From Knowledge Deficit to Trust in Institutions: Participation in the Canadian Biotechnology Regime

Abstract: participation is increasingly considered a critical element in policy making. Notions like distributed governance and public deliberation have not only opened new spaces for participation, but also raised expectations that it should be broadly implemented. In most industrialized countries governments state that participation is meant to foster citizens' trust in institutions; this is the case in Canada. However, we argue that in the case of Canadian biotechnology the institutional setting and the state-centered mechanisms of participation militate against the full implementation of a trust in institutions model.

The Growing Role of Participation

The growing importance of participation and an increasing attention towards creating a participation model that fosters trust in governmental agencies are clear patterns in most industrialized countries (Brunk, 2006; de Jonge, et al. 2008; Peter, Lang, Sawicka, and Hallman. 2007; Wynne, 2006).

A sector were this process may be particularly important is biotechnology because applications in both the medical and non-medical fields have the potential to generate complex ethical, health and economic issues and their analysis is complex and hinges on multi-level governance and activity from various groups including both civil society and government (Rothmayr Allison 2009). The protection of personal genetic information, establishing and enforcing appropriate health and environmental protection standards and designing tools that would balance market development and consumer protection and information are just some of the possible issues that policy-makers face when they engage biotechnology policy regimes. The notion that biotechnology is a critical area for public engagement seems borne out by the increasing use of Danish-style consensus conferences in countries like Norway, the Netherlands, France, Japan, South Korea, New Zealand, the United Kingdom, and the United States (Seifert 2006:77). The reception of biotechnology in general (Coyle and Fairweather 2005; Hornig Priest 2006; World Health Organization 2005), in the medical field (Greely 2001; Avard, Grégoire, and Jean 2008), and of genetically modified foods in particular (Andrée 2006; Durant and Legge 2006), highlight these concerns and the need for an analytical/educational approach minimizing the negative impact these technologies have on public perceptions of products under development. The level of effective participation that the public and stakeholders are allowed in the process is important to the acceptance of these technologies (Avard, Grégoire, and Jean 2008). In Canada, the Canadian Biotechnology Advisory Committee (CBAC) noted that public confidence in the process through which these new technologies are introduced is critical to their acceptance (BSDE Expert Working Party. 2006: 16). In general, representation in the consultation and engagement processes tends to favour members of what we call 'expert communities': academics, government officials and members of the industry.

Gutteling *et al.* (2006:111) found that in the Netherlands "trust is related to the way government or politicians are inclined to involve the public within decision-making, how industry is handling consumer interests, and individuals' perception of the way biotechnology may influence their life." A recent survey notes how an important section of the US and Canadian population wants to have a voice in the debate on gene

technology (Hornig Priest 2006). Beyond these points, what Sharp, Yudell, and Wilson (2004: 3) call constructive catalysts, the process of focusing attention upon a particular event so to influence policy change, may be critical for genomics. A crucial part would be played in this case by popularizing the research and by opening up discussion to a broad range of stakeholders.

The field of genomics policy may still benefit from a more participatory and informative approach to the diffusion of genomics technology than have been made to date (Sharp, Yudell, and Wilson 2004; Haga and Willard 2006; Pew Initiative on Food and Biotechnology 2006; Abelson, Giacomini, Lehoux, and Gauvin 2007; Avard, Grégoire, and Jean 2008). This may be relevant to more than just inclusive policy making as we know that the attitude of consumers is related to what they know about the kind of benefits and risks that are associated with GM foods (Brown and Qin 2005), and to their level of information (Costa-Font and Mossialos 2005). In the United States, the public has shown to be relatively segmented on the issue of GM foods and their labelling is also showing different results (Teisl, Radas, and Roe 2008). Public opinion in Canada on such matters is nuanced in its understanding of public policy in the field of genetics, but there is a call for weighing the benefits and drawbacks of these technologies (Hornig Priest 2006). A call for more deliberative dialogue in the country was put forward by the Canadian Biotechnology Advisory Committee in the place of the usual "polling and adversarial dialogue" (BSDE Expert Working Party. 2006: 30). We believe that in Canada the process of participation related to the field of biotechnology is relatively advanced in its implementation, as most governmental agencies have engaged in public consultations and the policy processes are relatively transparent and open. Here we shall use the differentiation noted by Castle and Culver (2006) between engagement (a process largely limited to informing the public), and consultation (a process where information is then augmented by actual consideration of the public's opinion). However, we argue that in Canada participation of either kind has had relatively little effect on the type of policy regime that has emerged being mostly limited to what appears akin to a voice option (Hirschman 1970), because it is embedded in a state-centered model of participation. Furthermore, we argue that while Canadian institutions have embarked in the task of shifting towards a trust in institutions model, the fact that they operated in a state-centered model of participation may limit the success of this move. In the next section we detail the nature of the Canadian biotechnology policy regime highlighting its foundational elements. In section three we explain why we believe that the Canadian system deploys a 'voice' option rather than a truly meaningful process of consultation. Finally we conclude by examining the tension that exists between the existing technology assessment model (based on a quasi-promotional biotechnology regime, which is grounded in a scientific rationality model) and the proposed trust-in-institutions model that many federal departments have seen as their goal in public participation.

The Canadian Biotechnology Policy Regime

In biotechnology, policy regime strategies and regulatory frameworks are correlated (Kleinman et al 2009). Regulatory frameworks deliver the details required to foster and enforce the specific direction and set of goals of National Science and Technology Policies. Biotechnology policy regimes have a critical national dimension,

but remain linked to international regulatory frameworks like the Cartagena Protocol on Biosafety (Newell 2008), or the Codex Alimentarius for food safety (Lindner 2008). However, within this common international policy space, different countries regulate, foster, and support biotechnology differently (Lindner 2008). This occurs both at the 'metalevel' regarding the choice of the principles that shape the regime, at the legislative level, and at the level of regulation.

