

CAE

Electronic Working Papers Series

Paper No. DEG 001

**The prospects for governing biotechnology in
Canada**

James Tansey

**W. Maurice Young
Centre for Applied Ethics**

Faculty of Graduate Studies
University of British Columbia
227 – 6356 Agricultural Road
Vancouver, British Columbia
V6T 1Z2
604-822-8625
ethics@interchange.ubc.ca
www.ethics.ubc.ca

The prospects for governing biotechnology in Canada

James Tansey

Abstract

This paper seeks to place issues related to the governance of biotechnology in Canada within a broad social, cultural and regulatory context and to examine the assessment techniques used to evaluate the safety of biotechnology. The paper suggests that decision makers need to recognise that public controversies cannot be forestalled using weak consultative approaches to stakeholder engagement. While regulators may focus on evaluating the safety of proposed biotechnologies, public policy controversies can and will arise regardless of the outcomes of the regulators activities.

The first half of the paper describes a more complex and less deterministic model of governance and the forms of hybrid science used to assess technologies in modern industrial societies. The second half of the paper examines Canadian governance of biotechnology, locating early attempts at public consultation within the spectrum of methodologies identified in the literature. The paper concludes by identifying some of the key emergent issues related to biotechnology.

This research was supported, in part, by the Center for Integrated Study of the Human Dimensions of Global Change, through a cooperative agreement between the National Science Foundation (SBR-9521914) and Carnegie Mellon University and by Genome Canada through the office of Genome British Columbia.

Please observe standard academic conventions for citation. For example:

Tansey, James (2003). "The prospects for governing biotechnology in Canada"
Electronic Working Papers Series. W. Maurice Young Centre for Applied Ethics.
University of British Columbia at www.ethics.ubc.ca.

Table of contents

| | | |
|----|--|----|
| 1. | Introduction..... | 1 |
| | The allure of the genome: the language of God..... | 3 |
| 2. | Context..... | 5 |
| | Tradition and the nation state..... | 5 |
| | Globalization and governance..... | 8 |
| 3. | The modern context of governance..... | 15 |
| 4. | Risk: probability multiplied by magnitude | 19 |
| | The economic theory of risk | 22 |
| | The psychometric theory of risk | 23 |
| | The cultural theory of risk..... | 24 |
| 5. | Governing biotechnology in Canada | 28 |
| | Regulating technological innovation | 30 |
| | Assessing biotechnology in Canada..... | 34 |
| | Substantial equivalence..... | 37 |
| | The precautionary principle | 39 |
| | Labelling | 39 |
| | The Government of Canada's response to the Royal Society report (2001) | 40 |
| | Report of the Institute on Governance (2002) | 42 |
| | CBAC final report..... | 42 |
| 6. | New approaches to risk and environmental management..... | 45 |
| | Restructuring governance | 46 |
| | Reform from within | 49 |
| | Evaluating public participation | 57 |
| 7. | Biotechnology and citizen involvement in Canada | 61 |
| 8. | Discussion: Postman always knocks twice | 63 |
| 9. | Bibliography | 69 |

The prospects for governing biotechnology in Canada¹

James Tansey

1. Introduction

There is a tendency in much of the literature on public policy to see “governance” as synonymous with the activities of formal government organizations, *i.e.*, agencies, ministries and departments. The discourse that results from this narrow framing of governance tends to imply that decision makers and politicians have within easy reach levers of control they can exercise at will to produce any given outcome.

In this simplified governance model, omnipotent decision making power is directed by the collective will (the public) through the election of representatives or through other more direct forms of democracy. If things go wrong—if, for example, a decision appears to conflict with the interests of the collective—the most common diagnosis is that there is a disconnect between the collective will and the activities of those in government. This typically leads to calls for more participation and/or a more transparent process.

This paper sets out a more complex model of governance, one that pays particular attention to the historical conditions that led to the emergence of modern, secular industrial states like Canada. This discussion provides a background for examining:

- the conditions under which biotechnology² is regulated in Canada; and
- the range of techniques that have been used to allow for greater citizen involvement in the policy process.

Following a brief description of some of the cultural shifts in the West that pre-dated the technological changes associated with the Industrial Revolution, the paper examines the idea that modern societies are governable in some deterministic fashion. This in turn is

¹ This paper is one of three written through the W. Maurice Young Centre for Applied Ethics, UBC, for *Democracy, Ethics and Genomics: Consultation, Deliberation and Modelling*, a research project funded by Genome Canada and Genome BC.

² The author has focused primarily on food biotechnology while recognizing that there are significant issues in the development of pharmacogenomic products, as well as genomic banking. The latter issue is addressed in a separate paper.

followed by an overview of the environmental and risk assessment techniques that have emerged in the last fifty years to regulate modern technologies.

Section 4 is devoted to a review of the regulations governing biotechnology in Canada, while section 5 looks briefly at new approaches to risk and environmental management. This is followed by a review of the limited citizen involvement in biotechnology in Canada.

Three points recur throughout this paper.

1. Technologies are socially-embedded; they must be understood in the context of the social and historical conditions that both enable and constrain them. Recognizing this I emphasizes biotechnology as a powerful symbolic project of the modern liberal state. Understanding the governance of biotechnology necessarily involves considering the role of the vast capitalist infrastructure that is coalescing around it.
2. Techniques used to assess the social and environmental impacts of technologies are not in the realm of normal science. While biotechnology is a product of science, the techniques used to assess the effects of biotechnology are weakly predictive and operate under conditions of great uncertainty.
3. Although governments in Europe and North America are going to great lengths to prove novel technologies safe, “safety” is only one of the factors influencing the emergence of public controversies surrounding these technologies. Others include such things as the moral and ethical concerns of non-governmental organizations.

While the discourse surrounding novel technologies—in the case of this study, genomic technologies—is often described in terms of who is (objectively) right or wrong, these three points reinforce the notion that often it is an issue of who has power and holds an effective veto. Beneath these three points is a unifying question inspired by the neo-Luddite, Neil Postman³:

³ In a lecture to the Vancouver Institute, Neil Postman recounted the saga of trying to buy a car. The salesman was trying to encourage him to buy a number of extras including cruise control. He asked the salesman “What is the problem that cruise control is designed to solve?”.

What is the problem that deliberative or consultative⁴ processes are designed to solve?

The allure of the genome: the language of God

In his book *Serendipities*, Umberto Eco (Eco 1999) describes historical attempts to discover an original, perfect language that mapped precisely onto the objects of the world. In Christian literature, this “Adamic” language was the language of God, or at the very least, Adam. While some philosophers supported Hebrew as the original language, others (*e.g.*, 17th century Jesuit Athanasius Kircher⁵) argued that Egyptian hieroglyphics contained the original tongue.

While philosophers debated the merits of various languages and whether the deity spoke or transcended the need for oral language, it is clear from Judeo-Christian mythology that the deity’s Word is synonymous with creation. Uttering “let there be light” and naming the day and the night brought routine to existence on earth, exemplifying the power of language to create order through by classifying objects.

Language and this creation myth are important in the context of this paper for two reasons. First, many contemporary writers in the field of genomic research present the deciphering of the genome as the pinnacle of modern scientific achievement; some even seem compelled to describe the achievement in metaphysical terms⁶. Leiss, (for example) in *In The Chamber of Risks: Understanding Risk Controversies*—largely a traditional policy analysis text—suggests that:

In the ultimate promise of genetic engineering—to reshape the work of Creation—we come face to face with ourselves, i.e., with the meaning of human existence on earth, or with what was meant traditionally by the human “soul.”(Leiss 2001: 260).

⁴ The term ‘deliberation’ is used in most of this paper, recognizing that it is interchangeable with consultation, participation, engagement and democratization.

⁵ Kircher’s translations were superseded when hieroglyphs were finally translated in the 19th century.

⁶ More material, less metaphysical accounts focus on the potential utility of the research to address a wide range of human concerns from hereditary illness to sources of fuel and food for the future.

Ridley in his *Genome: the autobiography of a species in 23 chapters* describes human chromosomes as chapters containing three-letter words (codons) composed from the four letters (bases) that make up the genetic alphabet (Ridley 1999). Read in the correct sequence, these “words” supply the information for constructing proteins, the building blocks of organisms. God spoke in codons and bases not Hebrew or hieroglyphics.

The second reason for the language/creation reference is to open an important yet neglected space for debate about potential risks associated with genomic research and biotechnological applications. Modern risk management regimes focus almost entirely on ensuring the physical safety of modern technologies⁷. This typically depends on a scientific assessment of the technology in question, combined with some attempt to credibly predict the plausible impacts of the application of a technology on human and natural systems.

However, even a cursory examination of the debates surrounding genomic research and biotechnological applications indicates that concerns about novel technologies reflect not only their capacity to cause physical harm—the realm of risk management—but also their capacity to transgress moral boundaries. The social opposition to stem cell research that emerged in the United States exemplifies this questioning of the moral implications of basic science. The protests, which focused on the practices associated with the scientific research rather than the goal of the research, made it clear that “playing God” (Borger 2001), regardless of the goals or the consequences, research is unacceptable to some individuals and groups, and will always be seen as a danger to guard against.

⁷ The report of the Royal Society of Canada on Food Biotechnology (2001) recognized the problems with a narrow concept of risk as direct harm to humans, but was constrained by its terms of reference to focus on the science of biotechnology.

2. Context

Tradition and the nation state

The relationship between humans and the technologies they create can be studied at a range of spatial and temporal scales. In framing this section I begin with a very broad historical view of the emergence of the institutions that have supported and enabled the emergence of a range of technologies including those associated with genomics. Life in the industrialized West has been deeply penetrated by the technologies that have emerged in the last two centuries. According to Leiss:

our society's commitment to sustained technological innovation is so much taken for granted, and so fundamental a part of our economy and well-being, that if we were to be deprived of it suddenly, the world would no longer make sense to most of us (Leiss 2001: 259).

That said, there is nothing inevitable about the emergence and application of technologies in society. In *Unintended Consequences*, Deepak Lal compares historic patterns of economic growth and cultural attitudes to technology (Lal 1998) to demonstrate that the modern industrial system is the product of the actions of specific institutions at specific points in time rather than a historical accident.

Lal begins his comparison at a coarse scale by using the well-established parameters of *extensive* and *intensive growth* to distinguish between the manner in which different societies exploit material resources or factor endowments—their natural capacity. Extensive growth expands the output of an economy to keep up with the demands of a growing population, the imperative being to expand territory on the basis that land and resources are the primary drivers of growth. Typically, extensive growth maintains a level of income at or around subsistence for an expanding population that is ultimately constrained by the availability of land. If the population continues to grow then the result is a decline in the material base. Thomas Malthus' apocalyptic predictions—based on the hypothesis that the supply of agricultural products increases, at best, linearly, while population growth increases geometrically—is the archetypal study of the consequences of extensive growth.

Lal identifies two types of intensive growth: Smithian⁸—characterized by the increasing productivity of capitalist production and by new ways of organizing human labour—and Promethean (Lal, 1998: 20)⁹, characterized by the shift from an agriculture-based economy to an economy dependent on an expanding mineral base. Smithian intensive growth, even in an organic, pre-industrial economy, reduces the cost of production and increases *per capita* income (ibid: 20). Promethean intensive growth saw energy, extracted initially from coal and later from higher quality hydrocarbon resources, applied to the fundamental transformation of materials on an unprecedented scale. Since the Industrial Revolution, the Promethean ability to unlock energy stored in chemical and physical forms has affected every aspect of human life.

According to Lal, intensive growth does not burst forth spontaneously once scientists and intellectuals achieve a certain level of understanding natural systems. Comparable scientific knowledge existed in 11th century China, but its application in the world of commerce was suppressed by a form of bureaucratic authoritarianism that sought to protect the power of the Sung dynasty. Lal actually argues (in a highly contested account) that Confucianism—the value system that guided governance in China—promoted anti-market/anti-merchant attitudes in China that effectively suppressed the expansion of technologies (Lal, 1998: 47). This suggests that the adoption and diffusion of technology is not driven just by science, curiosity or cleverness, it is also fundamentally shaped by the form and values of the state within which that technology sits. To brutalize another aphorism, “It’s not what you know, it’s where you know it.”

Lal’s *Unintended consequences* inverts many accepted wisdoms about the emergence of the modern nation state from the diffuse European political landscape. For example, rather than accepting Weber’s assertion (Weber 1958) that the Industrial Revolution helped to create the modern nuclear family, Lal points to papal edicts of the 11th century that, largely out of self-interest, created rules about right and wrong models for the family. These interventions by the church weakened patterns of heirship and kinship.

⁸ The economist Adam Smith first described the benefits of the division of labour in industrial society.

⁹Lal prefers this label to the more commonly used ‘Schumpeterian growth’.

These patterns traditionally channeled and retained wealth within clans; intervention redirected the flow of capital and assets into the hands of the church¹⁰.

Concurrent with the rise of bureaucracies was a decline in the role of religion in governing European states. The Reformation and Renaissance (early 14th to late 16th century) opened new space for indeterminacy and doubt in human life, reducing religious authority over social practices and enhancing the role of reason. The status of Christianity's God in the latter half of the millennium was steadily reduced from that of the divine creator, to the divine watchmaker and eventually to the status of the blind watchmaker. Authoritative laws were revealed not through holy writs, instead 'God's laws were recorded in the Great Book of Nature that the scientific revolutions of the nineteenth century had begun to decipher' (Lal, 1998: 103). (Lal, 1998: 103).

The rise of this new faith (science), which supported a worldview that saw society molded less by *fortuna* and more by the power of humans over nature and their fellow beings (Giddens 1990)—occurred in parallel to and was intimately connected with the rise of the secular European state. The Treaty of Westphalia (1648) formalized (among other things) the boundaries of states and the exercise of authority within those boundaries; governance of religious matters was generally delegated to these states. And while it is true that labels such as 'Industrial Society' and 'Knowledge Society' tend unrealistically to imply monotonic driving force, it is also true that "curiosity" and institutional intervention in the West created conditions for the individualism that shapes, and in turn is shaped and sustained by modern technologies.

Science played a central role in creating the conditions for the Promethean intensive growth that drove the Industrial Revolution; science is now central to the process of governing. In all spheres of Western life, there is now a resource and energy intensive mercantile system of capitalism that drives technologies into every corner of everyday social life to the extent that in the West, we spend more of our time living as consumers than as citizens.

¹⁰ Lal's comparison of Western, Indian, Chinese and Islamic society shows how the institutions of kinship and heirship continue to play a significant role in these non-Western societies.

Globalization and governance

Over the last fifty years, the once fiercely guarded boundaries of nation states have become increasingly permeable. This is, in part, because these states sought to develop shared markets¹¹ rather than expand their power bases through invasion and conquest. This created conditions whereby previously national-scale activities became global in scope.

Hand-in-hand with this change, the complex logistics of modern production that seek the best trade offs between low costs and high quality has helped create firms with production and marketing systems that increasingly span great distances (Castells, 2000: 163-215) and multiple jurisdictions¹². As a consequence, by the early 1990s the capacity of any single nation state to intervene effectively in the marketplace had been drastically reduced¹³. This poses serious challenges to any attempt at effective governance and raises numerous questions about what exactly any regulating government is able to guarantee to its citizens. In fact, given the complexity of the current system, it is not clear that citizens will be able to exert a choice over whether they wish to consume genetically modified organisms (GMO).

