# 11 Participation in the Canadian Biotechnology Regulatory Regime

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## The Relevance of Participation

The increasing relevance of public participation in industrialized countries (Brunk 2006; de Jonge et al. 2008; Peters et al. 2007; Wynne 2006) can be framed from the vantage point of institutional contexts to assess the nature and extent of this participation and to individuate how institutions foster, direct, or limit participation itself. It is of particular interest to focus on policy and regulatory regimes to address these questions.

A sector where public participation can be particularly important is biotechnology because applications in both the medical and the non-medical fields can generate complex ethical, health, and economic issues. Policy makers face a variety of potential issues when they engage biotechnology policy regimes. These issues include protecting personal genetic information, establishing and enforcing appropriate health and environmental protection standards, and designing tools to balance market development and consumer protection and information alike. 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 such as 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 (Avard, Grégoire, and Jean 2008; Greely 2001), 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 impacts that these technologies have on public perceptions of products under development. An important factor in the acceptance of these technologies appears to be the level of effective participation that the public and stakeholders have been allowed in the process (Avard, Grégoire, and Jean 2008). For example, Gutteling and colleagues (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 the industry is handling consumer interests, and individuals' perception of the way biotechnology may influence their life." Another case in which public debate assumed an important dimension in the area of genetically modified foods was the public debate during 2002 in Zambia regarding genetically modified food aid (Mwale 2006). 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 on a particular event to influence policy change, could be very important for biotechnology. A crucial part would be played in this case by popularizing the research and opening up discussion to a broad range of stakeholders.

Calls for a more participatory and informative approach to the diffusion of biotechnology have been made by various groups (Abelson et al. 2007; Avard, Grégoire, and Jean 2008; Haga and Willard 2006; Pew Initiative on Food and Biotechnology 2006; Sharp, Yudell, and Wilson 2004). This might be relevant to more than just inclusive policy making since the attitudes of consumers are related to what they know about the benefits and risks 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 been shown to be relatively segmented on the issue of GM food, and the effect of labelling on such foods is 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 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, for most governmental agencies have engaged in public consultations, and the policy

processes are relatively transparent and open. Here we use the differentiation noted by Castle and Culver (2006) between engagement (a process largely limited to informing the public) and consultation (a process that actually considers 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).

## The Canadian Biotechnology Policy Regime

As Kleinman et al. (2009) noted, policy regime strategies and regulatory frameworks in the biotechnology sphere are interconnected: the latter delivering the needed detail in enforcing and fostering a specific direction and set of goals for national science and technology policies. These policy regimes emerge at the national level, though they are closely connected with international developments in terms of their links with regulatory frameworks such as the Cartagena Protocol on Biosafety (Newell 2008) or the Codex Alimentarius in the area of food safety (Lindner 2008). Within this common international policy space, however, different countries regulate, foster, and support biotechnology in different ways (Lindner 2008).

On this basis, Isaac (2001, for example, has argued that North American and European Union approaches to the regulation of agricultural biotechnology differ according to their diverging interpretations of the precautionary principle. North American jurisdictions highlight and prioritize scientific concerns, and European countries tend to emphasize social concerns and responsibilities (see Table 11.1).

This analysis is general and requires a more fine-grained approach if local variations in biotechnology regulation are to be understood. This is especially true in the context of a shifting pattern of regulatory behaviour brought about by the extension of biotechnology activity away from an emphasis on GMOs and toward a less interventionist but much broader application of genomics, metabolomics, transcriptomics, and proteomics. Genomics as the study of an organism's genome is not to be confused with genetic manipulation. Although relatively little government or political hindrance is posed to the study of the genome's structure, the application of this knowledge to genetic manipulation is much more politically difficult. The two areas can be considered cognate since genomics research is one of the prerequisites of genetic manipulation. There is little regulation directed specifically toward the former, whereas the latter is both regulated and often perceived as dangerous by the public. There is little doubt, however, that