For example, Isaac (2002) argued that the European Union and the North American approaches to regulating agricultural biotechnology diverge on their interpretations of the precautionary principle. The latter highlights and prioritizes scientific concerns, while the former emphasizes social concerns and responsibilities (see Table I).

Table I – *Scientific vs. Social Rationality in Genomics Regulation*

	Scientific Rationality (North America)	***Social Rationality (Europe)***
General Regulatory Issues		
Belief	Technological Progress	Technological precautions
Type of risk	Recognized Hypothetical	Recognized Hypothetical and Speculative
Substantial Equivalence	Accepts S.E.	Rejects S.E.
Science or other factors in risk assessment	Safety Health	Safety Health Quality Socio-economic Factors
Burden of proof	Traditional: Innocent until proven guilty	Guilty until proven innocent
Risk tolerance	Minimum risk	Zero risk
Science or other factors in risk management	Safety- or hazard-based: Risk management is for risk reduction and prevention only	Broader socio-economic concerns: Risk management is for social responsiveness
Specific Regulatory Issues		
Precautionary principle	Scientific interpretation	Social interpretation
Focus	Product-based, novel applications	Process- or technology-based
Structure	Vertical, existing structures	Horizontal, new structures
Participation	- Narrow: technical experts' - Judicial decision-making	- Wide: 'social dimensions' - Consensual decision-making
Mandatory labelling strategy	Safety or hazard based	Consumers' 'right to known'-based

Isaac (2001:2)

While this is an interesting starting point for our analysis is too general and a finer-grained approach is needed to study local variations in biotechnology regulation. This is especially true for patterns of regulatory behaviour generated by the extension of

biotechnology activity away from an emphasis on agricultural GMOs to a less interventionist but much broader application of genomics, metabolomics, transcriptomics and proteinomics to a wide number of fields. Genomics should not to be confused with genetic manipulation. While the two areas are cognate as genomics research is a prerequisite of genetic manipulation, little government or political regulation is attached to the study of an organism's genome structure, genetic manipulation is much more controlled and likely to generate political concern. However, it is clear they are attracting increasing interest from the public and this interest is not always benign or unconcerned.

Haga and Willard's (2006) approach embodies some of the details useful in understanding and exploring regulatory activity in this public policy sector. They argue five types of regulatory issues in the genomics/biotechnology area can be identified. These highlight the manner in which biotechnology regulation occurs at the intersection of a set of legal issues and public research investment, and underscore how way risk-management and regulatory oversight in the policy deliberation process are key features of the regimes that have developed over the past 20 years (Talukder and Kuzma 2008:131). Table II below lists eight basic issues with which biotechnology/genomics regulation has grappled, along with the five dimensions it touches upon.

Table II –*Regulatory Issue Field in Biotechnology*

Issue Areas	**Research issues**	**Legal issues**	**Economic issues**	**Education issues**	**Acceptance and Implementation issues**
Intellectual property rights	-Patent policy	-Intellectual property and licensing practices	-Cost-effectiveness		- Acceptance of biotech private ownership
Public information Inclusiveness of deliberation	-Ethics Review	-Privacy and confidentiality	-Cost of broad consultations -Intellectual property	-Development of clinical guidelines -Classroom education - Public education -Risk communication	-Behaviour modification in response to biotechnology results
Commercialization Retail Trade	-Patent Law	-Trade agreements	-Market value and pricing -Supply and demand -Commercialization of public-sector initiatives -Creation of new market segments	-Labelling	-Public adoption of biotechnology
Food and Health Safety	-Creation of a regulatory framework	-Regulatory oversight (product and manufacturing review, labelling, laboratory quality and environmental impact)	-Costs related to testing	-Education of health professionals	-Acceptance of the safety of food products by the public
Human Health	-Creation of a regulatory framework	-Regulatory oversight (product and manufacturing review, labelling, laboratory quality and environmental impact) - Issues of privacy -Genetic discrimination	-Market value and pricing vs. public provision of health care -Costs related to testing	-Education of health professionals	-Acceptance of the safety of health products by the public
Consumer choice	-Media Advertising	-Genetic discrimination	-Different responses in consumer behaviour	-Information directed towards consumers	-Cultural respect
Public research investment	-Prioritization of research areas (basic, applied and technology development) -Allocation of funds -Provision of facilities -Access to tools and research samples	-Protection of human subjects -Ownership of research results	-Research and Development funding -Economic incentives for biotechnology research	-Information directed towards citizens	-Acceptance of the value of biotechnology investment
Commercialization of biotechnology-related products	-Reliance on university generated research -Patent policy	-Intellectual property rights	-Accessing Venture Capital -Creation of Technology Licensing Organizations	-Labelling -Pedagogical research	-Acceptance of the value and safety of biotechnology products -Public Opinion Research

Source: Haga and Willard (2006:967)

Regulatory policy-making in biotechnology requires actors to design and adopt a set of policies dealing with the issues listed in the table above, which will correlate with the specific circumstances existing in the sector in a given country. This model highlights substantial differences among countries that the Isaac's model (2002) missed. Consider the example of Canadian and American GMO policies (Montpetit 2005), and the variance between agricultural and medical GMOs regulation within both countries (Sheingate 2006).

A similar system was employed by Paarlberg (2000) to analyze issues areas related to 'first generation' biotechnology policy. The goal was to generate a country (or sector) measure of policy openness to biotechnology. The result was a policy continuum composed of four levels, 'promotional', 'permissive', 'precautionary' and 'preventive', describing the nature of the policy system. Policies that accelerate the spread of GM crop and food technologies domestically are termed "promotional." Policies that are neutral toward the new technology, neither speeding nor slowing its spread, are called "permissive." Those policies intending to slow down the spread of GM technology are termed "precautionary." Finally, policies tending to block or ban the spread of the new technology are defined as "preventive" (Paarlberg 2000:4). These four categories intersect the issue areas of intellectual property rights, biosafety, trade, public research investment, food safety, and consumer safety. Thus, they create different sets of policy responses depending on the system's orientation. Haga and Willard' (2006) work is also important because it highlights the relevance of risk management and regulatory oversight in the policy deliberation process (Talukder and Kuzma 2008:131), a topic that Paarlberg (2000) did not focus upon. Public and stakeholders' participation in the policy process, especially in the area of new technologies has recently received a great deal of attention (Sharp, Yudell, and Wilson 2004; Haga and Willard 2006; Haddow, Laurie, Cunningham-Burley, and Hunter 2007; Metha 2004; Tutton 2007). It is important to include this dimension, considering that public perceptions and attitudes towards genomics/GMOs are often confused (Fischhoff and Fischhoff 2001).