Many theorists suggest that Promethean intensive growth in the most advanced industrial societies—growth once largely driven by applying human ingenuity to transforming physical resources—has been changing. These theorists observe a steady trend to de-industrialization across much of the West, driven in part by competition from industrializing countries that can produce commodities at lower costs. Companies wishing to increase their profitability have five broad strategies at their disposal. Technology and science are important to the extent that they can be applied to achieving these goals:

¹¹ One of the goals of the European Union in its original form was to reduce the likelihood of war by creating shared markets Keohane, R. O. a. J. S. N. (1987). "Power and Interdependence revisited." International Organization **41(4):725-53**.

¹² By 1998, 53,000 multinational corporations with global sales of \$9.3t accounted for 20-30% of world output and 66-70% of world trade.

¹³ The fact that the release of \$16b by the Japanese government to maintain the ratio of the yen to the dollar had little effect Ohmae, K. (1990). The Borderless World. London: Collins.

dramatically suggests both that states no longer have the degree of control over the value of their currency that they once exercised, and that the relative value of currency is no longer determined by the 'fundamentals' of economic performance.

- reduce production costs;
- increase productivity;
- broaden the markets to which their products and services are sold;
- accelerate capital turnover; and
- add value to products.

The first strategy is the most widely practiced within companies in the manufacturing sector. The goal is to reduce the cost of all factors in production, from labour to raw materials. Ohmae points to the example of Japanese companies that have traditionally competed with each other and with firms from the United States and Europe by engaging in a race to the bottom with regards production costs (Ohmae, 1990.). If every company pursues this strategy, then eventually competition will eliminate profit for all of them. The second strategy—increasing productivity—has driven efforts to improve the technologies used in production processes. The third strategy—broadening markets—has become easier as trade barriers are removed, but again, in a competitive market, ultimately the competition between companies will drive profits down.

The fourth strategy—accelerate capital turnover—is dependent on investors being willing to bear risk through speculation. In this strategy, economic returns can be derived independent of the transformation of material resources, although it is not clear what wider impact this has on the prices of commodities. Financial capital moves around the world in the pursuit of value creation through speculation over risk. In 1998 the capital turnover of the currency markets was in the region of US\$1.5trillion, more than 110% of the GDP of the United Kingdom in the same year (Castells, 2000: 104).

For Ohmae, the most important strategy is to add value to clients by investing significantly more time and research effort in the development of products. While GM rice, which produces the precursor to vitamin A, is perhaps an example of a value added product, to date, most of the proposed biotechnology products have been developed to reduce production costs or increase productivity. For instance, incorporating the Bt gene into a number of crops reduces the need for more expensive artificial pesticides and, if effective, should reduce production costs. Similarly, the inelegantly named “Flavr-Savr” tomato offered to reduce costs by increasing the resilience of the fruit to transportation.

A volume edited by Ericson and Stehr (2000) is one of many recent attempts to address the challenges facing modern industrial democracies. They begin by asserting that the modern state has become “somewhat ungovernable”; certainly a less dystopic view than some commentators. They describe the range of diagnoses of the causes of this malaise of modernity. For Habermas and others, the problem is, in part, that markets have replaced political institutions. For both Habermas and Rhodes (Rhodes 1994), the increasing role of the markets both in providing services that were traditionally the sole responsibility of the state and in settling conflicts among technologies by providing a forum within which they can compete, has resulted in a weakening of the institutions of democratic accountability. Some of these diagnoses are simply recognition that the state-centred analyses that have long dominated realist theories in international relations and much of political science have simply understated the role of other relatively autonomous institutions. Others have argued that in contrast to the golden era of economic growth, deference towards and trust in the state, we have seen a decline in the legitimacy of the state.

Ericson and Stehr examine the conservative analyses of the state of the early seventies that was concerned that the governance system in the United States had stalled and was incapable of addressing social problems:

Analyses of the stalled society employ such terms as “rigidity”, “strait-jacket”, “suffocation”, “trap”, “paralysis”, “stagnation”, and “involution” (ibid: 7).

According to Ericson and Stehr, there are two linked causes of this stall. The first is that the mechanisms of governance have been overwhelmed with the demands of citizens.

Drawing on the work of Crozier, they identify two symptoms of this diagnosis:

- an overload of the system with the demands of various, often competing groups; and
- the contrast between the (inflated) claims of the ability of the state to intervene and the (actual) capacity of the state to intervene.

The conservative thinkers in political theory see governance in elitist terms and argue that a great concentration of power is required in order to achieve an efficacious state. They

see the key challenge to modern governance as that of overcoming the stall or stagnation of progress by a range of interest groups represents a failure of the governance system. To others, the fact that social interests can intervene to slow or halt technological implementation represents a success of modern democracies.

The second reason for the stall is that the nature of citizen demands has changed. The authors describe a transition from an era where citizenship was thought of in terms of a deferential relationship between individuals and the state, to the contemporary context where more highly educated citizens demand greater accountability and resist the authority of the representatives of the state. They use the surge in democratic activism and demands for participation seen in the sixties as evidence of this trend. This argument is part of a broader thesis: society is in a transition towards a “post-material” state where citizens pursue a broader set of values related to personal and collective freedom, self-expression and quality of life (ibid: 13). Education is seen as one of the primary drivers behind the emergence of these values, although this seems to equate education with the achievement of some deeper wisdom rather than more instrumental outcomes related to employability and the technical competence of individuals in the workforce.

The role of science changes in the context of a more self-aware, confident and active citizenry. Science is no longer synonymous with authority and recognition that science does not produce unambiguous knowledge built around expert consensus has made it available as a resource for non-state interests (ibid: 8):

Knowledge adds to the capacity for action. It does so equally for opponents of a regime and for the administrative apparatus in power. Instead of being the source of reliable, trustworthy knowledge, science becomes a source of uncertainty (ibid: 8).

There is rarely a single scientific consensus on the technical dimensions of public policy and Ericson and Stehr describe how, in the new politics of a post-material society, science is used to support contradictory positions. We ask a great deal of science in the policy process and, as examples below from the biotechnology sector will show, statements cannot be treated as scientific, just because a scientist utters them. In a famous article Oreskes and her colleagues (Oreskes 1994) show that the conditions for

true scientific prediction can rarely be satisfied outside of a controlled laboratory setting. Instead the policy process relies on more ambiguous post-normal (Funtowicz 1985) or ‘mandated’ (Salter et al. 1988) science. While Huntington (1975) predicted that under these conditions, domestic policy problems become intractable—government is trapped between the mixed expectations of the population and their capacity to meet them—Ericson and Stehr's view is less pessimistic. These authors seek to balance the predominant concerns about the ungovernability of the state with an emphasis on the possible benefits. Declining concentration of power in state institutions is a potentially positive change that creates new opportunities and is consistent with a number of “ends” that many would consider to be positive, including expanding education, extending and reconfiguring citizenship and defusing class conflict (p16). For them, knowledge represents a new bundle of social competencies that will drive political participation and create newer and better forms of citizenry.

Conservative analysis focuses on the emergence of what are considered to be unreasonable demands on the state by new and emergent interest groups. In addition to Ericson and Stehr’s post-material hypothesis, Hannigan (1995) lists three alternate (although somewhat interdependent) explanations for the changing demands of the citizenry. The first is the reflection hypothesis, which suggests that:

- the 20th century saw a rapid expansion of the industrial system both in capitalist democracies and in centrally planned states;
- this expansion resulted in widespread environmental damage; and
- public concern about the environment was the result.

There are a number of problems with this explanation. Among other things, widespread public concern came rather late; environmental quality had been deteriorating for at least a century. Even the smog that hit London in the 1950s and resulted in changes to the laws regarding fuels did not generate a backlash against industry. In fact, concern about air pollution rose when many of the more common air pollutants were on the decline.

Hannigan’s second explanation is the “New Middle Class” thesis. Unlike the post-material explanation which suggest that the values and priorities of whole societies are changing, this explanation suggests that there is a new social class—a subset of the

population drawn from the segment of society called “social and cultural specialists,” including teachers, social workers, journalists, artists and professors—that drives the rise of environmental concerns.

Two reasons are given for why this segment of society is thought to be more concerned than the rest of society:

- they have greater exposure to environmental and social problems, so they are more sensitized to them; and
- they have a strong (non-altruistic) interest in seeing these issues given greater significance, since they work in sectors that stand to benefit from the dedication of greater resources to these problems.

The problem with this explanation is that the people involved in these new social movements come from a wide range of professions. It may just be the case that social and cultural specialist groups simply have more freedom to be able to protest and question where society is going than individuals from other social classes. In other words, they may not be more concerned, just more politically active.

The final explanation—the regulationist/political closure explanation—assumes that these new social movements have arisen as a reaction to the intrusion of the state and industry into more areas of our everyday lives. For instance, developing new technologies, including nuclear power and biotechnologies, creates moral and physical dangers that are unprecedented. The explanation also assumes that the traditional political system has changed. Since the rise of new kinds of relationships between government and industry, where they work much more closely together to provide public services, the interests of government and industries interests now overlap and people no longer feel they can hold people accountable through the traditional system.

In the past, it was assumed that government was there to regulate the activities of businesses in order to protect the population. Now there is a concern that the traditional democratic system does not function in the public interest and that voting makes very little difference. So people resort to new kinds of political activity. They join environmental groups or other NGOs, pay a membership fee and create new kinds of pressure for change within the political system. However, subjecting technocratic

decision-making in government to the scrutiny and control of citizens may not be sufficient to alter the trajectories and unintended impacts of emerging technologies.

While the rational modernization project has always had its detractors, ranging from the Luddites, who attacked the industrialization of the workplace on the basis that it displaced labourers, to the early environmentalist who lamented the damage wrought by smokestacks and wage labour and longed, even then, for a kind of pastoral ideal, many have argued that the real fissures appeared in the second half of the twentieth century. In the next section I focus on the seemingly scientific practices that emerged to regulate the hazards, both to humans and the environment, of technological progress and the strategies that emerged in response to concerns regarding the role of these technocratic procedures.

3. The modern context of governance

So far I have emphasized an historical account of the emergence of the modern state and of the evolution of the forces that enable and regulate the development of novel technologies. In this section the emphasis switches to an institutional account that examines the dynamics of technology governance and some the factors that have led to the demand for more open and participatory approaches. This provides context for the following section where I examine the regulation of biotechnology in Canada.

Much of political science and political theory focuses on the art of government; classical texts have examined both the authority of the state and the relationship between the state and citizens, subjects or comrades. For many issues, governance is not concentrated in a single site. The modern state is composed of decentralized continually changing, interactive components. Each component stores the information most important to it in its own memory, only rarely storing all available information. Because there is no true unity of information there is a shift of emphasis from government by traditional political institutions to governance models where outcomes are negotiated among the system components.

A recent study by the British sociologist Perri 6, provides a useful overview of the literature on the governance of technology (6 2003). Perri 6 argues that the primary emphasis has been on government subsidy, policy for scientific research, national innovation policy, government spending on military technology, regulation of assorted technological risks, and responses to employment pressures created by technological change. He is critical of this emphasis on policy, seeking to broaden the definition of governance to include things such as network activities involving government, businesses and non-governmental organizations and new contractual approaches to government service provision described as “new public management.”

Perri 6’s study builds on a typology developed as part of an extensive review of governance literature by Pierre and Peter (2000). They review identified four governance structures:

- 1 governance as hierarchies: includes both the bureaucracies of government and their role in enabling and regulating the markets and civil society;
- 2 governance as markets: includes both the role of government as a major purchaser of commercial services and the “loose order” that appears in purely commercial markets;
- 3 governance as networks: includes forms of intrasectoral alliance that are typically voluntary and emphasize horizontal arrangements of power; and
- 4 governance as steering: includes the more traditional liberal notion of the role of government in steering and regulating.

Perri 6 argues that a number of other activities are needed to complete the taxonomy. His list describes the three most common governance mechanisms—carrots, sticks and education—and a fourth ubiquitous mechanism, coping.

- governance through deliberate planned control (sticks): includes substituting for direct provision—*e.g.*, establishing nationalized industries—and steering and regulating—*i.e.*, establishing legitimate boundaries to activity and then working with a regulated organization to ensure compliance or to punish transgressions¹⁴;
- governance as inducement (carrots): includes regulation through financial incentives—*i.e.*, taxes on ‘bads’ (*e.g.*, cigarettes, alcohol, gasoline) or tax relief—and direct subsidy of activities that meet policy goals—*i.e.*, capital investment to support research or exploration;
- governance through influence (education): includes information/advertising, persuasion or public education; and
- governance through coping. This is the least familiar form of governance, and while certainly the hardest to evaluate, it is also ubiquitous. Coping is a reactive rather than a strategic activity and reflects the fundamentally uncertain nature of the modern policy world. Coping is clearest in the case of a crisis (*e.g.*, the recent discovery of a case of bovine spongiform encephalopathy in Canada) when agencies seek to respond and react within the limitations of their mandate. It is

¹⁴ Perri 6 points out that while the symbolic and instrumental power of these mechanisms is high, the financial costs to the public purse are also significant (*ibid*: 4).

only later that more strategic mechanisms of direct control and regulation emerge..

The definition of governance that emerges from this synthesis of the literature is that:

...governance means the development and use of the principal means of power insofar as this leads, intendedly (in the case of hierarchy and communities and certain kinds of networks) or unintendedly (in the case of markets and other kinds of networks) to produce more rather than less orderly and coherent patterns of structures of social, economic and political life (Perri 6, 2003: 3 emphasis removed).

For example, in the face of uncertainty over the direction of biotechnology in Canada, the federal government's 1983 *National Biotechnology Strategy* focused primarily on enabling and resourcing research capacity and stimulating private sector involvement. The shift in emphasis to accommodate the need for regulation emerged in 1998 in the form of the *Canadian Biotechnology Strategy*, when it was felt that the pre-existing regulatory framework might need modification to address novel technologies. This definition, and the typology presented by Pierre, Peters and Perri 6, has significant implications for researchers studying policy development and emerging genomic technologies. Perhaps the most important is its acknowledgement that while government is a major actor in modern societies, it does not have the kind of absolute power envisaged in Hobbes' *Leviathan*: politicians and policy decision makers cannot pull levers to produce the desired outcome. It is for this reason that it makes more sense to talk about governance than government. Further, governance is more than simply a process of developing and enforcing rules to regulate institutional and individual action in the interests of the collective. This is recognizable in modern industrial societies where the trend appears to be away from government attempting to govern through traditional hierarchical practices toward a governance model built on partnerships with the private-sector. This shift is evident in practices that emphasize voluntary regulation of industry, matched public-private funding both for research in public institutions, public-private partnership in the construction and operation of hospitals, roads and prisons and the further commercialization of the education system. In each case, traditional institutions of

government share both the costs and benefits of enabling research and development with the private sector, thereby enabling the emergence of novel technologies that must at some point be assessed and regulated.

While history suggests that there has never been a “golden era” of direct democracy in the biography of the modern state, the notion that direct democracy, or the more active and demanding notion of deliberative democracy, can assume a stronger and more direct role in governing the adoption and diffusion of technology appears to run counter to a governance model based on public-private partnerships. Rhodes and others fear that government’s intimate engagement with business, and its transfer of the function of providing public goods to the private sector, results in a “hollowing out” of the modern state.

