Feeding the Future: Can Scientists, Regulators and Activists Agree?

Lisa Clark[1], Michele Mastroeni[2] and Cami Ryan[3]

May 21, 2014

The DRAFT policy brief is to be presented and discussed as part of Genome Canada's *GPS* series*: Where **G**enomics, Public **P**olicy and **S**ociety Meet*
to be held during the 2014 Congress of the Humanities and Social Sciences
Wednesday, May 28, 2014, 10:00 - 12:00 at Brock University

[1] Research Associate, Johnson-Shoyama Graduate School of Public Policy, University of Saskatchewan, Saskatoon, Canada. Lisa.clark@usask.ca
[2] Senior Analyst, Innovation and Technology Policy, RAND Europe, Cambridge, UK. mastroen@rand.org
[3] Professional Affiliate, Department of Bioresource Policy, Business & Economics, College of Agriculture University of Saskatchewan, Saskatoon, Canada cami.ryan@usask.ca

1. 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 noted 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 this type of uncertainty comes both 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 described, then the regulatory structure adds to the complexity of the innovation process 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 that which is procedural only serves to distract from complicated policy issues such as those associated with technology. While accepting that a functioning regulatory structure is complex means that it may be more difficult to implement, it also means that such a structure would be more transparent, fair and legitimate.

The current regulatory system for approving technologies for commercialization adheres to the principle that decisions must be based on scientific evidence generated through reproducible and repeatable sets of rules and standard operating procedures. Using rigorous scientific methods to calculate the probability of harm, and 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 different 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; that an exclusively evidence-based approach erodes the normative basis of policy-making and undermines the capacity for

developing appropriate and social valuable policy (Sanderson 2002, 2003, 2006, 2009). This brings into question the what, who and how of policy to life in our complex, technologically-driven world and where and when – exactly – evidence is needed to inform the policy-making process. Further complicating matters is that spheres of dialogue (online and other) are being muddied with misinformation which, undoubtedly, affect the policy making process (McHughen and Wager 2010; Ryan and Doerksen 2013; Ryan 2014).

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 still encouraging 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 policy 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 and 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, and 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.

2. The Issue

Within deliberative democracies like Canada, patterns of engagement are largely dependent upon the policy issue at hand, and often but not always draw from established 'best practices' and standards developed in other jurisdictions (e.g., the USA) that generally 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. This aspect of the decision-making process is particularly important in the policy issue area of agricultural biotechnology, where scientific determinations of the potential for comingling, toxicity and allergenicity levels of a GM crop are important factors indicating whether or not it gains regulatory approval for 'unconfined' environmental release. 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' and an acceptable level of safety, and what types of evidence should be included in regulatory decision-making which determines what is considered '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 so when dealing with 'contentious' technologies commonly associated with future, unknown risks like GM crops (Goncalves, 2004; Beck, 1992).

In situations of complexity, knowledge is in a permanent process of evolution, and it is not possible to foresight (and in some cases even to imagine) 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 both the products they regulate and the tools used to assess such products. Uncertainty of future risk cannot be eliminated; however, it may be reduced through appropriate information gathering and analysis, and 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 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) and knowledge are packaged in political debates over regulation (Clark 2013). Furthermore, Gold (2009) distinguishes multiple pathways through which research may get utilized in policy making. The pathways, themselves emphasize different strategies, stakeholders and motivations which may help of hinder movement along that pathway (Ryan et al 2013). Scientific approaches can therefore 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 has not been immune from controversies over the approval and use of GMOs in its food system. In response to growing public concerns over uncertainties related to GMOs' 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 2014). 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, and how the plant is used and its potential to comingle with other species. Decision Documents are written and issued by the original applicants which 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, forthcoming). The Notices of Submission feature of the approval system in Canada

allows for the government to respond to environmental petitions presented to the Auditor General by a member of the public (Government of Canada 2004). These strides towards addressing transparency and access to information have provides 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 has 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, Health Canada and Environment Canada).

With the changes described above, however, the time involving registration and regulatory affairs is increasing from a mean value of 44.5 months for an event introduced before 2002, to the current estimated value of 65.5 months (Phillips McDougall, 2011). The overall cost to bring a new biotech trait to the market between 2008 and 2012 is on average $136 m and 25.8% of the total cost arose as a result of regulatory testing and registration.

