Technology in Society xxx (2010) 1–8

Contents lists available at ScienceDirect

Technology in Society

journal homepage: www.elsevier.com/locate/techsoc

# The Canadian biotechnology regulatory regime: The role of participation

Michael Howlett*, Andrea Riccardo Migone

*Department of Political Science, Simon Fraser University, Burnaby BC, Canada V5A 1S6*

*Keywords:*
Participation
Canada
Biotechnology policy
Regulatory regime

A B S T R A C T

In this article, we ask the question: how important is the participation element in the creation and reproduction of the Canadian biotechnology policy regime? We find that within the quasi-promotional regime currently in place in Canada, participation plays an interesting role (close to Hirschman's 'voice' option), but not a core one in setting or modifying policy structure. It depends largely on the institutional setting within which the policy regime was originally constituted. We expect that in Canada, participation will make few inroads in changing the policy regime unless some core elements of the latter change.



## 1. The importance of participation in policymaking

The growing importance of participation and an increasing attention towards creating participation models that foster trust in governmental agencies is a clear pattern in policymaking in most industrialized countries.

A sector where this process should be particularly important is biotechnology because applications in both the medical and non-medical fields generate complex social ethical, health and economic issues which are difficult for governments to resolve at an exclusively state level. 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 issues which require societal input that policy-makers face when they engage in biotechnology policymaking [1–4].

An important factor in the acceptance of these technologies is the level of effective participation that the public and stakeholders have been allowed in the process [5,6].[1] Promoting more inclusive policymaking, however, requires more than just enhancing opportunities for participation and consultation as the attitudes held by participants is related to what they know about the kind of benefits and risks that are associated with biotechnology products [7] and thus to the level of information they hold [8]. This means enhancing participation also must include an enhanced educational as well as a deliberative component. The reception of biotechnology in general [12–14], in the medical field [5,15], and of genetically modified foods in particular [16,17], have all highlighted the need for an analytical/educational approach that minimizes negative public perceptions of products under development.[2]

Gutteling et al., for example, 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" [18, p. 111]. Another case, in a developing country context, in which public debate assumed an important dimension in the area of the acceptance of genetically modified foods was the public debate that took place on the subject during 2002 in Zambia [19].

* Corresponding author. Tel.: +1 778 782 3082; fax: +1 778 782 4786.
*E-mail address:* howlett@sfu.ca (M. Howlett).

[1] Participation of the public and stakeholder groups in the policy process when new technologies are involved is a subject that has received a great deal of attention in recent years. See, for example, [9–11].

[2] The distinction noted by Castle and Culver [28] 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) is useful in this regard. For an extensive review of specific mechanisms using this distinction, see Rowe and Frewer [29].

0160-791X/$ – see front matter © 2010 Elsevier Ltd. All rights reserved.
doi:10.1016/j.techsoc.2010.10.004

**Table 1**
Scientific vs. social rationality in agri-food biotechnology regulation.

| | Scientific rationality (North America) | Social rationality (Europe) |
|---|---|---|
| *General regulatory issues* | | |
| Belief | Technological Progress | Technological precautions |
| Type of risk | Recognized | Recognized |
| | Hypothetical | Hypothetical and speculative |
| Substantial Equivalence | Accepts S.E. | Rejects S.E. |
| Science or other factors in risk assessment | Safety | Safety |
| | Health | 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' | - Wide: 'social dimensions' |
| | - Judicial decision-making | - Consensual decision-making |
| Mandatory labelling strategy | Safety- or hazard-based | Consumers' 'right to known'-based |

Isaac [27, p. 2].

## 2. The potential to enhance public participation: the role of policy regimes

The notion that biotechnology is a critical area for public engagement is borne out, for example, 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 [20] and calls for a more participatory and informative approach to the diffusion of biotechnology technology have been made by various groups [5,9,10,21,22].

The extent to which this can be achieved in practice, however, is heavily context-dependent. As Kleinman et al. [23] noted policy strategies and regulatory frameworks in the science-policy sphere are interconnected: the former delivering the needed detail in enforcing and fostering a specific direction and set of goals for national science and technology policies in areas such as biotechnology while the latter provides a set of tools or mechanisms for implementing them. Together these two elements make up the basis of a *policy regime,* that is a set of institutions, ideas and logics which drive both the content and process of policy-making, including its susceptibility to public input [24–26].[3]

Thus surveys have noted how an important section of the US and Canadian population wants to have a voice in the debate on gene technology [13]. But popularizing research and opening up policy discussion to a broad range of stakeholders may be desired by a range of actors yet very difficult to put into practice depending on the nature of the policy regime in place in a country and how open it is to enhanced public participation.