There has been a broader debate about whether such shifts undermine the democratic accountability of modern institutions (Rhodes 1994). Indeed, Lal (1999) points out that full democracy followed the secularization of the state, the emergence of a mercantile class that established autonomous markets, and after the era of Promethean growth was in full swing. If this is the case, then what is the appropriate role of participatory processes in governing technology when, historically, they seem to have been largely irrelevant in shaping the current state of affairs? Scientists and decision-makers, who in principle, seek to protect the public interest from the potential physical dangers associated with the release of new technologies, have traditionally dominated this field. In the last three decades a critique has emerged of the institutions of risk management, and the most common cure has been to call for more participation, more democratization and more accountability. Within this section I will examine the regulatory system that has been used in Canada to assess the health and environmental impacts of biotechnology.

4. Risk: probability multiplied by magnitude

The Promethean intensive growth that appeared in the West prior to and during the Industrial Revolution resulted in a new relationship between humans and nature. The mills, mines and plants of the early industrial system were dangerous places that killed and injured workers and created chronically hazardous ambient environmental conditions. Traditional physical threats to the public, including infectious disease and violent conflict, were both tempered and enhanced by the products and by-products of the industrial system.

As representative democracy and organized labour gained a foothold in many industrializing societies, the demand for safer workplaces and safer localities gained strength¹⁵. In these same societies, traditional hierarchies had earlier been replaced with a secular order that saw science and reason as the pathway to salvation. In its essential concern with liberating individuals from the ravages of natural hazards, risk management is located on the advancing frontier of this enlightenment project.

Enlightenment, as described by Kant (1953) sees human endeavour directed towards emancipation and autonomy. According to this definition, risk is strongly associated with the notion of individual safety that is the systematic reduction of hazards to which individuals are exposed.

Renn (1998) seeks to narrow the focus on risk, while accepting the historical perspective:

...risk has always been a part of human existence and the field of risk research started as early as human beings started to reflect on the possibility of their own death and contemplated actions to avoid dangerous situations.... However, a systematic scientific attempt to study risks in society and to professionalise risk management agencies is a rather more recent addition. (Renn, 1998: 50)

The first risk assessments using knowledge from the natural sciences date back to the early nineteenth century. In the UK, the first most famous early legislation to regulate

¹⁵ Workers' compensation legislation was the first piece of legislation drafted in British Columbia without reference to the British Privy Council.

industrial activity was the Alkali Act of 1863. Subsequent Acts created the framework for the assessment and management of risk that we see today both in the United Kingdom and in most other industrialized countries. By mid-twentieth century, the legitimacy of the state depended to an increasing degree on the capacity of its institutions to protect the population from natural and industrial hazards.

Since the 1960s, risk analysis as a field of research has burgeoned. Science is used to both characterize and assess the nature of industrial hazards and to propose interventions that will lead to risk reductions. A wide range of techniques have been used to assess the risks associated with specific technologies and with technologies aggregated into complex systems such as industrial processing plants. While these techniques may make use of the normal science of laboratory and experimental research, they typically involve much higher levels of uncertainty than a conservative peer-review system would tolerate. Methodologies such as dose-response analysis—used to establish acceptable of exposure both to known hazards such as radiation and to establish safety margins for pharmaceutical chemicals—often rely on extrapolations from established experimental research to the complexities of the real world. For example, an industrial plant is composed of multiple technical systems, all of which have known probabilities of failure based on experimental testing, but the system as a whole is rarely tested.

The process of assessing the risks associated with these aggregates of technologies requires considerable expert judgement and risk management practices play an uncomfortable, often ambivalent role:

- the technologies that science is used to assess are usually the product of research and were subject to regulations based on scientific assessment;
- even pure scientific research is shrouded in uncertainty; technology assessment almost always involves extrapolating beyond the highly controlled conditions of the scientific experiment but often obscures these uncertainties ; and
- the process of risk and technology assessment always affects the distribution of costs and benefits across social interests in society. More regulation often means more costs that must be incorporated into production processes. New technologies

may displace labour or create a situation where minor marginal increases in risk might be offset by the financial benefits of employment or compensation.

The very ambiguity of science makes it vulnerable to manipulation by social interests and in the modern setting it is unusual to find consensus on any scientific fact. Yet despite over thirty years of research into the social dimensions of risk (Renn 1998), modern risk management practices¹⁶ are still dominated by the view that the primary role of government is to **scientifically** assess technologies to ensure that they do not represent an unacceptable hazard to society.

This approach has been largely successful in controlling the substances that are released into the human and natural environments, ensuring that negative effects of technologies are reduced to levels that are “As Low as Reasonably Practicable.” And given this reasonable track record, many scientists and decision makers may ask whether there is a problem. When acknowledged, the most common cure for its perceived failures has been a call by all parties for more public participation, more democratization and more accountability.

Risk is not only contested because it is a battleground for conflicts among social interests. Risk management interventions often require that state power be mobilized in order to protect the collective interest. For instance, immunization programs typically require high levels of coverage to prevent disease transmission. The case is made for the collective benefits of immunization and in some cases this is pursued with the force of law, pitting the authority of the state against the liberty of the individual. The less extreme and more common dilemmas are exemplified by the case of smoking; individual freedom results in individual harm and potential cost to the public purse. In addition, risk researchers have discovered systematic biases in the perception of risks, for instance, unfamiliar but small risks may be perceived as more significant while familiar, more significant risks are

¹⁶ Covello and Munpower (1984) argue that risk management originated in 3200 BC with the Asipu of the Tigris-Euphrates valley. The Asipu acted as ‘consultants’ in risky decisions and, using signs from the gods, compiled data to identify the possible alternative courses of action. The word ‘risk’ probably comes from the French *risque* (Bellaby, 1990). Covello and Munpower (1984) trace the word back to the Greek term *rhiza*. Both terms describe the assessments of merchants of the chances of shiploads of goods to arrive safely in port. These assessments were used to derive appropriate levels of insurance against loss.

downplayed. This results in a conflict between lay and expert opinion described as the disjunction between actual and perceived risk.

Where outcomes are contested, social scientific methods are used to mediate conflict and to determine the optimal distribution of social benefits. Kasperson (1992) identifies the major variations from conventional approaches to risk management described above. The most striking of these is that between technical analysis of risk as safety, and social theories of risk. The three major social theories of risk are economic, psychometric and cultural. The social amplification of risk model set out by Kasperson and his colleagues (Kasperson 1988 ; Kasperson 1992) recognizes that these three approaches refer to different risk dimensions and encourage integration in recognition that hazards:

...interact with psychological, social, institutional, and cultural processes in ways that can heighten or attenuate individual and social perceptions of risk and shape risk behaviour. (Renn, 1998: 63)

In the following section, the three broad approaches are briefly summarized, recognizing that a complete analysis probably requires all of them.

The economic theory of risk

The economic theory of risk is most consistent with the dominant technical definition and shares similar assumptions regarding human responses to risk events. The indivisible unit of analysis is the individual acting according to some variant of the utility principle.

Gross and Rayner summarize the utility principle as applied by economic rationalists as:

...individuals decide to take a risk by first weighing its potential costs and benefits and then opting for the course of action that they think will maximize the advantages that will accrue. (Gross and Rayner. 1985)

The economic approach converts the risk events into negative utility (cost) that can be compared with possible positive utility (benefit) that may accrue from risky activities. This concept of utility, derived from utilitarian philosophical assumptions, implies that something is good if it increases personal satisfaction and bad if it decreases it. This abstraction to “satisfaction” allows for costs and benefits to be traded off and for a range of decisions to be compared on the basis of a common unit. “Preventative” regulations

have, for many years, been subject to this kind of calculation on the basis that the government's capacity to intervene in the name of safety is fiscally constrained.

For instance, in the zero-sum game of government finance, an effective but expensive technology to improve the efficiency of an airport is evaluated against the opportunity cost to other parts of the system¹⁷. In theory this results in the most effective use of scarce resources in the social production of safety, but in practice the analysis is biased towards effects that can be directly quantified and monetized and toward an instrumental notion of justice. A cost/benefit analysis of an airport can more easily quantify changes in land values than it can identify the financial value of lost habitat.

While a range of alternative valuation methods have emerged (Pearce and Turner 1990) in the last two decades, they are rarely used in decision making processes, are expensive to apply and rely on contested methodologies. Moreover, for some people, the act of assigning a monetary sum to a natural system is perceived as symptomatic of the very problem in human-environment relations. If a habitat is considered sacred, its value cannot be expressed in a currency of monetary value. Values held on deontological grounds are not subject to the calculations essential to cost-benefit analysis; if a practice is wrong it precludes the kind of trade-offs among costs and benefits that are implicit to this kind of rational analysis.

The psychometric theory of risk

The psychometric view of risk has a subtly different view of the cognitive process of weighing positive and negative utilities. Psychometric accounts still assume individual rationality, but suggest that consistent heuristics, such as “dread” or “controllability” influence the perception and ranking of risks (Kahneman and Tversky. 1974; Slovic 1992). Chai (1997) suggests that introducing these hard-wired heuristics is a response to the weaknesses of the rational utility model of human action. To the psychometricians, risk is predominantly about the disjuncture between perceptions and reality (Slovic, 1992). While economic approaches seek to standardize social values into monetary terms, the

¹⁷ (Glickman and Gough Glickman, T. S. and M. Gough (1990). Readings in risk. Washington, D.C. Baltimore, Resources for the Future ; Distributed by the Johns Hopkins University Press.

psychometric approach goes further, and seeks to understand the reasons why some risks are perceived to be of greater concern than others.

The cultural theory of risk

The clearest ontological disjunction in risk management is between the economic and psychometric theories of risk and the cultural theories of risk. The ontological assumptions about the basic objects of theory are fundamentally different and are to a large extent mutually opposed. While the economic and psychometric approaches assume the individual to be the indivisible unit of analysis, cultural approaches focus on the importance of sociality in human relations.

Culture is the shared interpretive framework of social groups or networks of actors (Gross and Rayner, 1985). It accords with one of the many definitions of institutions, as “predetermined social commitments” (Jordan and O’Riordan, 1995a: 18) embodying the norms and values that shape human action. A cultural approach to risk starts from the minimal assumption that social institutions always mediate “objective” risk events.

A range of approaches has emerged under the banner of cultural approaches to risk. These include the social amplification framework—giving primacy to the role of social institutions in exaggerating or attenuating perceptions of hazards—as well as less macroscopic approaches focusing on the mediating role of social institutions (Schrader-Frechette 1991 ; Wynne 1996) and on the importance of the processes of interaction between the different institutions of which societies are composed. Cultural approaches to risk assume that social institutions bring order to social life and focus on the context within which hazards are interpreted. As a consequence, risk becomes intermingled with questions surrounding the power and legitimacy of the institutions intervening as part of the risk management process (Douglas 1992).

Renn has come closest to providing an encompassing definition of risk:

Risks refer to the possibility that human actions or events lead to consequences that affect aspects of what humans value (Renn, 1998: 51).

This definition reminds us that risks have negative and positive consequences. For instance, the construction of an industrial processing plant close to a residential

community will result in potential dangers related to the production process but will also bring benefits, such as local employment and improved infrastructure. At the heart of risk management are processes that negotiate politically viable trade-offs between these costs and benefits.

Mary Douglas (Douglas 1966 ; Douglas 1970 ; Douglas 1992) approaches the issue of risk from an anthropological perspective following the lineage of Evans-Pritchard. Douglas argues that there is no fundamental difference between the rationality of the pre-industrialized and industrialized society¹⁸. In the forensic theory of danger, dangers—and by implication risks—are always politicized in ways that may be peculiar to one culture. For example, Jewish dietary laws identify pig, camel and rock badger as dangerous foods for reasons that are rational within a cultural system informed by the Old Testament (Douglas 1966). No amount of scientific research, health and risk assessment will alter this culturally embedded sanction against consumption of these meats.

It is not only possible to envisage an analogous reaction to GM foods, consumer reactions in Europe have this absolute quality to them. The issue is not whether scientists are right or wrong, but rather what culturally embedded norms and political strategies inform this position.

Giddens (1990) and Beck (1992) take a more macroscopic approach to risk. Using the concept of reflexivity, Giddens contrasts pre-modern societies where this process largely involved the “reinterpretation and clarification of tradition” with modern societies where:

...[t]he reflexivity of modern social life consists in the fact that social practices are constantly examined and refined in light of incoming information about those very practices (Giddens, 1990: 38).

Beck’s central argument is that post-industrial society does not fit with the post-modern vision of an increasingly fragmented society. The “modernization project” is not crumbling but rather is incomplete; new social forces are substituting for the old ones. In

¹⁸ The terms ‘primitives’ and ‘moderns’ are an unfortunate legacy of the last century and contrast simplicity with complexity. Blainey (1978) points out that the so-called ‘primitive’ Australian Aborigines have one of the most complex social systems in the world. The modern equivalents of ‘developing and developed’ fair no better in capturing the complexity of societies, presumed to be the laggards. Since, as Giddens has argued, ‘developed’ refers to technological advancement, the terms industrialized and non-industrialized will be employed throughout this thesis, along with the more specific term ‘tribal’.

the light of endemic lower level risks and risks that are primarily anthropogenic “modernization is becoming *reflexive*; it is becoming its own theme” (Beck, 1992: 20). Beck argues that the logic of risk production begins to dominate the logic of wealth production: “The productive forces have lost their innocence in the reflexivity of modernization processes (Beck, 1992: 13).”

Beck contrasts wealth society with risk society; the key differences are outlined in Table 1.

Table 1: The Contrasts between Wealth Society and Risk Society

| Wealth Society | Risk Society |
|---|---|
| Wealth desirable in context of scarcity | Risk undesirable in context of abundant threats |
| Positive logic of acquisition | Negative logic of disposition |
| Share the pie | Spared the pie |
| Equality | Safety |
| I am hungry | I am scared |
| Commonality of need | Commonality of anxiety |

(from Beck, 1992)

Beck suggests that this shift in emphasis could initiate a dialectal process where the dominant institutions of modernity are challenged. He argues that we need to change the way we understand social opposition to technology from ‘solidarity motivated by need, to solidarity motivated by anxiety’ (Beck, in (Rustin 1994 : 397).

According to Rustin, Beck implies that modernization has its own logic, an abstract rationality. From a neo-Marxist perspective Beck generally fails to acknowledge that society is driven by the instrumental rationality of capital. As Rustin points out:

Even “globalization” is driven not merely by technology in the abstract, but by the deployment of technology by corporations for their own purposes. (Rustin, 1994: 400)

The distinction between a society organized around wealth creation and a society organized around risk avoidance (or needs satisfaction as opposed to anxiety avoidance) may be spurious. The satisfaction of the most basic needs (defined in Maslovian terms) such as access to food, water and shelter can also be understood as the avoidance of risks. The same logic may be applied to higher needs such as community, family and culture if we accept that these are defining features of human sociality. The possible loss of these represents a threat to individual security. In this context, ‘Risk Society’ is not a new paradigm; it is the nature of the threats that has changed.

Risk management is dominated by practices that rely on scientific assessment to measure and assess the dangers produced by industrial society. More subtly, the emphasis on measurable harm constrains the discourse on the appropriateness of modern technologies in a way that appears to preclude the discussion of their broader moral dimensions. For example, the response of the British government to the political controversy surrounding the introduction of products containing genetically modified organisms in the late 1990s was to commission research and limited experiments to establish whether the products caused direct harm and whether they had the potential to invade and displace species that populate the British countryside (Levidow, 1999). However, the politics of opposition was more nuanced and complex and focused on whether the processes of modification were appropriate or constituted “playing God.” The fact that the main proponent of the new technologies was a massively successful US company created further concerns about commercial imperialism.

