



Policy Briefs

Nos. 1-15 October 2009 – December 2010

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About VALGEN



Value Addition through Genomics and GE3LS or VALGEN is a four year, \$4.5 million social science research project 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, Canada Research Chair in Science and Society at the University of Ottawa.

The project addresses three critical questions about the future of genomics. When any innovation emerges, those questions are: Who owns it? Who controls it? Who wants it?

The VALGEN team is investigating how new discoveries leave the laboratory as intellectual property, and the legal and business tools surrounding that property. It is also working to identify models for governing these new products and to determine how Canadians' views about new crops and bioproducts can most effectively be integrated into decision-making. This leading-edge research will inform future public policy that regulates how innovative products move from the laboratory to the marketplace.

The VALGEN team includes researchers from the University of British Columbia, University of Calgary, University of Regina, University of Western Ontario, University of Ottawa, McGill University (Montreal), and Laval University (Quebec City). Over 100 students and employees, as well as 60 industrial and government partners contributing to research design and development, are working on the VALGEN project.

Academic partners include the ESRC Centre Innogen, University of Edinburgh, The Scottish Centre for Research in Intellectual Property and Technologies (SCRIPT), University of Edinburgh, The Delft University of Technology Kluyver Center for Genomics of Industrial Fermentation, and the Universite de Versailles Saint-Quentin-en-Yvelines in Paris.

VALGEN is supported by Genome Canada and managed by Genome Prairie. Major funding partners include the Government of Saskatchewan, Western Economic Diversification, Genome Alberta, Genome BC, Genome Quebec, the Canola Council of Canada, and SRC Holdings Ltd.

VALGEN began October 1, 2009.

Visit WWW.VALGEN.CA for more information about VALGEN.

Large interdisciplinary research networks benefit from deploying several different techniques for knowledge mobilisation at once. VALGEN uses a wide array of techniques for mobilising knowledge, including scientific cafés, workshops, conferences and in print. With respect to written material, VALGEN research is published in traditional academic outlets such as books, chapters and peer-reviewed journal articles. Other written work includes working papers, opinion-editorials and submissions to government committees.

Policy briefs are a method by which knowledge can be mobilised in format that is easy to comprehend because if they do not presume expert knowledge, they are written in the present tense, and they focus on critical issues rather than reviewing background information. A widely used and very successful format for policy briefs is the *Oxford Analytica* style briefing note which is used by government and the private sector. The format has four main parts: 1) An important *event* is described; 2) its *significance* is clearly explained; 3) further *analysis* of the meaning of the event is provided; 4) *conclusions* about implications are drawn.

Since its inception, VALGEN has produced monthly policy briefs in the *Oxford Analytica* style. The briefs correspond to VALGEN research themes organised by activity, and are posted on the VALGEN website (www.valgen.ca) and distributed by email to a growing list of contacts.

Activity 1	GE ³ LS Integration
Activity 2/3	Intellectual Property Management and Technology Transfer
Activity 4/5	Regulation and Governance
Activity 6/7	Democratic Engagement

The briefs have initially focused on Activity 1 in light of the networking and capacity building function of VALGEN among the other Genome Canada projects funded in the ABC competition. The even-numbered Activities (2,4 and 6) refer to the ‘normal science’ phase of the project, and briefs in those themes will eventually migrate to the ‘foresight phase’ Activities (3,5 and 7).

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2	November 2009	1	Relationship-Building: A Key Social Convention for Researchers
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5	February 2010	6	Impact and Uptake of Democratic Engagement in Science Policy
6	March 2010	1	The Delphi Method and its Application to Genomics and GE ³ LS
7	April 2010	2	Intellectual Property Landscapes for Bioproducts and Crops
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9	June 2010	1	Integrated GE ³ LS Within the Genome Canada ABC Competition
10	July 2010	4	Type I and Type II Errors in Decision Systems
11	August 2010	4	The Institutional Analysis Development (IAD) Framework
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LAUNCH OF AN INTERNATIONAL RESEARCH NETWORK



Event

An international research network, *Value Addition through Genomics and GE³LS (VALGEN)*, is launched October 1, 2009.