TABLE 11.1

**Scientific versus social rationality in genomics regulation**

| | Scientific rationality (North America) | Social rationality (Europe) |
|---|---|---|
| *General regulatory issues* | | |
| Belief | Technological progress | Technological precaution |
| Type of risk | Recognized<br>Hypothetical | Recognized<br>Hypothetical and speculative |
| Substantial equivalence | Accepts SE | Rejects SE |
| Science or other factors in risk assessment | Safety<br>Health | Safety<br>Health<br>Quality<br>Socio-economic factors |
| Burden of proof | 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"<br>Consensual decision making |
| | Judicial decision making | |
| Mandatory labelling strategy | Safety or hazard based | Consumers' "right to know" based |

*Source:* Isaac (2001, 2).

both are beginning to attract increasing interest from the public and that this interest is not always benign or unconcerned.

Haga and Willard (2006) provide some of the details required to understand and explore the regulatory activity undertaken in this emerging area of public policy. They argue that we can identify five types of regulatory issue field in the biotechnology sector, such as health, commercialization, and intellectual property rights, which intersect the issue areas. How these legal issues, the public research investment, and the ways in which risk management and regulatory oversight in the policy deliberation process are handled determines the key features of these regimes (Talukder and Kuzma 2008, 131).[1] Table 11.2 provides a list of eight basic issues that they identify with which biotechnology regulation has grappled, along with the five dimensions that each involves.

Regulatory policy making in the field of biotechnology involves the design and adoption of a set of policies to deal with the issues noted in Table 11.2 that will dovetail with country-specific circumstances in the sector. Viewed in this light, there are substantial differences among countries lost in Isaac's model. Two good examples of such variations are in the variance between US and Canadian GMO policies (Montpetit 2005) and between agricultural and medical GMOs within both countries (Sheingate 2006).

Paarlberg (2000) used a similar system to score issue areas linked to first generation biotechnology policy to generate a country (or sector) measure that ranged policy approaches in terms of their "promotional," "permissive," "precautionary," and "preventive" nature. Policies that accelerate the spread of GM crops and food technologies within the borders of a nation can be termed "promotional." Policies that are neutral toward the new technology, intending neither to speed nor to slow its spread, are called "permissive." Policies intended to slow the spread of GM crops and foods for various reasons are termed "precautionary." Finally, policies that tend to block or ban entirely the spread of this new technology are defined as "preventive" (Paarlberg 2000, 4) (see Table 11.3).

Haga and Willard (2006) play an important part here on another level, for they highlight the importance of risk management and regulatory oversight in the policy deliberation process (Talukder and Kuzma 2008, 131), a topic that Paarlberg (2000) did not consider. Participation by the public and stakeholder groups in the policy process when new technologies are involved is a subject that received a great deal of attention in recent years (Haga and Willard 2006; Sharp, Yudell, and Wilson 2004; Tutton 2007). Considering that public perceptions of and attitudes toward genomics/GMOs are often

TABLE 11.2

**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<br>Intellectual property | Development of clinical guidelines<br>Classroom education<br>Public education<br>Risk communication | Behavioural modification in response to biotechnology results |
| Commercialization and retail trade | 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 |
| 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)<br>Issues of privacy<br>Genetic discrimination | Market value and pricing versus public provision of health care<br>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 to consumers | Cultural respect |
| Public research investment | 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 to citizens | Acceptance of the value of biotechnology investment |
| Commercialization of biotechnology-related products | Reliance on university-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 (2006, 967).

TABLE 11.3

**Paarlberg model of policy options and regimes toward GM crops**

| | Promotional | Permissive | Precautionary | Preventive |
|---|---|---|---|---|
| Intellectual property rights | Full patent protection, plus plant breeders' rights (PBRs) 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 uncertainties owing to novelty of GM process | No careful case-by-case screening; risk assumed to be cause 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 the hope 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 |

*Source:* Paarlberg (2000, 4).

confused (Fischhoff and Fischhoff 2001), including this dimension in the analysis is beneficial.