5. Governing biotechnology in Canada

There is little doubt about the rate of expansion of commercial biotechnology; a report by the Canadian Biotechnology Advisory Committee predicted that the world market for biotechnology would expand from \$20bn in 1995 to \$50bn by 2005 (Canadian Biotechnology Advisory Committee 2000). The more modest Canadian biotechnology sector involves 358 companies¹⁹ and was expected to generate \$5bn in 2002 against expenditures of \$1.5bn.

The Government of Canada has played a role in enabling the emergence of technologies that goes beyond regulating products to reduce the probability of harm to individuals and the environment. In fact, this regulatory function may be one of the later roles assumed by the federal government in the biography of biotechnology²⁰.

Although earlier public funding of research created the conditions for many of the discoveries that underpinned government's strategy, biotechnology in Canada has been actively supported and promoted by various arms of government since the 1980s. Leiss (2001) describes the battles within government departments during the 1980s over who should own the biotechnology portfolio. Environment Canada (EC), the weakest federal department, battled for control with Industry Canada, Agriculture Canada and Natural Resources and was ultimately forced to share the task of regulation with the latter agency. Leiss adds that EC is internally divided as an agency and suggests that tensions between the regional departments and Ottawa further complicate the task of regulation.

The 1983 *National Biotechnology Strategy* located in Industry Canada focused entirely on promoting research capacity. The four objectives of the strategy were:

1. to focus biotechnology research and development on areas of strategic importance to Canada;

¹⁹ 80% of all firms are in BC, Ontario and Quebec Boucher, L. J., D. Cashaback, et al. (2002). *Linking In, Linking Out, Linking Up: Exploring the Governance Challenges of Biotechnology*. Ottawa, Institute on Governance: 43.

²⁰ While Leiss (2001) describes this dual role as a conflict of interest that undermines public confidence in government, Macdonald (2000) is perhaps more accurate in describing the issue in terms of a conflict of obligations: the government of Canada is mandated to promote domestic economic interests but must also protect public health.

2. to ensure an adequate supply of high-quality, trained human resources in biotechnology;
3. to encourage communication and collaboration between researchers in different disciplines and sectors; and
4. to create a climate conducive to investment by industry in biotechnology.

This strategy was revised in 1998. The *Canadian Biotechnology Strategy* sought to involve nine key federal departments and agencies as partners, thereby presenting a somewhat more balanced strategy for governing biotechnology in Canada (Canada 1998) by seeking:

- to strike a balance between industrial development and social and ethical concerns; and
- to engender more effective co-ordination across the relevant ministries.

Listed among the nine strategies for further promoting biotechnology and enhancing science capacity are objectives relating to enhancing public awareness and understanding of biotechnology through open and transparent dialogue.

Adopting the Strategy led to the creation of the Biotechnology Ministerial Co-ordinating Committee (BMCC) and the Canadian Biotechnology Advisory Committee (CBAC). The BMCC provides direction to and receives advice from the CBAC and is further supported by an eight member co-ordinating committee of deputy ministers and agency heads. The Canadian Biotechnology Secretariat provides support to the CBAC, is directed to raise public awareness of biotechnology in Canada and to implement the Strategy. CBAC has held three cross-country consultations and undertaken targeted research projects.

A difficulty with the system for governing biotechnology in Canada is the fact that the portfolio does not fit easily into any one department (Boucher et al. 2002). Added to this are the complications engendered by the Canadian constitution which delegates responsibility for the terrestrial environment and natural resources to the provinces. The result is that:

- the provincial and federal governments are all heavily involved in promoting biotechnology strategies; and

- projects have been required to submit to both provincial and federal environmental assessments²¹.

Regulating technological innovation

The regulatory framework in Canada creates an impression that the release of GM technologies is manageable. The federal government regulates biotechnology within the existing regulatory framework through a suite of tools known as Environmental Assessment (EA) and Risk Assessment (RA). The government has adopted these well-established tools on the basis that the techniques involved in biotechnology are simply incremental extensions of well-established practices. EA techniques depend on applying scientific research at project and strategic levels to predict the potential impacts of activities and processes on ecosystems over extended periods of time. RA techniques typically focus on unintended impacts of activities and processes on human subjects. These techniques have emerged over the last four decades and are present in varying forms in all industrialized nations.

The United States led the way with developing EA techniques with the National Environmental Policy Act (1969). The belief was that a systematic assessment of the possible effects of a project could improve the quality of decisions involving public money and avoid negative unintended or collateral effects.

Canada established the *Environmental Assessment and Review Process* (EARP) in 1973 as an administrative policy. Stopping short of formally legislated requirements, the federal government hoped to avoid court battles, but eleven years later, the process was formalized with the approval of the *EARP Guidelines Order*. These guidelines, which were not intended to be mandatory, were tested in the courts and found to be legally binding. This resulted in the 1995 Canadian Environmental Assessment Act, which applies to large and small public and private projects (Gibson et al. 2003).

21 BC under the NDP had the most stringent EA framework in Canada and signed an agreement in 1997 with the Federal government to harmonize procedures such that only one submission was necessary for relevant projects (http://www.ceaa.gc.ca/0009/0001/0003/0001/0002/canada-b.c._news_e.htm). The BC Environmental Assessment Act was amended in 2002 “to provide much greater flexibility to customize review procedures on a project-by-project basis.” The increased flexibility is intended to contribute to the government’s strategic priorities for an improved investment climate while preserving high environmental standards.’ (reference www.eao.gov.bc.ca).

Over the last four decades, EA has evolved to be more than a narrow technical assessment of the anticipated biophysical impacts of a project or development to encompass broader environmental effects and the need for more intensive public engagement to ensure social impacts are adequately addressed. The evolution directed is away from a narrow environmental assessment and towards a “sustainability assessment” although at this stage, legislators are still trying to come to terms with what such a methodology would look like (Gibson, 1999).

Reality is that policy processes and the legal system demand a great deal from science and in most instances, the demands violate the principles of credible scientific prediction²². The most common mistake is to confuse scientific explanation and scientific prediction. While scientists are often in a position to explain what is occurring at a particular point in time in, for instance an aquatic ecosystem, they cannot scientifically predict what will occur if the system conditions are changed. Such prediction is only possible in a closed system with sufficient data. Consequently, in most instances, the science used in EA is not the science of the physics laboratory or an ecological experiment, but a form of professional consultancy.

In professional consultancy or “post-normal science,” values and framing assumptions exert a significant influence over the results²³. Andrew Stirling warns that while there is a stunning array of hybrid techniques including RA, cost-benefit analysis and multi-criteria analysis:

...a proliferation of candidate understandings is not necessarily a sign of imminent enlightenment ... many of the analytic approaches aspire to develop a nice, clean ‘analytical fix’ for the messy (and intrinsically political) business of decision-making (Stirling, 1999)

22 A strong technical argument is made in Oreskes, N. K., Shrader-Frechette, K., and Belitz, K. (1994). "Verification, validation and confirmation of numerical models in the earth sciences." Science, 263: 641-6.

23 For a review of the different forms of science, see Funtowicz, S. O., and J.R. Ravetz. (1985.). Three Types of Risk Assessment: A Methodological Analysis. In C. Whipple and V. Covello (eds.) Risk Analysis in the Private Sector, New York: Plenum.

In broad terms, the sources of uncertainty in environmental decision-making are the result of²⁴:

- the resilience of ecosystems and the fact that it is rarely possible to identify where their thresholds lie;
- uncertainty about the value of changes to ecosystems, both at the intrinsic level and with regards the functions and service they supply to human systems; and
- uncertainty regarding the future supply of ecosystem functions.

That said, it is misleading to suggest that the problems related to the role of science in the policy process simply represent a crisis of overconfidence. In many instances, science and the political struggle for power and influence are inseparable²⁵. Science becomes an instrument in the pursuit of power and decisions informed by interests and values are given a polished veneer of objectivity through the selective framing of studies and through the partial revelation of findings. The myth that is perpetuated in this process is that scientific research involves the production of truth. In practice, scientific research often generates a greater perplexity and uncertainty, although this uncertainty that disappears from view in the course of applying science to decision-making processes. While scientific practice is a systematic and rigorous analysis of the natural world, the legitimacy of a given policy intervention or environmental assessment requires science to be embedded in a much broader process. To put it bluntly, the mere fact that a scientist is speaking or contributing to an environmental assessment does not make the findings scientific. EA and RA techniques are not scientific in the conventional sense of the word; they are hybrid approaches that represent an ‘uneasy marriage’ between science and policy²⁶.

24 Young, R. A. (2001). Uncertainty and the Environment, Edward Elgar.

25 There is an extensive literature on this topic including Schrecker, T. (1984). *Political Economy of Environmental Hazards*. Ottawa, Law Reform Commission of Canada: 112.
and Jasanoff, S. and B. Wynne. (1998.). Science and Decisionmaking. In S. Rayner and E. Malone (eds.) Human Choice and Climate Change, Vol 1., Columbus: Battelle Press. pp1-87.

26 The implications for EA are explored in Farrell, A., S. D. VanDeever, et al. (2001). "Environmental Assessment: four under-appreciated elements of design." Global Environmental Change **11**: 311-333.

Ultimately, the challenge technological regulation presents the legal and political system in developed countries requires greater clarity than normal or post normal science can deliver. At the broadest level, Homer-Dixon argues that this represents an ‘ingenuity gap’²⁷ between the technologies of modern societies and our ability to govern and regulate the demands they place on natural systems.

EA is always based on a wide range of framing assumptions. The key social elements that influence the design of EA programs at the strategic and project levels are²⁸:

- assessment initiation and context: Who called for the assessment and why?
- science-policy interaction: Are the roles distinct or do they overlap?
- participation: Is the level of stakeholders participation nominal or engaged?
- assessment capacity: Is the organization carrying out the EA competent to carry out the necessary research?

The effect of framing choices and assumptions can be significant. For example, in one case the range of external environmental costs of a coal fired power station based on 32 different government and industry assessments varied by more than four orders of magnitude²⁹.

There is a great deal of literature on the treatment of science in the policy process and on the issue of scientific uncertainty more generally, but it is useful to point to the distinction between hard and soft uncertainty³⁰. Soft uncertainty exists where the set of possible future actions is known and where their probability distributions are understood. It has been argued that the instances where both of these conditions are satisfied are rare, particularly with respect to environmental decision-making. More commonly, decisions are made under conditions of hard uncertainty, where the full set of future actions is

27 Homer-Dixon, T. F. (2000). The ingenuity gap. New York, Knopf.

28 Farrell, A., S. D. VanDeever, et al. (2001). "Environmental Assessment: four under-appreciated elements of design." Global Environmental Change **11**: 311-333.

29 Stirling, A. (1999). "The appraisal of sustainability; some problems and possible responses." Local Environment **2**(2): 111-135.

30 Young, R. A. (2001). Uncertainty and the Environment, Edward Elgar.

unknown or where the set of future actions is known but their probability distributions are not.

It is a mistake to assume that because science can address issues of soft uncertainty through methods such as RA and through quantitative models, that this represents the total set of possible outcomes. The apparent solidity of these results provides support to decision makers, but does little to ensure that the long-term effects of an intervention in natural systems can be managed.

Assessing biotechnology in Canada

The lead agency in Canada for approving food biotechnology is the Canadian Food Inspection Agency (CFIA). The Agency is responsible for field trials for crop plants and for approving GM feed for animals. Health Canada focuses on assessing food safety and Environment Canada shares responsibility for assessment under the Canadian Environmental Protection Act (CEPA). Although the Department of Fisheries and Oceans is responsible for the marine and aquatic environment, the department has not yet developed regulations specific to genetically modified organisms.

GM technologies are not selected for special attention among novel technologies; all novel foods in Canada are assessed. The guiding principle is that:

...it is the nature of the product that determines the nature and level of associated risk; it is not the novelty of the science used in its production (Committee 2001: 18).

A recent report suggests that only in Canada would variants of Canola produced through transgenic methods and by accelerated mutagenesis be assessed prior to release (Committee 2002).

CBAC suggests that the current system focuses on assessing all novel foods; the system compares GM variants with their conventional counterparts to see if the introduction of novel traits has altered their environmental influence. The criteria—taken from *Regulatory Directive (94-08)* relating to plants with novel traits—examine the consequences of gene flow and the effect of the modified organism on non-target organisms and biodiversity. An assessment is not triggered in every case and at the time

of the 2001 Royal Society report³¹, the system used ‘substantial equivalence’ as the decision threshold. As of 2002, 51 novel foods had been authorized for sale by Health Canada, 42 of these are transgenic. CFIA had authorized 39 plants for unconfined release, 31 are transgenic.

Biotechnology firms wishing to field trial a GM crop or species apply to CFIA for permission. The firm must provide a detailed description of the history and characteristics of the organism in question and must also provide a detailed plan of the field trial. Field trials of agricultural organisms are limited to one hectare per site to a maximum of five sites per province. The submission must include plans for public notification (ibid: 36), although the agency is only obliged to release details regarding the basis for approval of the organism and not the details of the field trials or the results in the *Decision Document*. The standard required for experimental design in these plots is intended to be equivalent to academic peer review, although the Royal Society Expert Panel questioned this:

In the absence of independent peer review, however, the Decision Document is in no sense equivalent to a peer-reviewed scientific paper ... the decision-making process in general lacks transparency, and thus credibility (ibid: 36).

It is widely expected that the first application to CFIA for assessing a GM animal for food production will be for salmon. Research on transgenic fish has proceeded at much more rapid pace than research on other animals because the techniques for introducing new genetic material into fish embryos have proved to be simpler and more effective (Royal Society, 2000: 26). This is not to suggest that the mechanisms and effects of genetic modification of fish are fully understood; rather that it has been easier to create modified variants of fish than other species.

Evaluating the environmental impact of transgenic fish is likely to be difficult; it is not feasible or desirable to release transgenic fish into the natural environment and the Royal Society report suggests that a great deal of research is required before genetically modified fish can be safely raised in offshore pens. Currently the risk analysis is

³¹ The Royal Society of Canada was commissioned to examine both the science of food biotechnology and the Canadian regulatory framework.

informed by subjective evaluations based on the scientific literature, rather than on scientific analysis or experimentation by DFO. Given the complexity of the issue, the Panel concluded that:

DFO's Aquatic Organism Risk Analysis, despite its laudable intentions, will be unable to provide strong, accurate, reliable assessments of potential risk to the environment posed by the introduction and transfer of GM fish' (ibid: 167).

The authors conclude by recommending a moratorium on GM fish in aquaculture.

The Panel also noted that while there is a formalized decision framework for assessing novel organisms, implementation varies significantly from case-to-case. While this allows the process to be tailored to the unique characteristics of the organism under scrutiny, the Panel was concerned that this flexibility may affect the quality of the decision-making process.

Health Canada's role in assessing novel food biotechnologies focuses on the human food supply system. Assessment is based on a comparison between the molecular, compositional and nutritional data of the traditional foodstuff and the modified form. If this analysis does not satisfy the department's concerns, then further toxicity testing may be required. However, the Panel reported that, based on a review of Health Canada documents and interviews with officials:

...no formal criteria or decision-making framework exists for food safety approvals of GM products by Health Canada (ibid: 37).

Relying on an *ad hoc* system, the approval process occurs over 90 days and no independent laboratory testing is required. The product is a *Decision Document* similar to those released by CFIA³².

Environment Canada assesses the potential effect of novel organisms on exposed ecosystems. Field trials are assessed under the CEPA using a detailed checklist that the proponent must fill with research from laboratory experiments or published literature.