Isaac [27], has argued that different countries vary quite dramatically in how they interpret the general precautionary principles articulated in international agreements with respect to the introduction of novel biotechnologies. North American and European Union approaches towards the regulation of agricultural biotechnology, for example, he argued, differ according to their diverging interpretations of the precautionary principle. North American jurisdictions feature regimes which tend to highlight and prioritize scientific concerns while European countries tend to emphasize social concerns and responsibilities. This difference, Isaac argues, carries through many aspects of biotechnology regulatory activity to generate two very different styles of regulation in the two regions: one which is more open to public concerns than the other (see Table 1).

This analysis is quite general, however, and requires a more fine-grained approach if local and sectoral variations in biotechnology participation are to be understood, especially in the context of a shifting pattern of regulatory behaviour brought about by the extension of biotechnology activity away from an emphasis on agricultural GMOs to much broader application of genomics, metabolomics, transcriptomics and proteinomics-related techniques not only in 'traditional" fields such as pharmaceuticals and health, but also in many others such as biofuels and other energy and industrial applications.

Haga and Willard [10] provide some of the details required to understand and explore the different kinds of regulatory activity that has been undertaken in different sectors and how it has been affected by public participation. They argue that a set of basic types of policy issues can be identified in different biotechnology contexts which occur at the intersection of specific sets of legal issues and regulatory concerns [32]. Table 2 below provides the list of issues they identify in this fashion.

[3] Biotechnology policy regimes are sectorally specific and emerge at the national level in most countries. Although they are closely connected with international developments in terms of their links with regulatory frameworks like the Cartagena Protocol on Biosafety [30], or the Codex Alimentarius in the area of food safety [31], as in the case of Canada, Australia, Germany and other federal systems, they also contain an important sub-national, regional or local dimension. Thus within a common international policy space different countries regulate, foster, and support different biotechnologies in different ways [31]. Understanding these differences in important in understanding the role public opinion and public participation plays in different national contexts.

Please cite this article in press as: Howlett M, Migone AR, The Canadian biotechnology regulatory regime: The role of participation, Technology in Society (2010), doi:10.1016/j.techsoc.2010.10.004

**Table 2**
The regulatory issue field in biotechnology.

| Biotechnology areas of activity | Regulatory concerns | | | | |
|---|---|---|---|---|---|
| | Research-related | Legal | Economic | Education-related | Acceptance and implementation-related |
| Intellectual property rights | - Patent policy | - Intellectual property and licensing practices | - Cost-effectiveness | | - Acceptance of biotech private ownership |
| Public information and deliberative activities | - Ethics Review | - Privacy and confidentiality | - Cost of broad consultations<br>- Intellectual property | - Development of clinical guidelines<br>- Classroom education<br>- Public education<br>- Risk communication | - Behaviour modification in response to biotechnology results |
| Retail and trade activities | - Patent Law | - Trade agreements | - Market value and pricing<br>- Supply and demand<br>- Commercialization of public-sector initiatives<br>- Creation of new market segments | - Labelling | - Public adoption of biotechnology |
| Health and 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 |
| Consumer activities | - Media Advertising | - Genetic discrimination | - Different responses in consumer behaviour | - Information directed towards consumers | - Cultural respect |
| Research investment activities | - Prioritization of research areas (basic, applied and technology development)<br>- Allocation of funds<br>- Provision of facilities<br>- Access to tools and research samples | - Protection of human subjects<br>- Ownership of research results | - Research and development funding<br>- Economic incentives for biotechnology research | - Information directed towards citizens | - Acceptance of the value of biotechnology investment |
| Commercialization activities | - Reliance on private or public generated research<br>- Patent policy | - Intellectual property rights | - Accessing Venture Capital<br>- Creation of Technology Licensing Organizations | - Labelling<br>- Pedagogical research | - Acceptance of the value and safety of biotechnology products<br>- Public Opinion Research |

Source: Haga and Willard [10, p. 967].