Significance

Unprecedented in Canadian research and development on applied genomics research in bioproducts and crops, VALGEN supports ground-breaking research on social aspects of science and technology innovation.

Analysis

Resulting from the competition in Applied Genomics Research in Bioproducts or Crops (ABC), Genome Canada invests in twelve large-scale projects focused on applied genomics research in bioproducts and crops with a total value of \$112M. VALGEN, a four year, \$5.4M project is a unique among these projects with its focus on ethical, environmental, economic, legal and social issues in genomics (GE³LS). VALGEN is 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 responds 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 examine 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 blindspots.

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 adds value to the eleven GE³LS projects 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 furthers the reach of ABC project 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 is a chief priority of VALGEN.

Conclusion

Canadian prosperity depends on science and technology innovation. Bioproducts and crops research benefits from GE³LS 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 provide insight into the social determinants of successful innovation.

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 be 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 in its own right, one with implications for knowledge mobilisation 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 mobilisation are unhelpful because they conceal the complex and typically unpredictable nature of relationships and patterns of network development and knowledge creation and mobilisation. The knowledge-intensive, multi-disciplinary, multi-institutional and geographically dispersed network that comprises GE³LS research is better interpreted as a loosely organised system. The GE³LS research network operates more as an ecosystem with a structure and function affected by a complex blend of externalities and 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 for or constraints on individual action. SNA can help to identify boundary spanners, gatekeepers, knowledge bottlenecks and, most importantly, can identify under and over-utilised individuals, organizations or resources. SNA is a tool that will enable 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 mobilisation efforts can be characterized. SNA allows VALGEN to fine-tune its three-theme research portfolio and enables the calibration of value-adding activities to maximize impact on GE³LS and scientific research communities.

Kauffman, S.A. 1993. *The Origins of Order: Self Organization and Selection in Evolution*. Oxford: OUP.

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.

¹ Etzkowitz, H. and L. Leydesdorff. 2000. The dynamics of innovation: From national systems and "Mode 2" to a triple helix of university-industry-government relations. *Research Policy* 29:109-23.

² Bozeman, B. 2000. Technology transfer and public policy: A review of research and theory. *Research Policy* 29:627-55.

³ Bercovitz J. and M. Feldmann. 2006. Entrepreneurial universities and technology transfer: A conceptual framework for understanding knowledge based economic development. *Journal of Technology Transfer* 31:175-88.

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.¹

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 pluriform (diverse), self-referential, asymmetrically interdependent and dynamic, and consequently do not share the same goals, operating styles, skills, worldviews, incentives and priorities.²

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 middlemen, 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.³

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.⁴ 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 preventive⁵ or distinguished between restrictive and permissive policy designs.⁶ 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.

¹ Graff, G., D. Zilberman and A. Bennet. 2009. The contraction of agbiotech product quality innovation. *Nature Biotechnology* 27:702–704.

² Salamon, L. and O. Elliot (eds). 2002. *The Tools of Government: A Guide to New Governance*, Oxford: Oxford University Press.

³ Phillips, P. 2007. *Governing transformative technological innovation: Who's in charge?* Cheltenham: Edward Elgar.

⁴ Howlett, M. and J. Rayner. 2006. Globalization and governance capacity: Explaining divergence in national forest programs as instances of “next-generation” regulation in Canada and Europe. *Governance*. 19:251-75.

⁵ Paarlberg, R.L. 2000. Governing the GM crop revolution. *Policy Choices for Developing Countries*. Washington, DC: IFPRI.

⁶ Montpetit, E., Rothmayr C. and F. Varone. 2005. Institutional vulnerability to social constructions: Federalism, target populations, and policy designs for assisted reproductive technology in six democracies. *Comparative Political Studies* 38:119-42.

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 policy making, 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.¹

¹ Einsiedel, E., Jelsøe, E. and T. Breck. 2001. Publics at the technology table: the Australian, Canadian and Danish Consensus Conferences. *Public Understanding of Science*. 10:83-98.

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.

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, who 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.

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 N°2 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.