³² The Royal Society report notes that approval for food additives derived from GM microorganisms are evaluated as new food additives based on a submission by the proponent. While there may be general labelling requirements, it is not necessary to show that they are GM derived.

Additional assessments may be required under the Seeds Act and by the Pest Management Regulatory Agency, which is responsible for regulating biological control agents. A full RA of an entirely novel product would require a combination of laboratory testing on animals, dose-response evaluations, exposure assessment and risk characterization³³; however, no additional assessments have been proposed to date.

The development of GMOs exemplifies the kind of intensive growth described above. Intensification in agriculture has occurred through massive increases in chemical fertilization, large-scale mechanization and through the development of increasingly specialized crop varieties through selective and mutagenic breeding. Much of the debate has focused on whether it is desirable to introduce technologies which ultimately increase the intensity of agriculture. However, in marking the limits of its terms of reference, the Royal Society report points out that there is a wider debate that it is unable to address, about alternatives to intensive industrial agriculture. The debate, as framed by government, is about what forms of biotechnology are appropriate, rather than about whether the dominant agricultural system as a whole is appropriate. However:

[t]here are probably alternatives to some biotechnology products; many of these alternatives are likely not other products, but instead the systems and methods of sustainable agriculture (Royal Society of Canada, 2001: 29).

Substantial equivalence

The Royal Society Expert Panel was particularly concerned about the use of “substantial equivalence,” a principle used in assessing non-transgenic seed varieties. Plant breeders refine varieties by interbreeding for desirable characteristics among highly refined breeding lines. Equivalence implies that interbreeding among closely related and highly refined species will produce substantially similar progeny.

The expectation borne out by years of successful crop variety development, is that “barley is barley is barley” (i.e. most, if not all, of the new gene combinations will produce a “barley” phenotype) (ibid: 177)

³³ These procedures typically test for toxicity; an entire chapter of the Royal Society report addresses allergenicity, which is not typically examined in technology assessments.

Protagonists for using substantial equivalence in assessing GMOs suggest that, since modification only typically alters one gene, the resultant variety is substantially equivalent to the non-transgenic parent and is, therefore, safe for release. Those opposed suggest that since genetic modification often seeks to introduce completely new genetic material into a breeding line, the test of substantial equivalence cannot be met.

Substantial equivalence has been hotly debated at the Organisation for Economic Cooperation and Development, the World Health Organization and the Food and Agriculture Organization and the Royal Society Report suggests that the resulting redefinition is effectively a rejection of its validity with respect to GMOs. However, from the perspective of the companies promoting GM crops, the substantial equivalence designation is likely to be seen as highly desirable since it significantly reduced the cost of the approval process³⁴.

The Royal Society argues that only a scientific assessment of an organism can determine whether novel genetic material is substantially equivalent and questions substantial equivalence as a decision threshold used to by-pass a more detailed assessment. The Panel preferred a “safety standard” that rigorously tests whether significant alterations have occurred. The Panel suggests that biological systems are far more complex than the linear model³⁵ suggests and that these complexities are still being revealed (ibid: p185).

A more recent report produced by CBAC sought to clarify the use of the substantial equivalence criterion and concluded that—contrary to what is implied in the Royal Society report—it has not been used as a decision threshold to exempt GM foods from appropriate regulatory oversight (Committee 2002: 27). The report accepts substantial equivalence as a safety standard, but also recognizes that the next generation of GMOs, which may incorporate multiple gene transfers, is likely to generate much greater challenges for established assessment procedures.

³⁴ The substantial equivalence designation for GM canola crops meant that no further assessment of the new variant was required Canada, R. S. o. (2001). Elements of Precaution: Recommendations for the regulation of Food Biotechnology in Canada. Ottawa.

³⁵ The linear model of the transfer of genetic material into the DNA of an organism implies that only the predicted phenotypes intentionally transferred across species needs to be assessed. According to this model, one gene codes for one characteristic and does not interact with other genes within the DNA of the target species.

The precautionary principle

Recognizing the inherent uncertainties of biotechnological research, the Royal Society report considered what role the precautionary principle might play in regulation. Their review suggests that the principle is widely used in international regulations, but is less common in domestic law³⁶. The Panel also found the concept to be inconsistent with the accepted norms of both science and law; it favours Type I false positives over Type II false negatives, or, to use a legal analogy, it assumes guilty until proven innocent.

In its strong form, the precautionary principle can be highly conservative and anti-technological, emphasizing reducing all risks to an (impossible) zero level. The Panel preferred a version of the precautionary principle that places more of the burden of proof on the proponent to ‘carry out the full range of tests necessary to demonstrate reliably that they do not pose unacceptable risks’ (ibid: 206). Guided by the United Kingdom’s experience with bovine spongiform encephalopathy, they further propose that:

Where there are scientifically reasonable theoretical or empirical grounds establishing a prima facie case for the possibility of serious harms to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product (ibid: 206).

This implies that the current system does not exercise this degree of prudence and that, in the opinion of the Panel, greater prudence is advisable.

Labelling

While there has been a trend in Europe towards mandatory labelling of all GM products, the Royal Society Expert Panel remained more circumspect. While the case for labelling products that contain a risk of health effects for a proportion of the population—*e.g.*, for products that may transfer nut allergies—is non-controversial, the Panel concluded that

³⁶ This begs the question: “What is it about international law that favours such devices?” This question is beyond the scope of this paper but it is worth noting that the international system of law and regulation is not the same as the domestic system. The precautionary principle may be a concession to interests who are only weakly and voluntarily bound by regulations that international regimes produce. Nor should the reader assume that international regulations trump domestic laws as the apparent hierarchy might imply.

mandatory labelling of GM products is not justified on scientific grounds. The view of the committee seems to be that production processes behind GM products are not sufficiently different to conventional food product to merit mandatory labeling. This issue becomes more complex where individuals or groups hold moral concerns about GM products, which are not reducible to a technical analysis (e.g. no amount of scientific research will convince orthodox Jews that pork is safe to eat) and labelling at least allows for the possibility of informed consent. The Panel noted that they were not mandated to include socio-political justification, however, they did note that many exotic non-GM foods are introduced into the food system with no requirement that they be identified.

GM foods are already widely integrated into the North American food production system and commercial interests lobbied strongly against labelling the products and against producers of non-GM products inferring that they are superior by labelling their products as non-genetically modified. Indeed, some GM companies have tried to acquire organic status on the basis that their products use reduced or no pesticides in the production process.

This raises some important issues from a labelling perspective. If the product conferred a direct benefit to consumers, the labelling issue would be redundant; companies would market the product as value added in order to distinguish it from competitors (a similar point is made by Leiss, 2001: 32). For instance, there was no intent to hide the fact that the 'Flavr-Savr' tomato, which ultimately failed to gain a hold in the market, was a GM product.

However, when the primary benefit accrues to producers (e.g., through reduced production costs or higher productivity) but results in an indistinguishable commodity, producers are likely to resist labelling. From the consumers' perspective, unless there are significant price differences, rejecting GM products incurs no additional costs.

The Government of Canada's response to the Royal Society report (2001)

The Government of Canada responded to the Royal Society report in 2001 in a formal statement that demonstrated a willingness to accept and address many of the concerns raised by the Society (Canada 2001). The response represents the position of Health Canada, CFIA, Environment Canada, Agriculture and Agri-foods Canada and the

Department of Fisheries and Oceans and resulted in the commission of a series of internal reviews.

In particular, the government accepts that substantial equivalence was used ambiguously and inconsistently across different legislation and accepts the safety standard definition. Government also accepts that a precautionary approach be employed as defined in the Rio Declaration on Environment and Development:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation (Principle 15).

The report also accepts the need for:

- greater transparency in decision making processes;
- more advanced toxicological assessments;
- better assessments of environmental safety; and
- a reform of the Fisheries Act to regulate transgenic fish.

In most instances, the government's proposed actions will result in further research and review. This signals recognition that many of the issues are important, but stops short of actually altering regulations. For instance, with respect to antibiotic-resistance markers used in transferring genes to mark the site of insertion, the Royal Society recommends:

...that in view of the availability of suitable alternative markers, antibiotic resistance markers should not be used in transgenic plants intended for human consumption (Recommendation 4.3 in the Royal Society Report).

In response, the government commits to:

...work with product developers as well as national and international experts to determine the "state of the art" regarding alternative markers as a tool in the development of new biotechnology products

The Society's recommendation is a low cost precautionary harm avoidance strategy and yet the response is to wait for more research. A number of other responses could similarly

be interpreted as unnecessarily delaying the implementation of sound policy interventions³⁷(see above: Perri 6's "governance through coping").

Report of the Institute on Governance (2002)

A report by the Institute on Governance (Boucher et al. 2002) sought to explore some of the governance challenges raised by the Royal Society through a literature review and interviews with senior staff in government agencies. The report states that most interviewees were comfortable that separating promotion and regulation of biotechnology between Agriculture and Agrifoods Canada and the Canadian Food Inspection Agency (respectively) avoided conflicts of interest³⁸.

The interviews also suggested that it was not clear to the interviewees who is in charge of biotechnology and that co-ordination across ministries has been weak. For instance, it appeared that between 1998 and 2002, the Biotechnology Ministerial Co-ordinating Committee had met only once; respondents reported that the opportunity costs of interministerial activities were high. The interviews revealed concerns that locating the Canadian Biotechnology Secretariat within Industry Canada may become problematic when it comes to maintaining public credibility.

The Institute was clear in stating that problems related to biotechnology governance cannot be ignored; they will surface in the courts if they are not addressed by legislation.

CBAC final report

According to the final report of the CBAC (Committee 2002), some progress has been made in some legislative and non-legislative areas. This includes:

- consultation with the Canadian Council of Grocery Distributors and the Canadian General Standards Board regarding labelling;

³⁷ As of Spring 2003 the author was unable to find reference to the Department of Fisheries and Oceans regulations on the transfer and release of transgenic fish other than those found in the draft proposals.

³⁸ A more detailed review of CFIA confirms that regulatory and promotional activities of CFIA are handled by two distinct offices within that agency--the Plant Biosafety Office and the Office of Biotechnology--but does suggest that even this administratively distinct cohabitation may create problems of public confidence Prince, M. (2000). *Regulators and Promoters of Genetically Modified Foods in the Government of Canada: An Organizational and Policy Analysis*. Ottawa, Canadian Biotechnology Advisory Committee: 44.

- introduction of a Private Members Bill to require labelling of GM foods (the bill was defeated);
- reports by the Agriculture and Agri-Foods Canada, the Privy Council and a joint report by CFIA/Health Canada addressing the structure of the biotechnology sector, the use of the precautionary principle, and draft guidelines for novel foods.

CBAC has supported the development of a large number of reports that examine the wider social and ethical context within which biotechnology is evolving. These include reports on the legislation relevant to biotechnology (Doern 2000; MacKenzie 2000; Prince 2000), patenting (Schrecker and Wellington 2001) and the development of ethical frameworks for governing biotechnology (McDonald 2000; Sherwin 2001). The work by McDonald and Sherwin presents the greatest challenges. Indeed, the frameworks that describe the principles by which governance should be guided suggest challenges that extend well beyond issues of biotechnology. For example, the frameworks propose that assessment methodologies be broadened to include direct and indirect social and economic impacts, such as the effect of a rapid transition to a particular GM crop on employment security in rural areas, and the viability of communities or “fourth hurdle” concerns³⁹.

This broader agenda will rely on the extension of predictive methodologies to a much wider range of outcomes, as well as to complex social systems, a practice fraught with difficulties. The kind of science used in this form of assessment will always be incomplete and fallible. Even the most robust and sophisticated assessment regime will at some point fail to predict the social or environmental impacts of a novel technology. This suggests that some effort ought to be expended on working through what will be done when something does go awry, rather than focusing just on the impossible task of building the perfect, predictive regulatory framework. The precautionary goal ought to be to build regulatory mechanisms that allow for the release of a GM organism to be reversible or at least containable. For instance, the DFO requirement that all GM fish

³⁹ The “fourth hurdle” refers to distribution, equity and community interests. The first three hurdles are safety, quality and efficacy according to Schrecker T, Hoffmaster CB, et al. (1998). *Biotechnology, Ethics and Government*. In Renewal of the Canadian Biotechnology Strategy. Resource Document 3.4.1, Background Research Papers, Ethics, I. Canada. Ottawa, Government of Canada: 135-261.

released or transferred for commercial use must be sterile would prevent establishing transgenic fish species that could interbreed with wild populations⁴⁰.

The demand to broaden assessments does reflect the emphasis of the review process initiated by CBS. This process focused on improving the transparency of government and the quality and scope of the science-based technical assessment methodologies used in regulating biotechnology.

⁴⁰ Ironically, Monsanto's ill fated terminator gene, which ensured that farmers would have to purchase new seed each growing season, similarly reduced the likelihood that seeds would propagate outside of the agricultural system. The terminator gene was subject to a worldwide campaign since it created a commercial dependency between farmers and Monsanto.

6. New approaches to risk and environmental management

One of the central messages of the sociology of risk and of ethical frameworks is that the development of technologies must be embedded in social processes that allow the appropriateness of the proposed technologies to be deliberated and negotiated. From an instrumental perspective, this commitment to openness and transparency may result in legitimate challenges to the substantive knowledge used in technology assessment. From a procedural perspective, deliberation can, at the very least, reveal in greater depth the deeper reasons for social concern about biotechnologies.

The species scientists hope to modify and the landscapes these technologies will alter are often important cultural and political symbols. It is impossible to understand European opposition to biotechnology without understanding how agriculture and the cherished countryside are much more strongly intertwined there than in North America, where the industrial agricultural heartlands are in a separate spatial category from wilderness areas. Similarly, the debate about transgenic salmon will be inseparable from the debate about salmon aquaculture, which is perceived to be a threat to the viability of the iconic wild salmon.

Contrary to the strategy of the British government, these issues cannot be resolved by proving scientifically that biotechnology is safe. Indeed it is not really a question of who is right or wrong, rather on some level the challenge for those involved in governance is to recognize that the groups campaigning against biotechnology wield legitimate power in modern liberal democracies.

The recurrent theme in response to concerns about the emergence of a biotechnological regime is to propose a dialogue either among the key stakeholders, or, more ambitiously, involving the whole citizenry. While admitting that the framework is an ideal one, McDonald describes one version of what ethicists would like to see occurring:

...[T]he hope is that a set of fundamental principles (interpreted against a background of commonly accepted cases) will command a consensus amongst all rational members of society (McDonald 2000: 15).

This position is one among many calling for an expanded public dialogue about the kinds of technologies society should develop and the conditions under which they should be released. In these accounts, science may play an important role but must be accompanied by processes that seek to transform citizens from a passive into an active role.

Two distinct schools of thought have proposed cures for the “malaise of modernity.” Both call for restructuring governance through more open decision-making, the repoliticization of decision-making or the democratization of technology assessment. The school represented by such critical theorists as Marcuse and Habermas proposes a radical restructuring of governance—recapturing enlightenment from the control of technocrats—to address the deep-rooted problems of modernity. The other school seeks to reform the system from within by building more participatory forms of engagement (*e.g.*, citizens’ juries, science shops, and focus groups) into the traditional policy cycle.