**Table 3**
Paarlberg model of policy options and regimes towards GM crops.

| | Promotional | Permissive | Precautionary | Preventive |
|---|---|---|---|---|
| Intellectual property rights | Full patent protection, plus plant breeders' rights (PBR) under UPOV 1991 | PBRs under UPOV 1991 | PBRs under UPOV 1978, which preserves farmers' privilege | No IPRs for plants or animals or IPRs on paper that are not enforced |
| Biosafety | No careful screening, only token screening, or approval based on approvals in other countries | Case-by-case screening primarily for demonstrated risk, depending on intended use of product | Case-by-case screening also for scientific un certain ties owing to novelty of GM process | No careful case-by-case screening; risk assumed because of GM process |
| Trade | GM crops promoted to lower commodity production costs and boost exports; no restrictions on imports of GM seeds or plant materials | GM crops neither promoted nor prevented; imports of GM commodities limited in same way as non-GM in accordance with science-based WTO standards | Imports of GM seeds and materials screened or restrained separately and more tightly than non-GM; labelling requirements imposed on import of GM foods or commodities | GM seed and plant imports blocked; GM- free status maintained in hopes of capturing export market premiums. |
| Food safety and consumer choice | No regulatory distinction drawn between GM and non-GM foods when either testing or labelling for food safety | Distinction made between GM and non-GM foods on some existing food labels but not so as to require segregation of market channels | Comprehensive positive labelling of all GM foods required and enforced with segregated market channels | GM food sales banned or warning labels that stigmatize GM foods as unsafe to consumers required |
| Public research investment | Treasury resources spent on both development and local adaptations of GM crop technologies | Treasury resources spent on local adaptations of GM crop technologies but not on development of new transgenes | No significant treasury resources spent on either GM crop research or adaptation; donors allowed to finance local adaptations of GM crops | Neither treasury nor donor funds spent on any adaptation or development of GM crop technology |

Viewed in this light, there are substantial additional differences between countries than those listed in Isaac's model. Regulatory policymaking in a specific biotechnology field or sector involves the design and adoption of a set of policies to deal with the issues noted in Table 2 above, which dovetails with the specific circumstances and orientations that exist in the sector in a particular country.[4]

Paarlberg [33] used just such a system to score issues in areas linked to 'first-generation' agri-food biotechnology policy in order to generate a country and sector-specific measure that ranged policy approaches in terms of their 'promotional', 'permissive', 'precautionary' and 'preventive' nature. Policies that accelerated the spread of GM crop and food technologies within the borders of a nation he termed "promotional." Policies that were neutral towards the new technology, in tending neither to speed nor to slow its spread, were called "permissive." Policies intended to slow the spread of GM crops and foods for various reasons were termed "precautionary." Finally, policies that tended to block or ban entirely the spread of this new technology were defined as "preventive" [33, p. 4] (see Table 3).

As Paarlberg and others have noted, the institutional setting heavily influences not only the amount but also the effects of participation. In creating specific biotechnology policy regimes, governments have adopted one or more of five basic approaches to biotechnology regulation [10]. These are a legislative approach, featuring enactment of laws; a regulatory approach focused on the addition of new mandatory rules and standards; a guidelines approach promoting best practices; a voluntary approach leaving matters to the self-regulation of industry; or a public consultation approach involving widespread public hearings and information campaigns. 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) and the general nature of the policy regime influences the type of participation instruments that are chosen.

If we consider a set of participation instruments ranging between polling, requests for feedback, the constitution of commissions or expert groups, public consultations and consensus conferences, we would expect them to be arranged more or less in the following manner (see Table 4).

Regimes that rely heavily on scientific rationality are more inclined to use a state-centered approach in the selection of participation instruments while ones that focus on social rationality are more comfortable with public ones.

Thus biotechnology policy regimes leaning towards social rationality will typically see more participation instruments aimed at consultation, while scientific rationality models are more likely to be more preoccupied with educational efforts and less concerned with consultation. In the European Union, for example, the leading principle in food safety policy has been a precautionary one [31] whose social protection

**Table 4**
Distribution of participation instruments.

| State | → | public |
|---|---|---|
| Polling | Commissions | Public Consultation |
| Request for feedback | | Consensus Conferences |

[4] Two good examples of such variations are to be found in the variance between US and Canadian GMO policies [34], and between agricultural and medical GMOs within the both countries [35].

