficiently and effectively commercialize and use technologies in a timely and sustainable manner.

The current federal strategy (and most predecessor plans) asserts that federal effort and complementary action by provinces, universities and industries should focus on expanding entrepreneurial activity, strategically directing research to some specific, high impact areas and increase the supply of high quality personnel — otherwise called skilled and experienced workers (Government of Canada 2007). In short, the strategy seeks to

link strong minds and new or innovative ideas through private and entrepreneurial action. Overall, there is a focus on research excellence as the key goal of the plan.

While this sounds on first hearing to be a plausible approach, it suffers upon further reflection. In the first instance, we may not need a "science and technology" strategy — rather, we may need an innovation agenda or strategy, and likely a complementary industrial strategy. The Federal strategy, largely confirmed by the Conference Board Report Card, notes that Canada has a strong basic science, technology and research capacity — concentrated in a number of relatively well-networked, strategic, cutting-edge areas, as assessed by the Council of Canadian Academies.

Where we face difficulties is getting that knowledge into use in Canada. The federal benchmarking here is more problematic. It shows that Canada appears to be somewhat weaker in terms of the skills and talents of our workforce — we have the largest portion of our population with tertiary education but rank below average in our share of the population with either PhDs or natural science and engineering degrees — and that our public sector and universities contribute a relatively larger portion of R&D in Canada than in most other OECD countries.

The implication is that private activity is somehow weak or ineffectual, an implication borne out by private sector investment in R&D that has plateaued. In essence, one might conclude that the basic problem in Canada is not about how much (or even how) Ottawa spends on S&T. What is at issue is what Canada ought to do with the science and technology that is either languishing in public laboratories and universities or that is unceremoniously pushed out to an unwilling or incapable private sector. If this is the root of the productivity gap, then Ottawa is unlikely to be able to spend its way out of this private sector problem.

An investigation of federal activities offers a tantalizing glimpse of the issue, but it is far from clear how federal efforts can overcome private sector weakness. Before governments invest, they should at least be clear about whether they are addressing the symptoms or a set of underlying problems. One way to look at the problem would be to examine how Canada differs from the US. Canada appears to be relatively well endowed with good science, to have many of the same industries and firms as the US, to have a labour force that is as well or better trained than that of the US and to have as many entrepreneurs per capita as in the US. Most of the implementation measures presented by the federal S&T strategy do not explain the gap but merely further define the scope of the gap. Furthermore, heavy reliance on indirect support in Canada relative to that in the US and other international comparators may simply amplify Canada's disconnect between the world-class science and industrial uptake and use. This would be relatively straightforward to address.

There may be two further fundamental differences between Canada and the US that could contribute to Canada's relatively poor innovation performance and are not addressed by the current federal strategy. First, Canada simply lacks the scale of the US. Recent research indicates that value added per employed person rises as the population of a local economy rises. The underlying logic is that larger centres offer bigger, more sophisticated markets that can allow land, labour, capital and ideas to be employed in their best uses. This makes intuitive sense. If a lawyer, for instance, is trained and experienced in intellectual property law for biotechnology, he or she would likely make more money if able to solely practice in that field. If the local market is too small to allow for full specialization, then the lawyer will be forced to offer less differentiated services that will earn less. The effect of scale is significant. A survey of the literature (Venables, 2006) showed that doubling any city's size would increase productivity between 3% and 8%. Thus, moving from cities of 50,000 (e.g. Cornwall or Shawinigan) to 200,000 (e.g. Regina or Saskatoon) would increase productivity between 9% and 24%. Increasing to one million (e.g. urban Ottawa, Calgary or Edmonton) would raise productivity by 15% to 40%. Cities the size of Toronto (>5 million) would have productivity about 50% higher than those of cities of 50,000. Overall, approximately 45% of our population lives in million plus cities, compared with 53% of the US population. Moreover, our larger cities are smaller. New York and LA, with 18 and 12 million population each, dwarf Toronto, Montreal and Vancouver. While Canada cannot and probably does not want to become just like the US, federal policy should not exacerbate the challenges of small market size. Currently federal development policies and provincial and municipal strategies create barriers or provide incentives that artificially subdivide our economic sectors. While economic development is appropriate, it should be used to build on areas of strength and not myopically spread the wealth around in ways that undercuts economies of scale.