Specifically in terms of regulatory tools, Haga and Willard (2006) argue that the policy issue areas for GMO technology have been tackled with one, or a mix, of the regulatory approaches in Table 11.4. These regulatory approaches can be synthesized within two broad categories (state versus public approaches) and linked to Paarlberg's categories to create the comparative national matrix shown in Figure 11.1. State approaches are based on scientific rationality and include legislative, regulatory, and guideline approaches. Public approaches are based on voluntarism or public consultation. Starting from this matrix, we can rank countries or sectors within four policy quadrants reflecting the preferences shown in utilizing either elite or public policy approaches in their dealings within the subject area. An example of the application of this tool is given in Table 11.5.

TABLE 11.4

**Haga and Willard list of regulatory approaches to GM issues**

| Approaches | GM issues |
|---|---|
| Legislative | *Genetic discrimination:* more than twenty bills introduced in the United States to prohibit genetic discrimination by health insurers and/or employers |
| Regulatory | *Genetic testing:* proposal to revise the US Clinical Laboratory Improvement Amendments regulations to add the quality of genetic testing as a specialty |
| Guidelines | *Gene patenting:* revisions to the utility criteria of the US patent examination guidelines |
| | *Licensing:* US National Institutes of Health have published best practices for the licensing of genomic inventions |
| Voluntary | *Genetic discrimination:* Association of British Insurers Concordat and Moratorium on Genetics and Insurance |
| | *Genetic testing:* establishment of EuroGenTest Network to ensure quality of tests |
| Public consultation | *Genetic discrimination:* an eighteen-month public consultation carried out by the Australian Law Reform Commission<br>*GM foods:* GM Nation public dialogue in the United Kingdom |

*Source:* Haga and Willard (2006, 968).

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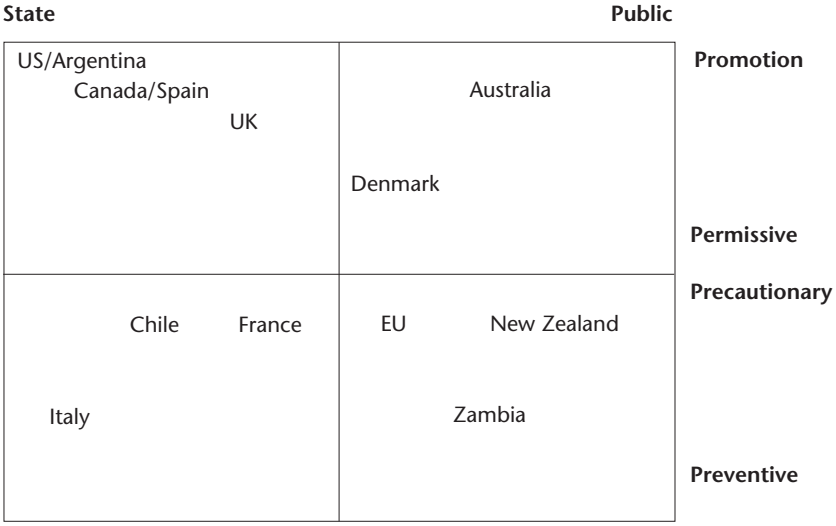
FIGURE 11.1

**Comparative biotechnology regulatory regimes**




Denmark, for example, marries a tradition of using consensus conferences where public comments on biotechnology are formulated (Seifert 2006) with rather strict guidelines regarding cloning and a more open genomics research aspect. During 2001-2, Zambia instituted a process of public debate that led to the refusal to accept a shipment of what might have been GMO corn (Mwale 2006). In the European Union, the leading principle in food safety policy has been the precautionary one (Lindner 2008, 142) mixed in with at least some examples of increased bottom-up models (Seifert 2006). This has partially changed since 2004, when the World Trade Organization found that the European Union had implemented a de facto moratorium on GMO products. Since then, various types of GMO corn and (in March 2009) the now obsolete T45 type of canola were approved for import into the European Union. In general, however, countries such as Greece, Italy, and France have maintained a negative attitude toward GMOs.