In terms of regulatory tools, Haga and Willard (2006: 968) argue that the policy issue areas for GM technology are generally tackled with one, or with a mix, of five approaches, which they divide in legislative, regulatory, guidelines, voluntary approach and public consultation. Various countries use different approaches for similar areas. For example, in the United States legislation has often been used to prohibit of genetic discrimination, and in Australia a public consultation approach was followed in the same area by the Australian Law Reform Commission. We synthesise these regulatory approaches in two broad categories (state-centered and public) and link them to Paarlberg's categories to generate the comparative matrix shown in Table III. State approaches are based on scientific rationality and include legislative, regulatory, and guideline approaches. Public approaches are based on voluntarism or public consultation. Thus, we place countries or sectors in four policy quadrants, according to the preferences shown in their use of either elite or public policy approaches when dealing with biotechnology.

Table III *Comparative Biotechnology Regulatory Regimes*

State	Public	
US/Argentina Canada/Spain UK	Australia	Promotion
	Denmark	Permissive
Chile France	EU New Zealand	Precautionary
Italy	Zambia	Preventive

Denmark has used consensus conferences bringing together public comments on biotechnology (Seifert 2006), along with rather strict guidelines on cloning but is more permissive as far as genomics research is concerned. In 2001/2002, Zambia went through a public debate that ultimately led the African country to refuse a shipment of what might have been GM corn (Mwale 2006). In food safety policy, the European Union subscribes to the precautionary principle (Lindner 2008:142) and we find at least some examples of increased bottom up models (Seifert 2006). This has partially changed since 2004 when the World Trade Organization found the EU guilty of having implemented a de facto moratorium over GM products. Since then various types of GM corn and (in March 2009) the now obsolete T45 type canola were approved for import in the European Union.

It is within this varied context that public participation takes place. We argue that institutional settings influence the effects of participation. In the simplest policy cycle (Agenda Setting, Policy Formulation, Adoption, Implementation, and Evaluation) participation is likely to at least affect the agenda setting, policy formulation and evaluation phases. When we analyze the interactions of participation and policy, we should distinguish between the instruments of participation and the effects of participation on policy. We also argue that while the instruments that are chosen to channel participation affect the eventual shape of a policy (say by choosing to limit participation to a request for general feedback or by expanding it through consensus conferences), the general rationale of the policy regime in which this participation occurs influences the type of participation instruments that are chosen. This echoes the effects of institutional settings on policy instruments. We believe that in a biotechnology policy regime leaning towards social rationality we may see more participation instruments aimed at actual consultation, while a scientific rationality model is likely more preoccupied with educational efforts and would be more likely to show limited inclusion in the consultation process and more inclined towards what Castle and Culver (2006) called engagement.

We see participation tools as policy instruments and according to our model we would expect the use of specific participation instruments in biotechnology to be correlated to the State-centered/Public dimension, with the public side being more likely to see real participation as opposed to engagement and we would expect them to be arranged more or less in the following manner.

Table IV. *Distribution of Participation Instruments*

State		Public
Polling	Commissions	Public Consultation
Request for feedback		Referenda
Focus group	Public Hearings	Consensus Conferences

It is harder to place these instruments on the promotional to preventive dimension because their ultimate use depends on the basis upon which biotechnology is perceived in a certain country. For example, referenda have tended to promote increased state intervention in biotechnology regulation (Rothmayr Allison and Varone 2009). It would seem fair, however, to assume that regimes that rely heavily on a scientific rationality may be more inclined to use a more state-centered approach in the selection of participation instruments while ones that focus on social rationality may be more comfortable with public ones.

We argue that the Canadian biotechnology sector can be summarized in terms of this analysis in the results contained in the table below, offering a quasi-promotional environment for the development of biotechnologies and relying mostly on a guidelines style approach for regulation.

Table V. *The Canadian Biotechnology Sector Policy Regime*

Level	**Operating element**	**Implementation Processes**
Policy Regime	Quasi Promotional Approach with mainly top-down scientific risk assessment	-Permissive with elements of precaution in testing and screening of novel foods. -Promotional in the public research, IPR and consumer choice areas. -Promotional/permissive in the trade area.
Regulation	Guidelines style within a 'novel traits' regulatory approach	-A preference for incorporating legislative and regulatory tools about biotechnology in existing legislation and regulation. -Equating the products of biotechnology with non-biotechnology ones. -Labeling remained voluntary for GMOs. -Guidelines tend to be the tool of choice for the specialized agencies that supervise and foster biotechnology development.
Innovation	Industrial Complex to Italianate District Model	-Canada tried to foster the creation and market application of biotechnology in keeping with the original of the field as an economic opportunity. This attitude is visible in the goals of the federal Science and Technology policy. -The practical implementation of this vision passed through important research funding and investment and research incentives for the private sector. -Results have been mixed, for example the choice of supporting multiple biotechnology research centers across Canada did not result in multiple successes.
Participation	Participation instruments correlated to the State-centered approach.	-Canada has a hybrid TA system that is based on a office model structure but is increasingly showing signs of incorporating public participation elements.

		-Efforts in educating the Canadian public have been mixed with limited engagement and relatively little policy change that was not generated by the federal government (i.e., voluntary approaches to GMO disclosure).