Second, research excellence is not a direct guarantee of commercial and economic development. The evidence is in – Canada does high quality research without productivity gains. Yet the best ideas or products are not assured of surviving and thriving because Canada tends to lumber where it needs to be fleet of foot. Easily the least adaptable and flexible actor is the Canadian regulatory system that tries to "manage innovation" in a rational way. However, "management of innovation" is an oxymoron because innovation by nature is chaotic and unpredictable. It only truly thrives where there are competing models, competing structures, competing ideas, competing investments and competing organizations. Those who interact with Canadian regulatory or development agencies assert that that decision-making processes are slow, overlapping and sometimes inconsistent. Canadian governments are focused on excellence and accountability rather than speed, adaptability and effectiveness. One structural factor that contributes to this is that federal, provincial and municipal governments tend to want to work together — costs rise and innovation slows as agencies attempt to coordinate and collaborate on far too many activities (See Smyth, Castle and Phillips 2014).

In contrast, the US has more of a distributed system, where different governments sometimes do complementary but more often do competing things, often without reference to other levels of government. Moreover, the US has strong proponents for action — while state governments tend to be relatively weaker than Canadian provinces, the combination in the US of relatively strong and independently minded municipalities using funds raised locally and aggressive private venture capital corporations are a hallmark of the American model. What distinguishes these actors is their decisiveness — they act and react quickly and effectively.

New Policies, Strategies and Tactics

If the root of the Canada-US productivity gap is scale and governance, then the Canadian strategy of supporting S&T, education and entrepreneurship may not make much of a difference. Ultimately, governments may need to look to their own structures, and create conditions that will reduce the burdens of scale and over-governance. Theory and evidence suggests three possible policy responses.

First, governments need to create the room to innovate and try new things. Canada does not have that in many regions and sectors. Canadian governments frequently set rules that require single solutions to complex and differentiated problems — either at the community, provincial, regional or national level. Monopoly solutions often strangle innovation. A particular problem is that rational decisions are made by higher orders of government to nurture, develop and support strategic initiatives. Some of these work very well, but oftentimes the lessons and models are then inappropriately applied to other areas. The result is the short-term, realizable innovations that will generate immediate payoffs are foregone in hopes of a big win down the road. Our policies need more balance between assisting firms to pursue small, immediate and realizable gains and large-scale efforts to create long-term structural change.

Second, innovation needs the right reward structures. Too often governments spend a disproportionate amount of time worrying about losers from change, and seeking ways to tax winners and subsidize those losers. While some redistribution may be necessary, it should not be the only or even the prime focus. Almost every new product, technology, process, organization and market will undercut somebody else's value. If the winners in Canada always have to compensate the losers, then fewer truly novel innovations will be tried here first. Experience shows that the biggest gains from innovation accrue to early adopters — if they are discouraged from acting in Canada, the benefits will be lost.

Third, Canadian policy needs to be more tolerant of failure. Innovation inevitably delivers many failed experiments. Currently municipalities, provinces and the federal government spend an inordinate amount of time, energy and financial capital trying to prevent failure, or if it happens, examining why something has failed and trying to attribute blame. As a result, governments often end up actually adding to the losses of failed enterprises. Governments instead need to find ways to efficiently and effectively release and recycle the resources that are stranded in failures. Accountability is important, but it becomes counterproductive if it ends up dissipating the value left in the investments.

At root, improved performance will be more likely found by getting the rules, structures and decision models better aligned with innovation than through the application of more funds or the redistribution of those funds to different actors. Canada's decision tool kit is quite dated. The idea that science, technology and innovation (STI) can be put to work in solving pressing public policy challenges is an article of faith in the

positivist tradition in public policy, heavily subscribed to by think tanks, governments, universities and industry. Massive investments in science in both hard and soft infrastructure are premised on the expectation that significant benefits will accrue to individuals and society as a whole. National competitiveness is presumed to be a function of innovative capacity. The ability to translate discoveries through commercial or non-commercial adaptation and adoption has never been more important to decision makers in government, industry and the social economy. Yet, bringing the fruits of science to governments and to markets has never been more difficult.