Transparency and accessibility of information are ongoing challenges for the innovation process in Canada and are not restricted to conflicting ideas about risk and uncertainty between 'the public', the science community and regulators. These challenges have implications for strategies to improve governance in the agricultural-biotechnology sector. The Jenkins Report (2011) states that although Canada excels in research, it lags the rest of the world in terms of commercialization of innovation. The Report suggests that the lack of a broad, transparent connection between science and government contributes to the challenges of promotion and growth of Canada's high technology sectors. Though stakeholders may have overlapping objectives in terms of promoting innovations, the way that information is exchanged and the dynamics of interactions within decision-making forums are crucial to determining how resources are organized and how to best manage high technology sectors. This is part of a larger problem of agenda setting in the policy system (Ryan et al 2013), but it also has implications for how the agricultural biotechnology sector in Canada responds to governance challenges regarding access to information and engagement strategies between and amongst stakeholders. The Jenkins Report points towards the need to strengthen knowledge flows among stakeholders, though this still remains a significant challenge in many high technology sectors in Canada. The issues are not because there is a lack of information or infrastructure to address concerns about the risks and uncertainties that are endemic to every innovative technology, but that the kinds of connections between stakeholders which foster transparency and information flows tend to receive less attention in policy

analysis. What information is shared, and more importantly how it is shared, is fundamental to better understanding how to address the role risk perceptions and notions of uncertainty play in decision-making frameworks.

3. 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-based 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 (1983; 1996). This model has proven successful especially for established technologies such as pesticides and industrial chemicals. For many new products or processes seeking approval for commercialization, this approach to evaluating safety and developing guidelines for safe use has proven effective. However, 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 addressed some concerns stakeholders have over transparency of information used in the approvals process (Wolt and Peterson 2000:42). 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 as well as the US including those for approving GM crops and foods.

One of the core principles of the approval system for GM crops and foods is that a 'novel' plant (all plants that undergo some form of modification that have not previously been used in Canada could be considered novel) must be put through a rigorous set of risk-assessment and biosafety procedures before it is declared 'safe' for unconfined environmental release and commercialization. Considering a plant as novel is not exclusive to genetically modified plants, but includes all plants that undergo some form of modification that has not previously been used in Canada (e.g., mutagenesis, cell fusion, and traditional breeding) (Clark and Phillips, 2013:116). Although Canada's PNT regulatory system for innovative crop-based technologies has been deemed efficient in minimizing risks (Smyth and McHughen 2013), challenges remain to this approach.

Putting a PNT through the regulatory approval process in Canada can take up to ten years to gain approval and can cost millions of dollars, which can put significant constraints on publicly funded research (Phillips McDougall 2011). All PNTs seeking regulatory approval are subjected to the same biosafety protocols. There is also concern that increased regulatory requirements for PNTs are not tied to or justified by any increase in risk to human and/or environmental health and safety (Smyth and McHughen (2013). For example, advanced testing protocols that can detect the presence of GM-content at minute levels have led to regulations for lower thresholds for traceable GM content in non-GM products (Ryan and Smyth 2012); these regulations were added, however, despite no actual increase in the presence of GM content, or an increase in health or safety concerns.

Challenges to effective and efficient policy to manage the use of agricultural biotechology in the food system is closely linked to broader issues facing science and innovation policy in Canada, such as with 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; however more recent changes indicate that further amendments and attention to these issues are needed.
One of the goals for 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.[4] 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. Many of these decisions involve risk assessments that arouse public concerns about their health, safety and long term well-being " (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

[4] For full list of CSTA authored documents see: http://artsites.uottawa.ca/sca/en/council-of-science-and-technology-advisors/reports/

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. It reports to the Junior Minister of Science in the federal government, but 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 that 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 into evidence of 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 2014). The process, however, has been criticized for its lack of transparency and accountability (Stewart 2014).

4. Policy Options

Governance structures for GM crops and foods need to be inclusive and to consider socio-economic concerns as well as questions regarding the management and contingency plans for addressing uncertainty in future outcomes in the decision-making process. Faults in the governance structure, such as level of transparency, means that stakeholders lose a source of information that can help cope with uncertainty, and the legitimacy of the system is therefore negatively impacted. The *strategic thinking model* (STM) helps to frame the following policy options (which are not mutually exclusive) and this is discussed below. 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). 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 for policy options that can be applied to specific to GM crops and foods, but we also discuss 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 policy making.