Please cite this article in press as: Howlett M, Migone AR, The Canadian biotechnology regulatory regime: The role of participation, Technology in Society (2010), doi:10.1016/j.techsoc.2010.10.004

rationality has led to public consultations which in turn have led to various kinds of bans and moratoria on the use of specific biotechnology products such as GM foods [20].[5]

## 3. The Canadian case

Now we will apply this model and hypothesis to a specific country case, that of Canada. We have chosen the Canadian case because the country has a sizeable biotechnology sector [36], which it has tried to develop through a long-standing science and technology policy in the field [37], and because there have been high-profile calls for more deliberative dialogue on biotechnology policy in the country. The Canadian Biotechnology Advisory Committee, for example, has argued that enhanced participation could serve as a substitute for the usual "polling and adversarial dialogue" typically found in Canadian policymaking and regulatory activities in the area [6, p. 30].

### 3.1. The Canadian biotechnology policy regime

In terms of its biotechnology policy, Canada has positioned itself closer to the open approach chosen by the United States rather than to the less permissive one typical of the European Union [38]. However, significant differences exist between the US and Canada on many important biotechnology policy dimensions. In the United States, for example, the public has been shown to be relatively segmented on the issue of GM food and the effect of labelling on such foods is also showing different results between the two countries depending on the knowledge consumers have of specific techniques such as genetic modifications [39].

The early phase of biotechnology adoption and regulation in Canada (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. In the agri-food sector, for example, since 1994 Health Canada has approved over 100 novel foods, many of these involving genetic manipulations [40].[6]

A generally promotional approach to biotechnology is reflected in many areas and initiatives within the Canadian regulatory regime; although not to the extent found in the U.S. 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. While generally far from EU standards,[7] this approach is still stricter than the one in place in the United States. Similarly in the *Harvard Mouse*[8] decision, the Supreme Court of Canada established, unlike in the U.S., that higher life forms did not fall under the definition of invention found in Section 2 of the Patent Act as "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." Also, Canadian testing processes and their triggers remain more restrictive than the American ones. While formally applying a similar "substantial equivalency" risk assessment principle [40], the Canadian regulatory process is still tougher and more broadly geared towards checking the nature of new GM products than the US one. Thus the Canadian regime features a somewhat hybrid or 'quasi-promotional' nature as the overall approach to the production and commercialization of biotechnology is promotional while research, commercialization and testing processes are more permissive in nature. The general nature of the regime is set out in Table 5, which shows Canada offering a quasi-promotional environment for the development of biotechnologies relying mostly on a guidelines-style approach to regulation.

### 3.2. The role of participation in the Canadian regime

What is the role, and the efficacy of, participation in this Canadian biotechnology regime? First, it is important to note that many new biotechnology techniques, such as 'marker-assisted selection' (MAS) in the agri-food or health sectors, do not trigger existing regulatory thresholds, fall outside of the scope of most regulation, and thus avoid any kind of mandated participatory policy processes associated with them. Nevertheless, because of the public nature of most R&D funding, and especially the importance of public support for the purchase of any products emerging from the commercialization of new technologies and their applications, involvement of the public is still important in many other aspects of biotechnology policymaking. The Canadian Biotechnology Advisory Committee, for example, has repeatedly noted that public confidence in the process through which the new technologies are introduced is critical to their acceptance [6, p. 16], and has called for a more deliberative and inclusive policy dialogue to be implemented in Canada [6, p. 30].

The Canadian federal government has tried to address these concerns with projects like the Biotechnology Notices of Submission Project, within which the Canadian Food Inspection Agency posts on its website the notices of applications for GMO product approval and allows for submissions from the public. Questions from the public are then explored by CFIA or Health Canada if they are of a scientific nature or streamlined into a less specific area if they are not. On a more procedural front, in 2003 Health Canada asked for public input into the revision of its

[5] This has partially changed since 2004 when the World Trade Organization found that the EU had implemented a de facto moratorium over GMO products in violation of the GATT/WTO Treaties. Since then various types of GMO corn and (in March 2009) the now obsolete T45 type canola have been approved for import in the European Union despite negative public views of these developments.

[6] The OECD BioTrack database provides useful data on approved biotechnologies [41].

[7] Compare the Canadian approach with the EU regulation 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 though these regulations exempted products like milk, eggs and meats from animals fed with GMO feeds, they created major limitations to trade and in 2006 the World Trade Organization ruled that they constituted a de facto moratorium on US, Canadian and Argentine products.

[8] The case *President & Fellows of Harvard College v. Canada* (Commissioner of Patents) [2002] SCC 76 (the Harvard Mouse case).