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 have important

FIGURE 11.2

**Distribution of participation instruments**

| **State** | | **Public** |
|---|---|---|
| Polling | Commissions | Public consultation |
| Request for feedback | | Consensus conferences |

effects in agenda setting, policy formulation, and evaluation. Yet it is important to distinguish between the instruments of participation and the effects of participation on the policy. We also argue that, while the instruments 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 chosen. This echoes the effects of institutional settings on policy instruments. We believe that, in a biotechnology policy regime leaning toward social rationality, we might see more instruments aimed at participation, whereas a scientific rationality model is likely more preoccupied with educational efforts and would be more likely to show limited inclusion in the consultation process.

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/public dimension, with the public side being more likely to see real participation as opposed to engagement. If we consider a set of participation instruments ranging from polling, to requests for feedback, to the constitution of commissions or expert groups, to public consultations and consensus conferences, we would expect them to be arranged more or less as shown in Figure 11.2.

It is harder to place these instruments on the promotional to preventive dimensions because their ultimate use depends on the basis on which biotechnology is perceived in a certain country. For example, referenda have tended to promote increased state intervention in biotechnology regulation (Rothmayr and Varone 2009). It seems fair to assume, however, that regimes that rely heavily on a scientific rationality might be more inclined to use a more state-centred approach in the selection of participation instruments,

whereas ones that focus on social rationality might 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 Table 11.5, offering a quasi-promotional environment for the development of biotechnologies and relying mostly on a guideline style for regulation.

In terms of biotechnology regulation, Canada positioned itself closer to the open approach chosen by the United States rather than 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 them involving genetic manipulation (Canada 2007, 5).[2] The promotional approach to biotechnology is reflected in various areas.[3] 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 percent of the product.[4] Although 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,[5] the balance partially shifted toward 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. Although formally applying a substantial equivalency risk assessment principle (Canada 2001, 11), the Canadian regulatory process is still tougher and more broadly geared toward 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

What are the spaces reserved for, and the efficacy of, participation in the Canadian biotechnology system? Canada uses a product-based approach to the regulation of biotechnology. This means that the Canadian regulatory system is highly geared toward the detection and regulation of novel traits, and many new techniques, such as marker-assisted selection (MAS) and other genomics tools, therefore fall outside the scope of most regulation.

TABLE 11.5

**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 | Preference for incorporating legislative and regulatory tools for biotechnology in existing legislation and regulation<br>Equating biotechnology products with non-biotechnology ones<br>Voluntary labelling for GMOs<br>Guidelines 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 framing 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 centres across Canada did not result in multiple successes. |
| Participation | Participation instruments correlated to state-centred approach | Efforts to educate 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). |

The Plant Biosafety Office (PBO) decides whether a plant with novel traits can be released into the environment.

Because of the relevance for research and especially commercialization of public support of these technologies and their applications, more effective involvement of the public might be important. The Canadian Biotechnology Advisory Committee has noted that public confidence in the process through which new technologies are introduced is critical to their acceptance (BSDE Expert Working Party 2006, 16). The same report called for a more deliberative dialogue to be implemented in Canada (30). The federal government has tried to address these concerns with projects such as the Biotechnology Notices of Submission Project within which the CFIA posts on its website the notices of submission for GMO products and allows for submissions from the public. The questions received are then explored by the CFIA or Health Canada if they are of a scientific nature or streamlined into a less specific area if they are not.[6] This project started in 2003 and is still active. Again in 2003, Health Canada asked for public input into 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.[7]

Counter to what Canadians would like to see happen (Longstaff, Burgess, and Lewis 2006), we believe that in Canada participation is largely limited to venues that do not engage the public in the policy process and meaningful negotiation. Although it is important to 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 the system remains akin to a "voice" option rather than true consultation. For example, though Castle and Culver (2006) argue correctly that there was proper consultation in the process that led to the voluntary labelling of GMO foods in 2004, we see this as a minor change in the policy regime structure. Regarding this issue, consumer demand in Canada seemed to be 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 the Food and Drugs Act) to give more information to Canadians regarding the content of their food, which resulted in the 2004 voluntary standard. The question remains 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. While waiting for the

standard to emerge, organic labelling standards were perfected in various provinces, giving consumers an alternative to the original project. For many large retailers, this was a perfect solution in that they could sell an organic product and prominently label it so, without being forced to identify products containing GMOs. In general, though 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 support for genetically modified products.