Event

For the first time in its funding history, Genome Canada requires all research proposals submitted to the competition on Applied Genomics Research in Bioproducts or Crops (ABC) to have an integrated GE³LS (iGE³LS) component. Of the twelve projects funded through the ABC competition, eleven science and technology projects have an iGE³LS component and the twelfth project, VALGEN, is a stand-alone GE³LS project.

Significance

New opportunities for cross-project collaborations between the network of iGE³LS components and VALGEN have been created, enabling researchers to leverage value in multiple iGE³LS projects through VALGEN-supported collaborations.

Analysis

The iGE³LS components of ten ABC projects science and technology projects and VALGEN were analysed. Based upon the original proposals, the iGE³LS research objectives have been organized into the following categories: intellectual property (IP); regulatory and governance; democratic engagement; economics of science; environmental review; and ethics.

Eight projects are undertaking IP research aspects, involving IP landscape evaluations and assessing alternative IP strategies. Several projects identified that patents could act as barriers to research. To ensure commercialization of the research, an assessment of existing patents would be required.

Seven projects have regulatory and governance objectives, focusing on how the existing Canadian regulatory system applies to products and services arising from ABC research. For example, several projects take innovative approaches to biofuel research and development, but the regulatory response cannot be reliably predicted. Reviews of existing regulations are being undertaken, but researchers are collaborating to open a dialogue process with the federal regulatory agencies so that insights and information can be shared.

Four projects include aspects of democratic engagement, focusing on surveys to study public attitudes toward potential new products and services. In addition to surveys, more deliberative approaches to engagement are being undertaken.

The economic value of specific genetic traits and the potential returns to agricultural research is studied in two projects. This research will provide an impact analysis for novel traits identified by scientists to determine which of the traits has the highest potential economic value.

Life cycle analyses are being conducted in three projects that have specific environmental objectives. Climate change mitigation is an important component of biofuel projects and a detailed examination of the biomass contribution to climate change will be completed within these projects, providing insights into the carbon footprint of biofuels.

One project has an ethical focus on the food-versus-fuel debate. This project will undertake a survey that includes questions of an ethical nature regarding the development and transfer of biofuel technologies to developing nations.

The methodological approaches being applied vary considerably, including: patent landscape assessments (six projects); public surveys (three projects); life cycle analysis (three projects); regulatory impact evaluations (three projects); data analysis (three projects); empirical modeling (three projects); and bibliometric/literature scans (four projects).

Conclusion

Opportunities for cross-project collaborations between the network of iGE³LS components and VALGEN are evident. A recent workshop for all ABC investigators established that synergies between the network of iGE³LS projects and VALGEN exist. As the example of GE³LS research on biofuels suggests, researchers are pursuing opportunities to leverage value from collaboration, and VALGEN is taking the lead in coordinating and supporting these research collaborations.

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 appropriate 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 which 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 error 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.

Conclusions

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

The 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, 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. The action arena consists of actors and an action situation which interact, leading 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 ultimately 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 important 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. All of 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 – such as horizontal connections through MRA and knowledge exchange. The IAD can help to 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 used 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 unpack and understand the nature of complex, learning, dynamic systems.

Ostrom, E. 2005. *Understanding Institutional Diversity*. Princeton: Princeton University Press.

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 to 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.

Phillips, P. 2009. Democracy, governance and public engagement: A critical assessment. Conference on "Publics and emerging technologies: hindsight and foresight," Banff, October.

Warren, M. 2009. Citizen Participation and Democratic Deficits: Considerations from the Perspective of Democratic Theory. In J. DeBardeleben and J. Pammet (eds.), *Activating the Citizen: Dilemmas of Participation in Europe and Canada*. Basingstoke: Palgrave Macmillan.

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.

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 reevaluating 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 last August.¹

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 license 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. But 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."² 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 end result was an award slightly higher than the license 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

¹ *Rivett v. Monsanto*, 2010 FCA 207, <http://decisions.fca-caf.gc.ca/en/2010/2010fca207/2010fca207.html>.

² *Monsanto v. Schmeiser*, 2004 SCC 34, <http://csc.lexum.umontreal.ca/en/2004/2004scc34/2004scc34.html>, para. 102.

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.

Novelty as a regulatory trigger for new bio-products 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.