Please cite this article in press as: Howlett M, Migone AR, The Canadian biotechnology regulatory regime: The role of participation, Technology in Society (2010), doi:10.1016/j.techsoc.2010.10.004

**Table 5**
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.<br>- Promotional in the public research, IPR, and consumer choice areas.<br>- Promotional/permissive in the trade area. |
| Regulation | Guidelines style within 'novel traits' regulatory approach | - A preference for incorporating legislative and regulatory tools about biotechnology in existing legislation and regulation.<br>- Equating the products of biotechnology with non-biotechnology ones.<br>- Labelling remains voluntary for GMOs.<br>- 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 idea of the field as an economic opportunity. This attitude is visible in the goals of the federal Science and Technology policy.<br>- The practical implementation of this vision passed through important research funding and investment and research incentives for the private sector.<br>- 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. | - 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). |

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.

While it is important to notice that the process of consultation in many Canadian policy areas is well developed, involving both simple engagement and consultation [28], in most biotechnology sectors the system remains akin to a 'voice' option rather than a true consultation model. In countertendency to what many Canadians would like to see happen [42],[9] participation in Canadian biotechnology policymaking remains largely limited to venues that do not engage the public at large or result in meaningful negotiation and impact on final outcomes.

For example, while Castle and Culver [28] argue correctly that there was effective consultation in the process that led to the voluntary labelling of GMO foods in 2004, this was only a minor change in the policy regime, took a very long time to enact and, as we have seen, was very weak compared to regulations found in other jurisdictions, such as the European Union. And the question remains whether voluntary labelling is an effective tool, or even broadly legitimate, given that many groups that supported mandatory labelling did not participate in the process.[10]

In general, the Canadian system of biotechnology participation has relied on a relatively broad process of consultation and tends to limit discussion to safety rather than expand it to larger issues of ethical concern that go beyond the safety rubric [43]. In 2003, for example, 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 made clear that while public participation is welcome, its use is dependent on the timeframe of the decision and on the context. Soon after the development of this framework, the federal government began working on the application of "smart" regulations to the field. The principles upon which these efforts were based called for enhanced effectiveness, efficiency, timeliness, transparency, and accountability, but they also called for synchronizing Canadian policy with US policy, with risk assessment based on an instrumental cost-benefit analysis, and a greater role for the private sector in regulatory processes [44]. In 2007 the Cabinet Directive on Streamlining Regulation noted 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.

Much the same approach continued to be followed with *Mobilizing Science and Technology to Canada's Advantage* [37], the newest national science and technology policy background statement. In it the federal government called for more private-sector commitment to science and technology and for the better transformation of research into marketable products and services. The four core principles to be followed in this effort were: 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. Consultation did not figure highly in this discussion and the new strategy reduced the number of venues available for participatory policymaking by wrapping together the Advisory Council on Science and Technology, the Council of

[9] Regarding this issue, consumer demand in Canada was well ahead of the regulatory curve. In 1999, under pressure from 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.

[10] This situation can be contrasted with organic labelling standards which were perfected in various provinces at around the same time.

Please cite this article in press as: Howlett M, Migone AR, The Canadian biotechnology regulatory regime: The role of participation, Technology in Society (2010), doi:10.1016/j.techsoc.2010.10.004

Science and Technology Advisors, and the Canadian Biotechnology Advisory Committee into a new Science, Technology and Innovation Council (STIC). As of November 2009 the STIC had only produced a small innovation roadmap, and not taken an effective role in policy leadership.

## 4. Conclusion

The application of the Haga and Willard model allows us to derive several conclusions with respect to Canadian biotechnology regulation and the role of public participation within it. That is, Canadian biotechnology policy processes fail to promote forms of consultation/engagement, which can affect the development and overall orientation of existing policies because they involve regimes which encompass a scientific rationality principle at the heart of a quasi-promotional biotechnology regime.

This is apparent in the commercialization approach of the current Canadian science and technology policy, which pushes for the conversion of the research into marketable products, a process which requires only very limited forms of public engagement rather than consultation on policy goals. This is a method of participation that sees the public as in need of 'education' on the issues of biotechnology, the argument being that once educated the public will respond more positively to innovations in the area [45]. This orientation has driven the regulatory and policy processes towards favouring engagement as an important aspect of legitimizing top-down decisions taken largely between the state and industry, rather than as an alternative method of policymaking and regulatory goal-setting.