From the point of view of regulation, the federal government has tried to make the process friendlier to the approval of biotechnology. In 2003, the Framework for the Application of Precaution in Science-Based Decision Making and Risk was approved; although it mainly looked at establishing a precautionary principle for science and technology policy, it made it explicit that its application has limits. First, it is intended to be executed on a temporary basis (according to the progression of scientific knowledge). Second, domestic and international obligations might limit its application. Third, though public participation is welcome, its effective use is dependent on the time frame of the decision and the context. This means that the cost–benefit analysis to which the precautionary principle is subject involves both social and economic values.

Soon after the application of this framework, the federal government began working on the application of smart regulations to the field. The background work was based on the activity of the External Advisory Committee on Smart Regulation, which in 2004 released a final report including a recommendation for the streamlining of regulations along with the statement that the health and safety of Canadians must be protected by regulation. This encompassed the areas of biotechnology and environmental assessment. The principles on which the report argued for this streamlining were effectiveness, efficiency, timeliness, transparency, and accountability, but it also set forth four more claims that can be more easily contested. 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 easily be able to cooperate in the process of regulation; and it suggested that smart regulation is no 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.

Although 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 on this path of smart regulation, finally ending with the creation of the 2007 Cabinet Directive on Streamlining Regulation. Once again consultation was involved, but it appears to have been heavily dominated by actors favourable to the smart regulation approach.[8] The 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.

Much the same approach continued to be followed with *Mobilizing Science and Technology to Canada's Advantage* (Canada 2007), the Science and Technology Policy backgrounder. In it, the federal government called for more private sector commitment to science and technology and the transformation of research into marketable products and services. This process is guided by four core principles: promoting world-class excellence, encouraging partnerships among actors, enhancing accountability of the system, and focusing on key priorities. These priorities are environmental science and technology, health and life sciences and technologies, natural resources and energy, and information and communication technologies.[9]

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, STIC had produced only a small innovation roadmap, presenting a set of subpriorities for the four priority areas, and a report on the state of innovation in Canada for 2008.

The question remains 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 at the basis of the quasi-promotional regime. The principle drove the regulatory process toward favouring models of engagement rather than consultation. This is rooted in the attitude that sees the public as in need of "education" on 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 toward the adoption of biotechnology innovation. This is reflected in the comparative findings of Weldon and Laycock (2009) on the US, New

Zealand, and Canadian wine industries. 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, producers were much less concerned about possible responses from members of the public, who were considered unsophisticated regarding the application of biomarker technology, but were just as concerned as the American and New Zealand producers about the use of GMOs. The second answer lies in the commercialization approach of Canadian science and technology policies that, for some time now, have pushed toward 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 core elements of the policy regime, remain bound to a voice option rather than a more participatory orientation.

## NOTES

1 Participation of the public and stakeholder groups in the policy process when new technologies are involved has received a great deal of attention in recent years (Fischhoff and Fischhoff 2001; Haddow et al. 2007; Haga and Willard 2006; Metha 2004; Sharp, Yudell, and Wilson 2004; Tutton 2007).

2 The OECD BioTrack database is useful for a general comparison of approved biotechnology; see http://www2.oecd.org/.

3 Compare the Canadian approach with the EU regulations 1830/2003 on 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 percent 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 such as milk, eggs, and meat 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; the Codex Committee on Food Labelling (CCFL) of the Codex Alimentarius Commission has discussed this topic for over fifteen years without making much progress.

4 Under this standard, processing aids, enzymes below 0.01 percent by weight in a food as offered for sale (for exceptions, see paragraph 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 a product of genetic engineering.

5 The case *President and Fellows of Harvard College v. Canada (Commissioner of Patents),* [2002] SCC 76 (the Harvard Mouse case), established that 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."

6 The format might 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." See http://www.inspection.gc.ca/.

7 On the topic of food from cloned animals, Canada appears to be more inclined toward 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 on the 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 of any difference between cloned animals and regularly bred ones in terms of their health risk when used as food.