In terms of biotechnology regulation Canada positioned itself closer to the very open approach chosen by the United States rather than to the less permissive one typical of the European Union (Cantley 2007). The early phase of biotechnology adoption and regulation (between the mid-1970s and the mid-1980s) saw important gains in the development and expansion of the technology and in the acceptance and commercialization of its products, progressively relaxing the relevant regulatory frameworks. Since 1994, Health Canada approved over 100 novel foods, many of these involved genetic manipulation (Canada 2008:5).[i] However, the promotional approach to biotechnology is reflected in various areas. [ii] For example, only in 2004 did the Canadian General Standards Board produce a voluntary labelling standard for genetically modified foods where genetically engineered material is over 5% of the product.[iii] While generally far from EU standards, this approach is still stricter than the one in place in the United States. In the Supreme Court of Canada Harvard Mouse case decision,[iv] the balance partially shifted towards the social rationality principle leading to tighter regulations, and more economic difficulties and conditions for firms engaged in the development and use of biotechnology. Also, the Canadian testing process and its triggers remain more restrictive than the American ones. While formally applying a substantial equivalency risk assessment principle (Canada 2001:11), the Canadian regulatory process is still tougher and more broadly geared towards checking the nature of new GM products than the US one. This reflects the hybrid nature of the overall approach to the production and commercialization of biotechnology with promotional research and commercialization processes and a permissive testing side.

Participation as Voice: The Canadian Experience

In the face of the increasing importance attached to public participation in biotechnology we are now asking with the question of what are the spaces reserved for, and the efficacy of, participation in the Canadian biotechnology regime we outlined above. First and foremost the Canadian regulatory system is geared towards the detection and regulation of novel traits. For example, using the product-based approach to the regulation of biotechnology means that regulatory oversight is triggered by the novelty of a trait that an organism possesses. For plants the Plant Biosafety Office (PBO) decides whether a plant with novel traits can be released in the environment. This makes the introduction of genomics tools like 'marker-assisted selection' (MAS) a non-issue in regulatory terms, falling outside of the scope of most regulation.[v]

Because public support for these technologies and their applications is important for research and especially for their commercialization, more effective involvement of the public may be needed. The federal government has tried to address these concerns with projects like the Biotechnology Notices of Submission Project that since 2003 has CFIA posting on its website the notices of submission for GM products and allowing for submissions from the public. Questions of a scientific nature are then looked at by CFIA or Health Canada, while more general ones are streamlined into a less specific area.[vi]

Also in 2003, Health Canada asked for public input in the revision of its Guidelines for the Safety Assessment of Novel Foods and in 2005 for an options analysis paper on the Environmental Assessment Regime for New Substances in Products Regulated under the Food and Drugs Act.[vii]

While we should notice that the process of consultation in the Canadian biotechnology sector is well developed, involving both simple engagement and consultation (Castle and Culver 2006), we argue that in Canada, participation is by and large limited to venues that do not engage the public at large in the policy process and in the negotiation process. This seems to be in countertendency with what Canadians appear to favour (Longstaff, Burgess, and Lewis 2006). We argue that the system remains akin to a 'voice' option rather than a true consultation model. For example, while Castle and Culver (2006) correctly note that proper consultation developed in the case of voluntary labelling of GM foods we see this as a minor change in the policy regime structure. In this case, consumer demand in Canada seemed to anticipate regulation. In 1999, pressed by the public, the Canadian Council of Grocery Distributors launched an initiative to create a national labelling standard (outside of the Food and Drugs Act) to give more information to Canadians regarding the content of their food, which ultimately resulted in the 2004 voluntary standards. The question remains of whether the latter is an efficient or even broadly legitimate tool given that many groups that supported mandatory labelling did not participate in the process. In general, while the Canadian system of biotechnology discussion relied on a relatively broad process of consultation, it tended to limit discussion to safety rather than expand it to issues of ethical concerns (Moore 2007). This alienated some of the participants and possibly undermined the support for genetically modified products.

The Canadian federal government has tried to make the regulatory framework friendlier to the approval of biotechnology. In 2003, the *Framework for the Application of Precaution in Science-Based Decision Making and Risk* was approved and while it mainly looked at establishing a precautionary principle for science and technology policy, it explicitly stated that the precautionary principle is of a temporary nature (based on the progression of scientific knowledge), that domestic and international obligations may limit its application, that while public participation is welcome, its effective use depends on the timeframe and on the context of the decision. The precautionary principle is subject to a cost-benefit analysis that involves both social and economic values. Soon after this framework was approved, the federal government started working on applying smart regulations to the field. The background work was based on the analysis of the External Advisory Committee on Smart Regulation and its 2004 final report, which included the recommendation to streamline of regulations including biotechnology and environmental assessment, alongside the statement that the health and safety of Canadians must be protected by regulation. Supporting this streamlining were the principles of effectiveness, efficiency, timeliness, transparency and accountability. At the same time, four more claims that can be more easily contested were made. It called for a synchronization of Canadian policy with that of the United States, it claimed that risk assessment should be based on an instrumental cost-benefit analysis (much as the 2003 framework did), it noted that the private sector would be easily able to cooperate in the process of regulation and that smart regulation is not regulation. To make matters more suspicious to some, the authors of the report tended to be drawn from a pro-business and

pro-deregulation milieu (Graham 2005). While many groups opposed this reading of the process of regulation and there were some notable voices raised against this approach (Graham 2005), the government continued towards smart regulation finally ending with the creation of the 2007 Cabinet Directive on Streamlining Regulation. While consultation was included in the process, it appears to have been heavily dominated by actors favouring the smart regulation approach.[viii] The Cabinet Directive notes the dual objectives of protecting Canadians while carefully examining the economic costs of doing so and the importance of carefully measuring the impacts of regulation on international competitiveness and international obligations before creating it. The Canadian federal government stayed the course in its newest Science and Technology Policy backgrounder: *Mobilizing Science and Technology to Canada's Advantage* (Canada 2007). There, we find a call for more private-sector commitment to science and technology and for the transformation of research into marketable products and services. Four core principles guide it: the promotion of world class excellence, encouraging partnerships among actors, enhancing the accountability of the system and focusing on key priorities, which are environmental science and technology, health and life sciences and technologies, natural resources and energy, and finally information and communication technology.[ix] The new strategy also wrapped together the Advisory Council on Science and Technology, the Council of Science and Technology Advisors, and the Canadian Biotechnology Advisory Committee into the Science, Technology and Innovation Council (STIC). However, as of March 2010 the STIC had only produced a small innovation roadmap, presenting a set of sub-priorities for the strategy four priority areas and report on the state of innovation in Canada for 2008.