Restructuring governance

A critique of the transition towards a “one-dimensional society” has been a consistent theme of the first group (Marcuse, 1972). Marcuse criticized the increasing dominance of industry and work over people’s lives, as well as the reduction of high culture to low culture; Habermas has been concerned with the colonization and depoliticization of what he refers to as the life-world. Emancipation for Habermas comes not through the destruction of the modern capitalist system but through rational and uncoerced communication among groups of individuals, who through reasoned argument are able to free themselves from the constraints imposed on them by modern society.

Habermas’ view of the state is that it is not a taken-for-granted entity that exists external to the social realm, rather it is a set of institutions that seek to exert power and influence over the social world, “[a] governing regime [that] requires legitimation to justify its domination over the social realm” (in Wuthnow 1984 : 216). Science and the knowledge it produces are inseparable from the power of the state; it is a form of ideology that leads to ‘distorted communication’ and the emergence of a false consensus (Wuthnow 1984). Those in positions of power to mediate conflict call on science to foreclose decisions by lending authority to what Habermas considers ought to be political choices. This reliance on “rational purposive action” emphasizes the technical skills of experts and the

application of scientific reasoning to the management of both natural and human systems over what is perceived as value laden, subjective, and therefore inferior, lay knowledge. Technological progress seem inevitable and the instrumental ends of economic growth dominate, leaving little room for self-conscious reflection about values.

As the mandate of the state increases in response to both the need for legitimacy and the increasing demands of the population, Habermas fears that rational purposive action will, in his words, increasingly colonize the lifeworld:

Habermas believes modern culture is caught up in a more complex, sophisticated form of ideological domination than ever before. Technocratic consciousness increasingly pervades government and the economy, and technological progress has become indispensable to economic growth (Wuthnow et al, 1984: 226).

Habermas argues that it is only through communicative action—free and open speech, debate and reflection with other individuals—that the values that inform social action can be revealed. Opening up decision making to public debate is the cure to a range of social ills.

Described as the “Ideal Speech Situation”, “communicative competence” or the “public sphere,” this approach involves creating a political space⁴¹ where decisions are no longer dominated by technical expertise, but instead are informed by achieving consensus among affected individuals on the basis of mutual concerns. The key criteria for process design are fairness (ensuring all involved in the process have equal voice) and competence (the ability to access information and the ability to communicate). Habermas argued that under these conditions, the values that inform the positions of social actors can be shared, evaluated and understood.

In the absence of efforts to open up new political spaces, Habermas argued that modernity will continue to suffer from two broad structural problems. The first—the

⁴¹ This setting resembles the eighteenth century bourgeois public sphere in Europe where private individuals engaged in critical public debates regarding the decisions of the state (Hohendahl, 1979 in Wuthnow et al 227). It is also consistent with the Athenian model of democracy, which valorized free open debate (at least for the men who were not slaves), but apparently even Habermas was pessimistic about whether universities could create this political space (Wuthnow et al, 1984: 227).

legitimation crisis—refers to the mismatch between demands on the state and its capacity to fulfill the demands. The second—the motivation crisis—results from the erosion of shared cultural values between citizen and state, leading to a fixation with family concerns, leisure and consumption and a form of civil privatism. The act of faith demanded by Habermas is belief that the uncoercive context of the Ideal Speech Situation will produce consensus both about what is true about the world *and* what is morally right.

While Habermas may be critiqued on many grounds, his work remains radical, advocating a fundamental restructuring of modern governance. His emphasis on process over outcomes is important since it implies that, regardless of the outcome, any form of technocratic decision-making is a form of alienation and, conversely, any outcome produced by the Ideal Speech Situation is good⁴².

The argument presented in Habermas' work is largely theoretical rather than empirical, but has nonetheless been highly influential, particularly in the fields of planning and environmental management. In these fields, his influence can be seen in the closely related literatures on deliberative democracy, collaborative planning and “strong democracy” (Oels, 2000).

Perhaps the most coherent attempt to operationalize Habermas does so by blending his ideas with a dose of pragmatism. Renn, Webler, et al. (Renn et al. 1995) shift the emphasis away from the radical reform of the modern state and towards processes that can open up new deliberative spaces largely within the structures of the modern state. In this way, the radical ideas of the critical theoretic tradition have come to influence a vast literature of forms of public participation.

While Habermas and his followers point to the crises and disasters of modernity, for them the dominance of rational purposive action over communicative action is a problem, regardless of the outcomes it produces. This locates their work at the extreme end of a continuum of methods of governance.

42 The author is grateful to Michael Burgess for pointing out this logical conclusion.

Reform from within

A review of the rise of *Deliberative and Inclusionary Processes* reveals three justifications for public participation in decision making that are broadly consistent with the changing context of governance (Bloomfield et al, 1998). The first argues that citizens of Western society should embrace the cultural diversity of which it is composed. This implies both that Western society has, in the past, ignored marginal social groups and that forms of identity and traditional class-based identities have been replaced in politics by identity constructed on the basis of gender, sexuality, ethnicity, age, lifestyle and “post-material” values.

The second justification argues that there is a growing sense of powerlessness in modern societies. This may reflect concern or suspicion over the intimate relationship between government and industry and suggests that the concentration of power and authority in expertise leaves citizens alienated and leads to declining trust in the state (Putnam 1995 ; Paxton 1999; Stehr and Ericson 2000). Many authors see the growing demand for participation and the democratization of governance as civil society’s response to this sense of alienation. While invigorating the non-governmental sector is seen as a means of creating greater accountability, it is not synonymous with achieving direct democracy. It may simply broaden the range of interests engaged in the adversarial politics of the state.

The third justification is that participation is necessary because of the environmental imperative: modern industrial practices have tended to ignore the environmental impact of Promethean growth. In this case, participation may be valuable for substantive reasons (e.g., local resource users in the Mackenzie pipeline inquiry had a better understanding of the ecosystems that would be affected).

In examining the literature on public participation, it is important to distinguish between the goals of a process and the design of the process, the means to particular ends.

Although the metaphor and labels she uses reveal the author’s bias, the typology most widely used in the literature to make this distinction is Sherry Arnstein’s *Ladder of Citizen Participation* (Arnstein 1969).

The version of Arnstein’s ladder presented in Table 2 includes two modifications. The first is to turn the ladder on its side to represent a continuum rather than a method of

distinguishing good from bad processes. The second is that the labels are more value neutral⁴³. The final row distinguishes between approaches that are entrenched in the traditional processes of representative government and those that are increasingly being demanded in order to strengthen participatory governance.

Table 2: Styles of citizen engagement

| Style | Marketing (manipulation) | Education (therapy) | Informing | Consultation | Placation | Partnership | Delegated power | Citizen control |
|--------------------|---|------------------------|---|---|---|--|--|--|
| Description | One-way flow of information from government to citizens through media | | Direct contact, but largely an expert monologue | Dialogue without diffusion of power | Sharing of power by citizen appointment onto committees | Stakeholder decision making involving multiple interests | Delegation of power to citizen committees | Full autonomous control of process by citizens |
| Vehicles | Advertising, public education campaigns, brochures, pamphlets. | | Public inquiry | Public meetings and consultation | Citizen's Advisory committees | Roundtables, 'holistic government' | Democratize technology assessment (see below). | |
| Relevance | Traditional government ← | | | Increasing degrees of participatory governance → | | | | |

The distinction between the goals and the design of public participation processes is important. Levidow (1999) compares two seemingly similar processes used for public involvement in decision-making regarding biotechnology in Denmark and the United Kingdom. While the processes were similar in design, their mandate and authority differed. In Denmark, participants worked within broad terms of reference and had a direct influence on policy making. In Britain, participants were constrained in the issues they could address and the outcome of the process was treated as one source of advice among the many that influence the ultimate decision-making process.

This distinction between goals and design blurs toward the right-hand side of the spectrum. At the extreme right-hand it is neither possible nor legitimate to determine

⁴³ Arnstein's original labels are included in brackets. The second and third rows on the table provide more detailed descriptions of Arnstein's labels.

which specific process should be used, since citizen control implies that the participants make the choice of process.

This distinction is important. While processes like In-depth Discussion Groups (Burgess et al. 1988a ; Burgess et al. 1988b) can achieve more radical transformative or therapeutic ends, the process does not necessarily signify direct (or even indirect) influence in decision making. If a consultative process is commissioned by a decision-making authority, (for instance, (Macnaghten 1995), it is usually with the intention of supplementing rather than replacing traditional decision making processes. In most of these types of cases, the client (*e.g.*, government agency) does not have the authority to delegate or replace this activity.

The specific processes referred to in the literature have most commonly been designed, described and tested by academic researchers. These processes are often experiments, with no moral or political authority, conducted independent of mainstream governance processes. Since the costs of engaging the whole citizenry in such processes is prohibitive, these experiments simply reveal:

*...what the electorate **would** think if, hypothetically, it could be immersed in intensive deliberative processes. ... if it could be given an opportunity for extensive reflection and access to information (Fishkin 1991:81 in Oels, 2000).*

Focusing on the right-hand side of Arnstein's typology, there is a literature that demands that the processes by which society produces technology be democratized. Feenberg (1999) develops a diagnosis of the malaise of modernity by arguing that Weber's fears have come true and that the increasing role of calculation and control in social life has resulted in an "iron cage of bureaucracy" (ibid: 1) This reflects the notion that social life is increasingly structured and controlled by a range of organizations such as corporations, state agencies and medical institutions.

Richard Sclove sees technologies as forms of social structure comparable to laws, and political and economic institutions in their significance and suggests that they should be subject to the same strictures of democratic accountability (Sclove 1999). Echoing concerns about the power of technocracy, he criticizes the rise of health professionals

associated with centralized health care administrations and the resultant changes that displace local practices. His program is:

...grounded morally in the belief that people should be able to shape the basic social circumstances of their lives. This implies struggling to organize societies along relatively equal and participatory lines, a vision of egalitarian decentralization and confederation ... strong democracy (ibid: p20).

Sclove also sets out design criteria for democratic outcomes based on a number of dimensions: democratic community, democratic work, democratic politics, democratic self-governance, economic self reliance, globally aware technologies, and ecological sustainability. This description of outcomes appears to confuse means with ends; if the process emphasizes the importance of collective self-determination then the shape and the outcome of the process cannot be determined in advance.

Moving toward the left side of Arnstein's typology, Mitcham claims to provide a more balanced view of the relationship between technology and democracy, suggesting it is characterized both by symbiosis and antipathy (Mitcham 1999). This view runs against the dominant tradition in sociology and political science, where technologies and the institutions that produce them are analyzed in terms of their anti-democratic potential.

Mitcham argues that actual conflict in modern democracies is often ends rather than means oriented. For instance, a goal may be to ban nuclear power, rather than to secure citizen access to governance processes as a general goal in and of itself. While Sclove and Feenberg feel that the influence of technology is so significant it should be judged by the same democratic standards as other institutions, Mitcham points out that the democratic standards used to judge political institutions are generally thin and shallow rather than the thick and deep model of democracy demanded in the alternate account.

Mitcham distinguishes between two broad theories of democracy: realist and participatory. The realist model sees democracy in adversarial terms focused not on producing common good, but on the competitive struggle to secure the people's vote. The concentration of power in the hands of decision makers and experts is justified on the basis that most people are not really interested in politics; hence what is required is the

representative or republican system. Realists value political stability above all else, and the representative system provides this. According to this model, rule by representation leads to more democratic outcomes because openness and engagement lead to fission.

If the broad electorate were in fact deeply interested, informed and active, it would also tend to be deeply divided and viciously fractious.

Commitment and knowledge seldom lead to consensus. Mitcham, 1999: 44

Supporters of the participatory model point to the shortcomings of the adversarial system, including the possibility of excluding minority views under a tyranny of the majority. These theorists describe a low level of participation as the product of the undemocratic structures that constrain opportunities for engagement⁴⁴. In the participatory model, self-government becomes an end in itself. Political life is presented as a human need that has been stymied by the dominant systems of government in modern democracies.

Mitcham's pragmatic framework specifies eight distinctive arguments in favour of the principle of public involvement in technical decision-making:

- Techno-social realism: Experts cannot escape the influence of biased social interests with the result that their input to decision-making process cannot be objective. This is not simply the result of crude interest-based manipulations of the system.
- Public demand: Individuals and social groups increasingly demand a direct role in government beyond the representative system that structures the system.
- Expert bias: Experts inevitably tend to promote their own self-interest or values.
- Consent: Those affected by technical decisions should have some say.
- Moral autonomy: Closely related to the notion of consent, this more nuanced justification treats humans as moral agents who have a right to be consulted.
- Pragmatism: Public participation will lead to better outcomes than might have been achieved otherwise.
- Educational enlightenment: Only through active engagement and participation will individuals become more intelligent and aware of the social reality in which

⁴⁴ For some opponents of biotechnology, the narrower framing of the debate means they may choose to remain on the outside of the debate.

they are embedded. This view is derived from the educational philosophy of John Dewey.

- Postmodern reality: In the absence of any strong moral consensus, tolerance, diversity and “public ethical minimalism” are goals to which society should aspire.

Mitcham suggests that the very complexity of modern societies requires a kind of ethical eclecticism that recognizes that more than one approach to analysis is required in order to make robust policy decisions. Public or stakeholder engagement is a means of achieving this greater pluralism of perspectives. The distinctions between Mitcham’s argument and the more radical views of others is important, since it endorses public participation for quite different reasons. In contrast to the Habermasian framework, Micham’s pragmatic middle ground proposes that modern social systems are composed of semi-autonomous institutions with potentially divergent interests. Citizen involvement or public participation most commonly involves opening up a space within which these interests can interact, negotiate and potentially contribute both to making and implementing decisions.

Dorcey and McDaniels (2001) describe two waves of enthusiasm for citizen involvement beginning in the late sixties and early seventies, offering an extensive review of efforts to operationalize citizen involvement over the last thirty years. Their review highlights two underlying trends:

- there is an industry that focuses on producing a diverse array of participatory processes; and
- these processes are most commonly applied to the environment, although the authors recognize that their emergence has occurred in parallel with a more general trend of ‘openness’ in government and the courts.

These authors acknowledge that consultation has become a fact of environmental decision making in North America and that methods continue to evolve. They suggest that while the United States has been the testing ground for many of these methods, there have been many innovative applications in Canada. Further, while negotiation and participation often emerged in the United States as an alternative to costly and polarizing

court battles, participation in Canada has simply been incorporated into policy development, often independent of legal challenges⁴⁵.

For McDaniels and his colleagues, neither extreme of Arnstein's typology is satisfying and they stake out a middle ground between the highly structured and technocratic methods used in cost-benefit analysis and the open ended participatory and deliberative methods characteristic of the right hand side of the table (for instance Arvai et al. 2001; Dorcey and McDaniels 2001). The framework they offer recognizes that most examples of citizen involvement do not transfer or delegate power directly to the participants; instead participants most commonly play an advisory role.

Dorcey and McDaniels note that open ended, self-designed processes create expectations that the wider political context, and the institutionalized legal accountability systems, cannot satisfy. Moreover, experimental decision research has suggested that humans are rarely capable of the kind of calculated rational deliberation that policy making demands⁴⁶. Starting with the landmark paper by Kahneman and Tversky (1974) decision researchers have identified numerous consistent biases in rational decision making that suggest that humans are:

- bad at complex unaided decisions;
- demonstrate predictable biases in response to information, for instance perceiving losses and gains of the same magnitude differently;
- appear to have little instinctive ability to clarify objectives; and
- tend to employ heuristic reasoning processes.