8 For a list of participants in this phase of consultation, see the Regulation Canada website at http://www.regulation.gc.ca/.

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

## REFERENCES

Abelson, J., M. Giacomini, P. Lehoux, and F.P. Gauvin. 2007. "Bringing 'the Public' into Health Technology Assessment and Coverage Policy Decisions: From Principles to Practice." *Health Policy* 82, 1: 37-50.

Andrée, P. 2006. "An Analysis of Efforts to Improve Genetically Modified Food Regulation in Canada." *Science and Public Policy* 33, 3: 377-89.

Avard, D., G. Grégoire, and M.S. Jean. 2008. "Involving the Public in Public Health Genomics: A Review of Guidelines and Policy Statements." *GenEdit* 6, 2: 1-9.

Brown, J.L., and W. Qin. 2005. "Testing Public Policy Concepts to Inform Consumers about Genetically Engineered Foods." *Choices* 20, 4: 233-37.

Brunk, C.G. 2006. "Public Knowledge, Public Trust: Understanding the 'Knowledge Deficit.'" *Community Genetics* 9, 3: 178-83.

BSDE Expert Working Party. 2006. *BioPromise? Biotechnology, Sustainable Development, and Canada's Future Economy.* Report to the Canadian Biotechnology Advisory Committee. Ottawa: Canadian Biotechnology Advisory Committee.

Canada. 2001. *Action Plan of the Government of Canada in Response to the Royal Society of Canada Expert Panel Report.* Ottawa: Queen's Printer.

–. 2007. *Mobilizing Science and Technology to Canada's Advantage.* Ottawa: Industry Canada.

Cantley, M. 2007. *An Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-Food*. Paris: OECD.

Castle, D., and K. Culver. 2006. "Public Engagement, Public Consultation, Innovation, and the Market." *Integrated Assessment Journal* 6, 2: 137-52.

Costa-Font, J., and E. Mossialos. 2005. "Is Dread of Genetically Modified Food Associated with the Consumers' Demand for Information?" *Applied Economics Letters* 12, 14: 859-63.

Coyle, F., and J. Fairweather. 2005. "Space, Time, and Nature: Exploring the Public Reception of Biotechnology in New Zealand." *Public Understanding of Science* 14, 2: 143-61.

de Jonge, J., J.C.M. van Trijpa, I.A. van der Lansa, R.J. Renesb, and L.J. Frewer. 2008. "How Trust in Institutions and Organizations Builds General Consumer Confidence in the Safety of Food: A Decomposition of Effects." *Appetite* 51, 2: 311-17.

Durant, R.F., and J.S. Legge. 2006. "'Wicked Problems,' Public Policy, and Administrative Theory: Lessons from the GM Food Regulatory Arena." *Administration and Society* 38, 3: 309-34.

Fischhoff, B., and I. Fischhoff. 2001. "Publics' Opinions about Biotechnologies." *Journal of Agrobiotechnology Management and Economics* 4: 155-62.

Graham, J.E. 2005. "Smart Regulation: Will the Government's Strategy Work?" *Canadian Medical Association Journal* 173, 12: 1469-70.

Greely, H.T. 2001. "Human Genomics Research: New Challenges for Research Ethics." *Perspectives in Biology and Medicine* 44, 2: 221-29.

Gutteling, J., L. Hanssen, N. van der Veer, and E. Seydel. 2006. "Trust in Governance and the Acceptance of Genetically Modified Food in the Netherlands." *Public Understanding of Science* 15, 1: 103-12.

Haddow, G., G. Laurie, S. Cunningham-Burley, and K.G. Hunter. 2007. "Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal." *Social Science and Medicine* 64, 2: 272-82.

Haga, S.B., and H.F. Willard. 2006. "Defining the Spectrum of Genome Policy." *Nature Reviews Genetics* 7, 12: 966-72.

Hirschman A.O. 1970. *Exit, Voice, and Loyalty: Responses to Decline in Firms, Organizations, and States*. Cambridge: Harvard University Press.