The question remains of why Canadian processes of consultation/engagement fail to have any great effect on the policy regime. One immediate answer can be gleaned from the scientific rationality principle that is at the basis of the quasi-promotional regime. This drove the regulatory process towards favouring models of engagement rather than of consultation. This is rooted in the attitude that sees the public as in need of 'education' on the issues of biotechnology, the argument being that once educated the public will respond better to innovation. Consumer ignorance and the level of engagement in public consultations also affected the attitude of the industry towards the adoption of biotechnology innovation. This is reflected in the comparative findings of Weldon and Laycock (forthcoming) on the US, New Zealand and Canadian wine industry. In the Sonoma and New Zealand cases, where recent public consultations had raised the profile and controversy of biotechnology and GMOs, producers were concerned about adopting either biomarkers or GMOs especially as first wave innovators. In Canada, however, the producers were much less concerned about the possible response from members the public, whom were considered unsophisticated in the matter, regarding the application of biomarker technology, but were just as concerned as the American and New Zealand producers in using GMOs. The second answer lies in the commercialization approach of the Canadian Science and Technology polices that have for some time now pushed towards the conversion of the research into marketable products. Because of these elements we believe that the role of participation in the Canadian context will, at least until some major changes are effected in the core elements of the policy regime, remain bound to a voice option rather than to a more participatory orientation.

The Trust in Institutions Model in Canada

In this section we examine the nature of the Technology Assessment (TA) process in the area of biotechnology in Canada and its correlation to the attempted shift in the Canadian federal public administration from a knowledge deficit model of participation to a trust in institutions one. The knowledge deficit model is a well known approach according to which expert forms of knowledge are the soundest basis for all policy decisions and education and public relations are the best methods to generate public support for all sorts of different areas, including biotechnology. While studies show that deference towards this type of expert/scientific knowledge is actually a good predictor of the acceptance of biotechnology (Brossard and Nisbet 2007), we are also faced with an increasingly broad challenge to this paradigm (Brown 2009; Sturgis 2004). There is, however, little doubt that trust is a critical component in the acceptance of new technology (Chalmers and Nicol 2004; Peters, Lang, Sawicka, and Hallman 2007; Macoubrie 2006; Portinga and Pidgeon 2003), and that the source of information is critical to that trust developing and holding (Lang, O'Neill, and Hallman. 2003; Priest, Bonfadelli, and Rusanen 2003). While there has been a broad interest in public engagement in the area of new technologies, the results have been generally less impressive than what the ado about the process may have led many to expect (Kurath and Gisler 2009). We believe that in Canada (as well as other countries dealing with an increased demand for public participation in biotechnology assessment) governments are interested in creating a trust-in-institutions model that would increase public acceptance of these products and processes by increasing public trust in the role of the governmental branches that look at and screen these novel technologies. We define a trust-in-institutions model as a institutional setting in which the public at large is confident that governmental institutional units assess technology and processes in a fair and balanced manner that is mindful of the preferences and the needs of the public (including here producers, consumers, and various users) and is cognizant of the need to protect the health of the public and the environment. Part of this effort hinges on increasing the levels of participation and engagement of the public in this area to the point where the public is generally satisfied that levels of access and input into the policy-making process are meaningful and effective.

Technology assessment is a critical juncture at which effective participation can be built into the biotechnology system. Of course this is not to say that TA is the only avenue for increased participation, as the latter can be built in most phases of a public policy, but it certainly is one of the most relevant. This is why it is important to understand both the principles that shape the process of TA and the practical mechanisms through which it is undertaken. The Canadian government grounds its regulation upon scientific rationality and a risk-based assessment process, much like the US and UK and utilizes existing agencies to administer them.[x] The two most important fields in biotechnology assessment in Canada are food and medicine. The Canadian Food Inspection Agency (which took over food biotechnology assessment from Agri-Food Canada in 1997) uses novel traits as its trigger for environmental review in new plant material. Health Canada also uses novelty as a trigger for its review of foods. However, all products go through the same risk management process whether or not they are the

result of genetic modification (Montpetit 2005).

Pre-market notification to Health Canada of biotechnology products became mandatory in 1999 and under the interim Policy on Foods from Cloned Animals (2003) the Food Directorate of Health Canada also requires that all products derived from cloned animals produced through somatic cell nuclear transfer (SCNT) also be subject to the novel foods definition of the *Food and Drugs Act*.[xi] This product-based approach became institutionalized through the 1993 *Regulatory Framework for Biotechnology*. This approach is based on the assumption that products derived from genetic manipulation are not inherently riskier than any other product. In practice, this meant that the Canadian government modified existing legislation inserting triggers for risk analysis related to genetic manipulation in the *Feeds Act*, the *Fertilizers Act*, the *Seeds Act*, the *Health of Animals Act*, and the *Plant Protection Act*. Biotechnology was 'tagged on' to the regulatory and legislative process as just another way through which novelty may emerge. Additions to legislation like the *Canadian Environmental Protection Act* (1988) and the *Plant Breeders' Rights Act and Regulations* (1990) were designed to strike a balance between the safety of the public and of the environment and a favourable business climate for companies that were interested in investing in biotechnology in Canada.