4.1 Option 1: Science and Technology Advisory Councils

There are several countries (USA, UK, Australia) that 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, (JSF 2014), the impetus for which was the need for government to have "accurate, timely understanding of rapidly advancing science, technology and engineering (STE) 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 ranges 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 much bigger and brings in people at all levels to serve in all the different branches of 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 and to help research scientists 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 Parliamentary Office of Science and Technology produces a bimonthly briefing for members of parliament to contribute to parliament-based 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 council that 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. The result of the extensive study of a very complex set of socio-economic-technical issues was a set of six principles they believed that 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 the technology is discussed in light of each principle, the challenges that can be faced 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 the principles are designed in a way 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 group is non-partisan and 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. 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 exchange 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.

4.2 Policy Option 2: Enhancing Deliberation in Policy Frameworks

Including or enhancing deliberative elements into decision-making structures when it comes to regulating innovative technologies within a 'science-based' system of assessment is fraught with challenges. The examples discussed here are drawn from policies in place at the EU level of decision making, the Norwegian approach and the third not yet realized option for enhancing deliberation is drawn from the Canadian context.

In contrast to the science-based risk assessment framework used by Canada and the US to evaluate the biosafety of GM crops and foods seeking regulatory approval, Europe 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 (UNCED, 1992). Approval of products can be withheld until further satisfactory evidence of their safety is provided by applicants. The European process ends with a political decision in that, even if evidence for biosafety presented to the European Food Safety Administration (EFSA) is assessed as showing no potential harm to the health and safety of humans or the environment, the European Commission can vote to withhold approval (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 the GM crop or food seeking approval. 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 that are not supported by scientific evidence (Skevos et al, 2012). 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 (BSE and Hoof-and-Mouth disease) has been shaped by non-governmental organizations and 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 supposed 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 2011, the European Commission reviewed existing 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 also 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 to 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 that, "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" (Chp. 2, sec. 12, NME, 1993; NDNM 2011).

While the regulatory burden may have increased, however, 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.

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 (Pal and Maxwell 2004: 10). 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: 14). In practice, the PIAF essentially amounts to prioritizing uncertainty as a factor in decision-making within regulatory frameworks. 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: 114).

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. 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.

4.3 Policy 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 an important element 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. The pathways for ensuring that knowledge reaches the end-users (e.g., government, the public) requires strategies for knowledge synthesis and exchange. KM pathways are multifaceted, nuanced, dynamic and iterative pointing towards the complexity of the 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. 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 worrying scientists, industry and government with 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 applications to medicine 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 also 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 appears to be 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 its environment is important, 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). However, there are 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, to share and to receive information. For example, in the context of GM crops and foods and related science, it appears that mobilization models are lacking. Ryan et al (2013) conduct a preliminary analysis of agri-food knowledge mobilization models (comparing to the 'gold standard' Cochrane Model) including the Biosafety Clearing House (BCH), Center for Environmental Risk Assessment (CERA) and the Pew Initiative on Food and Biotechnology (PIFB), It was found that gaps exists in multiple areas within the models that affect their efficacy. Gaps include, but are not limited to, a lack of stakeholder participation, accountability, responsibility and transparency (Ryan et al (2013); Phillips 2007 drawing on Black 2002).

5. Future Research Questions

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 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?

It is evident that gaps exist within the current regulatory system that affect 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 scientific knowledge while incorporate more inclusive, deliberative models for stakeholder engagements would go a long way in building trust in the regulatory system. How to accomplish this is the challenge. Next steps might include a Delphi survey of experts; 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.

6. 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 general public's perception of risk and fears regarding unknown (but possible) negative effects of emerging technologies. It is being asked to address the fears 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 regards 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. 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 general public in a non-technical manner (Lewandowsky et al 2011). The provision of this 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 where their evidence came from, how they are funded and who they represent. For example, some anti-GM groups are funded by organic farming organisations 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 values broadly representing the society it is in, but these should only be the starting point of a regulatory process; the process and decisions should then reflect the previously accepted scientific and technical processes.

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