Hornig Priest, S. 2006. "The Public Opinion Climate for Gene Technologies in Canada and the United States: Competing Voices, Contrasting Frames." *Public Understanding of Science* 15, 1: 55-71.

Isaac, G.E. 2001. "Transatlantic Regulatory Regionalism." *AgBiotech Bulletin* 9, 8: 1-4.

Kleinman, D.L., A.J. Kinchy, and R. Autry 2009. "Local Variation or Global Convergence in Agricultural Biotechnology Policy? A Comparative Analysis." *Science and Public Policy* 36, 5: 361-71.

Lindner, L.F. 2008. "Regulating Food Safety: The Power of Alignment and Drive towards Convergence." *Innovation: The European Journal of Social Science Research* 21, 2: 133-43.

Longstaff, H., M. Burgess, and P. Lewis. 2006. "Comparing Methods of Ethical Review for Biotechnology Related Issues." *Health Law Review* 15, 1: 37-38.

Montpetit, É. 2005. "A Policy Network Explanation of Biotechnology Policy Differences between the United States and Canada." *Journal of Public Policy* 25, 3: 339-66.

Moore, E.A. 2007. "The New Agriculture: Genetically-Engineered Food in Canada." *Policy and Society* 26, 1: 31-48.

Mwale, P.N. 2006. "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* 15, 1: 89-102.

Newell, P. 2008. "Lost in Translation? Domesticating Global Policy on Genetically Modified Organisms: Comparing India and China." *Global Society* 22, 1: 115-36.

Paarlberg, R.L. 2000. *Governing the GM Crop Revolution: Policy Choices for Developing Countries.* Washington, DC: International Food Policy Research Institute.

Peters, H.P., J.T. Lang, M. Sawicka, and W.K. Hallman. 2007. "Culture and Technological Innovation: Impact of Institutional Trust and Appreciation of Nature on Attitudes towards Food Biotechnology in the USA and Germany." *International Journal of Public Opinion Research* 19, 2: 191-220.

Pew Initiative on Food and Biotechnology. 2006. *Grapes, Wine, and Biotechnology: The Application of Biotechnology – Issues, Opportunity, and Challenges.* Washington, DC: Pew Initiative on Food and Biotechnology.

Rothmayr, A.C., and F. Varone. 2009. "Direct Legislation in North America and Europe: Promoting or Restricting Biotechnology?" *Journal of Comparative Policy Analysis* 11, 4: 425-49.

Seifert, F. 2006. "Local Steps in an International Career: A Danish-Style Consensus Conference in Austria." *Public Understanding of Science* 15, 1: 73-88.

Sharp, R.R., M.A. Yudell, and S.H. Wilson. 2004. "Shaping Science Policy in the Age of Genomics." *Nature Reviews Genetics* 5: 1-6.

Sheingate, A.D. 2006. "Promotion versus Precaution: The Evolution of Biotechnology Policy in the United States." *British Journal of Political Science* 36, 2: 243-68.

Talukder, K., and J. Kuzma. 2008. "Evaluating Technology Oversight through Multiple Frameworks: A Case Study of Genetically Engineered Cotton in India." *Science and Public Policy* 35, 2: 121-38.

Teisl, M.F., S. Radas, and B. Roe. 2008. "Struggles in Optimal Labelling: How Different Consumers React to Various Labels for Genetically Modified Foods." *International Journal of Consumer Studies* 32, 5: 447-56.

Tutton R., 2007 "Constructing Participation in Genetic Databases Citizenship, Governance, and Ambivalence." *Science Technology and Human Values* 32, 2: 175-92.

Weldon, S., and D. Laycock. 2009. "Public Opinion and Biotechnological Innovation." *Policy and Society* 28, 4: 315-25.

World Health Organization (WHO). 2005. *Genetics, Genomics, and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries.* Geneva: WHO.

Wynne, B. 2006. "Public Engagement as a Means of Restoring Public Trust in Science: Hitting the Notes, but Missing the Music?" *Community Genetics* 9, 3: 211-20.