The case study suggests that if the main conception of a biotechnology field is one of scientific rationality, then 'educating' the public becomes paramount, and too much actual participation may be seen as potentially dangerous. In practice, this leads to a situation in which the preference is given to consultative models where the actual impact of public demands is not very great. In this situation government agencies are more interested in developing processes where participation is shifted towards the end of policy processes after important decisions have already been taken; often through the use of techniques such as the use of focus groups or asking for feedback on already established regulations or decisions.

Given this basic orientation, the role of participation in such contexts, including Canada, will, at least until some major changes are effected in the core elements of the policy regime, is likely to remain bound to a voice option rather than to a any kind of substantive consultative orientation.

## References

[1] Brunk CG. Public knowledge, public trust: understanding the 'knowledge deficit'. Community Genetics 2006;9:178–83.
[2] de Jonge J, van Trijpa JCM, van der Lansa IA, Renesb RJ, Frewer LJ. How trust in institutions and organizations builds general consumer confidence in the safety of food: a decomposition of effects. Appetite 1998;51(2):311–7.
[3] Peters H, Peter JT, Lang MS, Hallman WK. Culture and technological innovation: impact of institutional trust and appreciation of nature on attitudes toward food biotechnology in the USA and Germany. International Journal of Public Opinion Research 2007; 19(2):191–220.
[4] Wynne B. Public engagement as a means of restoring public trust in science: hitting the notes but missing the music? Community Genetics 2006;9:211–20.
[5] Avard D, Grégoire G, Jean MS. Involving the public in public health genomics: a review of guidelines and policy statements. GenEdit 2008;6:1–9.
[6] BSDE Expert Working Party. BioPromise? Biotechnology, sustainable development and Canada's future economy, Report to the Canadian Biotechnology Advisory Committee. Ottawa: Canadian Biotechnology Advisory Committee; 2006.
[7] Brown JL, Qin W. Testing public policy concepts to inform consumers about genetically engineered foods. Choices 2005;20:233–7.
[8] Costa-Font J, Mossialos E. Is dread of genetically modified food associated with the consumers' demand for information? Applied Economics Letters 2005;12:859–63.
[9] Sharp RR, Yudell MA, Wilson SH. Shaping science policy in the age of genomics. Nature Reviews Genetics 2004;5:1–6.
[10] Haga SB, Willard HF. Defining the spectrum of genome policy. Nature Reviews Genetics 2006;7:966–72.
[11] Fischhoff B, Fischhoff I. Publics' opinions about biotechnologies. AgBioForum 2001;4(3, 4):155–62.
[12] Coyle F, Fairweather J. Space, time and nature: exploring the public reception of biotechnology in New Zealand. Public Understanding of Science 2005;14:143–61.
[13] Hornig Priest S. The public opinion climate for gene technologies in Canada and the United States: Competing voices, contrasting frames. Public Understanding of Science 2006;15:55–71.
[14] World Health Organization (WHO). Genetics, genomics and the patenting of DNA. Review of potential implications for health in developing countries. Geneva: WHO; 2005.
[15] Greely HT. Human genomics research: new challenges for research ethics. Perspectives in Biology and Medicine 2001;44:221–9.
[16] Andrée P. An analysis of efforts to improve genetically codified food regulation in Canada. Science and Public Policy 2006;33:377–89.
[17] Durant RF, Legge JS. "Wicked problems" public policy, and administrative theory: lessons from the GM food regulatory Arena. Administration and Society 2006;38:309–34.
[18] Gutteling J, Hanssen L, van der Veer N, Seydel E. Trust in governance and the acceptance of genetically modified food in the Netherlands. Public Understanding of Science 2006;15:103–12.
[19] Mwale PN. Societal deliberation on genetically modified maize in Southern Africa: The debateness and publicness of the Zambian national consultation on genetically modified maize food aid in 2002. Public Understanding of Science 2006;15:89–102.
[20] Seifert F. Local steps in an international career: A Danish-style consensus conference in Austria. Public Understanding of Science 2006;15:73–88.
[21] Pew Initiative on Food and Biotechnology. Grapes, wine and biotechnology, The application of biotechnology: issues, opportunity, and challenges. Washington, DC: Pew Initiative on Food and Biotechnology; 2006.
[22] Abelson J, Giacomini M, Lehoux P, Gauvin FP. Bringing 'the public' into health technology assessment and coverage policy decisions: from principles to practice. Health Policy 2007;82:37–50.
[23] Kleinman, Daniel Lee, Abby J. Kinchy, Robyn Autry. Local variation or global convergence in agricultural biotechnology policy? a comparative analysis. Science and Public Policy 2009;36(5):361–71.
[24] Wilson CA. Policy regimes and policy change. Journal of Public Policy 2000;20(3):247–71.
[25] Migone A, Howlett M. Classifying biotechnology-related policy, regulatory and innovation regimes: a framework for the comparative analysis of genomic policymaking. Policy and Society 2009;28 (4):267–78.
[26] Jochim AE, May PJ. Beyond subsystems: policy regimes and governance. Policy Studies Journal 2010;38(2):303–27.
[27] Isaac GE. Transatlantic regulatory regionalism. AgBiotech Bulletin 2001;9(8):1–4.
[28] Castle D, Culver K. Public engagement, public consultation, innovation and the Market. Integrated Assessment Journal 2006;6(2):137–52.
[29] Rowe G, Frewer LJ. A typology of public engagement mechanisms. Science, Technology & Human Values 2005;30(2):251–90.
[30] Newell, Peter. Lost in translation? domesticating global policy on genetically modified organisms: comparing India and China. Global Society 2008;22(1):115–36.
[31] Lindner, Line Friis. Regulating food safety: the power of alignment and drive towards convergance. Innovation: The European Journal of Social Science Research 2008;21(2):133–43.