At best, groups do as well as their more deliberative or well informed members would do on their own and group processes tend towards entrenched positions and to group think:

In short, there are many reasons to expect that, left to their own devices, individuals (either lay or expert) will often not make informed, thoughtful

⁴⁵ There are a number of cases in Canada where an Environmental Assessment has been overturned because of insufficient consultation Gibson, R., J. Tansey, et al. (2003). Environmental Assessment and Sustainability, Earthscan, forthcoming.

⁴⁶ This research is important regardless of whether the goals of a consultation process are substantive or procedural. In the former case, psychology distorts knowledge so that the quality of input is reduced, in the latter case collective interests may be distorted by the dynamics of a group process.

choices about complex issues involving uncertainties and value trade-offs
(Dorcey and McDaniels, 2001: p275).

The alternative is to help avoid some of the worst pitfalls of human rationalization by embedding citizen decision making with structured decision processes. Those who favour these approaches suggest that they create a more meaningful context for interaction and create the conditions for more meaningful decision tasks.

The processes lead participants through a number of stages beginning with a clear definition of the nature of the decision—including problem formulation and likely objectives—before examining the range of alternatives the stakeholders could support. The framework developed by Dorcey and McDaniels (2001) identifies the core features of this approach to citizen involvement:

- Value-focused thinking (Keeney 1992) identifies what is important and how to achieve it;
- Adaptive management (Holling 1986): decision making as an iterative process rather than a one time exercise;
- Structured decision process: ends, objectives, alternatives to achieve them, information to characterize, trade-offs among them, alternatives supported; and
- Informative decision rule: fosters learning about the process and places and emphasis on what participants in the process could bear rather than on achieving unanimity.

The authors recognize that both experts and members of the public can benefit from well-designed processes when dealing with complex decisions. Consequently, this framework represents a model of engagement that may be appropriate for incorporating a wider range of views into governance biotechnology. The emergence of structured decision processes reflects the extent to which public participation methods have evolved and the extent to which insights from the social sciences have been incorporated into their design.

Importantly, it has been recognized that public participation is not a panacea for the weaknesses of the modern governance system. Contingent approaches help to identify whether consultation is necessary and if it is, what methods should be used to best meet

the needs of the sponsor and to best address the problem in hand (Dorcey and McDaniels 2001).

Evaluating public participation

The typology presented in Table 2 is not a smooth continuum; the table hides disjunctions between the normative commitments of those proposing models of decision making. This disjunction means that there is no single standard for evaluating public participation.

The right hand side of Arnstein's typology appears to display an underlying commitment to the autonomy and sanctity of individual values⁴⁷ as a democratizing development to counterbalance the forces of technology and technocracy. In its extreme form, this position suggests that the act of collectively engaging in a process of negotiation has transformative power, akin to group therapy. For most of the advocates of these strong participatory methods, once the process delivers an agreement on a decision, those values become binding and should be faithfully followed in the process of implementation.

The processes captured in the middle of the typology are broadly consistent with the logic of the modern pluralist state: the state is a powerful actor and must often assume the role of mediator among competing interests. Public participation in this case informs complex decision making processes, it does not supplant the power of elected decision-makers and technocrats. In some cases, such as co-management of environmental resources where governmental, non-governmental and even private partners play a role in policy implementation, consultation processes typically occur early in the policy cycle. Implementation is left to bureaucrats and regulators. In these processes, human values are negotiable, not sacred.

Moreover, both the lay public and experts are vulnerable to systematic psychometric biases that affect their ability to make balanced and informed decisions. The purpose of well-designed processes is to correct for the effects of these biases.

In what remains one of the most ambitious and systematic attempts to evaluate methods of public participation, Renn, Webler and Wiedmann (1995) sought to operationalize

⁴⁷ It is not clear that this is necessarily the case, but the position is part of the rhetoric in support of greater participation: technocracy leads to a loss of self and processes of engagement are presented as a form of therapy in the face of this assault.

Habermas' ideal speech situation to develop a framework for assessing a range of methods⁴⁸. Their framework is not pure Habermas; they combine his theory of the normative foundations of human action with research from the practical application of his ideas in the field of planning. The result is a more pragmatic framework for process evaluation built around:

- the ethical criterion of fairness—deliberation over values that is free of coercion, where all participants are on an equal footing. This includes equal opportunity:
 - to speak;
 - to determine the agenda and the rules for interaction among participants;
 - to raise questions;
 - to access knowledge and interpretations (ibid: 38); and
- the functional criterion of competence—the ability:
 - to use language; and
 - to defend interests and contribute to the debate about which values should reign.

In broad terms, competence relates to:

...psychological heuristics, listening and communication skills, self reflection and consensus building. (ibid: 30).

The authors set out four rules (Table 3) to guide implementing these two criteria.

⁴⁸ The authors are quite explicit in their assertion that the ideal speech situation is unachievable (see page 41).

Table 3: Rules to guide process design

| Fairness | Competence |
|--|--|
| 1. Anyone who considers him or herself to be potentially affected by the results of the discourse must have an equal opportunity to attend the discourse and participate. | 1. Every potential discourse participant must meet minimal societal standards for cognitive and lingual (sic.) competence. |
| 2. Every discourse participant must have an equal opportunity to make validity claims to comprehensibility, truth, normative rightness and sincerity. | 2. Every discourse participant must have access to the knowledge needed to make validity claims and criticize others. |
| 3. Every discourse participant must have an equal opportunity to influence the challenge the comprehensibility, truth, normative rightness and sincerity validity claims made by others. | 3. Speakers must verify the results of any attempt to translate expressive claims. |
| 4. Every discourse participant must have an equal opportunity to influence the choice of how the final determination of validity will be made and to determine discourse closure (<i>i.e.</i> to decide how to decide when there is no consensus) | 4. Judgments about conflicting validity claims must be made using the most reliable methodological techniques available. |

Source: (Renn et al. 1995: p51, 59)

These criteria embody a number of critiques of Habermas’ original formulation and are used as the foundation for an evaluation framework that can be applied to eight participatory methods (*ibid*: 10):

- citizen advisory committees;
- citizens panels;
- citizens juries;
- citizen initiatives;
- negotiated rule making;
- mediation;
- compensation and benefit sharing; and

- Dutch study groups.

These methods all place a heavy emphasis on deliberation and the meaningful engagement of citizens in decision-making. Although the study came to no overall conclusion about which was the best method to use, the evaluation confirms that there are different tools for different jobs and no single tool does everything.

Dorcey and McDaniels review other attempts to develop evaluation processes.

- Chess and Purcell's work produced mixed results: satisfaction with process was not necessarily associated with satisfaction with outcome and the role of the sponsoring agency was important.
- Yosie and Herbst suggest that despite the rising trend of citizen involvement in the United States, processes are often poorly managed because of a lack of knowledge regarding the details of process design. They also found that citizen involvement challenges the ability of the scientific community to participate effectively in a growing number of environmental decisions.

7. Biotechnology and citizen involvement in Canada

There has not been extensive citizen involvement in policy development related to biotechnology in Canada. Developing the *Canadian Biotechnology Strategy* (1997-8) involved stakeholder consultations across Canada on the vision for the future of the sector. In addition, a poll of 1,500 respondents was conducted to assess public views regarding biotechnology. Subsequent surveys by the Canadian Biotechnology Advisory Committee have been developed for more specific issues and are available electronically⁴⁹ although it should be noted that only a small number of respondents—36 in the case of the food biotechnology survey—completed them.

While the Strategy process was extensive, it was largely expert led and qualifies as “Informing” (see Table 2). The goals of the Strategy include engaging citizens to:

...improve public awareness and understanding of biotechnology through open, transparent communications and dialogue (Canadian Biotechnology Strategy, 1998⁵⁰).

Both this goal and the general tenor of the federal government’s approach to citizen engagement in biotechnology have been to address what are considered to be misconceptions of biotechnology through information and education—“Marketing” and “Education” in Table 2.

National consultations under the leadership of the Committee used a methodology that appears to have been influenced by the literature on structured decision-making (specifically value-focused thinking). The consultations recruited 35-40 stakeholders who were to be evenly representative of consumers/civil society, industry and health professional, academics and provincial government representatives. The final report notes that representation from civil society and consumers was poor and indeed a group of 50 non-governmental organizations boycotted the proceedings, choosing instead to present a petition stating their concerns regarding the independence of the Committee and the

49 http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/h_ah00038e.html

50 Available online at:

[http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwapj/6889eng.pdf/\\$FILE/6889eng.pdf](http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwapj/6889eng.pdf/$FILE/6889eng.pdf)

consultation process, and questioning whether it would have any effect on government policy.

We believe the [CBAC process] is fundamentally and importantly flawed and that NGO participation in the consultation could legitimate CBAC's wholly inadequate mandate and process and undermine demands for true democratic processes and widespread public consultation.⁵¹

The consultation did result in a proposal for regulating biotechnology, including a list of values that should guide the policy development and regulatory process in Canada. The most important of these are: accountability/leadership, transparency, science based approaches, informed choice/public choice/knowledge and safety and caution. It is too early to tell whether these will be translated into a regulatory framework; however, in light of the withdrawal of NGO representatives from the process, the consultation can only be considered successful on logistical grounds.

One of my key conclusions is that The Government of Canada's concerns should not be to prove that "their" science is right and that the concerns of NGOs and others are wrong. Instead, they should recognize that biotechnology can become a highly controversial risk issue without a scientifically measurable disaster occurring. They should distinguish between risk management—a science driven process—and risk issue management—a social process (Leiss, 2001).

Public and NGO reactions to GM crops in Europe have led to a large-scale rejection of the use of this technology. While NGOs have not achieved the same ends in Canada, they can, and often do, have significant political and public influence. The current model of engagement needs to shift to a more pluralist basis that recognizes the potential power of the NGOs. It is not a question of who has the best science; it is a question of who has power.

51 It proved relatively difficult to find a copy of the petition, even though CBAC publications proposed that it be included in the final version of the report. In the report CBAC refers to the petition in Annex D, but the report finishes at Annex C.

8. Discussion: Postman always knocks twice

This paper began with the reframing of a question by Neil Postman: “What is the problem that public participation is designed to solve?” The answer, in part, is that while the range of public participation processes can be crudely plotted along a continuum, they are all designed to solve different problems by addressing an immediate and pressing challenge to modernity: the search for legitimacy and accountability.

Proponents invest great faith in the power of their favourite processes and there is evidence that well-designed processes have made a difference to the quality of decision-making. But public participation is neither a panacea for good governance nor can it necessarily address problems associated with the fundamental uncertainties associated with many technologies. At one extreme, process is an end in itself. For the theorists in this realm, culture, which defines humanness, is founded on language and shared communication; public participation has profound transformative powers. Modelled on Habermas’ ideal speech situation, public participation has the capacity to rejuvenate democracy and release individuals from the calculating rational embrace of modern technocracy. However, there are problems with this approach. Among other things:

- liberation is not a costless process;
- it is not evident that individuals always wish to be freed of their apparent dependence on technocracy; and
- even if individuals could collectively agree on the values that ought to shape their lives, it is unlikely that the values could be translated into action without at least some degree of coercion. It is crude sociology to suggest that collective values can map onto the minds of humans and script behaviour.

According to Olson (1969), collective action is always undermined by free rider effects, the co-operator’s dilemma (*i.e.*, even if intentions are good, there are always many incentives along the way to not co-operate) and the transaction costs of mutual monitoring. Despite Olson’s pessimism, collective action occurs all the time in society. This is not necessarily the conscious, thoughtful collaboration that Habermas assumes

would follow from the hard cognitive labour of the ideal speech situation, but still collective action.

For some sociologists, the kind of discursive abstract reflection on decisions that leads to individual and group reform is rare in the social world. Much of what humans do on a daily basis is structured by practical consciousness, the unreflective force of habit. Indeed, structuralist sociologists might argue that humans are little more than the sum of their habits. They emphasize ritual activity and normalized routines of practice and behaviours that establish an envelope of appropriateness within which individuals can express agency. So the therapeutic reflection produced by well-intentioned processes will inevitably encounter the inertia of routine and habit.

This dilemma is encountered in all realms of the social and policy world, from massive campaigns to alter smoking habits to attempts to induce lifestyle changes towards more climate friendly alternatives. A significant critique of Habermas and others who demand that technology be democratized is that there is often a vast canyon between knowledge or behavioural intentions and behavioural change.

To be fair, authors such as Sclove and Feenberg argue less in favour of reform at the micro level and more for institutional reform where the democratic mechanisms used to elect representatives should be applied to the processes by which society produces technology. While this approach is less therapeutic and more pragmatic, it is also optimistic about how well established democratic institutions actually translate collective will into policy. It implies a mechanical model of government/governance akin to the medieval omnipotence described in Thomas Hobbes' *Leviathan*.

While modern industrial societies are not governable in a deterministic sense—they are not the product of a series of intentional interventions by government representatives on behalf of citizens—such a model is certainly implicit in much of the literature on the role of citizen involvement. There is a common assumption that participatory processes can be invested with the authority to direct technology development.

An even greater danger lurking beneath consultation processes is that they provide a sense of assurance that through broader input and scrutiny, environmental disasters can be avoided. While governance processes designed to create accountability appear to be

achievable, the challenge of governing the impacts of technology, under conditions of high and unspecifiable uncertainty are more daunting. In an era when so many question whether societies are governable at all, the rallying cry “More Democracy” may be naïve.

The more contained styles of public participation that populate the middle of Arnstein’s typology better reflect the adversarial nature of politics and the fragmented nature of the modern polity. For every problem, there are multiple stakeholders (*e.g.*, governments, the private sector and, increasingly, NGOs) vying to exert influence and to be heard. Dorcey and McDaniels’ (2001) heavy emphasis on public participation as mediation among competing interests is a response to this reality. Techniques used in mediation, such as value-focused thinking, can help reveal underlying values, but what matters more is the extent to which power is transferred to the mediating body.

Implicitly these “middle” processes prize order and more reasoned structured debate between interests over disruptive conflict in public politics. This requires that actors at least accept the legitimacy of the mediator or sponsor. Clearly, at the radical end of the activist spectrum, this cannot be taken for granted.

Levidow is skeptical of all the examples of public participation that he describes and suggest that at best, they achieve marginal benefits:

Participatory exercises help legitimize the neoliberal 'risk-benefit' framework, which offers a free consumer choice to buy 'safe' genetic fixes (ibid: 65).

Levidow’s critique recognizes that public participation is typically applied rather late in the process of developing technologies. Public controversies are rarely sensitive to the nuances of scientific debate—they rely on high-level classification—and lead-time for research and technology development is long and typically involves significant public and private investment, which provides its own momentum⁵². If a technology gains a life of its own, then reactive mediation or public participation may come too late. Indeed, it is often the case that there is no issue for public debate until some controversy has emerged

⁵² Altering the way in which research into technology is funded and promoted is rarely proposed and could radically alter the exploratory nature of the research process, the funding regime and the commercial aspects of the intellectual property it produces.

through the media. By the time a controversy has appeared, it may be impossible to effectively contain the problem⁵³.

The environmental and risk assessment techniques referred to in this paper subtly determine or frame which decisions should be included in the regulatory process. These techniques evaluate the likelihood that novel technologies will cause material harm to humans or to environmental systems. Ethical issues and issues of social acceptability are, in the worst case, relegated to the status of subjective concerns that are addressed in marketing and promotion of technologies that have been proven safe.