Each of the Canada's core sectors faces specific challenges that raise governance questions. The description of the issues in each sector varies. Agriculture faces the challenge of "sustainable intensification" which amplifies regional specialization, which will increasingly require robust institutions that facilitate exchange and trade; these systems are not obviously present. Meanwhile, the forestry, mining and energy sectors are already highly specialized, but they are fundamentally challenged by a range of feedback loops embedded in their global networks that jeopardize their business models. The challenges are amplified by the uneven and confounding public engagement that we use. Our lack of understanding regarding perceptions of risk and the framing of choices under conditions of uncertainty stands directly in the way of creating a scientific discourse that lay people can understand and contribute to. While cognitive science has made significant progress over the past forty years, the application of these insights to debates about these new technologies has been sporadic. At root, these governance issues call for new decision models. Governing instruments, particularly regulation, have become sites of disagreement involving diverse perspectives on the benefits and risks involved in developing these highly contested and disruptive technologies. Understanding how perceptions about risks and benefits are shaped poses one of the most pressing issues facing those committed to a science-based, evidence-informed policy system. With recent theoretical advances, it is now possible to advance a range of theories and methods to assess the relative role of ideation, decision architecture and human cogitative capacity in key decision systems in government, industry, research systems and NGOs.

At the core of the Canadian challenge and global opportunity in the biosciences is the ability to manage the challenges of disruptive, transformative technology. Transformative technologies present major difficulties because they: draw on different epistemic bases of cutting-edge science; represent step-changes in the scale and direction of development of human capabilities; have consequences distributed widely over many areas of life, are of sufficiently high profile to attract the attention, interest and risk perception of social movements, citizens, politicians and regulators; precipitate public debate and the attention of journalists and ethicists; and have trajectories that span long and indeterminate periods (Phillips 2007).

It is time to move from theorizing and debate towards prototyping and application. Sophisticated decision tools are available that could help decision makers in Canada and abroad in the public sector, private industry, universities, funding agencies and farmer organizations more effectively and efficiently adapt, adopt and exploit value enhancing technologies and products. Those tools (socio-economic and institutional analytical approaches, social network analysis, agent-based models, interactive surveys and behavioural experiments) offer real potential to accelerate uptake and use of the inventions and potential innovations emerging from Canadian investments and from abroad.

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Value Addition through Genomics and GE3LS (VALGEN™) was a five-year research project (2009-2014), supported by Genome Canada, managed by Genome Prairie and co-led by Dr. Peter W.B. Phillips, a professor with the Johnson-Shoyama Graduate School of Public Policy at the University of Saskatchewan and Dr. David Castle, then Chair of Innovation in the Life Sciences at the University of Edinburgh. The VALGEN™ team included researchers from across the country, from the Universities of British Columbia, Calgary, Regina, Ottawa, McGill, Laval and Saskatchewan. Over 100 students and employees, as well as 60 industrial and government partners contributing to research design and development, worked with the VALGEN™ project. Academic partners included The University of Edinburgh (Scotland), Kluyver Center for Genomics (The Netherlands), and the Universite de Versailles Saint-Quentin-en-Yvelines in Paris. Major funding partners included the Government of Saskatchewan, Western Economic Diversification, Genome Alberta, Genome BC, Genome Quebec, the Canola Council of Canada, and SRC Holdings Ltd.

The research products of VALGEN™ can be found at: www.valgen.ca

The Centre for the Study of Science and Innovation Policy (CSIP) is an academic research institute in the Johnson Shoyama Graduate School of Public Policy, hosted at both the Universities of Regina and Saskatoon. The centre supports the advancement of understanding about policy options through the application of robust theory, innovative method and evidence-informed discussion and provides new opportunities for student training and experience. Our mission is to equip and enable public, private and civil society sectors to successfully consider, debate and make decisions about new discoveries and technological applications.

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