At an institutional level, Canadian biotechnology policy was couched in a system of governmental committees. In 1999, the Federal government created the Canadian Biotechnology Advisory Committee (CBAC) mandating it with providing comprehensive advice on the social, ethical, legal, scientific, regulatory, environmental, and health elements of biotechnology while providing Canadians with information on the topic and acting as a discussion forum. In 2000, the Canadian Regulatory System for Biotechnology (CRSB) was approved by the Treasury Board. It was premised upon four key objectives (technical capability, public awareness, efficiency and effectiveness, and knowledge) and it aimed at increasing the capacity of departments to deal with a wide range of issues emerging from the application of biotechnology

The CBAC was embedded in the Federal structure, operating along the Canadian Biotechnology Secretariat (CBS), to which it fell to coordinate the horizontal activity of departments and agencies involved in the Canadian Biotechnology Strategy, and reporting to the Biotechnology Ministerial Coordinating Committee (BMCC).[xii] The BMCC members represented the federal Ministers of Industry, Agriculture and Agri-Food Canada, Health Canada, Environment Canada, the Department of Fisheries and Oceans, Natural Resources and International Trade. CBAC operated between September 1999 and May 2007, when it was replaced by the Science, Technology and Innovation Council (STIC), which under the new Science and technology policy outlined in the *Mobilizing Science and Technology to Canada's Advantage* (Canada 2007) now brought together the Advisory Council on Science and Technology, the Council of Science and Technology Advisors, and the Canadian Biotechnology Advisory Committee.

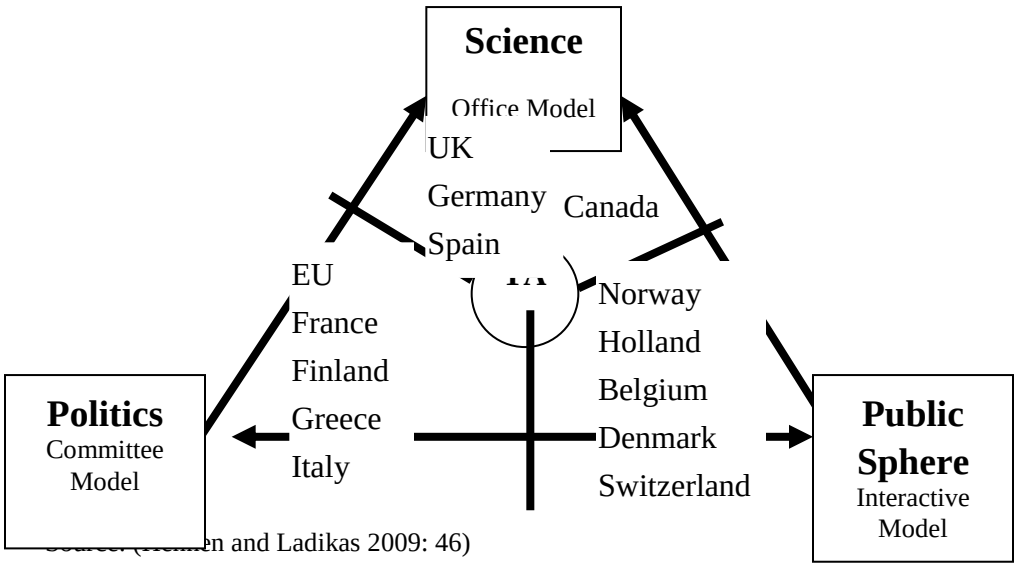
Beside the institutional landscape, the actual job of assessing biotechnology is a critical part of the regulatory and governmental input in the system. In our assessment of TA we focus primarily on biotechnology even if the process is broader. Consider for example the notion of Health Technology Assessment (HTA), itself a subset of TA. The Canadian health system relies on decentralized structure in which 13 provinces and territories administer different health insurance programs. While predominantly

provincially based, the Canadian HTA makes decisions, at the federal level, on pre-market authorizations, at the provincial and local level on what will be funded through the public purse, what drugs and devices will be chosen (Menon and Stafinski 2009).

In Canada, biotechnology assessment falls under the jurisdiction of the federal government. This, as noted above, regards GMO technology. Regulation of health biotechnology, which also includes food, falls under the scope of Health Canada and the Canadian Food Inspection Agency (CFIA) with Environment Canada dealing with residual issues in the area of chemicals and enzymes. For example Plant Biosafety Office (PBO),[xiii] which is a branch of CFIA, decides whether a plant with novel traits can be released in the environment. Environmental biotechnology assessment is divided between Health Canada, the Pest Management Regulatory Agency (under the control of Health Canada), Fisheries and Oceans, and the Canadian Food Inspection Agency. These same agencies also assess agricultural biotechnology. Finally, industrial biotechnology is assessed through Environment Canada.

To place Canada in a comparative technology assessment space we use Hennen and Ladikas (2009) model. These authors argue that technology assessment can be approached in three different ways: a science, a politics and a public sphere approach. If science dominates as the interpretive tool we generally find ourselves faced with an office model (similar to what happens in Canada). Independent institutes of parts of the public administration take on the tasks given to them by parliamentary authorities. In a politics-driven model of technology assessment we generally find a committee model in which parliamentary committees set their own agendas and invite experts to give testimony or organize workshops and conferences. Finally, in a public sphere approach the model we find is an interactive one where parliamentary bodies cooperate closely with external independent entities and is generally open to participation from the public. The figure below illustrates this space and places various countries in the respective quadrants.

Figure I. The Technology Assessment Space



Source: (Hennen and Ladikas 2009: 46)

Regarding biotechnology assessment, Canada is located in terms of its

institutional setting in the science area, following an office model that has however been hybridized. While TA processes are held closely by ministerial units (within Health Canada, Agriculture and Agri-Food Canada, and Environment Canada for example), contacts with external, independent sources are also sought to supplement lack of in-house capacity but also when the government is looking for broader context answers and inputs from the public. Recently the federal government has underscored the importance of involving the public in the decision-making process through various participation tools. In this sense, the direction of the policy system is moving towards the public sphere area. We argue that this move is hindered in practice by the existing institutional model which negates at least in part the interactive model that is matched with the public sphere.