Please cite this article in press as: Howlett M, Migone AR, The Canadian biotechnology regulatory regime: The role of participation, Technology in Society (2010), doi:10.1016/j.techsoc.2010.10.004

[32] Talukder, Kana, Jennifer Kuzma. Evaluating technology oversight through multiple frameworks: a case study of genetically engineered cotton in India. Science and Public Policy 2008;35(2):121–38.
[33] Paarlberg RL. Governing the GM crop revolution: policy choices for developing countries. Washington, DC: International Food Policy Research Institute; 2000.
[34] Montpetit É. A policy network explanation of biotechnology policy differences between the United States and Canada. Journal of Public Policy 2005;25:339–66.
[35] Sheingate AD. Promotion versus precaution: The evolution of biotechnology policy in the United States. British Journal of Political Science 2005;36:243–68.
[36] van Beuzekom B, Arundel A. OECD biotechnology statistics – 2009. Brussels: Organization for Economic Co-operation and Development; 2009.
[37] Mobilizing science and technology to Canada's advantage. Ottawa: Industry Canada; 2007.
[38] Knight, Andrew J. Perceptions, Knowledge and ethical concerns with GM foods and the GM process. Public Understanding of Science 2009;18(2):177–88.
[39] Teisl MF, Radas S, Roe B. Struggles in optimal labelling: how different consumers react to various labels for genetically modified foods. International Journal of Consumer Studies 2008;32:447–56.
[40] Action plan of the Government of Canada in response to the Royal Society of Canada expert panel report. Ottawa; 2001.
[41] OECD. http://www2.oecd.org/biotech/byCountry.aspx.
[42] Longstaff H, Burgess M, Lewis P. Comparing methods of ethical review for biotechnology related issues. Health Law Review 2006; 15(1):37–8.
[43] Moore EA. The new agriculture: genetically engineered food in Canada. Policy and Society 2007;26:31–48.
[44] Graham JE. Smart regulation: will the government's strategy work? Canadian Medical Association Journal 2005;173(12): 1469–70.
[45] Weldon S, Laycock D. Public opinion and biotechnological innovation. Policy and Society 2009;28(4):315–25.

**Michael Howlett** is Burnaby Mountain Chair in the Department of Political Science at Simon Fraser University. He specializes in public policy analysis, political economy, and resource and environmental policy. His most recent book is Designing Public Policy (Routledge 2010). His articles and book chapters have been published in numerous professional journals and collections in Canada, the United States, Europe, Latin America, Asia, and Australia and New Zealand.

**Andrea Migone** teaches in the Department of Political Science at Simon Fraser University where he has held a Post-Doctorial Fellowship working on GE3LS issues in genomics research sponsored by Genome Canada and GenomeBC.

Please cite this article in press as: Howlett M, Migone AR, The Canadian biotechnology regulatory regime: The role of participation, Technology in Society (2010), doi:10.1016/j.techsoc.2010.10.004