For some, the fact that we can make objective decisions informed by science, instead of subjective decisions informed by moral sentiments and variants of traditionalism, is a marker of how modern we have become. That said, the lesson from risk management is that it is never possible to depoliticize the moral acceptability of a technology; these issues are ignored at the peril of incumbent governments. Consequently, in anticipation of an inevitable backlash against what was seen as an illegitimate consultation process by a large number of NGOs, the federal government should establish a more independent process in recognition of the influence that non-governmental actors are able to exert over the progress of public policy. In the context of the typology indicating the range of possible styles of intervention, this represents a shift towards partnership or multi-lateral models of engagement.

The story of biotechnology governance in Canada begins with a strategy that for fifteen years was focused on promoting biotechnology and enhancing the country's research capacity. It was only in 1998 that regulatory issues came to the fore and a broader sense of the need for public engagement emerged. The Royal Society Expert Panel on food biotechnology was the starting point for the regulatory review and it produced a thorough account of the current state of the science while pointing to the limitations of the current regulatory system.

However, there remains a disjunction between the findings of the Society's report—which identifies rather radical changes to the regulatory system in response to the limits

⁵³ For example, genetically modified Soya products in North America are now so pervasive that even labelling policies that offer consumer choice may be impossible.

of knowledge in biotechnology, and the response of the regulatory agencies, which give the impression that the issues are manageable through incremental change. There are voices in academia who point to this disjuncture. E. Ann Clark, a plant agriculturalist from Guelph, Ontario, in a speech to the Association Canadienne Francaise pour l'Avancement des Sciences, argues that the findings of the Panel have been diluted and that there is not a strict separation of the two potentially conflicting mandates of the federal government to both regulate and promote biotechnology⁵⁴.

Even if stricter regulations were incorporated into legislation, it is by no means assured that they will be implemented in practice. Harrison (1996) points out that the Fisheries Act gives the Department of Fisheries and Oceans the authority to intervene to prevent any damage to the habitat of migratory fish⁵⁵. But in practice, the federal government has been reluctant to intervene in matters related to environmental protection because natural resources are within the jurisdiction of the provinces.

The point is not that uncertainty discredits biotechnology, rather the fact of uncertainty always exists in biotechnology should alter the criteria that inform the decision making process. If it appears that there are overwhelming benefits to novel biotechnologies then the imperative is to design regulatory systems that account for pervasive and unavoidable uncertainty. Since a number of GM organisms have been approved in Canada, at the very least, regulators should engage in an anticipatory planning exercise to consider how to respond if, for example, outbreeding occurs between gene modified canola and a pernicious weed with the successful transfer of herbicide resistance.

The politics of environmental and technological issues often produces two entirely polarized positions, one claiming overwhelming benefits, the other claiming overwhelming dangers. It is into this regulatory context that biotechnology issues emerge. A robust governance process would identify those instances where biotechnology does confer significant social and environmental benefits while limiting the associated hazards. Unfortunately, it is only under exceptional circumstances that

⁵⁴ The presentation is available at:
<http://www.plant.uoguelph.ca/research/homepages/eclark/quebec.pdf>

⁵⁵ The title of Harrison's book, *Passing the Buck*, describes how responsibility for environmental protection is juggled between provinces and the federal government with the result that accountability is weak.

current assessment techniques can be expected to reliably predict the full range of impacts of a technology. The structure of current system of regulation and governance in Canada lacks precaution regarding the science of biotechnology and seems to have downplayed or ignored at least some dissenting voices. This is likely to result either in a major social controversy or in significant unintended and unexpected impacts on human or environmental systems. The two outcomes could occur quite independently.

The rhetoric surrounding biotechnology suggests that the new language of God will allow humans to redesign organisms to correct the imperfections of nature and solve deeper metaphysical questions about human nature. Perhaps the greatest danger is that the appeal of this rhetoric will deafen decision-makers to the uncertainties of science and the realities of politics.

9. Bibliography

6, P. (2003). The Governance of Technology. London, White Paper prepared for the workshop 'Democratic Governance of Technological Change in an Era of Globalisation: 55.

Arnstein, S. R. (1969). "A Ladder of Citizen Participation." Journal of the American Planning Association 35,(4): 216-224.

Arvai, J. L., G. R., et al. (2001). "Testing a Structured Decision Approach: Value-Focused Thinking for Deliberative Risk Communication." Risk Analysis vol. 21(no. 6): 1065-1076.

Beck, U. (1992). Risk Society: Towards a New Modernity., London: Sage.

Borger, J. (2001). Bush Baulks at Playing God. The Guardian. London.

Boucher, L. J., D. Cashaback, et al. (2002). Linking In, Linking Out, Linking Up: Exploring the Governance Challenges of Biotechnology. Ottawa, Institute on Governance: 43.

Burgess, J., M. Limb, et al. (1988a). "Exploring Environmental Values through the Medium of Small Groups: 1. Theory and Practice." Environment and Planning A. 20: 308-26.

Burgess, J., M. Limb, et al. (1988b). "Exploring Environmental Values through the Medium of Small Groups: 2.Illustrations of a Group at Work." Environment and Planning A. 20:457-76.

Canada, G. o. (1998). Canadian Biotechnology Strategy: An Ongoing Renewal Process. Ottawa, Industry Canada: 29.

Canada, G. o. (2001). Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report. Ottawa, Government of Canada: 31.

Canada, R. S. o. (2001). Elements of Precaution: Recommendations for the regulation of Food Biotechnology in Canada. Ottawa.

Canadian Biotechnology Advisory Committee (2000). CBAC Annual Report - 1999-2000,. Ottawa, CBAC.

Committee, C. B. A. (2001). Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada: Interim Report to the Government of Canada Biotechnology Advisory Committee. Ottawa, Government of Canada.

Committee, C. B. A. (2002). Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada: Report to the Government of Canada Biotechnology Advisory Committee. Ottawa, Government of Canada.

Doern, G. B. (2000). Inside the Canadian Biotechnology Regulatory System: A Closer Exploratory Look. Ottawa, Canadian Biotechnology Advisory Committee: 42.

Dorcey, A. H. J. and T. McDaniels (2001). Great Expectations, Mixed Results: Trends in Citizen Involvement in Canadian Environmental Governance. Governing the

- Environment: Persistent Challenges, Uncertain Innovations. E. A. Parson. Toronto, University of Toronto Press: 247-302.
- Douglas, M. (1966). Purity and Danger: An Analysis of Conceptions of Pollution and Taboo., London: Routledge and Kegan Paul.
- Douglas, M. (1970). Natural Symbols, Explorations in Cosmology., Harmondsworth: Penguin.
- Douglas, M. (1992). Risk and Blame: Essays in Cultural Theory., London: Routledge.
- Douglas, M. T. (1966). Purity and danger; an analysis of concepts of pollution and taboo. New York,, Praeger.
- Eco, U. (1999). Serendipities: language & lunacy. San Diego, Harcourt Brace.
- Ericson, R. V. and N. Stehr (2000). Governing modern societies. Toronto, University of Toronto Press.
- Farrell, A., S. D. VanDeever, et al. (2001). "Environmental Assessment: four under-appreciated elements of design." Global Environmental Change 11: 311-333.
- Feenberg, A. (1999). Escaping the Iron Cage, or, Subversive Rationalization and Democratic Theory. Democratising Technology. R. Von Schomberg. Hengelo, International Centre for Human and Public Affairs: 1-15.
- Funtowicz, S. O., and J.R. Ravetz. (1985). Three Types of Risk Assessment: A Methodological Analysis. In C. Whipple and V. Covello (eds.) Risk Analysis in the Private Sector., New York: Plenum.
- Funtowicz, S. O., and J.R. Ravetz. (1985.). Three Types of Risk Assessment: A Methodological Analysis. In C. Whipple and V. Covello (eds.) Risk Analysis in the Private Sector., New York: Plenum.
- Gibson, R., J. Tansey, et al. (2003). Environmental Assessment and Sustainability, Earthscan, forthcoming.
- Giddens, A. (1990). The Consequences of Modernity., Cambridge: Polity Press.
- Glickman, T. S. and M. Gough (1990). Readings in risk. Washington, D.C. Baltimore, Resources for the Future ;
Distributed by the Johns Hopkins University Press.
- Gross, J. L. and S. Rayner. (1985). Measuring Culture., New York: Columbia University Press.
- Harrison, K. (1996). Passing the buck : federalism and Canadian environmental policy. Vancouver, UBC Press.
- Holling, C. S. (1986). The Resilience of Terrestrial Ecosystems: Local Surprise and Global Change. Sustainable Development of the Biosphere. W. Clark and R. Munn. Cambridge, Cambridge University Press.
- Homer-Dixon, T. F. (2000). The ingenuity gap. New York, Knopf.

- Huntingdon, S. P. (1975). The United States. The Crisis of Democracy: Report on the Governability of Democracies to the Trilateral Commission. J. Watanuki. New York, New York University Press.
- Jasanoff, S. and B. Wynne. (1998.). Science and Decisionmaking. In S. Rayner and E. Malone (eds.) Human Choice and Climate Change, Vol 1., Columbus: Battelle Press. pp1-87.
- Jordan, A. and T. O'Riordan. (1995a). Institutional Adaption to Global Environmental Change I: Social Institutions, Policy Change and Social Learning., UEA, Norwich, CSERGE Working Paper GEC 95-02. pp41.
- Kahneman, D. and A. Tversky. (1974). "Judgement Under Uncertainty: Heuristics and Biases." Science. 185:1124-31.
- Kant, I. (1953). The Groundwork of the Metaphysic of Morals. Trans H.J.Paton under the title of The Moral Law., London: Hutchinson University Library.
- Kasperson, R. (1992). The Social Amplification of Risk: Progress in Developing an Integrative Framework. In S. Krimsky and D. Golding (eds.) Social Theories of Risk., Westport: Praeger. pp153-178.
- Kasperson, R. E., O. Renn, P. Slovic, H.S. Brown, J. Emel, R. Goble, J.X. Kasperson and S. Ratick . (1988). "The Social Amplification of Risk: A Conceptual Framework." Risk Analysis. 8(2):177-187.
- Keeney, R. L. (1992). Value-focused thinking : a path to creative decisionmaking. Cambridge, Mass., Harvard University Press.
- Keohane, R. O. a. J. S. N. (1987). "Power and Interdependence revisted." International Organisation 41(4):725-53.
- Lal, D. (1998). Unintended consequences : the impact of factor endowments, culture, and politics on long run economic performance. Cambridge, Mass., MIT Press.
- Leiss, W. (2001). In The Chamber of Risks: Understanding Risk Controversies. Montreal & Kingston, McGill-Queen's University Press.
- Levidow, L. (1999). Democratizing Technology or Technologizing Democracy? Regulating Agricultural Biotechnology in Europe. Democratising Technology. R. Von Schomberg. Hengelo, International Centre for Human and Public Affairs: 51-70.
- MacKenzie, D. J. (2000). Analysis of Relevant Canadian Legislation. Ottawa, Canadian Biotechnology Advisory Committee: 25.
- Macnaghten, P., R. Grove-White, M. Jacobs and B. Wynne. (1995). Public Perceptions and Sustainability in Lancashire: Indicators, Institutions and Participation., Report for Lancashire County Council, University of Lancaster.
- McDonald, M. (2000). Biotechnology, Ethics and Government: A Synthesis. Ottawa, Canadian Biotechnology Advisory Committee: 27.
- Mitcham, C. (1999). Why the Public Should Participate in Technical Decision Making. Democratising Technology. R. Von Schomberg. Hengelo, International Centre for Human and Public Affairs: 39-50.

- Ohmae, K. (1990). The Borderless World., London: Collins.
- Oreskes, N. K., Shrader-Frechette, K., and Belitz, K. (1994). "Verification, validation and confirmation of numerical models in the earth sciences." Science. 263: 641-6.
- Paxton, P. (1999). "Is Social Capital Declining in the United States? A Multiple Indicator Assessment." American Journal of Sociology 105(1): 88-127.
- Pearce, D. W. and R. K. Turner (1990). Economics of natural resources and the environment. Baltimore, Johns Hopkins University Press.
- Pierre, J. and B. G. Peters (2000). Governance, politics, and the state. New York, St. Martin's Press.
- Prince, M. (2000). Regulators and Promoters of Genetically Modified Foods in the Government of Canada: An Organizational and Policy Analysis. Ottawa, Canadian Biotechnology Advisory Committee: 44.
- Putnam, R. (1995). "Bowling Alone: America's declining social capital." Journal of Democracy. 6(1):65-78.
- Renn, O. (1998). "Three Decades of Risk Research: Accomplishments and New Challenges." Journal of Risk Research. 11:49-72.
- Renn, O., T. Webler, et al. (1995). Fairness and Competence in Citizen Participation., Dordrecht: Kluwer . pp381.
- Rhodes, R. (1994). "The Hollowing Out of the State." The Political Quarterly 65(2): 138-51.
- Ridley, M. (1999). Genome : the autobiography of a species in 23 chapters. New York, HarperCollins.
- Rustin, M. (1994). "Incomplete Modernity:Ulrich Beck's Risk Society." Dissent. Summer:395-400.
- Salter, L., E. Levy, et al. (1988). Mandated science : science and scientists in the making of standards. Dordrecht, Holland ; Boston [Mass.], Kluwer Academic Publishers.
- Schrader-Frechette, K. S. (1991). Risk and Rationality. Philosophical Foundations for Populist Reforms., Berkeley: University of California Press.
- Schrecker, T. (1984). Political Economy of Environmental Hazards. Ottawa, Law Reform Commission of Canada: 112.
- Schrecker T, Hoffmaster CB, et al. (1998). Biotechnology, Ethics and Government. In Renewal of the Canadian Biotechnology Strategy, Resource Document 3.4.1, Background Research Papers, Ethics. I. Canada. Ottawa, Government of Canada: 135-261.
- Schrecker, T. and A. Wellington (2001). Patenting of Higher Life Forms and Human Biological Materials: An Introduction to the Issues. Ottawa, Canadian Biotechnology Advisory Committee: 27.

- Sclove, R. E. (1999). Design Criteria and Political Strategies for Democratizing Technology. Democratising Technology. R. Von Schomberg. Hengelo, International Centre for Human and Public Affairs: 17-38.
- Sherwin, S. (2001). Towards an Adequate Ethical Framework for Setting Biotechnology Policy. Ottawa, Canadian Biotechnology Advisory Committee: 43.
- Slovic, P. (1992). Perception of Risk: Reflections on the Psychometric Paradigm. In S. Krimsky and D. Golding (eds.) Social Theories of Risk., Westport: Praeger. pp117-152.
- Stehr, N. and R. V. Ericson (2000). The Ungovernability of Modern Societies: States, Democracies, Markets, Participation, and Citizens. Governing modern societies. N. Stehr. Toronto, University of Toronto Press: 3-25.
- Stirling, A. (1999). "The appraisal of sustainability; some problems and possible responses." Local Environment 2(2): 111-135.
- Weber, M. (1958). The Protestant Ethic and the Spirit of Capitalism. New York, Scribners.
- Wuthnow, R., J. Davison Hunter, A. Bergesen and E. Kuzweil. (1984). Cultural Analysis., London: Routledge and Kegan Paul.
- Wynne, B. (1996). May the Sheep Safely Graze? A Reflexive View of the Expert-Lay Knowledge Divide. In S. Lash, B. Szerszynski and B. Wynne (eds.) Risk, Environment and Modernity., London: Sage. pp44-83.
- Young, R. A. (2001). Uncertainty and the Environment, Edward Elgar.