For example, Health Canada has in the past few years embarked on a complex and wide-ranging effort to increase the level of public participation in the technology assessment process seeking such participation not only because it enhanced the democratic process and heightens accountability, but also because "sharing information and including a range of perspectives in the decision-making process enhances the quality, credibility, and accountability of the decisions the Health Products and Food Branch makes about a regulated product, and encourages public trust in its decision making" (Health Canada 2007: 2) and in the . Similar opportunities are envisioned in the Health Canada Policy Toolkit for Public Involvement in Decision Making (Health Canada 2000) and in the Health Products and Food Branch (HPFB) Public Involvement Framework (Health Canada 2005). There is an obvious goal here of extending the level of trust that Canadians hold in the institutions that regulated their safety. Alongside policy statements, the federal authorities have also engaged in institutional reform focusing on public participation. For example in the last decade Health Canada has worked on the need to increase access to its activities by creating in 2000 the Office for Consumer and Public Involvement (OCAPI) within HPFB, which was tasked with both an educational and a participation enhancing role. OCAPI fostered participation in health care, on pesticides and on workplace health using expert and public advisory committees and public consultations.

In 2008, Health Canada reorganized its structure by creating the Public Affairs, Consultation and Communication Branch (PACCB),[xiv] and OCAPI saw some of its public participation and educational roles transferred to PACCB. This new institutional approach is clearly intended to focus on increased avenues of participation and engagement for Canadians in the area of health. There are however some important caveats that should be noted. First of all, the extent and type of participation vs. engagement in these exercises needs to be carefully assessed on a case-by-case basis. For example, the *Food and Drugs Act* establishes that public input is considered if and only if it meets the statutory criteria of safety, quality and efficacy. This is understandable from the point of view of the bureaucratic machinery and has a logic explanation in the quasi-promotional regime that Canada has embraced in biotechnology, but it still leaves some critical areas of public participation out in the cold. That said, more input is being sought outside of the expert knowledge communities, trying to involve consumers and patients in the process and increasing the level of transparency that advisory bodies (the main source of information and input in the TA process) have.

Two other departments in the Canadian federal structure have key roles in assessment of biotechnology related issues: Environment Canada and Agriculture and

Agri-Food Canada. Both have engaged in a variety of public consultation exercises designed to enhance the trust that Canadians have in this process. Environment Canada has long tried to engage the public and the private sector in discussions and public consultations related to the Canadian Environmental Protection Act, 1999. Between 1999 and 2009 Canadians were consulted on an average of 30 issues every year. Generally speaking this type of engagement consisted in a request for the submission of a comment to the appropriate departmental office and covered a disparate series of issues ranging from the amending of emergency environmental regulations to the status of specific chemicals. In 2004 a Review of the New Substances Notification Regulations (Organisms) multi-stakeholder consultation process took place that centered around the field of biotechnology. The consultation drew 123 participants in workshops across the country and representatives of civil society groups were present. The 2004 review was followed up in December 2007 by a two-day consultation that discussed amendments to the existing regulation.

Agriculture and Agri-Food Canada has engaged in public consultations on issues like rural policy (organizing conferences for example) and on biotechnology. In 1988, the department was given responsibility for conducting confined research field trials for plants with novel traits and it undertook a series of multi-stakeholder consultations the most interesting of which was a workshop of experts (which included federal and provincial government officials, academics and members of the private sector) under the direction of the Canadian Agri-Food Research Council (CARC), which resulted in the decision to adopt as a trigger for safety assessments a trait-based approach rather than a process based one. The concept of regulatory transparency is also often quoted by government documents as including a consultation process with multiple stakeholders. However, these stakeholders tend to be drawn predominantly from expert communities such as government, industry, and academia. This was the case, for example, for the international framing that the domestic regulation regarding plants with novel traits was and still is mindful of and that was influenced by expert consultations that the World Health Organization, the OECD and the Food and Agriculture Organization developed for biotechnology regulation. When in 1996 the Seeds Act, Feeds Act, Fertilizers Act, and Health of Animals Act were amended to encompass the new issues generated by biotechnology applications, consultations with stakeholders preceded the amendments.

In 1998, various departments began the Consultation on Regulating Livestock Animals and Fish Derived from Biotechnology, which involved once again a number of experts but was also open to private citizens and First Nations and aimed at obtaining input on how to improve the Canadian regulatory system in the area of biotechnology and to increase the awareness of biotechnology and of its uses. While this was an interesting step, in 2003 another workshop aimed at the future developments of animal biotechnology in Canada was limited to members of the expert communities. This also had been the case for the expert panel report "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada" (Royal Society of Canada 2001) that was commissioned by the federal government.

The above is not to say that broad consultation does not take place in Canada, one example was the consultation exercise that surrounded the labelling of biotechnology-derived foods and the review of the regulations on the notification of new substances and organisms are good examples here. However, while engagement processes (submission

of opinions for example) and involving expert communities are very well developed, the Canadian system is still struggling to meaningfully involve on an ongoing basis the broader public and members of civil society. In Canada technology assessment processes face significant pressures from at times contrasting positions regarding the level of participation and engagement that the public should be allowed. On the one hand, the public is increasingly interested in and expects to be involved in the process of technology assessment. On the other, government organizations face barriers in term of their duty to protect confidential information coming from the private sector and must work within the institutional and regulatory constraints that the existing regime imposes on the sector. In this sense, the biotechnology sector in Canada is in tension between a bottom-up pressure from consumers and various advocacy groups, which is at least partially taken up by various departments in the federal government, and an institutional framing that tends to limit the space for public involvement to an engagement level. While the attention that administrative units like PACCB pay to an increased participation from the public is commendable and moves in the right direction for both better policy-making and a more fulsome trust in these institutions and higher levels of acceptance of biotechnology, there still appear to be barriers to the full establishment of a trust-in-institutions model. Many of them are dependent on the quasi-promotional regime that is in place in the biotechnology sector and are related to the scientific rationally approach on which the latter is based. Unless more radical changes in these areas take place the trust-in-institutions model will ultimately face severe limitations in its practical implementation.

Endnotes

[i] The OECD BioTrack database can be very useful for a general comparison of approved biotechnology [http://www2.oecd.org/biotech/byCountry.aspx].

[ii] Compare the Canadian approach with the EU regulations that 1830/2003 on the Traceability and Labelling of GMOs and 1829/2003 on Genetically Modified (GM) Food and Feed (implemented in 2004), which required that any more than a 0.9% of unintended presence of an EU approved genetically engineered substance would trigger a mandatory labelling of the product as GMO. Even if this regulation exempted from labelling products like milk, eggs and meats from animals fed with GMO feeds, it created massive limitations to trade and in 2006 the World Trade Organization ruled that this was a de facto moratorium on US, Canadian and Argentine products. General international standards have also been elusive, as the Codex Committee on Food Labelling (CCFL) of the Codex Alimentarius Commission has discussed this topic for over 15 years without making much progress.

[iii] Under this standard, processing aids, enzymes below 0.01% by weight in a food as offered for sale (for exceptions, see par. 6.2.7 a.), veterinary biologics, animal feeds, and substrates for micro-organisms (where the substrate itself is not present in the finished food product) do not affect whether a food or ingredient is considered to be or not to be a product of genetic engineering.

[iv] The case President & Fellows of Harvard College v. Canada (Commissioner of Patents), [2002] SCC 76 (the Harvard Mouse case) established the higher life forms did not fall under the definition of invention found in Section 2 of the Patent Act "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."

[v] It should be noted that Marked Assisted Selection is also not regulated in Canada and abroad as it does not change the nature of the products

[vi] The format may not be the most reassuring for opponents of GMOs but certainly illustrates the relevance attached by the federal authorities to the scientific rationality principle. "Scientific questions or information will be forwarded to CFIA and Health Canada evaluators for consideration in the assessment. Non-scientific input will be evaluated and appropriate ways of addressing it will be explored."

[http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml].

[vii] On the topic of food coming from cloned animals, Canada appears to be more inclined towards a precautionary principle. An Interim Policy (the Food Directorate Interim Policy on Foods from Cloned Animals) was put forward in 2003 requesting a voluntary moratorium to development of cloned animals, which is still in place, until more information emerged. A similar moratorium was put in place in 2001 in the United States by the Food and Drug Administration (FDA), but in January 2008 the FDA concluded that meat and milk from cloned animals are safe for human consumption. In July 2008, the European Food Safety Authority concluded that there was no evidence that of any difference between cloned animals and regularly bred ones in terms of their health risk when used as food.

[viii] For a list of participants in this phase of consultation see the Regulation Canada website. [http://www.regulation.gc.ca/consultation/consultation-eng.asp]

[ix] The rhetoric of the federal science and technology strategy speaks of building three advantages: a people advantage, a knowledge advantage, and an entrepreneurial advantage.

[x] The agencies that are most relevant in the regulation of biotechnology in Canada are Health Canada (for drugs, foods, health products and laboratory testing and research), the Canadian Food Inspection Agency, the Pest Management Regulatory Agency (regulation of pesticides), Fisheries and Oceans (for the environmental release of fish and aquatic plants) and Environment Canada (for issues like the notification of new substances and industrial applications of biotechnology and residual products).

[xi] The trigger of novelty is used by Health Canada under the *Food and Drugs Act* to deal with novel foods defined as "foods derived from genetically modified organisms" (Health Canada 2003:5). Health Canada deals with the pre-market assessment of the safety levels of the new products, the post-market monitoring of the food and its labelling. Beside the food areas, Health Canada also covers the medical technology linked to biotechnology including vaccines, radiopharmaceuticals containing a biotechnology component, drugs, and medical devices. Here some questions remain because of the lack of a unified national policy on the research on human subjects in medical technology. The very important Research Ethics Boards to which it is left the duty to vet the research have little enforcement capacity and proceed to the accreditation of their members according different rules across the country. This makes for a "system of research governance [that] is fragmented, and decentralized, without a consistent, accountable, and transparent system of ethics review" (Cranley Glass 2006:44). It should be noted that products derived from other cloning techniques have been considered safe and the marketing of this livestock and products is generally not restricted.

[xii] The shape of the interdepartmental coordination and policy-making process was actually a bit more complicated as it involved, beside the Biotechnology Ministerial Coordinating Committee (BMCC), which was operating at the broader level, three other committees. The Biotechnology Deputy Minister Coordinating Committee (BDMCC) dealt with providing strategic policy guidance and setting governmental priorities in the field. The Biotechnology Assistant Deputy Minister Coordinating Committee (BACC) linked the key federal department with the main Canadian granting agencies, and finally the Biotechnology Director General Coordinating Committee (BDGCC) was set up as a venue to discuss possible policy options and issues of mutual concern. It was chaired by the Canadian Biotechnology Secretariat's Executive Director. [http://www.bioportal.gc.ca/English/View.asp?x=537&mid=35].

[xiii] In fact, the PBO has a broad mandate in terms of plants with novel traits which covers the approval and inspection of their confined research field trials, the approval of their unconfined release, and the assessment of import applications for plants with novel traits. It further deals with developing domestic regulatory policies related to their environmental release and international regulatory policies.

[xiv] PACCB is composed of five units: Ethics and Internal Ombudsman Services; Marketing and Communications Services Directorate; Planning and Operations Division; Public Affairs and Strategic Communications Directorate; Stakeholder Relations and Consultation Directorate.

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